TEXAS Health and Human Services | Texas Department of State Health Services

Texas Vaccines for Children and Adult Safety Net Provider Manual 2021

Texas Department of State Health Services

Tel: (800) 252-9152
Fax: (512) 776-7288

1100 West 49th Street
Austin, TX 78756

www.ImmunizeTexas.com
Immunization.Info@dshs.texas.gov

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Introduction to the 2021 Provider Manual for the Texas Vaccines for Children (TVFC) Program

I. Provider Manual Information

The Texas Department of State Health Services (DSHS) Immunization Unit has prepared the Texas Vaccines for Children (TVFC) Provider Manual. Consultation on the policies in this manual are conducted routinely with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), DSHS, and other organizations.

Purpose:
This manual is to consolidate TVFC and ASN policies and information into one source.

The purpose of the TVFC Provider Manual is to consolidate TVFC policies and information into one source. You may consult the manual as needed, for the handling and management of TVFC vaccines. Throughout the year, the DSHS Immunization Unit will announce new policies via official policy letters, memorandums and the monthly newsletter, TVFC/ASN Digest. This manual will undergo a comprehensive review annually. Both the manual and the latest updates in the TVFC/ASN Digest Newsletter can be found on the DSHS Immunization website.

II. Public Health Law Establishing the Vaccines for Children (VFC) Program

The federal VFC Program is authorized by the Omnibus Budget Reconciliation Act (OBRA), Section 1928 of the Social Security Act.

Funding from the federal VFC Program is supplemented with federal 317 funds that allow the federal purchase of vaccines and State General

Revenue funds to support TVFC, and all immunization activities across Texas. Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels.

TVFC enables over 4.3 million Texas children to have access to immunizations. This is accomplished through a network of support provided by DSHS and with assistance from DSHS Public Health Regions (PHRs) and contracted Local Health Departments (LHDs). These organizations function as Responsible Entities (RE) to ensure compliance with state and federal standards and the effectiveness of vaccine distribution. As a TVFC-enrolled site, you will contact your RE for more information and for the details about required vaccine reporting.

III. Vision and Mission of the DSHS Immunization Unit

Vision

To create a Texas free of vaccine-preventable diseases.

Mission

To remove barriers to complete and timely vaccination, increase vaccine coverage levels and reduce the burden of vaccine-preventable diseases for all Texas infants, children, adolescents, and adults.

IV. Goals of the DSHS Immunization Unit

- Raise and sustain vaccine coverage levels for infants and children.
- Improve adolescent vaccine coverage levels.
- Improve adult vaccine coverage levels.
- Prevent and reduce cases of vaccine preventable diseases.
- Maintain and improve public health preparedness.

- Promote and practice the safe handling of vaccines and ensure the accountability of all program components.

V. Goals of the TVFC Program

- Eliminate vaccine cost as a barrier to immunizations.
- Reduce the need for referrals by private clinics to public clinics by keeping children in their "medical home" for comprehensive health care.
- Provide a vaccine delivery system that is both efficient and effective for public and private enrolled sites.

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CHAPTER 1: TVFC SITE ELIGIBILITY AND ENROLLMENT

I. Signing Clinician Eligibility Requirements

To be eligible to enroll in the TVFC Program, signing clinicians 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)

NOTE:
Eligible signing clinicians

- *MD*
- *DO*
- *NP*
- *CNM*
- *PA*
- *RPh*

II. Enrollment Requirements

A. 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:

- 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 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 $14.85 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 Unit 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.

In jurisdictions where there are mass vaccinators enrolled, or circumstances where the enrolled provider is not providing direct services and other parties are involved with administering the vaccines, all parties involved with implementing the clinics, including the signing clinician and other groups who are directly administering the vaccine, must sign an agreement. There must be a written agreement attached to the TVFC Program Agreement detailing the responsibilities of each party involved.

B. Site Coordinator Responsibilities

The TVFC/ASN Programs require that the signing clinician designate a primary vaccine coordinator at the site 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 be named to serve as the alternate in the absence of the primary coordinator. Both coordinators must be physically located at the clinic site and must be fully trained in routine and emergency policies and procedures.

The primary and back-up vaccine coordinator are required to the following to implement, oversee, and monitor the TVFC and/or ASN Programs requirements.

- Ensure only eligible patients receive TVFC 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) two times each workday.
- Read and record the minimum and the 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 vaccine inventory information.
- Place orders for additional TVFC vaccine in the Electronic Vaccine Inventory (EVI) system.
- Report vaccines activities on a monthly basis in EVI.
- Track and document doses administered.
- Oversee proper receipt and storage of vaccines deliveries.
- Organize vaccines to monitor expiration dates.
- Ensure vaccine is stored and handled appropriately to safeguard vaccine viability.
- Review and analyze temperature data at least weekly to identify shifts in temperature trends.
- Respond to out-of-range temperatures excursions or respond 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, back-up vaccine coordinators, or signing clinician).

C. Initial Enrollment

The first step in joining the TVFC Program is to complete the TVFC Program Agreement. If you need assistance, you should contact your RE or the DSHS Immunization Unit at the phone number listed on the agreement

form. The TVFC Program Agreement is available on the DSHS Immunization Unit website at www.dshs.texas.gov/immunize/tvfc/info-for-providers.aspx.

The TVFC Program Agreement must be completed and updated each year. The agreement includes basic information about the facility and outlines the signing clinician's responsibilities. The signed agreement must be received and processed by the TVFC Program before the clinic receives state and federally-funded vaccines.

> ***NOTE:***
> *If the signing clinician leaves the practice, the Program Provider Agreement must be updated and signed by a new signing clinician.*

All licensed health care staff (MD, DO, NP, CNM, PA, or RPh) at the facility who have prescribing authority must be listed on the TVFC Program Agreement Form. The listing must also include the signing clinician's information.

Information required for all licensed health care staff include the following:

- Name,
- Title,
- Texas Medical/Nursing/Pharmacy License Number, and
- National Provider Identification (NPI).

If the signing clinician leaves the practice, the Program Provider Agreement must be updated and signed by a new signing clinician.

The profile section of the TVFC Program Agreement requests information about the site's patient population, which includes the projection and identification of clients the clinic will serve in the upcoming year. Existing sites must provide accurate data from the previous 12 months and must also include the number of insured patients served by the site. These numbers must be specific to the clinic site and not combined with other clinics' patient numbers. Data sources may come from the following:

- Immunization registry,
- Benchmarking,

- Number of Medicaid Claims or other billing data, or
- Client encounter data.

The RE will assist the staff through the enrollment process. Two staff members at each site must be designated as primary and back-up vaccine coordinators. The two staff members will be educated by the RE on how to complete the two required CDC "You Call the Shots" training modules and the most current TVFC Provider Policy Training module upon initial enrollment. After completing the modules, the Certificates of Completion must be electronically uploaded to the TVFC Program Agreement RE.

The RE will provide education by conducting an initial enrollment visit with the primary and back-up vaccine coordinators.

To participate in the TVFC Program, sites must enroll in and report to the Texas Immunization Registry (ImmTrac2). The RE will provide necessary education on ImmTrac2.

NOTE:
In order to participate in the TVFC Program, sites must be enrolled in and report to the Texas Immunization Registry, ImmTrac2.

The RE will submit required paperwork to the DSHS Immunization Unit. The DSHS Immunization Unit checks the Office of the Inspector General's (OIG) List of Excluded Individuals or Entities to ensure that all licensed healthcare professionals listed on an enrollment form are eligible to participate in the TVFC Program.

Once the forms are approved by the DSHS Immunization Unit, a Provider Identification Number (PIN) is issued. The PIN will be the clinic's vaccine account number for the duration of the clinic's enrollment in the TVFC Program.

The PIN is required to be included on all TVFC forms and communications. Sites must enter their TVFC PIN into their ImmTrac2 organization account. Information regarding ImmTrac2 may be found in Chapter 7: Documentation Requirements and on the ImmTrac2 webpage. The enrolled-

site will be contacted by the RE to schedule additional visits/contacts.

D. TVFC Enrollment Visit

All new sites to the TVFC Program must receive an enrollment visit prior to receiving vaccine. When the RE visits the new site, a review of all storage units in the office is performed to ensure adequate and approved storage units are being used. A certified and calibrated data logger must be in all units that will store TVFC vaccine, and temperatures must be documented twice daily for seven (7) operational days before any TVFC vaccine is received. A training for new clinics is conducted on TVFC Program policies to ensure they are understood and followed. The initial enrollment visit typically takes a minimum of three hours. The primary and back-up vaccine coordinator must both be available to meet with the RE for the duration of the initial enrollment visit.

Information for new sites is available at www.dshs.texas.gov/immunize/tvfc/provider-enrollment.aspx.

Training for new sites will include the following:

- Review and confirmation that the staff understand and will implement all TVFC Program requirements.
- Confirmation of the following:
    - Proper equipment is available to store TVFC vaccine,
    - The staff understands how to properly store, handle, and monitor TVFC vaccine, and
    - The staff knows who to contact if problems arise.
- Verification of the following:
    - Facility information provided on the initial enrollment form to include:
        - Shipping address,

    - Phone numbers,
    - Email address of signing clinician (must not exceed 40 characters), and
    - Medical license numbers and NPI of all listed licensed healthcare professionals.
  - A primary and back-up vaccine coordinator have been identified.
  - A plan for routine vaccine management is in place.
  - There are adequate water bottles in the refrigerator and frozen water bottles in the freezer.
  - Vaccine storage units have enough storage space to accommodate the maximum capacity of vaccine especially during back-to-school or flu season.
- Review the following forms:
  - Vaccine choice
  - Vaccine management plan
- Training also includes a review of the following:
  - TVFC Program Provider Manual
  - Vaccine ordering and accounting in EVI
  - Proper vaccine storage and handling
  - Vaccine quarantine bag
  - Immunization guidelines and schedules
  - Texas school and daycare requirements
  - ImmTrac2, Texas' Immunization Registry
  - Forms and literature
  - Vaccine Information Statements (VIS)

- Vaccine Adverse Events Reporting System (VAERS)
- Vaccine safety and other resources
- Standards of Child & Adolescent Immunization Practices
- Standards of Adult Immunization Practices (for providers who also participate in ASN)
- Vaccine types
- Administering vaccines
- Schedule and intervals of vaccines
- Anatomic sites
- Needle sizes
- Contraindications and precautions

E. TVFC Site Set-up

Once temperature charts are logged twice daily for seven (7) operational days and temperatures are within the required range, the RE begins the TVFC Program site 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 EVI
  - Setting up an initial order

  - Completion of a vaccine management plan
  - Completion of a temperature recording form
- Checks to ensure the following signage is displayed prominently within the clinic.
  - "Vaccine Management - Recommendations for Storage and Handling of Selected Biologicals" Poster (if available)
  - "How to Administer Injections" Poster
  - "Guide to Contraindications" Poster
  - "Giving All the Doses" Chart
  - Refrigerator Warning Signs
  - "Do Not Unplug" stickers on wall outlet and at the circuit breaker
- Provides immunization schedules, catch-up schedules, resource lists, and other materials.

If any of the items above were not provided to you as a new TVFC-enrolled site, contact your RE.

F. Vaccine Accountability

Vaccine accountability is a cornerstone of the TVFC Program and one of the highest priorities for the DSHS Immunization Unit.

When a site enrolls in the TVFC Program, the staff agree to the accountability requirements as a condition of participation. All TVFC-enrolled sites must ensure the following:

- TVFC vaccines are administered only to eligible children.
- Vaccine loss and waste are minimized and documented.
- Fraud and abuse (as defined in Chapter 6: Fraud and Abuse) does not occur.

- TVFC vaccine inventory is accurately reported monthly.
- Patients are screened at all immunization encounters for TVFC eligibility.

G. Provider Identification Number

A PIN is assigned to new sites upon initial enrollment into the TVFC Program. The PIN is the clinic's vaccine account number for the duration of the clinic's enrollment in the TVFC Program.

The PIN is required to be included on all TVFC forms and communications. PINs are associated with site visits, vaccine ordering, vaccine shipments and for overall program operations. As a result, separate PINs will be created for sites in different physical locations, even if they are supported by the same clinic staff.

The TVFC PIN must be entered in the site's ImmTrac2 user account. Information regarding ImmTrac2 may be found in Chapter 7: Documentation Requirements and on the ImmTrac2 website.

H. Provider Change of Information

It is the responsibility of the staff at the TVFC-enrolled site to maintain correct demographics, days and hours available to receive vaccine shipments, and profile information in EVI. The RE must be contacted immediately if there is a new signing clinician or a change in staff that are assigned the duties as a primary or back-up vaccine coordinator. In addition, it is the site staff's responsibility to update EVI with the new information.

New primary or back-up vaccine coordinators are required to complete the CDC "You Call the Shots" Module 10 and 16 and the most current TVFC Provider Policy Training module.

The TVFC Program agreement and profile must be updated if the site's patient population changes or when the signing clinician that signed the agreement form is no longer associated with the clinic. Failure to properly

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

I. Annual Re-Enrollment

TVFC re-enrollment will take place in October, to prepare for the following year. The TVFC Program requires that the TVFC Program agreement and profile be updated annually as these forms are required for continued enrollment in the TVFC Program. TVFC sites that are a Federally Qualified Health Center (FQHC) or a Rural Health Center (RHC) must also submit a copy of the Centers for Medicare & Medicaid Services (CMS) letter designating the sites as such.

The assigned primary and back-up vaccine coordinators are required to complete the most current TVFC Provider Policy Training module and an online re-enrollment form each year. The two CDC "You Call the Shots" training modules are recommended during re-enrollment.

Certificates of Completion for the most current TVFC Provider Policy Training module for the primary and back-up vaccine coordinator must be uploaded electronically as part of the re-enrollment process.

Clinics are required to be enrolled in ImmTrac2 to re-enroll into the TVFC Program. Staff that do not know their ImmTrac2 organization code should contact their RE for assistance. Information regarding ImmTrac2 may be found in Chapter 7: Documentation Requirements, II. The Texas Immunization Registry (ImmTrac2) and on the ImmTrac2 webpage.

Sites that fail to complete re-enrollment cannot continue participation in the program for the upcoming year. All sites that do not have a completed re-enrollment on file by the deadline will be subject to withdrawal and must complete a new enrollment to participate in the program for the upcoming year following all approving processes. Vaccine shipments may be interrupted for sites without current enrollment information on file.

NOTE: For sites that are also enrolled in ASN, the TVFC and ASN re-enrollment forms have been combined into a single re-enrollment form.

J. Deputization of Clinics

Deputization is used to support areas where an FQHC/RHC is unable to serve an UNDERinsured population. If an FQHC/RHC is unable to serve a specified population, then DSHS PHRs and LHDs are the second line to serve as a "safety net" for the UNDERinsured. Texas has implemented deputization of public health department clinics and LHDs. Delegation of Authority (DOA) or deputization, allows Texas FQHCs and RHCs to delegate authority to DSHS PHRs and LHDs to vaccine UNDERinsured children. With few exceptions, all PHR and LHD clinics must be enrolled in TVFC and ASN Programs. UNDERinsured children served in FQHC, RHC, or deputized sites are eligible for the federal VFC vaccine according to federal guidance.

III. Withdrawal from TVFC

The RE must be contacted if a TVFC-enrolled site wants to withdraw from the TVFC Program. The RE will arrange to pick up TVFC vaccine and will assist with final paperwork. Prior to withdrawal, it is requested that the clinic staff complete a Withdrawal Form (stock no. F11-11443) and submit it to the RE.

IV. Suspension from TVFC

If it is determined that the TVFC Program agreement or accountability requirements have been violated, the enrolled site may temporarily lose program privileges. Suspension is dependent upon the severity of the non-compliance issues and/or failure to complete the TVFC required corrective action plans. TVFC 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, failure in vaccine management, failure of required patient eligibility screening, improper storage and handling practices, or failure to complete monthly reporting requirements. Staff at suspended sites may be required to complete additional training as part of a corrective action plan.

V. Termination from TVFC

A site may be terminated from the TVFC Program for continued non-compliance with TVFC requirements, such as failure to complete required corrective actions associated with non-compliance.

A site may also be terminated for instances of fraud and abuse, as described in Chapter 6: Fraud and Abuse, of this manual.

All sites will be notified of termination from the program via a signed letter from the Immunization Unit Director. Terminated sites will be removed from the TVFC Program for a period of at least one year. Sites seeking re-enrollment following the minimum termination period must seek approval to re-enroll from the DSHS Immunization Unit.

VI. Re-enrollment after Termination

In the event that a terminated site is approved for re-enrollment in the TVFC Program, completion of the most current TVFC Provider Policy Training is required. Staff must participate in on-site education and confirm that any outstanding issues have been resolved through a focused site review and assessment.

Sites that are terminated for instances of fraud and abuse may be considered for re-enrollment after one year, and only if the signing clinician is actively enrolled in Medicaid at that time and is not listed on OIG's List of Excluded Individuals and Entities (LEIE).

The DSHS Immunizations Unit has the authority to determine whether a site is eligible to re-enroll in the TVFC Program.

CHAPTER 2: TVFC PATIENT ELIGIBILITY AND SCREENING

I. Patient Eligibility Requirements

A. TVFC Patient Eligibility Criteria

Any child who is 18 years of age or younger and meets at least one of the eligibility criteria listed below is eligible to receive TVFC vaccine:

- Enrolled in Medicaid, or is Medicaid-eligible;
- Is UNinsured;
- Is an American Indian or Alaskan Native (in accordance with 25 USC 1603);
- Is UNDERinsured:
    - A child who has commercial (private) health insurance, but coverage does not include vaccines; or
    - A child whose insurance covers only selected vaccines (TVFC-eligible for non-covered vaccines only);
- Enrolled in the Children's Health Insurance Program (CHIP).

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

The Texas Department of Insurance (TDI) defines health insurance as a contract that requires a health insurance company to pay some or all the health care costs in exchange for a premium. A patient may be considered UNinsured or UNDERinsured (for the purpose of the TVFC eligibility) if they have one of the following types of "other" health insurance:

- Short-term major medical
- Limited benefit health insurance

- Supplemental health insurance
- Health care sharing ministries (HCSM)
- Direct primary care

To determine if an insurance plan is covered by the State of Texas, visit the Texas Department of Insurance.

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

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

B. Children's Health Insurance Program (CHIP)

Texas has an insurance program called the Children's Health Insurance Program (CHIP). An agreement between the DSHS Immunization Unit and CHIP stipulates that vaccines for eligible CHIP enrollees are purchased through the federal contract.

Since children with CHIP are not eligible for the federal VFC Program, the DSHS Immunization Unit is reimbursed for doses administered to CHIP children based on CHIP enrollment data. TVFC sites that administer vaccines to CHIP children must actively participate in CHIP. If CHIP is not billed for administration fees by the staff at the site, CHIP children must not be vaccinated.

C. Medicaid as Secondary Insurance

Children with private health insurance and Medicaid as a secondary insurance are eligible for the TVFC Program. Medicaid can be billed for the administration fee. The parent or guardian of a child with Medicaid as secondary insurance should never be billed a vaccine administration fee.

D. Nineteen-Year-Olds

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 ASN vaccines regardless of their current health insurance status. The vaccine must be administered at a DSHS PHR or LHD clinic. This provision only applies to patients that have not yet reached their 20th birthday.

NOTE: A "series" in this case is specific to two doses of Hepatitis A; three doses of Hepatitis B; two or three doses of HPV; two doses of MCV4; two doses of MMR; three doses of Td/Tdap; and two doses of varicella. This policy does not apply to MenB, polio, Hib or influenza vaccines. This policy also does not apply to booster doses.

II. Patient Eligibility Screening Record

Screening for patient eligibility is the foundation of the TVFC Program 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 on screening for eligibility is required. In the event improper screening results in the administration of TVFC vaccine to a non-TVFC-eligible child, staff are responsible for documenting the error on a Vaccine Borrowing Form (stock no. EF11-14171) and immediately replacing the improperly used TVFC vaccine with private stock.

Eligibility documentation of each child receiving TVFC vaccine at every visit is required. During a child's initial visit, eligibility must be documented per the TVFC Program guidelines. Every subsequent visit must contain the child's eligibility information.

The Patient Eligibility Screening Record (stock no. C-10) may be used or staff may electronically store patient demographic information in the site's Electronic Medical Record (EMR). Eligibility screening must be completed/ updated for all children at every visit, even including children with a

previous record on file. A child's eligibility must be documented at every visit prior to vaccine administration. The screening form is to be completed by the parent, guardian, individual of record, or by a health care provider and is a self-declaration. Verification of the parent's/guardian's response is not required.

Eligibility screening must include all the following elements:

- Date of screening,
- Child's name,
- Child's date of birth,
- Parent/guardian's name,
- Clinic name, and
- Eligibility status for each visit.

NOTE:
Screening patient eligibility is the foundation of TVFC Program accountability.

Screening must be completed for all children at every visit. Verification of the parent or guardian response is not required.

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 easily retrievable.

It is also acceptable for sites to utilize an EMR system to capture and save the information from the patient eligibility screening record if the EMR captures all the required eligibility elements.

CHAPTER 3: VACCINE MANAGEMENT

I. Approved Vaccines

All vaccines and toxoids recommended by Advisory Committee on Immunization Practices (ACIP) are available from the TVFC Program to enrolled clinic sites.

- Diphtheria and Tetanus toxoids, adsorbed (DT)
- 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 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)
- 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 (PCV13)
- Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
- Rotavirus (RV)
- Tetanus and diphtheria toxoids, adsorbed (Td)
- Tetanus and diphtheria toxoids and acellular Pertussis (Tdap)
- Varicella

II. Vaccine Ordering

A. Vaccine Choice

All vaccines and toxoids recommended by the ACIP are available from the TVFC Program to enrolled clinic sites. Clinics participating in the TVFC Program are required to offer all ACIP-recommended vaccines to the eligible populations they serve, including influenza vaccine. House Bill 448 from the 81st Texas Legislature gives staff at TVFC-enrolled sites the opportunity to choose preferred brands and presentations of vaccines from available formularies.

The signing clinician at TVFC-enrolled sites may choose vaccine brands and presentations. For new clinics enrolling in the TVFC Program, the RE and the staff will create an initial vaccine order using the Pediatric Biological Order Form (stock no. EC-68-1). The biological order form will reflect vaccine choices, maximum stock levels (MSL), and order quantity.

Each quarter, staff at TVFC-enrolled sites will have an opportunity to choose the brand and presentation for each TVFC vaccine in EVI. Changes or adjustments to specific vaccine brands, presentations, and percentages within each vaccine "family" (i.e., DTaP) can be made, or sites can decide to take no action which will maintain the current selections. Staff at TVFC-

enrolled sites are encouraged to review all choice selections on a quarterly basis.

A site's primary or back-up vaccine coordinator may complete the process, however, the signing authority must be consulted and must agree to the vaccine choices. The vaccine choices, as well as the person making the changes, are captured electronically in EVI. All TVFC sites are notified prior to the opening and closing of the vaccine choice period.

Only vaccines supplied by the Centers for Disease Control and Prevention (CDC) to the TVFC Program will be available for vaccine choice.

If a chosen vaccine is not available, the TVFC Program has the authority to replace the unavailable vaccine with a comparable substitution until the chosen vaccine becomes available.

NOTE: Vaccine choice does 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.

B. Patient Population Profile Estimates

The patient-profile captures the number of Federal VFC- and Texas VFC-eligible children served in each facility. Information reported on the patient-profile must represent the populations served during the most recent 12-months. During initial enrollment and annual re-enrollment, DSHS requires that all enrolled sites complete the patient-profile.

This data is used to ensure that vaccine orders are in the appropriate amounts and that each site properly maintains their vaccine inventories. This data should be collected by using one or a combination of any of the following sources:

- Benchmarking
- Medicaid Claims
- Immunization Information System Data (ImmTrac2)

- Doses Administered
- Encounter Data
- Billing System
- Other Methods (including forecasting)

When there is a change in the population, the Changes to Enrollment Form (stock no. 11-15224) must be submitted to the RE.

To assist providers with the management of their vaccine inventories, maximum stock levels (MSL) are calculated. MSL is a calculated peak dose inventory (per vaccine type) and provides a suggested quantity of the maximum number of doses a site needs to maintain a 75-day inventory. Changes to the patient-profile data will impact MSLs.

C. Vaccine Inventory Plan and Maximum Stock Levels

The vaccine inventory plan requires all enrolled sites to maintain a 75-day supply of vaccine inventory. Staff at TVFC-enrolled sites should place vaccine orders monthly. DSHS recommends placing a vaccine order when there is a four-week supply of vaccine available at the site, to ensure there is enough vaccine in stock to allow for any potential delays. DSHS also recommends smaller, more frequent orders rather than larger orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. Additional orders may be placed during the month. Vaccine orders are not required each month but should be entered as needed to maintain a 75-day supply of vaccine.

Current inventory and unit storage capacity must be considered when vaccine orders are placed to ensure adequate storage for all vaccines is available.

Special circumstances may allow for monthly MSL adjustments on rare occasions. Staff at TVFC-enrolled sites must request a review and obtain permission from their RE prior to ordering more than their suggested MSL quantity.

Upon initial enrollment, REs work with the site staff to develop MSLs based on the patient population reported during enrollment. All MSLs are monitored and revised in EVI. Newly enrolled sites may have MSLs reassessed by the RE after six months with the TVFC Program. MSLs are recalculated monthly based on the previous 12 months of doses administered data. The monthly average MSL is determined from this data. Staff at TVFC-enrolled sites may not order vaccine in excess of their suggested quantity without permission from the RE.

See Section VIII. Reporting Requirements, for more details of the monthly reporting requirements.

D. Increasing and Decreasing Maximum Stock Levels

MSLs may be increased or decreased at any time if the number of TVFC-eligible children changes, or if there are any applicable changes to the status of the facility that might impact vaccine usage. Staff at TVFC-enrolled sites must notify the RE if a change is needed. Changes may also be made by the DSHS Immunization Unit based upon the data gathered during the calendar year.

To determine appropriate MSLs for the back-to-school season, calculations are done automatically in EVI using doses administered data from the previous June, July, August, and September.

MSLs may be lowered at sites that consistently order below the suggested quantity. MSLs may be increased at sites that place multiple orders during a given month. Final determination is made depending on the frequency and duration of the ordering patterns.

E. Short-Dated Vaccine

Short-dated vaccines are those that are within 60-90 days of expiration. Placing vaccine orders according to the established MSLs and rotating vaccines so that short-dated vaccines are used first will help to prevent losses due to expiration. Clinic staff must note vaccine expiration dates

when physically counting inventory at the end of the month. Short-dated vaccine must be used first. Vaccine surplus kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of unit failure. When vaccines are ordered, staff must have no more than the designated MSL in stock, including the order.

Each site is required to notify the RE 60-90 days prior to the expiration of vaccine. If the vaccine is not able to be administered prior to expiration, the RE may assist with moving the vaccine to another site, provided another site is willing to accept the vaccine.

> ***NOTE:***
> *Monthly reporting in EVI is required for all TVFC-enrolled sites, whether or not a vaccine order is placed.*

Vaccine diluents, the liquid mixed with a freeze-dried vaccine to reconstitute it, must be managed in the same manner as vaccines. The expiration date of diluents must be checked prior to every reconstitution. The diluent must be rotated to use the shortest expiration date first.

If vaccines 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.

F. Storage Capacity for Vaccine Orders

Sites must have adequate refrigeration and/or freezer space to accommodate a maximum order based on MSLs, including flu and back-to-school. Space needed for private stock vaccine must be taken into consideration when calculating storage capacity.

G. Vaccine Ordering in the Electronic Vaccine Inventory (EVI) System

The TVFC Program uses EVI for vaccine ordering. EVI allows TVFC-enrolled sites to manage vaccine inventory online. All vaccine orders will be placed

in EVI unless internet access is unavailable. Sites may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

Prior to placing a vaccine order, the following information must be entered in EVI.

- Verification of days and hours of operation that the staff at TVFC-enrolled sites are available to receive vaccine,
- The clinic's delivery address,
- Primary and back-up point of contact information,
- All vaccine doses received,
- All vaccine doses transferred,
- Any expired, spoiled, or ruined/wasted vaccine doses,
- All doses administered within the last calendar month,
- A physical count of all vaccines by brand, presentation, lot number, and expiration date on the Monthly Biological Report (stock no. C-33),
- If applicable, all doses that will expire within the next 60 to 90 days, and
- All scheduled clinic closures (including holidays) must be noted in the comments section of the order.

Monthly reporting is required for all sites, whether or not a vaccine order is placed.

The following reports must be submitted to the RE via fax or email:

- Temperature Recording Forms (EC-105),
- Vaccine Loss Report (if applicable), and
- Vaccine Borrowing Report (stock no. EF 11-14171) (if applicable).

All orders placed in EVI will be reviewed and approved by the RE after the completion and submission of the required monthly reporting and resolution of outstanding issues. Incomplete or inaccurate online orders will be placed on "Hold" pending corrections which may cause vaccine orders to be

delayed. Each site must abide by established MSLs when ordering vaccine. EVI uses the TVFC-enrolled site's MSLs and current on-hand inventory to determine a suggested quantity of vaccine on the "Place Order" tab. Any order placed over the established MSL during a vaccine allocation, will be reduced to the suggested quantity.

Vaccine loss is captured electronically in EVI. When a loss of expired, spoiled, or ruined/wasted vaccine is documented in EVI, the system will automatically place subsequent orders on "Hold" until the nature of the loss has been determined.

All sites can view vaccine order status on the "Order History" page of EVI. Status definitions are defined below.

OPEN	Indicates the order is ready to be sent to the distributor for shipment three business days from the date the order is placed and after approval by RE.
HOLD	Indicates the order has not been approved, pending the review of a Vaccine Loss Report (VLR), the need for additional documentation, or other identified issues.
PACKED	Indicates the order is with the distributor.
SHIPPED	Indicates the order is in transit or a transfer has been conducted in EVI.
RECEIVED	Indicates the vaccine order has been received.

If a discrepancy is found between the orders placed, the packing list, the fax confirmation, or the doses received, staff at TVFC-enrolled sites must immediately contact the RE for resolution. All vaccines must be appropriately stored immediately upon receipt regardless of errors in the order.

H. Vaccine Ordering for Sites without Internet Access

TVFC-enrolled sites without access to the internet must contact the RE. The RE will enter the TVFC vaccine order in EVI. The TVFC-enrolled site must submit the following paper forms to the RE to place a vaccine order.

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

The monthly biological report is reviewed by the RE 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-enrolled site, so the records can be corrected prior to ordering.

I. Vaccine Ordering for Newly Enrolled TVFC Sites

Newly enrolled TVFC sites are set up for vaccine ordering in EVI following completion of new provider training with the RE. The vaccine order is placed by the site staff after receipt of EVI login information and assignment of a PIN as part of the second visit/contact. The RE will collect and review the following paper reports prior to assisting the staff with placing the initial vaccine order.

- Pediatric Biological Order Form (stock no. EC-68-1); and
- Temperature Recording Forms (stock no. EC-105).

J. Ordering Influenza Vaccine

The ACIP recommends routine annual influenza vaccination of all persons aged 6 months and older. Additionally, as a member of the TVFC Program, signing clinicians have agreed to administer all ACIP-recommended vaccines to the eligible population that are served.

The pre-book for influenza vaccine is a commitment by the TVFC-enrolled

sites to order doses for the upcoming flu season. Annual influenza vaccine orders are typically pre-booked in the first quarter of each calendar year. An online survey tool is used to allow staff to select vaccine choices for the upcoming season. The survey link is made available to the TVFC sites in a memo and includes a brief description of the influenza vaccines available for the upcoming flu season.

NOTE:
DSHS recognizes that TVFC and privately-purchased flu vaccine may arrive at sites at different times during the flu season. Even if this occurs, TVFC vaccine must not be used on ineligible children.

If a site's influenza vaccine order exceeds the reported number of eligible children documented in the patient profile section of the enrollment form, staff may be contacted for an explanation. If a site sees TVFC-eligible children and does not order influenza vaccine for the upcoming season, they must complete a separate section of the survey explaining why they are not ordering the vaccine and should expect to receive a follow-up contact from the RE. TVFC-enrolled sites are required to follow all ACIP recommendations, including the administration of influenza vaccine.

The TVFC Program orders a limited quantity of additional doses to account for new sites that enroll after the closing of the pre-book survey. Other unforeseen situations that may occur between the pre-book and the actual release of the vaccines to the TVFC Program may also be considered for first round allocations.

Influenza vaccine will be allocated to TVFC-enrolled sites when it is made available to Texas. The TVFC Program typically completes all pre-booked and new TVFC-enrolled sites orders first as part of the first-round allocation. A second influenza survey tool is held for TVFC sites that did not order during the pre-book period. Sites that want to add to the original flu order may also order additional vaccine during this second round. When the first and second round orders are filled entirely, all remaining influenza vaccine will be added to the EVI system for open ordering by all sites. If

there is an additional need for influenza vaccine in a site or area of the state, the TVFC Program will contact other sites in Texas for a possible vaccine transfer or may place an additional order with the CDC.

DSHS recognizes that both TVFC-supplied and privately-purchased influenza vaccines may arrive at sites at different times during the influenza season. Even if this occurs, the TVFC Program does not allow TVFC vaccine to be borrowed to administer to non-TVFC eligible clients.

III. Vaccine Distribution

A. Vaccine Distributors

The TVFC Program uses two vaccine distribution centers.

- McKesson Specialty, a third-party distributor which ships the majority of TVFC vaccines which are refrigerated.
- Merck, the manufacturer of frozen vaccines, which ships directly to TVFC -enrolled sites.

B. Receiving Vaccine Orders

The TVFC Program requires that vaccine shipments always be accepted and never refused or returned without specific instructions from the RE or the DSHS Immunization Unit. The staff at TVFC-enrolled sites must ensure that the accurate clinic address and delivery hours are entered in EVI.

For sites 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. to 5:00 p.m. Each site establishes the hours available to accept vaccine shipments when the initial vaccine order is submitted in EVI. The vaccine will be shipped so that it will arrive when staff are available to accept the vaccine. The staff at the TVFC-enrolled site may not change available hours in EVI once an order is placed. The signing clinician is responsible for incomplete or erroneous information entered in EVI which can result in vaccine loss.

Sites can expect their approved orders approximately two to three weeks after placing the online order in EVI. It is important to recognize and store vaccine shipments immediately upon receipt to ensure vaccine viability. All staff at TVFC-enrolled sites are required to train other clinic staff on what a vaccine shipment looks like and must maintain a completed vaccine management plan in place to ensure the vaccine is stored quickly and correctly upon arrival.

NOTE:
Vaccine is packed by the manufacturer and distributor using qualified pack-outs and containers that have been tested to maintain appropriate temperatures.

The following steps are required when a vaccine shipment arrives.

- Check vaccines against the packing list to verify all vaccines have been received.
- Inspect the vaccines and check the temperature strip or other temperature reading device.
- Ensure adequate amount of diluent is included for those vaccines which require reconstitution (e.g., MMR, Varicella).
- Determine the length of time the vaccine was in transit by looking at the ship date and time on the packing list or the transport tracking link in EVI.
- Immediately contact the RE when:
    - The appropriate quantity and type of vaccine or diluent is not received,
    - Vaccines have been received in error, or
    - Vaccines appear to be compromised.
- Appropriately store all vaccines immediately upon receipt regardless of any errors in quantity, shipping, or transport.

- Check expiration dates and rotate stock to ensure short-dated vaccines are used first.
- Immediately accept receipt of the vaccines in EVI.

Each package shipped from McKesson comes with a temperature monitoring strip(s). If the monitor strip(s) indicates, or if staff suspects that the cold chain has been compromised, staff must immediately follow the instructions in subsection D below, Vaccines Received Warm or Questionable.

Staff at TVFC-enrolled sites are required to accept the vaccine at the time of receipt in EVI to maintain correct online vaccine inventory.

C. Manufacturer and Distributor Maintenance of the Cold Chain

The manufacturer and distributor 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 from McKesson are imprinted with "Temperature Sensitive Product" and include stickers reading "Refrigerate upon Arrival" to alert clinic staff to refrigerate contents immediately upon arrival.

Varicella and MMRV are shipped directly 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 packing slip, then the vaccine is viable. Staff must immediately place all vaccines in proper storage. If the vaccine arrives outside of the four-day pack-out, the staff must immediately place the vaccine in a vaccine quarantine bag provided by the TVFC Program, store the vaccine properly, notify the RE, and contact the manufacturer.

D. Vaccines Received Warm or Questionable

Vaccines must always be stored properly, even if viability is questionable.

Vaccines that are received warm, damaged, or in an otherwise questionable state require immediate contact to the RE. Questionable vaccine cannot be identified visually and must be placed in a Vaccine Quarantine Bag provided by the TVFC Program and separated in proper storage until viability can be determined.

Examples are below of questionable (potentially non-viable) vaccines:

- Vaccine shipment received with temperature indicator strip showing out of range.
- Vaccine is warm to touch.
- Ice/gel packs are melted.
- Ice/gel packs are missing.
- Vaccine is received damaged.

If vaccine viability is questionable upon receipt, staff must follow the steps below:

- Place the probe of the back-up 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 questionable vaccine in a vaccine quarantine bag and place the questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine itself.
- Contact the RE on the same day the vaccine arrived. If the RE is not available, contact the distributor(s) to determine if a shipping issue has occurred. Direct contact with the distributor(s) should only occur when there is a questionable temperature during shipment.
- Inform the RE of the determination of the viability of the vaccine.
- Vaccine must be kept quarantined until instructions for replacement, reporting loss, etc. are received.

NOTE: Vaccine returns due to shipping issues are required to be returned to McKesson within 48 hours. Merck requires that frozen vaccine be returned within 15 days of the original shipment.

E. Vaccines Received in Error

The RE must be contacted immediately upon receipt of vaccines that are received in error. Staff at the TVFC-enrolled site may choose to keep the vaccine if storage capacity is sufficient and the vaccine doses will be administered. If vaccine was ordered by the site incorrectly, it is the site's responsibility to keep the vaccine. If the site cannot absorb the vaccine due to storage capacity, the RE may assist in redistributing the vaccine to other sites to prevent vaccine wastage.

IV. Vaccine Loss

A. Expired, Spoiled and Ruined/Wasted Vaccine

The Immunization Unit requires all unopened or unused vials and syringes of expired TVFC vaccines be returned to the third-party distributor (McKesson). Staff must not discard TVFC vaccine unless specifically directed by the RE or the DSHS Immunization Unit. Exception to this rule will be communicated by the DSHS Immunization Unit on a case-by-case basis. Staff at TVFC-enrolled sites are to immediately notify the RE of vaccine cold chain failure events or vaccine wastage incidents involving TVFC vaccines upon discovery of the incident.

> ***Purpose:***
> *Expired or spoiled vaccine must be returned to the distributor within 6 months of the loss.*

Expired or spoiled vaccine is any non-viable vaccine in its original container such as a vial or syringe. This includes expired vaccine or vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage,
- Refrigerator temperature too warm (greater than 46ºF or 8ºC) or too cold (less than 36ºF or 2ºC),
- Freezer too warm (greater than +5ºF or -15ºC),
- Vaccine was not stored properly upon receipt,
- Vaccine was spoiled in transit due to provider error,
- Vaccine was spoiled in transit due to shipper error, no replacement will be sent, or
- Mechanical failure of a refrigerator or freezer unit.

Ruined/wasted vaccine is non-viable vaccine that cannot be returned. Below are examples of ruined/wasted vaccines.

- Vaccine drawn into the syringe but was not administered.
- Vaccine in an opened multi-dose vial where all doses have not been administered.
- Compromised vial (due to a drop causing damage to vial integrity or sterility).
- 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 was drawn or used for vaccine reconstitution.

Expired or 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. Lost vials must be adjusted in EVI.

Vaccine loss must be documented on a VLR in EVI no later than four (4) days past the date of the incident(s). All vaccine returns to McKesson must occur within six months of the loss.

B. Procedures for Vaccine Loss

Every dose of vaccine that is lost due to expiration or spoilage must be reported to the TVFC Program on a VLR electronically in EVI. VLRs are generated electronically by completing the wasted/expired tab in EVI. Expired or spoiled vaccine must be returned to the distributor within six months of the loss.

Staff must follow the procedures listed below when a vaccine loss occurs.

- Complete wasted/expired tab in EVI to generate a VLR. VLRs must be generated within four days after the date of the incidence or loss.
- Remove expired or spoiled vaccine from the vaccine storage unit and place in a vaccine quarantine bag.
- Contact the RE immediately with the following information:
    - Antigen,
    - Lot number,
    - Expiration date, and
    - Reason for the loss.
- If the storage unit was compromised, provide the RE with amount of time the product was out-of-range and the highest and lowest temperatures recorded (this information may be gathered by performing a download of the data logger).
- Document the vaccine loss on the wasted/expired tab in EVI to generate a VLR electronically within four (4) days after the date of the incident or loss. Explain the cause(s) of the loss and outline the steps taken to ensure vaccines will be protected in the future.
- The VLR must be printed and signed by medical personnel with prescribing authority listed on the site's enrollment form. The report must be emailed or faxed to the RE. Sites are not allowed to use signature stamps on the VLRs as it is expected that the signing authority be fully aware of the loss in the clinic.

- The following sections are required to be filled out on a VLR:
    - Clinic demographics
    - Date loss was discovered
    - Type of loss
    - Reason for the loss
    - Corrective action taken to avoid re-occurrence
    - List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost

The primary vaccine coordinator will receive a shipping label via email for returning expired or spoiled vaccine. Depending on the number of doses lost, multiple shipping labels may be received. Staff must wait until UPS returns to the TVFC-enrolled site to pick up the expired or spoiled vaccine to avoid paying a fee. Shipping labels expire after 30 days. If a provider received a shipping label and UPS has not picked up the package within 30 days, staff must contact the RE for a new shipping label.

- Staff must ensure that all vaccines listed on the VLR are included in the box for return. Do not return broken vials or syringes with needles attached.
- If more than one box is used to return non-viable vaccine, staff must indicate on the VLR the number of the box in which the vaccine is being shipped (e.g., "Box 1 of 2", "Box 2 of 2", etc.). Each box that is used to return vaccine must not weigh more than 70 pounds.
- Ruined or wasted vaccine (vaccine or diluent drawn into a syringe but not administered or refused by the patient, opened multi-dose vials, broken vials, or lost vials) listed on the VLR must be marked through with a single line as they must not be included in the box for return.

NOTE: Only unbroken, sealed vaccine vials or 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.

Staff must wait until UPS returns to the site with the next delivery to return the box. Calls to UPS to schedule a pickup will be subject to a fee set by UPS. McKesson will not schedule pickups on behalf of TVFC-enrolled sites unless special arrangements are made by the DSHS Immunization Unit.

Enrolled sites who have lost vaccine as a result of improper temperature storage must assess how long the vaccines were stored improperly and how many children may have received the affected vaccines. The signing clinician determines whether children will need to be recalled and revaccinated.

The TVFC Program will not provide the vaccine for recalled children in these circumstances. The clinic will assume all financial responsibility for the cost of vaccines for recalls. Clinic staff must contact the RE with the determination from the signing clinician.

C. Negligent Vaccine Loss

Signing clinicians at TVFC-enrolled sites are responsible for negligent vaccine losses. Following are examples of vaccine negligence.

- Drew up vaccine dose and the parent or patient refused.
- Drew up the wrong vaccine including:
    - The vaccine was mixed with the wrong diluent.
    - Only diluent was administered,
- Dropped vaccine dose resulting in:
    - Damage to the vial integrity or sterility.
    - Compromised vial.
- Expired vaccine and the site did not notify RE 60 to 90 days before expiration.
- Failure to store vaccine properly including:
    - Vaccines that were left out of appropriate storage.

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

TVFC or ASN-enrolled sites may be required to reimburse the DSHS Immunization Unit for vaccine losses that occur due to negligence.

D. Non-negligent Vaccine Loss

Non-negligent vaccine losses include the following:

- Damaged needle or seal, particulate in the vial, or discolored product;
- Expired flu, DT, pediatric Td, 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 opened multi-dose vial; and
- Vaccine spoiled in shipment due to shipper error

V. Vaccine Storage and Handling

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, and continues through the delivery to and storage at the enrolled 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. If there is a failure in the cold chain, the result can mean extra doses for patients, increased cost for sites, 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. Maintaining the vaccine cold chain will avoid incurring additional costs associated with loss and replacement of vaccines, as well as the need to recall patients for revaccination.

A. Refrigerator and Freezer Requirements

TVFC-enrolled sites are required to have appropriate equipment that can store vaccine and maintain proper conditions. The following are strong recommendations.

- Refrigerator and freezer units must be large enough to hold the year's largest inventory without crowding (such as influenza season or back-to-school).

- The DSHS Immunization Unit 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
  - Combination household unit
- In the event a combination household unit is used, the site is strongly encouraged to obtain a stand-alone freezer. Refrigerated vaccine is to be stored in the household unit and frozen vaccine will be stored in the stand-alone freezer.
- Combination units, if used to store both refrigerated and frozen vaccine, must have separate thermostats for each compartment.

NOTE:
Refrigerator and freezer units must be large enough to hold the year's largest inventory without crowding.

- Dorm-style and small combination refrigerator and freezer units with a single external door are never allowed for the storage of TVFC vaccine.
- Refrigerators with solid glass shelves are approved for use.
- The refrigerator compartment must maintain temperatures between 36° F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at 40°F (4°C).
- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C) for vaccine viability.
- An alarm system and back-up generator are recommended to help reduce vaccine loss when unexpected temperature fluctuations occur.
- Refrigerators and freezers storing vaccines must be plugged directly into a wall outlet with a plug guard installed to prevent accidental or intentional unplugging.

- Units containing TVFC vaccine must not be plugged into a multi-strip power outlet, surge protector, or an extension cord. In addition, units must not be plugged into an outlet that is controlled by a wall switch, or GFI outlets.

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 Program has not validated any product or service for compliance with TVFC Program requirements or standards.

NOTE:
DSHS prohibits the use of the following in units containing TVFC/ASN vaccine:
- *Gel packs*
- *Ice packs*
- *Vaccine shipment coolant packs*

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

Water bottles serve as a physical barrier to prevent placing vaccines in areas where there is greater risk for temperature excursions.

The following cooling materials must not 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

NOTE: Water bottles should not be used in pharmaceutical/purpose-built units if the manufacturer indicates that water bottles negatively impact the functionality of the unit.

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. All empty space in the unit should be filled with water bottles.

- For the refrigerator:
    - Ensure the door closes completely.
    - Replace crisper bins with water bottles to help maintain a consistent temperature (unless used for other medical equipment or supplies).
    - Label water bottles "Do Not Drink".
    - Post "Do Not Unplug" signs on the refrigerator, at the electrical outlet, and at the circuit breaker.
    - Place water bottles in unit doors carefully so they do not dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly.
    - Place water bottles on the top shelf of the refrigerator under the fan (if present).
    - Do not use the top shelf for vaccine storage.
    - Do not store food or beverages in the refrigerator with vaccines.
    - Do not put vaccines in the doors or on the floor of the refrigerator.
    - Do not drink from or remove the water bottles.
    - Leave 2-3 inches between all vaccine (if possible) and the refrigerator walls.
    - Vaccine with diluent must be kept together in the same box. The Merck diluent for MMR, MMRV, VAR, and Zoster vaccines may be

stored in the door of the refrigerator, but this diluent does not require refrigeration and must not be frozen.

- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents must not 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. Store vaccines and diluents with similar packaging or names (e.g., DTaP and Tdap or Hib and Hep B) 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.
- Always store vaccines in their original packaging with lids closed until ready for administration unless vaccines are stored in an auto -dispensing unit that requires vaccines to be removed from the original packaging.
- Never store loose vials or manufacturer-filled syringes outside of their packaging.
- Do not pack a storage unit too tightly. This may result in restricted air circulation and impact the unit's temperature.
- Vaccines must be centrally stored within the unit.
- Store privately-purchased vaccine on different shelves from TVFC vaccine to minimize the risk of administering TVFC vaccine to non-eligible patients. TVFC vaccines must be clearly marked to differentiate them from privately-purchased vaccines.

- For the freezer:
  - Ensure the door closes completely.

- Use frozen water bottles to help maintain a consistent temperature.
- Place water bottles against the walls, in the back, on the floor, and in the door racks.
- Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly.
- Post "Do Not Unplug" signs on the freezer and by the electrical outlet.
- Do not store food in the freezer.
- 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.
- Store each type of vaccine in a separate container.
- Vaccines must be centrally stored within the unit.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Attach labels to shelves and containers to clearly identify each type of vaccine.
- Store vaccines with similar packaging or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors.
- Store privately-purchased vaccine in a clearly marked container separate from TVFC vaccine to ensure TVFC vaccine is not inadvertently administered to a non-eligible patient.
- Clearly label the formulation "pediatric" or "adult," if applicable.

- Always store vaccines in their original packaging with lids closed until ready for administration.
- Never store loose vials or manufacturer-filled syringes outside of their packaging.
- Diluents must not be frozen.
- Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

NOTE: TVFC vaccine that is stored in an auto-dispensing or door-less purpose-built unit may require vaccine to be removed from the original packaging. The original packaging must be kept and readily accessible in the event the vaccine must be transported outside of the unit.

New or Repaired Units:

Prior to using a new or newly repaired unit to store vaccines, the TVFC Program requires seven (7) operational days of refrigerator or freezer temperature recordings (twice daily) on a Temperature Recording Form (stock no. EC-105) form using a certified calibrated data logger. Minimum and maximum temperatures are required to be recorded once daily, at the beginning of each business day, to ensure temperatures are within appropriate ranges.

Submit the recordings to the RE for review and approval, before placing vaccine in the storage unit. Minimum and maximum temperature readings must be reset from the day before at the end each business day (if the device requires this function).

If adjustments to a unit's temperature control is necessary, read the instructions carefully and 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 unit door.

Refrigerators and freezers that store TVFC vaccines are to be dedicated to storing vaccine only. Food or drinks in the same refrigerator or freezer as

vaccines is not allowed. If other biologics must be stored in the same unit, store them below the vaccines to avoid contamination.

Maintaining TVFC temperature logging requirements is mandatory for all TVFC-enrolled sites. The required steps are listed below.

- A Temperature Recording Form (stock no. EC-105) is required to be located on or near all units that store TVFC vaccines.
- Freezer and/or 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.
- Minimum and maximum temperature readings must be reset from the day before at the end of each business day.
- Temperatures must be recorded manually on temperature recording forms, using a data logger.
- Temperature recording forms must be posted on each vaccine storage unit door or nearby in a readily accessible and visible location; and
- Temperature recording forms must be maintained for five years and made easily available.

An electronic version of the Temperature Recording Form (stock no. C-105) is only acceptable if the generated report meets all the requirements listed above.

If an out-of-range temperature excursion is observed, the clinic staff must document all excursions and take the following actions immediately.

- Place vaccines in a vaccine quarantine bag.

NOTE:
TVFC-enrolled sites using data loggers must still comply with twice daily temperature and minimum and maximum recording requirements.

- Store vaccines in a unit where they can be kept under appropriate conditions.
- Generate a report from the data logger for discussion with the vaccine manufacturer.
- Contact the vaccine manufacturer that is listed on the box to obtain documentation for the viability of the vaccine.

Contact the RE to report the manufacturer's vaccine viability determination, submit the manufacturer's determination letter(s) or online validity results and complete the Vaccine Storage Troubleshooting Record, page 3 of the Temperature Recording Form (stock no. C-105).

Figure 3-1 illustrates the steps for handling a temperature excursion in your vaccine storage unit.

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion.
Identify temperature excursions quickly and take immediate action to correct them.
This can prevent vaccine waste and the potential need to revaccinate patients.

» **Notify** the primary or the back-up vaccine coordinator immediately to report the problem.

» **Notify** staff by labeling exposed vaccines, "DO NOT USE" and placing them in a separate bag or container apart from the other vaccines in the storage unit. Do Not Discard These Vaccines.

• Do not write on the vaccine itself.

» **Download** the data logger report to determine the length of time the vaccine may have been affected by out-of-range temperatures.

» **Document** details of the temperature excursion on page 3 of the temperature recording form.

- Include date and time.
- Storage unit temperature, (including minimum/maximum temperatures during the time of the event, if available).
- Room temperature.
- Name of the person completing the report.
- General description of the event (i.e., what happened, steps taken to resolve the issue, and the outcome.)

» **Contact** each vaccine manufacturer to determine vaccine viability. Be prepared to provide data logger information so they can offer you the best guidance.

» **Contact** the RE to report and submit the manufacturer's determination letter(s) for each vaccine affected.

Contact manufacturer for excursions

Merck	1-800-627-6372
Sanofi Pasteur	1-800-822-2463
GlaxoSmithKline	1-888-825-5249
Pfizer	1-800-438-1985
Seqirus	1-800-358-8966
Astra Zeneca	1-800-236-9933

» **Corrective** action should be taken if the temperature continues to go out of range. Do not stop the alarm until the cause is determined and addressed.

» Check the following items first:

- Power supply (i.e., batteries or power cord)
- Unit door(s)
- Storage unit thermostat settings
- If alarm continues to sound repeatedly, refer to manual or contact RE for assistance.

» If the excursion was the result of a temperature fluctuation, refer to the current Provider Manual Chapter 3, Vaccine Storage and Handling.

If you believe the storage unit has failed, implement your Emergency Vaccine Storage Plan. Never allow vaccines to remain in a non-functioning unit.

B. Data Logger Requirements

DSHS requires a data logger for all units that contain TVFC or ASN vaccines and a back-up data logger.

Units that store TVFC or ASN vaccines must contain a centrally located data logger probe with a current and valid Certificate of Calibration Testing, also known as a Report of Calibration (see page 57, Figure 3-2), 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.

Staff at TVFC-enrolled sites that use data loggers must still comply with twice daily temperature and minimum and maximum recording requirements. When reading the data logger, do not round the numbers up or down-only record the numbers to the left of the decimal point. Temperatures must not be converted from Fahrenheit to Celsius or Celsius to Fahrenheit. It is recommended that staff download the data from their data loggers at least once per week, on Mondays, to ensure that any excursions are identified and addressed in a timely manner.

The following are requirements for data loggers:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door.
    - The data logger must have functionality that does not require a computer password to access the temperature display.
    - The display must remain active for temperature readings (i.e., must not have sleep mode turned on).
- 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 +/-1°F (+/-0.5°C).
- Detachable probe in buffered material.
- Memory storage of at least 4,000 readings (device must not rewrite over old data and must stop recording when the memory is full).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

Probes must be 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 the following:

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

The TVFC Program does not allow the following temperature monitoring devices:

- Alcohol or mercury thermometers, even if placed in fluid-filled bio-safe liquid vial.
- Bi-metal stem temperature monitoring devices.
- Food temperature monitoring devices.
- Household mercury temperature monitoring devices.
- Chart recorders.
- Infrared temperature monitoring devices.
- Thermometers.

These devices can have significant limitations, can be difficult to read, and generally only provide information on the temperature at the precise time

they are read. Therefore, temperature fluctuations outside the recommended range may not be detected.

The following are requirements for data logger probes:

- Placed in the center of the unit.
- Placed as close to the vaccine as possible.
- Placed away from walls, ceilings, cooling vents, doors, floor, and back of the unit.

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

The data logger probe must not be suspended from wire shelves or suspended by tape or other means attached to the inside ceiling of the unit.

NOTE:
The back-up data logger is recommended to have a different calibration retesting date. By having different calibration dates, there will always be one data logger available for use.

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

A valid certificate of calibration matching the serial number of the data logger in use must be readily available for review and is recommended to be posted on or near the refrigerator and/or freezer. Calibration testing should be done every 1 to 2 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.

Data logger certificates of calibration must contain the following:

- Model number,

- Serial number,
- Date of calibration,
- Measurement results that indicates the unit passed the test and the documented uncertainty is within suitable limits (+/-1°F [+/-0.5°C]), and
- A statement indicating that it meets International Organization for Standardization/International Electronic Commission (ISO/IEC) 17025 standards.

All clinic sites must have at least one back-up data logger with a valid and current certificate of calibration. Back-up data loggers must be readily available in the event the primary data logger that is in use is no longer working appropriately, in the event of an emergency transport of vaccine or if calibration testing of the current equipment is required.

The back-up data logger must be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

The back-up data logger is recommended to 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. This will also negatively impact the results of the TVFC compliance site visit. By having different calibration dates, there will always be one data logger available for use.

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 as needed to maintain proper temperature. These units must meet all TVFC data logger requirements.

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

Figure 3-2. Example of a data logger Certificate of Calibration.

Data Logger Company

CERTIFICATE OF CALIBRATION

Certificate Information:

Certificate Number: C-13-04-16-019

Calibration Technician: S Perez

Calibration Date: 2013-

Next Calibration Due: 20-

CERTIFICATE OF CALIBRATION

Published D

Accuracy:

Range:

Resolution:

Point

Actual T

1 25

Initial Co

Gain: 1

Offset: 0

Device Error = Device-Standard

0

Calibration And Service:

Issued By: Date: 2013-04-26

Approved By: Date: 2013-04-26

Maintaining Calibration:

This product is manufactured from the highest quality components. The unit has been designed to remain within its specifications during normal use. However, the length of in-tolerance service can be affected by low battery voltage, age, temperature, humidity, shock, and other environmental influences. For those users with critical performance or validation requirements, MadgeTech, Inc. recommends that the unit be serviced and calibrated at regular periodic intervals.

Certificate Number: C-13-04-16-019

Date Created: 2013-04-26

Date Printed: 2013-04-26

Certificate Page: Page 1

Company Contact Information:

C. Vaccine Storage Requirements

Some vaccines are sensitive to light and their efficacy could be compromised if exposed to light. The following vaccines must be protected from light MenB, Hib, HPV, MCV4, MMR, MMRV, Rotavirus, and Varicella.

All these vaccines, except 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 (-50°C and -15°C). MMR vaccine may be stored in either a refrigerator or freezer.

All vaccines must be stored in the central area of the refrigerator and/or freezer, not in the vegetable bins, meat drawers, in the door, or on the floor. Storing vaccines in the central body of the refrigerator and/or freezer helps maintain proper temperatures for the vaccines.

Vaccines must be stored and/or stacked to allow cold air to circulate freely.

All TVFC vaccines must be stored separately from privately-purchased vaccines and must be labeled accordingly.

Clinics that are also enrolled in the ASN Program must separate TVFC-provided pediatric doses from ASN-supplied adult doses. Sufficient alternate space to store vaccines and maintain the cold chain during any period when the refrigerator/freezer is out of service must be identified.

D. Protective Equipment

The power supply for vaccine storage units must be protected by ensuring these practices are followed.

- Plug unit(s) directly into a wall outlet.
- Plug only one unit into an outlet.
- Plug guards are required to be used on all units that store TVFC vaccines. Plug guards are effective tools in preventing the accidental or intentional unplugging of equipment.

- A "Do Not Unplug" sign is required to be posted on or near all outlets where units are plugged in.
- A "Do Not Disconnect" sign must be posted on or near each circuit breaker.

Do not use the following for units that contain TVFC vaccine.

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

E. Personnel

Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle TVFC vaccine must be trained on proper storage, handling, and administration of vaccine as well as aware of and familiar with the written procedures for emergency situations to assure continued viability of the vaccines. The site is required to designate a primary and at least one back-up vaccine coordinator to ensure that TVFC vaccines are handled and stored properly.

NOTE:
The primary and back-up vaccine coordinators must complete the current TVFC Provider Policy Training module.

The following are training requirements for vaccine coordinators:

- Primary and back-up vaccine coordinators at all new TVFC-enrolled sites must complete the mandatory the most current TVFC Provider Policy Training module and the CDC "You Call the Shots" training modules 10 and 16 and provide the certificates of completion to the RE.

- Replacement primary and/or back-up vaccine coordinators must complete the mandatory the most current TVFC Provider Policy Training module and CDC "You Call the Shots" training modules 10 and 16 and provide the certificates of completion to the RE.
- During re-enrollment, the primary and back-up vaccine coordinators must complete the mandatory the most current TVFC Provider Policy Training module and upload the certificates of completion to the electronic re-enrollment form.

The Immunization Unit has developed Texas Vaccine Education Online (VEO) modules to provide short online training courses on topics related to vaccines. Individuals may log in and take any course free of charge. Additional information and a course listing are available at www.vaccineeducationonline.org.

F. Routine and Emergency Storage and Handling Plan

All TVFC-enrolled sites must have plans for routine and emergency vaccine management. The TVFC Program provides templates for the Vaccine Management Plan and the Emergency Vaccine Storage and Handling Plan Checklist (stock no. E11-14498).

The plan and checklist templates contain comprehensive information on best practices and the most current information about the storage and handling of vaccines.

Clinics are not required to use these templates, but they are valuable tools should assistance be needed when developing an emergency plan. If the templates are not used, staff at the site must develop routine and emergency vaccine management plans that include all the information on the templates provided by the TVFC Program.

The Vaccine Management Plan and the Emergency Vaccine Storage and Handling Plan Checklist (stock no. E11-14498) must be reviewed and up-dated annually. The signature, name, and title of the preparer as well as the date the documents were reviewed must be documented.

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

- Identify a responsible primary and back-up person to carry out the contingency plan. Contact information such as email addresses and home, office, and cell phone numbers for both persons must be included. Contact information must be updated annually or when changes occur.
- Identify an alternative location to take the TVFC vaccine for storage in the event of an emergency. 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 clinic site and can maintain the cold chain during any period when the TVFC clinic's refrigerator or freezer is out of service, as well as adequate space to accommodate the largest vaccine inventory. Temperatures for these temporary storage units are required to be monitored and recorded.
- Adequate supplies in amounts sufficient for packing and transporting the entire TVFC vaccine inventory must be available at the enrolled, in case of an emergency.
- Contact with staff at the emergency storage location is important to gain their approval before including them as part of the plan. List their contact person(s) and phone number(s) on the plan. An alternative back-up location must be considered in the event that the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.

The most current Emergency Vaccine Storage and Handling Plan will be reviewed during TVFC Compliance Site Visits and Unannounced Storage and Handling Visits. The documents must be posted on or near the refrigerator or freezer that contains TVFC vaccine. The clinic staff involved with vaccine management must be aware of this plan.

G. Vaccine Protection in the Event of an Emergency

As noted above, every facility maintaining an inventory of TVFC vaccine is required to develop and display an Emergency Vaccine Storage and Handling Plan (stock no. 11-14498) in the event of emergencies that could result in the loss of vaccine. Once completed, this template can serve as the required Emergency Vaccine Storage and Handling Plan (stock no. 11-14498).

This plan must be reviewed and updated 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, the RE must be contacted immediately to inform of the situation.

Staff at enrolled sites must be prepared to provide the following information.

- The temperature of the vaccine
- The amount of vaccine
- Expiration dates of the vaccine
- The amount of time the vaccine was exposed to inappropriate temperatures

The following information must be collected when transporting vaccine to the alternate location:

- Document the time of the emergency/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 (e.g., 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, documenting the number of doses of each vaccine and the expiration dates. Use a Vaccine Transfer Authorization Form which must be submitted to the RE.
- Ensure the Emergency Vaccine Storage and Handling Plan Checklist is available for documenting this process.

H. Cold Chain Management and Vaccine Transport

The TVFC Program requires vaccines to be stored properly from the time they are manufactured until the time they are administered. The system used to maintain and distribute vaccines in optimal condition is called the cold chain.

Sufficient alternative space to store TVFC vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service must be identified. Adequate supplies for packing and transporting the entire TVFC vaccine supply/inventory must be available in case of an emergency. These packing supplies must be available to show during the TVFC Compliance Site Visit. Facilities that do not have these materials on-hand at the time of the site visit will be contacted by their RE.

> ***NOTE:***
> *Adequate supplies for packing and transporting the entire TVFC vaccine supply must be available in case of an emergency. These supplies must be available to show during the TVFC Compliance Site Visit.*

Avoid prolonged temperature extremes inside vehicles by 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. If followed, the directions below will help maintain the cold chain for up to eight hours during transport of refrigerated vaccines.

Refrigerated Vaccine Transport

Assemble Packing Supplies

DSHS recommends transporting refrigerated vaccines with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls, Styrofoam vaccine shipping container, or other qualified container may be used as long as it maintains the recommended temperature range (36°F to 46°F [2°C to 8°C]).

- Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container requires the following:
    - Coolers should be large enough to hold the TVFC supply of refrigerated vaccines.
- Label the container with the facility name and "Fragile Vaccines – Do Not Freeze" and the date and time the vaccine was removed from the permanent storage unit.

NOTE: Do not use soft-sided collapsible coolers for transporting vaccine.

- Conditioned frozen water bottles are required.
    - Use 16.9 oz. 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.

NOTE: Do not reuse coolant packs from original vaccine shipping containers.

- Insulating material – two each of the following layers is needed.
    - 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.

- Insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least 2-inches thick above and below the vaccines. Ensure this layer covers the cardboard completely.

NOTE: Do not use packing peanuts or other lose material that may shift during transport.

- A data logger with a buffered probe must be used as a temperature monitoring device.
  - Prepare the probe by pre-chilling it in the refrigerator for at least five hours prior to transport.
  - Ensure the data logger has a current and valid certificate of calibration testing.
  - Ensure the data logger certificate is documented to be accurate within +/- 1°F (+/- 0.5°C).
  - The data logger 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.

Packing for Transport

- Line the bottom of the cooler with a single layer of conditioned water bottles.
- Place a sheet of corrugated cardboard over the water bottles.
- Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the cardboard.
- Stack boxes of vaccines on top of insulating material.
- When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler.
- Cover vaccines with another 2-inch layer of insulating material.

- Add the second layer of corrugated cardboard.
- Fill the remaining space in the cooler with conditioned water bottles.
- Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport.
- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines are removed.
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
- As soon as the destination site is reached, check and record the vaccine temperature.

As long as the vaccine temperature is 36°F to 46°F (2°C to 8°C), place the vaccine in the refrigerator.

If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), place the vaccine in a quarantine bag in the refrigerator and immediately contact the vaccine manufacturer to determine viability. Next, contact the RE with the manufacturer's viability determination.

NOTE: Always keep vaccine properly stored until otherwise instructed by the vaccine manufacturer or the TVFC Program.

Frozen Vaccine Transport

Varicella and MMRV vaccines are fragile and must be kept frozen.

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

Assemble Packing Supplies

- Portable Freezer – DSHS recommends transport with a portable freezer

unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent. Label the portable freezer with the facility name and "Fragile Vaccines – Keep Frozen" and the date and time the vaccine was removed from the permanent storage unit.

- Temperature Monitoring Device – Use a certified and calibrated 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.

- Cooler – If a portable freezer is unavailable, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used if temperatures between -58°F and +5°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.
    - Use frozen water bottles in the cooler. Dry ice is not allowed to be used for transporting vaccines, even for temporary storage or emergency transport. Dry ice may allow the vaccine to be exposed to temperatures colder than -58°F (-50°C).
    - Line the bottom of the cooler with a single layer of frozen water bottles.
    - Place at least a 2-inch layer inch of insulating material (i.e., bubble -wrap, packing foam, or Styrofoam) over the frozen water bottles.
    - Stack boxes of vaccines and diluents on top of insulating material.
    - When the cooler is halfway full, place the data logger probe in the center of the vaccines, keeping the display out of the cooler.
    - Cover the vaccines with another 2-inch layer of insulating material.
    - Fill the remaining space in the cooler with frozen water bottles.
    - Close the lid of the cooler securely and attach the data logger

display and a temperature log to the top of the lid to record and monitor the temperature during transport.

- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines are removed.
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
- As soon as the destination site is reached, check and record the vaccine temperature.
- Place the vaccines in a freezer that maintains a temperature range between -58°F and +5°F (-50°C and -15°C).
- Document the time and temperature the vaccine was removed from the transport container and placed in the alternate storage unit.
- Immediately contact the vaccine manufacturer for viability data and guidance when 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.
- Contact the RE with the viability determination from the manufacturer.

Figure 3-3 illustrates proper vaccine packing for transport during emergencies when portable refrigerators and/or freezers are not available.

Figure 3-3. Proper vaccine packing for transport during emergencies.

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

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

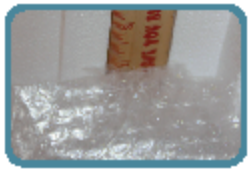
1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

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

Conditioned frozen water bottles

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



Insulating material — You will need two of each layer

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

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

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

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

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

Figure 3-3 (cont.). Packing refrigerated vaccines for transport during an emergency.

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

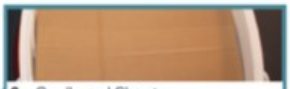
- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle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

8. Temperature Monitoring Device Display (on lid)

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

7. Conditioned Water Bottles

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


6. Cardboard Sheet

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

5. Bubble wrap, packing foam, or Styrofoam™

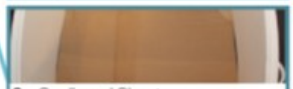
Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

4. Vaccines, Diluents, and Temperature Monitoring Device Probe

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

3. Bubble wrap, packing foam, or Styrofoam™

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


2. Cardboard Sheet

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

1. Conditioned Water Bottles

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

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

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

VI. Vaccine Transfers

The routine re-distribution of TVFC vaccine is not allowed. However, a vaccine transfer can be allowed when necessary to avoid vaccine loss. If a transfer must occur, a TVFC Vaccine Transfer Authorization Form (stock no. EC-67) must be submitted to the RE to receive approval prior to conducting vaccine transfers. The vaccine transfer can then be initialized as long as the TVFC Program PIN of where the vaccine is being transferred to is available. The transfer information must be documented and tracked in EVI.

> ***NOTE:***
> *If a vaccine transfer must occur, a TVFC Vaccine Transfer Authorization Form (EC-67) must be submitted to the RE to receive approval prior to conducting vaccine transfers.*

To conduct a vaccine transfer, the clinic transferring the vaccine must complete the following:

- Ensure that the vaccine transfer is occurring for one of the following reasons:
  - Short dated vaccine;
  - Withdrawal, suspension, or termination of a clinic from the TVFC Program; or
  - Other (emergency situations).
- Complete and sign the TVFC Vaccine Transfer Authorization Form (stock no. EC-67) and agree that the vaccine will be transferred in accordance to TVFC Vaccine Storage and Handling Guidelines to ensure the proper cold chain will be maintained throughout the transfer process. Each vaccine to be transferred must be listed on a separate row on the Vaccine Transfer Authorization Form and must include the following:
  - Vaccine type,
  - National Drug Code (NDC),

  - Lot number,
  - Expiration date, and
  - Number of doses being transferred.
- Fax the completed TVFC Vaccine Transfer Authorization Form (stock no. EC-67) to the RE. For emergency situations, call the RE prior to faxing the form.
- Once the DSHS PHR receives the form, they will approve or deny the transfer within two business days. If approved, a signed copy of the form will be faxed or emailed back to the TVFC clinic requesting the transfer and the LHD (if applicable). Once approval is received via fax or email, the transfer must be conducted in EVI.
- The RE must ensure that the vaccine is packaged using proper cold chain management as detailed in Section V – Vaccine Storage and Handling, subsection H – Cold Chain Management and Vaccine Transport and a certified, calibrated data logger is enclosed with the vaccine.
- Include a copy of the EVI Transfer Form in the transfer package. The EVI Transfer Form is printed after the transfer is conducted in EVI.
- Include a Temperature Recording Form (stock no. C-105) to document temperatures before, during, and upon conclusion of the vaccine transfer. The TVFC-enrolled clinic taking possession of the vaccine will attach the Temperature Recording Form (stock no. C-105) from the transfer to the site's monthly Temperature Recording Form (stock no. C-105).

The TVFC clinic taking possession of the vaccine must keep the TVFC Vaccine Transfer Authorization Form (stock no. EC-67) on file for a minimum of five years and must be easily available.

VII. Vaccine Borrowing

Vaccine borrowing is the utilization of TVFC vaccines as a replacement system for filling the vaccine needs of non-TVFC eligible patients.

The CDC requires that state immunization programs enhance oversight of all vaccine borrowing within TVFC sites. As such, the TVFC Program is enforcing its policy of not allowing vaccine borrowing between TVFC and ineligible TVFC patients.

All TVFC-enrolled sites are expected to maintain an adequate inventory of vaccine for both TVFC-eligible and privately insured patients. Vaccines supplied by the TVFC Program must not be provided to an ineligible patient. Undocumented borrowing and administering of TVFC vaccines to an ineligible patient is considered fraud. TVFC vaccines must not be used as a replacement system for filling the vaccine needs of a privately insured patient. For example, TVFC flu vaccine must not be administered to privately insured patients even if TVFC flu vaccine arrived in the office prior to the arrival of privately purchased flu vaccine.

> ***NOTE:***
> *All TVFC-enrolled sites must maintain an adequate inventory of vaccine for both TVFC-eligible and privately insured patients.*

If a TVFC dose is accidently administered to a privately insured patient, the following steps must be completed.

- Document the incident by completing the TVFC Vaccine Borrowing Form (stock no. EF11-14171). Each TVFC vaccine that was administered to an ineligible patient must be listed on a separate row on the form.
- Report the incident by faxing a copy of the TVFC Vaccine Borrowing Form (stock no. EF11-14171) to the RE within 24 hours. Adherence to HIPAA guidelines is mandatory when faxing this form. The TVFC Vaccine Borrowing Form (stock no. EF11-14171) must be kept as part of the TVFC Program records for a minimum of five years and be made easily available.

- Replace the vaccine immediately with privately purchased vaccine and account for the replacement in the EVI system.

It is the responsibility of the staff at the TVFC-enrolled site to ensure that all staff members are familiar with TVFC Program requirements. Adequate vaccine supply must be maintained in accordance with the clinic's patient population (TVFC and privately insured patients). The TVFC vaccine and private vaccine must be kept separate and clearly labeled as such. All vaccine usage must be tracked and all doses of TVFC vaccine must be accounted for in EVI.

Continued non-compliance with TVFC policies and procedures may be considered fraud and abuse. Referral may be made to the CMS Medicaid Integrity Group (MIG) Field Office.

VIII. Reporting Requirements

The TVFC Program requires the monitoring of the temperatures of all refrigerators and freezers containing TVFC vaccines and to submit TVFC Program forms on utilization of vaccine inventory and usage to the RE.

All records related to the TVFC Program are required to be maintained for five years and made easily accessible.

By the 5th of each month, the following documents must be completed and submitted to the RE.

These records include the following:

- Monthly Biological Report (stock no. C-33);
- Pediatric Biological Order Form (stock no. EC-68-1);
- Temperature Recording Form (stock no. EC-105);
- Refrigerator, Fahrenheit (stock no. EC-105RF)
- Refrigerator, Celsius (stock no. EC-105RC)
- Freezer, Fahrenheit (stock no. EC-105FF)

- Freezer, Celsius (stock no. EC-105FC)
- Vaccine Loss Report, if applicable;
- TVFC Vaccine Borrowing Form (stock no. EF11-14171), if applicable; and
- Any other reports or required documents.

Failure to submit required documents will result in future vaccine orders placed on hold by RE. Clinic staff must ensure that all reports are completed and submitted to the RE in a timely manner.

All forms are included in the TVFC Provider Manual in the Forms section, as well as under TVFC Forms & Publications on the TVFC website at https://www.dshs.texas.gov/immunize/tvfc/publications.aspx.

A. Reports Summary

Monthly Biological Report (stock no. C-33)

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

Qualified clinics that participate in the Adult Safety Net (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.

Sites without internet access must complete the Monthly Biological Report and submit it to the RE each month. The person completing the paper Monthly Biological Report must always sign and date the report and provide a telephone number.

Biological Order Form (stock no. EC-68-1)

This form is used only for initial orders or for those without internet access. The biological order form is used to order vaccines. All vaccines must be

ordered to bring the clinic up to their pre-determined Maximum Stock Level (MSL). For orders above the suggested quantity, an explanation is required in the comment section.

Temperature Recording Form (stock no. EC-105)

A temperature recording form is to be maintained on all refrigerators and freezers that store TVFC vaccine (including temporary day storage units). A Fahrenheit (EC-105RF and EC-105FF) or Celsius (EC-105RC and EC-105FC) form is required to be used to monitor temperatures.

All TVFC vaccines are required to be maintained at proper storage temperatures at all times. To ensure proper temperatures are maintained, the TVFC Program requires the recording of refrigerator and/or freezer temperatures twice daily for all units that store TVFC vaccine. The minimum and maximum temperatures are to be recorded in the morning.

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 to be submitted to the RE. In the event of a temperature excursion, immediate notification to the RE is necessary and must include the following information on page 3 of the Temperature Recording Form (stock no. 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 RE and the individual spoken to, and
- The results.

All documentation regarding temperature deviations must be retained for review during TVFC Compliance Visits and Unannounced Storage and Handling Visits. An example of the Vaccine Storage Troubleshooting Record can be found in the Forms section of this manual.

B. Monthly Requirements

By the 5th of each month, the following documents must be submitted to the RE:

- Monthly Biological Report (stock no. C-33) (only if internet access is unavailable),
- Temperature Recording Form (stock no. EC-105),
- Pediatric Biological Order Form (stock no. EC-68-1) (only if internet access is unavailable),
- Vaccine Loss Report (if applicable),
- TVFC Vaccine Borrowing Form (stock no. EF11-14171) (if applicable), and
- Any additional and/or associated forms as required by the RE.

> ***NOTE:***
> *Monthly vaccine management and reporting is required in EVI regardless of whether an order is submitted or not.*

Monthly vaccine management and reporting is required in EVI regardless of whether an order is submitted or not. Sites without internet access must submit a biological report each month to the RE.

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CHAPTER 4: BILLING AND ADMINISTRATION

I. Billing for Vaccine

Clinics enrolled in the TVFC Program are prohibited from charging any TVFC -eligible child for the cost of vaccines. TVFC vaccines are provided at no cost to clinics to vaccinate eligible children. Charging for the cost of vaccines supplied by the TVFC Program constitutes fraudulent behavior. Fraud in the TVFC Program will be handled in the same manner as Medicaid fraud.

Private clinics may not refer a TVFC-eligible child to another health-care facility for TVFC vaccines if the clinic has already accepted that child into the practice as their patient, unless directed by DSHS.

II. Administration Fee

NOTE:
The maximum administration fee for TVFC vaccine is $14.85 per dose.

Sites are required to enroll in the TVFC Program to obtain vaccines at no cost to vaccinate TVFC-eligible children, including Medicaid and CHIP children. A fee for administering TVFC vaccine to TVFC-eligible children may be charged. The maximum administration fee for TVFC vaccine is $14.85 per dose.

Medicaid and CHIP children must not be charged the administration fee for receiving vaccines. For Medicaid children, the clinic site must accept the reimbursement for immunization administration fee set by the state Medicaid agency or the contracted Medicaid health plans.

Sites are reimbursed the lesser of the billed amount or the maximum allowable fee. The state Medicaid agency may have the discretion to pay an administration fee up to the regional maximum amount.

Effective January 1, 2020, 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.

Children 0-18 years of age who are enrolled in Medicaid as their secondary insurance are eligible to receive TVFC vaccines.

As stated in the Medicaid Provider Manual, clinics should bill their usual and customary fee except for vaccines obtained from the TVFC Program.

For more information on Medicaid reimbursement, please refer to the Texas Medicaid Provider Manual located at http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx.

Children 0-18 years of age who are enrolled in CHIP are eligible to receive TVFC vaccines from active CHIP participating sites; however, TVFC clinic sites must bill CHIP for the administration of a vaccine to a CHIP-enrolled child. For more information on CHIP reimbursement, please refer to the CHIP Provider Manual located at http://www.texaschildrenshealthplan.org/sites/default/files/Provider%20Manual.pdf.

Vaccines are required to be available to all TVFC-eligible children. Services cannot be denied due to the parent's or guardian's inability to pay the administration fee and the parent or guardian must not be sent to collections. Penalties for the inability to pay administration fees must not be charged.

For additional information on the Vaccines for Children (VFC) statutory requirements for the VFC Program regarding the vaccine administration fee, please go to the following Centers for Disease Control and Prevention (CDC) link at http://www.cdc.gov/vaccines/programs/vfc/providers/index.html.

CHAPTER 5: PROGRAM EVALUATION

I. Standards for Childhood Immunizations

The National Vaccine Advisory Committee (NVAC), in collaboration with the Ad Hoc Working Group for the Development of Standards for Pediatric Immunization Practices developed a set of standards as to what constitutes the most essential and desirable immunization policies and practices. The DSHS website has the full article listed for reference. The standards are listed below.

- Availability of vaccines
- Assessment of vaccination status
- Effective communication about vaccine benefits and risks
- Proper storage and administration of vaccines and documenting of vaccinations
- Implementation of strategies to improve vaccination coverage

II. Clinic Site Visits

By signing the TVFC Program Agreement, the signing clinician agrees to allow DSHS or DSHS quality assurance (QA) contractors to conduct site visits at least every other year at their site. DSHS PHR and LHD clinics participating in TVFC will receive a scheduled site visit from a DSHS PHR reviewer annually. In some instances, site visits may be conducted by staff from an LHD. Newly enrolled sites will receive a site visit between 6-12 months after initial enrollment.

A. Compliance Site Visits

The purpose of the compliance visit is to assess, support, and educate the staff regarding TVFC policies and procedures, not to critique. This visit

consists of a questionnaire. If areas of concern are identified, the RE will provide a follow-up call or visit to assist the clinic with any changes or questions.

> ***NOTE:***
> *The purpose of compliance visits is to assess, support, and educate the site regarding TVFC policies and procedures.*

Clinic staff will be contacted prior to a scheduled compliance site visit and will receive a confirmation letter via email or fax that includes the date, time, materials needed, and summary of the site visit process.

During a compliance site visit, the reviewer will need access to the following:

- Space to work,
- Power source,
- Internet connectivity (if available),
- Access to patient records,
- Temperature logs or data for the last three months, or longer if deficiencies are found,
- Vaccine Borrowing Form (stock no. EF11-14171) for the previous 12 months,
- Circuit breaker,
- Admitting and billing personnel to clarify eligibility screening and billing processes, and
- All vaccine storage units where TVFC vaccine is stored.

III. Common Site Visit Structures

Site visits are conducted using different structures to ensure that each site is being evaluated based on the eligible populations served. These structures are described below.

A. Combined IQIP and Compliance Site Visit

This visit includes an Immunization Quality Improvement for Providers (IQIP) visit and a TVFC Questionnaire. A core component of this visit is to focus on assessing provider-level vaccination coverage rates using the data reported to ImmTrac2. During the IQIP site visit, staff at the facility will receive an IQIP Plan that will include quality improvement strategies, ImmTrac2 resources, and instructions on action items to be implemented at the facility. Once this portion of the site visit is completed, the site reviewer will transition into the TVFC Compliance portion. For more information on IQIP, visit https://www.dshs.texas.gov/immunize/Immunization-Quality-Improvement-for-Providers-Program/.

B. TVFC Compliance Site Visit Only

This visit will be conducted for those sites who have not been selected to participate in the IQIP portion of the visit. Only the TVFC Compliance visit is conducted. The purpose of this visit is to assess, support and educate the site regarding TVFC policies and procedures.

C. IQIP Site Visit Only

This visit does not include the TVFC compliance portion. Some sites may receive an IQIP only site visit. For more information on the IQIP portion of the visit, see Combined IQIP and TVFC Compliance Site Visit.

D. IQIP Follow- Up Only

These visits are conducted via telephone at 2, 6, and 12 months after the

initial IQIP visit is conducted. The purpose of this evaluation is to determine how well the IQIP quality improvement plan is working. At 12 months, the facility's coverage rates will be reassessed.

E. Unannounced Storage and Handling Visit

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

The RE will prioritize sites for unannounced visits based on the following criteria:

- Vaccine loss,
- Improper storage of vaccine,
- Improper documentation on temperature logs,
- Vaccine orders are inconsistent with population profile data,
- Newly enrolled sites, and
- Determination of the clinic's compliance with corrective actions.

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

IV. Follow-Up Activities

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

The vaccine coordinator must sign an Acknowledgement of Receipt (AR) following the visit. The AR is the document that attests to the fact that a site visit was completed, the results of the visit were received, and that

both the reviewer and the vaccine coordinator understand all non-compliance issues identified and the actions necessary to address them.

The RE will conduct all required follow-up activities. The purpose of follow-up activities is to ensure that areas for improvement identified by the RE or DSHS contractor are understood by the site's staff and corrective actions have been identified and implemented.

Follow-up activities are conducted as necessary to address all 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 the following:

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

The RE works with clinic staff on non-compliance issues by providing education and guidance regarding corrective actions, including monitoring.

If a site exhibits habitual non-compliance and does not follow corrective actions in response to education, the vaccine ordering privileges may be suspended. If non-compliance continues, termination from the TVFC Program may be implemented.

V. Electronic Medical Records (EMRs)

Sites with EMRs have the following immunization record review options, one of which must be available at the time of the visit:

- A dedicated staff member who can log-in to the EMR and sit with the field reviewer throughout the record review process to access EMR immunization and eligibility records.

- Print outs from the EMR of the immunization records and documentation of the child's eligibility. The immunization records must include all immunization histories, including records from other clinic sites.

NOTE: It is not acceptable to have a site staff member log-in and then turn the EMR screens over to the reviewer; the staff member is required to be present. The TVFC Program or the DSHS QA contractor will not pay for, nor reimburse, clinics for the copies when the staff chooses to print out immunization records from their EMR system.

VI. TVFC Provider Feedback Surveys

TVFC-enrolled providers are the best sources of information for evaluating which aspects of the programs are working or not working as planned.

In addition to evaluating operational components, surveys are used to gather information on educational needs of enrolled sites or their responses to education provided. Findings may determine which quality improvement projects may be undertaken. Enrolled sites can expect at least two surveys yearly.

A. Annual TVFC Satisfaction Survey

The TVFC Program conducts an annual TVFC Provider Feedback Survey to help identify areas of the TVFC Program that are working well and those that may need improvement. The survey will be conducted during re-enrollment and the results will be collected and submitted to program staff for review. Questions in the survey will address clinic staff satisfaction with the current vaccine ordering and shipping practices, TVFC policies and procedures, reporting requirements, customer service provided by TVFC staff at the state, regional, and local levels, as well as the communication methods of the TVFC Program. The survey will also ask TVFC sites about their use of the Texas Immunization Registry (ImmTrac2) as part of their daily practice.

B. Site Visit Assessment Survey

The site visit assessment survey is conducted following TVFC Compliance Visit or TVFC IQIP and Compliance Combination Visit. An email containing a link to an online survey is sent to the primary vaccine coordinator after a site visit is conducted. It offers the clinic staff an opportunity to provide feedback about their experiences during the visit.

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CHAPTER 6: FRAUD AND ABUSE

I. Fraud and Abuse

As the complexity of immunizations and immunization-related programs grow, sites enrolled in TVFC may become more vulnerable to unintentionally committing acts that could be construed as fraud and/or abuse. Fraud and abuse, whether intentional or not, is subject to all federal fraud and abuse laws.

II. Definitions

A working understanding of what constitutes fraud and abuse is critical for all persons working in the TVFC 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.

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.

Oversight - The act of training, monitoring, and providing assistance to clinic staff on TVFC Program policies and procedures.

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

Termination - Action taken when a site or signing authority is no longer eligible for the TVFC Program due to fraud, abuse, or non-compliance.

Waste - The careless, inefficient, or unnecessary use of TVFC Program resources.

III. Examples

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier to prevent or detect than others. All staff at TVFC-enrolled sites 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 vaccine to ineligible children
- Sell or otherwise misdirect TVFC vaccine
- Bill a patient or third party for TVFC vaccine (other than administration fees)
- Charge more than $14.85 per dose for administration of a TVFC vaccine to an eligible child
- Failure to meet licensure requirements for enrolled clinicians
- Deny TVFC-eligible children TVFC vaccine because of the inability to pay the administration fee
- Send a parent or guardian to collections or charge additional fees for non-payment of the administration fee
- Failure to implement TVFC Program enrollment requirements
- Failure to screen for and document TVFC eligibility at every visit
- Failure to maintain TVFC records for five years
- Failure to fully account for TVFC vaccine

- Failure to properly store and handle TVFC vaccine
- Order TVFC vaccine in quantities or patterns that do not match population profile or otherwise involve over-ordering of TVFC doses
- Loss of TVFC vaccine due to negligence

IV. Failure to Comply with TVFC Requirements

Enrolling in the TVFC Program is an agreement to comply with all the requirements of the program. Lack of adherence to the TVFC Program requirements by an enrolled site could lead to fraud and abuse of the TVFC Program by that site. Non-compliance with the TVFC Program requirements 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 of suspected TVFC fraud and abuse.

V. Fraud and Abuse Prevention

The TVFC Program actively works with enrolled clinics to help prevent fraud and abuse in the TVFC Program. The best methods to prevent fraud and abuse are strong educational components discussed during the initial enrollment process and during the TVFC compliance visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse.

VI. Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to the TVFC Program or the RE via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that promote potential fraudulent situations are also investigated.

The RE and DSHS QA contractors must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Unit in any form that merit further investigation may be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) 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.

CHAPTER 7: DOCUMENTATION REQUIREMENTS

I. Vaccine Record Keeping Requirements

The 1986 National Childhood Vaccine Injury Act (NCVIA) requires all vaccinators nationwide to record the following specific information in the medical record each time a vaccine is administered:

- Name of vaccine administered
- Date vaccine was 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 the health care professional administering the vaccine
- Address of the clinic where the vaccine was administered

If needed, the DSHS Immunization Unit provides immunization records that are designed to capture all information that is required when a vaccine is administered. Immunization records for clinics (Vaccine Information Documentation Form, stock no. C-100) and clients (Personal Immunization Record Card, stock no. C-102) can be ordered free-of-charge from DSHS (See Chapter 11: Ordering Forms and Literature) at immunizetexasorderform.com. The TVFC Program suggests the following recommendations regarding record keeping:

- Designate an immunization staff member to answer immunization questions for staff and parents.
- File patient records, keeping the immunization record and TVFC Patient Eligibility forms together.

- Place immunization records at the front of each patient's chart and make immunizations a priority.
- Encourage parents to bring their children's immunization records with them to facilitate complete documentation in the child's record of previous immunization history.
- If a child presents with no immunization record, obtain the history through the Texas Immunization Registry (ImmTrac2), or call previous medical facility to obtain the history.
- Empower all staff to become "Immunization Advocates" and have them assess each child's immunization status at every encounter.
- Give a personal immunization record to each vaccine recipient showing the date (month, day, and year) of when each vaccine was administered.

Copies of all TVFC documents must be maintained for five years and made available on request by the TVFC Program, the RE, or the DSHS QA contractor.

II. The Texas Immunization Registry (ImmTrac2)

ImmTrac2 is operated by the DSHS Immunization Unit and is an important component of Texas' strategy to improve immunization coverage rates. Texas Law requires vaccinators to report all immunizations administered to children 17 years of age and younger to ImmTrac2 within 30 days of administration of the vaccine.

ImmTrac2 is designed to consolidate immunization records from multiple sources throughout the state. The registry allows authorized organizations easy access to immunization histories of participating clients and has "Reminder" and "Recall" capabilities.

Adults may also 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. At the patient's 18th birthday, the immunization record stored in ImmTrac2 will be "hidden" from view until an adult consent is signed. If a patient does not sign an adult consent, the record will be deleted from ImmTrac2 on the patient's 26th birthday.

As a registered user of ImmTrac2, medical professionals can confirm whether a patient is in ImmTrac2 and can consent individuals in ImmTrac2 who desire to participate.

TVFC-enrolled sites must register as an authorized organization with ImmTrac2 by completing an online form. For information about ImmTrac2 or to register, call the ImmTrac2 Customer Support Line at (800) 348-9158 or visit the ImmTrac2 webpage at http://www.dshs.texas.gov/immunize/immtrac/default.shtm.

A. Reporting Vaccine Eligibility in ImmTrac2

Eligibility for the TVFC and ASN Programs must be reported in Immtrac2 using specific vaccine eligibility codes. The following codes must be used when reporting in ImmTrac2 online or by data exchange (HL7):

- Code: V02 – Medicaid or Medicaid-eligible patients
- Code: V03 – Uninsured
- Code: V04 – American Indian/Alaskan Native
- Code: V05 – UNDERinsured (for patients seen at a FQHC, RHC or Deputized LHD or PHR)
- Code: TXA01 – CHIP
- Code: TXA02 – UNDERinsured (for patients not seen at a FQHC, RHC or Deputized LHD or PHR Facility)
- Code: TXA03 – 19-Year-Old Completing Series
- Code: TXA04 – Uninsured Adult

B. Reporting Requirements During Disaster Declaration

In the event of a disaster declaration, providers are required to report Antivirals, Immunizations and other Medications (AIM) for disasters and emergencies to ImmTrac2. Disaster related AIMs are required to be kept in the registry for five (5) years following the end of the disaster declaration. For more information regarding required reporting of AIMs and other immunizations to ImmTrac2, please see the Texas Administrative Code Title 25 Part 1 Chapter 100 at https://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=100&rl=Y.

III. 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. The 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 medical staff. Medical staff that administer vaccines 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, vaccinators must have the skills necessary to deal with fears and misconceptions about vaccines, and the ability to provide a supportive and encouraging environment for patients.

When a parent or patient initiates the discussion regarding a vaccine concern, discuss the specific concern, and provide factual information. The VIS provides an outline for discussing vaccine benefits and risks. 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 or 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 any potential liability if a vaccine-preventable disease occurs in the unimmunized patient.

IV. Vaccine Adverse Events

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 signals 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 the following:

- Patients,
- Parents,
- Health care professionals,
- Pharmacists, and
- Vaccine manufacturers

Healthcare providers are encouraged to report all clinically significant adverse events after vaccination to VAERS, even if it is unclear whether the vaccine caused the event. Providers are also required by federal law to report certain adverse events found in the VAERS Table of Reportable Events. Some reporting requirements are vaccine-specific. Generally, reporting is also required for events described in a manufacturer's package insert as contraindications to additional doses of vaccine and for acute complications or sequelae including death.

Clinic staff should use the VAERS Reporting Website to report all adverse events after vaccination directly to VAERS. 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), a copy of the VAERS report must be submitted to your RE. This can be done most easily by using the “pdf upload” option on the VAERS website.

CHAPTER 8: OFF-SITE AND MASS VACCINATION CLINICS

A. Vaccine Ordering for Off-Site and Mass Vaccination Clinics

Off-site and 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. However, because most temporary mass clinics typically require vaccine transport on the day of the clinic, these temporary clinics require enhanced storage and handling practices. Providers that conduct off-site and mass clinics are not allowed to operate outside of their jurisdiction. If you are unsure about your jurisdictional boundaries, please contact your RE.

Clinic staff must develop mass vaccination protocols to ensure outreach efforts meet all TVFC requirements, including the following:

- Showing the established vaccine needs (e.g., provider profile);
- A schedule to include the date, location and estimated number of vaccines expected to be administered for each off-site clinic;
- A plan for overseeing vaccine ordering for each clinic site to ensure that proper amounts of TVFC stock are transported on each clinic day;
- The type of portable storage unit being used;
- How the cold chain will be maintained from the beginning to the end of the mass vaccination clinic; and
- Each site location must document temperatures on the Temperature Recording Form (stock no. EC-105).

The RE must review and approve a mass vaccination plan prior to initiation of the mass vaccination clinics.

Mass vaccinators where the enrolled site is not providing direct services and

other parties are involved with administering the vaccines, all parties involved with implementing the clinics, including the signing clinician and other groups who are directly administering the vaccine, must sign an agreement. There must be a written agreement attached to the TVFC/ASN Program Agreement detailing the responsibilities of each party involved.

B. Off-Site and Mass Vaccination Clinic Requirements

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

- All TVFC vaccine must be ordered and shipped directly to a location within the ordering clinic's DSHS PHR.
- The vaccine must be properly transported, not shipped, to local schools or other community sites where the mass vaccination clinics will be held.
- The total time for vaccine transport alone or vaccine transport plus clinic workday must not exceed a maximum of 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 amounts of vaccines that are appropriate, based on TVFC need, should be transported to each scheduled clinic.
- Vaccine must be transported to and from the scheduled mass vaccination clinic at appropriate temperatures and must be monitored by a data logger that meets TVFC requirements as listed in Chapter 3: VACCINE MANAGEMENT > V. Vaccine Storage and Handling > B. Data Logger Requirements. The data logger's display must be placed outside the storage unit for continuous monitoring.
- The vaccine being transported must be tracked to maintain accountability for monthly reporting in EVI. This includes the following:
    - Vaccine type(s) and brand names,

  - Quantity of each type,
  - NDC numbers,
  - Lot numbers, and
  - Expiration dates.
- Upon arrival at the clinic site, ensure the vaccine is stored to maintain the appropriate temperature throughout the clinic day.
- Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic using a data logger. Temperature Recording Form, (stock no. EC-105) may be used to document hourly temperatures.
- After each clinic day, a physical count of the remaining vaccine must be conducted, and assessment of temperatures performed prior to placing vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised.

Vaccines exposed to temperature excursions 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 the viability determination is made.

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CHAPTER 9: ADULT SAFETY NET PROGRAM

I. Adult Safety Net (ASN) Overview

The Texas Immunization Unit operates the Adult Safety Net (ASN) Program and provides vaccines for uninsured adults at enrolled sites. The ASN Program serves as a safety net for populations at risk for vaccine-preventable diseases. The ASN Program purchases and provides vaccine at no cost to enrolled clinic sites to immunize uninsured adults aged 19 years and older. The formulary of vaccines offered is based on epidemiological data and available funding.

ASN ensures that uninsured Texas adults have access to immunizations. This is accomplished through a network of support provided by DSHS and with assistance from PHRs and contracted LHDs. These organizations function as REs to ensure compliance with state and federal standards and the effectiveness of vaccine distribution. Vaccine reporting for the ASN Program is the same as for the TVFC Program.

II. ASN Eligible Facility Types

Clinic sites that are eligible to enroll in the ASN Program include, but may not be limited to, clinics that are formally recognized as one of the following:

- PHR clinics,
- LHD clinics, FQHC clinics, or
- RHC clinics.

III. ASN Enrollment

The first step in becoming an ASN-enrolled site is completing the TVFC/ASN Program Agreement form. If assistance is needed, contact the DSHS Immunization Unit or the RE. ASN-enrolled sites that are an FQHC or an RHC must submit a copy of the Centers for Medicare & Medicaid Services (CMS) letter that designates the site as such.

The TVFC/ASN Program Agreement form includes basic information about the facility and signing clinician. The agreement also outlines the responsibilities of clinic staff. Sites interested in participating in ASN must enroll in ImmTrac2. Upon completion of enrollment with ImmTrac2, the site will receive an ImmTrac2 organization code. The signed provider agreement form and ImmTrac2 organization code must be received and processed by the ASN Program prior to the clinic receiving state-funded vaccines.

All ASN-enrolled sites must agree to comply with the policies and requirements of both the TVFC and ASN Programs.

IV. ASN Patient Eligibility

A. Eligibility Criteria

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 to receive ASN vaccines. In addition, those who are underinsured (have insurance that does not cover immunizations) are not eligible to receive ASN vaccines.

Adults who have private insurance that covers vaccines are not eligible to receive ASN vaccines from ASN-enrolled sites, but instead must be referred to their medical home or other site that provides immunizations, such as a pharmacy. Adults who are enrolled with

NOTE:
Adults enrolled in MAP are eligible to receive vaccines from ASN-enrolled sites.

Medical Access Program (MAP) are eligible to receive vaccines from ASN-enrolled sites. Some ASN facilities may see patients that participate in Healthy Texas Women (HTW) Program. HTW is considered insurance with limited services and patients are not eligible to receive vaccines under the ASN Program. For more information on the HTW Program, please see www.healthtexaswomens.org.

An LHD, FQHC or RHC that provides comprehensive healthcare services to adults with private insurance may continue to serve as the medical home for their privately-insured patients. However, private stock vaccine must be purchased to vaccinate privately-insured adults.

B. Nineteen-Year-Olds

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 ASN vaccines regardless of their current health insurance status. If the dose is to complete the series, the patient is eligible to receive the vaccines under the ASN program however, booster doses are not eligible. The vaccine must be administered at a DSHS PHR or LHD clinic. This provision only applies to patients that have not yet reached their 20th birthday.

NOTE: A "series" in this case is specific to two doses of Hepatitis A; three doses of Hepatitis B; two or three doses of HPV; two doses of MCV4; two doses of MMR; three doses of Td/Tdap; and two doses of varicella.

This policy does not apply to MenB, polio, Hib, or influenza vaccines. This policy does not apply to booster doses.

C. Patient Eligibility Screening Record

Screening for patient eligibility is the foundation of clinic-level accountability. Screening all adults at every immunization encounter and documenting eligibility screening at every visit is the only way to ensure that ASN vaccine is used only for ASN eligible adults. As such, full

compliance on screening for eligibility is required. In the event improper screening results in the administration of ASN vaccine to an ineligible adult, sites are responsible for replacing the improperly used ASN vaccine with private stock. In this instance, a Vaccine Borrowing Form (stock no. EF11-14171) is required to be completed and submitted to RE.

Clinic sites are required to document the eligibility of each adult receiving ASN vaccine at every visit. During a patient's initial visit, the eligibility category must be documented according to the ASN Program guidelines and updated during each future visit.

> ***NOTE:***
> *Adult vaccines administered to female veterans are required to be reported monthly to DSHS.*
>
> *If no female veterans received ASN vaccine the previous month, the site staff must report zero in the survey.*

Clinic sites may use the Adult Eligibility Screening Record (stock no. EF11-12842) or electronically store patient demographic information (must include all information as contained on the Adult Eligibility Screening Record (stock no. EF11-12842). Eligibility screening must be completed/updated for all adults at every visit, including adults with a previous record on file. Eligibility must be documented at every visit prior to vaccine administration.

Documentation of eligibility screening must include the following elements:

- Date of screening,
- Patient's name,
- Patient's date of birth,
- Clinic name, and
- Eligibility status for each visit.

Adult 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 easily retrievable.

It is also acceptable for clinics to utilize electronic medical records (EMR)

system to capture and save the information from the adult eligibility screening record if the EMR captures all the required eligibility elements.

D. Vaccine Services to Female Veterans

In accordance with Senate Bill 805 from the 85th Texas Legislature, Regular Session, DSHS must collect and report the number of uninsured female veteran who receive ASN vaccines.

By the 5th of each month, all ASN-enrolled sites must document the number of female veterans who received ASN vaccines for the previous month using the Uninsured Female Veterans Reporting Form located online at www.dshs.texas.gov/immunize/ASN/publications.aspx. This online survey is password protected. Clinic staff must contact the RE to obtain the password for the online survey.

If no female veterans received ASN vaccine the previous month, clinic staff must report zero in the survey.

V. ASN Vaccine Formulary

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

- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Hepatitis A and Hepatitis B (Hep A-Hep B) combination
- Human Papillomavirus (9vHPV)
- Measles, Mumps, and Rubella (MMR)
- Meningococcal conjugate (MCV4)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23)

- Tetanus and Diphtheria toxoids (Td)
- Tetanus and Diphtheria toxoids and acellular Pertussis (Tdap)
- Varicella
- Zoster

It may be necessary for the DSHS Immunization Unit 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.

VI. Provider Enrollment Requirements

A. Specific Terms of Agreement

To participate in the ASN Program, clinic staff must agree to follow all program requirements. By signing the TVFC/ASN Program Agreement, the office and all practitioners associated with the medical office agree to the following:

- Submit a provider profile representing populations served by the facility annually.
- Screen for and document ASN eligibility of all adults at each immunization encounter.
- Administer ASN vaccine to uninsured adults 19 years of age or older.
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the ACIP.
- Maintain all records related to the ASN Program for at least five years and upon request, make these records available for review.
- Immunize eligible adults with publicly supplied vaccine at no charge to the patient for the vaccine.
- Not charge an administration fee in excess of $25.00 per vaccine dose.

- Not deny administration of ASN vaccine to an eligible adult because of the inability of the patient to pay the administration fee.
- Not send a patient to collections or charge additional fees for non-payment of an ASN administration fee.
- Provide a copy of the most current VIS for each vaccine at the time of administration.
- Comply with the ASN Program requirements for vaccine management, including ordering and proper storage and handling practices.
- Operate the ASN Program in a manner intended to avoid fraud and abuse.
- Participate in ASN site visits, including unannounced visits and other educational opportunities, as required.
- Acknowledge that the DSHS Immunization Unit 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 ASN vaccines.
- If a site voluntarily withdraws from the ASN Program, the office/facility agrees to return any unused vaccine within five days of withdrawal. Prior to withdrawal, the clinic staff must complete a provider withdrawal form and submit the form to the RE.

In jurisdictions where there are mass vaccinators enrolled, or circumstances where the enrolled site is not providing direct services and other parties are involved with administering the vaccines, all parties involved with implementing the clinics, including the medical director and other groups who are directly administering the vaccine, must sign the provider agreement.

There must be a written agreement attached to the TVFC/ASN Program Agreement detailing the responsibilities of each party involved.

B. Initial Enrollment

The steps for initial enrollment into ASN are the same as the steps for initial enrollment into TVFC. Those instructions can be found in the CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT > II: Provider Enrollment Requirements > C. Initial Enrollment section of this manual.

C. ASN Enrollment Visit

The components of the ASN enrollment visit are the same as the components of the TVFC enrollment visit. A description of the enrollment visit can be found in the CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT > II: Provider Enrollment Requirements > D. TVFC Enrollment Visit section of this manual.

D. ASN Site Set-up

The components of the ASN site set-up are the same as the components of the TVFC enrollment visit. A description of the enrollment visit can be found in the CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT > II: Provider Enrollment Requirements > E. TVFC Site Set-up section of this manual.

E. Vaccine Accountability

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

All ASN-enrolled sites must ensure the following:

- ASN vaccines are administered only to eligible adults;
- Vaccine loss and waste are minimized and documented;
- Fraud and abuse does not occur;

- ASN vaccine inventory is accurately reported monthly; and
- Patients are screened at all immunization encounters for ASN eligibility.

F. Provider Identification Number

A PIN will be assigned to the to the clinic upon initial enrollment into the ASN Program. Eligible sites currently enrolled in TVFC will use the same TVFC PIN number for participation in ASN.

For more information on PIN assignments, please see the CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT > II: Provider Enrollment Requirements > G. Provider Identification Number section of this manual.

G. Provider Change of Information

The requirements for clinic sites change of information notifications in ASN are the same as those for TVFC. Those instructions can be found in the CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT > II: Provider Enrollment Requirements > G. Provider Change of Information section of this manual.

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

H. Annual Re-Enrollment

ASN re-enrollment is completed electronically and is completed using the same re-enrollment form as TVFC.

For more information on annual re-enrollment, please see the CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT > II: Provider Enrollment Requirements > I. Annual Re-enrollment section of this manual.

VII. Vaccine Ordering

A. Vaccine Choice

The ASN Program supplies ACIP-recommended vaccines and toxoids. Sites participating in the ASN Program are required to offer all available ACIP-recommended vaccines to their eligible populations. House Bill 448 from the 81st Texas Legislature gives ASN-enrolled sites the opportunity to choose their preferred brands and presentations of vaccines from the available formularies.

The signing clinician can choose vaccine brands and presentations. For new ASN-enrolled sites, the RE will create the initial vaccine order using the Adult Biological Order Form (stock no. EC-68-2). The biological order form will reflect vaccine choices, maximum stock level (MSL), and order quantity.

Each quarter, ASN sites will have the opportunity to choose the brand and presentation for each ASN vaccine in EVI. Changes or adjustments for specific vaccine brands, presentations, and percentages within each vaccine "family" (i.e., Tdap), can be made, or staff may take no action to maintain the current selections. Clinic staff are encouraged to review all choice selections on a quarterly basis.

> ***NOTE:***
> *The vaccine inventory plan requires all enrolled sites to maintain a 75-day supply of vaccine inventory.*

Vaccine coordinators may complete the process however, the signing clinician must be consulted and agree to the vaccine choices. The vaccine choices, as well as the person making the changes, are captured electronically in EVI. ASN-enrolled sites are notified prior to the opening and closing of the vaccine choice period. Only vaccines supplied by DSHS to the ASN Program will be available for vaccine choice.

If a chosen vaccine is not available, the ASN Program has the authority to replace the unavailable vaccine with a comparable substitution until the chosen vaccine becomes available.

NOTE: Vaccine choice does 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.

B. Vaccine Inventory Plan and Maximum Stock Levels

The vaccine inventory plan requires all enrolled sites to maintain a 75-day supply of vaccine inventory. All sites should place vaccine orders monthly. All components of vaccine inventory management and MSLs are the same for TVFC and ASN. For more information, please see the CHAPTER 3: VACCINE MANAGEMENT > II: Vaccine Ordering > B. Vaccine Inventory Plan and Maximum Stock Levels section of this manual.

C. Increasing and Decreasing Maximum Stock Levels

The policies governing increasing and decreasing maximum stock levels are the same for TVFC and ASN. For more information, please see the CHAPTER 3: VACCINE MANAGEMENT > II: Vaccine Ordering > C. Increasing and Decreasing Maximum Stock Levels section of this manual.

D. Short-Dated Vaccine

The policies governing short-dated vaccines are the same for TVFC and ASN. For more information, please see the CHAPTER 3: VACCINE MANAGEMENT > II: Vaccine Ordering > D. Short-Dated Vaccine section of this manual.

E. Storage Capacity for Vaccine Orders

An ASN-enrolled site must have adequate refrigeration and/or freezer space to accommodate a maximum order based on MSLs. Sites must also take into consideration the space needed for private stock vaccine when calculating storage capacity.

F. Vaccine Ordering in the Electronic Vaccine Inventory (EVI) System

The ASN Program uses EVI system for vaccine ordering which allows for management of vaccine inventory online. All vaccine orders must be placed in EVI unless internet access is unavailable. Clinic staff may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

The policies governing vaccine ordering in EVI are the same for TVFC and ASN. For more information, please see the CHAPTER 3: VACCINE MANAGEMENT > II: Vaccine Ordering > F. Vaccine Ordering in the Electronic Vaccine Inventory (EVI) System section of this manual.

G. Vaccine Ordering for ASN Sites without Internet Access

An ASN-enrolled site without access to the internet must contact the RE for assistance with vaccine ordering. Clinic staff must submit the following paper forms to the RE to place a vaccine order:

- Monthly Biological Report (stock no. C-33);
- Adult Biological Order Form (stock no. EC-68-2); and
- Temperature Recording Form (stock no. EC-105).

The monthly biological report is reviewed by the RE to ensure that the beginning inventory matches the last month's ending inventory. Calculations must be correct. Any corrections needed are reported to clinic staff, so records are corrected prior to ordering.

H. Vaccine Ordering for Newly Enrolled ASN Sites

Newly enrolled ASN sites are set up for vaccine ordering in EVI after New Provider Training with the RE. A vaccine order is placed as part of the training. The RE collects and reviews the following paper reports prior to placing the new vaccine order:

- Adult Biological Order Form (stock no. EC-68-2); and
- Temperature Recording Form (stock no. EC-105).

VIII. Vaccine Storage

All ASN sites are required to follow the TVFC Program storage and handling guidelines at all times. ASN-enrolled sites also enrolled in the TVFC Program must separate TVFC provided pediatric doses from ASN supplied adult doses. The policies governing vaccine management are the same in TVFC and ASN Programs. Ensure CHAPTER 3: VACCINE MANAGEMENT section of this manual is read and adhered to in its entirety.

IX: Vaccine Management

It is critical that ASN-enrolled clinic staff familiarize themselves with expectations for vaccine management.

The policies governing vaccine management are the same in TVFC and ASN Programs. Ensure CHAPTER 3: VACCINE MANAGEMENT section of this manual is read and adhered to in its entirety.

X. Vaccine Transfers

The routine re-distribution of ASN vaccine is not allowed. However, vaccine transfer can be allowed between ASN-enrolled sites when necessary to avoid vaccine loss. If a transfer must occur, clinic site staff are required to submit a TVFC Vaccine Transfer Authorization Form (stock no. EC-67) to the RE and receive approval prior to conducting a vaccine transfer. The RE or clinic staff can then initialize a vaccine transfer in EVI as long as the ASN

NOTE:
ASN sites must submit a Vaccine Transfer Authorization Form and receive approval prior to conducting vaccine transfers.

Program PIN of where the vaccines are being transferred to is available. Transfer information must be documented and tracked in EVI.

The policies governing vaccine transfers are the same in TVFC and ASN. Ensure CHAPTER 3: VACCINE MANAGEMENT > VI: Vaccine Transfers section of this manual is read and adhered to in its entirety.

XI: ASN Billing and Administration

A. Billing for ASN Vaccine

Sites enrolled in the ASN Program are prohibited from charging any ASN-eligible adult for the cost of vaccines. ASN vaccines are provided at no cost to the enrolled sites to vaccinate eligible adults. Charging for the cost of vaccines supplied by the ASN Program constitutes fraudulent behavior.

B. 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.

> ***NOTE:***
> *The maximum administration fee that an ASN-enrolled site may charge is $25.00 per dose.*

XII: ASN Site Visits

A. Adult Immunization Standards

In 2013, the National Vaccine Advisory Committee (NVAC) revised the Standards for Adult Immunization Practice. The new standards are aimed at increasing adult immunization rates in the United States. The DSHS Immunization Unit highly encourages all ASN-enrolled sites to adopt the adult standards.

The Standards for Adult Immunization Practice are outlined below.

Assess

Assess immunization status for all patients at every clinical encounter. To accomplish this, policies should be implemented to ensure that patients are regularly screened for immunizations and reminded about vaccines needed.

Recommend

Strongly recommend all vaccines that patients need. Clinic site staff should stay up-to-date on information pertaining to adult vaccines to best inform patients.

Explain the reasons why a patient should receive the vaccine, as well as address questions and concerns the patient may have. A strong recommendation for a vaccine from a trusted healthcare professional can make the difference for whether a patient chooses to receive the vaccine.

Administer

Administer vaccines the patient chooses to receive. Vaccines that are currently in stock should be offered. If there are vaccines that the patient needs that are not in stock or available through the ASN Program, patients should be referred to sites in the area that offers the needed vaccine.

Document

All vaccines administered to adults must be documented and included in the patient's medical records. ASN-enrolled clinic sites must participate in ImmTrac2, the Texas Immunization Registry.

The ASN Program captures the aggregate number of doses administered through monthly reports in EVI. For more information regarding documentation requirements, see Chapter 7: Documentation Requirements.

For more information regarding the Standards for Adult Immunization Practice, visit http://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html.

In January 2017, DSHS incorporated the Standards for Adult Immunization Practices (stock no. 6-252) into ASN site visits. DSHS Immunization Unit has a contract with a QA contractor to conduct ASN site visits. DSHS PHR staff may also conduct ASN site visits.

ASN site visits are driven by data to ensure sites with the most needs are seen first. The purpose of the compliance visit is to assess, support, and educate the staff regarding ASN policies and procedures, not to critique. If areas of concern are identified, the RE will provide a follow-up call or visit to assist the clinic with changes or questions.

B. Adult Site Visits

ASN Compliance Visit Only

This visit focuses primarily on an ASN policy review and a storage and handling review. The storage and handling reviews are used to check for proper vaccine storage and handling. Any issues identified will be addressed immediately and staff are expected to make onsite corrections to safeguard the vaccine.

C. Site Visit Scheduling and Clinic Access

Clinic sites will be contacted prior to a scheduled ASN site visit and will receive a confirmation letter via email or fax that includes the date, time, materials needed, and summary of the site visit process.

During an ASN site visit, the reviewer will need access to the following:

- Space to work;
- Power source (Internet connectivity, if available);
- Access to patient records;
- All temperature logs or data for the last three months, or longer if deficiencies are found;
- All Vaccine Borrowing Forms (stock no. EF11-14171) for the previous 12 months;
- The circuit breaker;
- Admitting and billing personnel to clarify eligibility screening and billing processes; and
- Vaccine storage units where ASN vaccine is stored.

D. Components of the ASN Site Visit

During the ASN site visit, the QA contractor or DSHS PHR reviewer and a clinic staff member that is knowledgeable about the ASN Program will work together to do the following:

- Review the standards for adult immunization practices;
- Review required elements of patient immunization records (lot number, manufacturer, title & signature of person who administered the vaccine, date of the VIS, date VIS was given to patient for review, date vaccine was given, clinic name & address);
- Review ASN Program requirements (administration fee, temperature recording, eligibility collection, etc.); and
- Review vaccine management requirements for the ASN Program (temperature recording forms, water bottles, proper vaccine placement, valid calibrated data logger, etc.).

The reviewer will provide a summary of areas of strength and areas for

improvement. Resources/recommendations for improving practices will be provided.

E. Electronic Medical Record (EMR) Review

In recent years, the use of EMRs has become routine and has changed the way record reviews are conducted. If an EMR is in use at a site, clinic staff must do one of the following:

- Provide a dedicated staff member to login to the EMR and sit with the reviewer throughout the record review process to pull up EMR immunization and eligibility records; or
- Provide print-outs from the EMR of the immunization records and documentation of the adult's eligibility.

Site staff cannot login and turn access of the EMR over to the reviewer – clinic staff must be present if records have not been printed.

As a reminder, signing the ASN Program Agreement form is an agreement to participate in ASN site visits, Unannounced Storage & Handling Visits, and other educational opportunities associated with ASN Program requirements.

XIII. Mobile Vaccination Clinics

An ASN-enrolled clinic may conduct off-site, mobile vaccination clinics using ASN vaccines. However, ASN eligibility still must be collected through the use of the Adult Eligibility Screening Record (stock no. EF11-12842) or in an EMR for all patients that receive ASN vaccines at each visit. Additionally, required vaccine storage and handling guidelines must be followed at all times and the vaccine must be returned to the original approved vaccine storage unit at the end of each day. Vaccines are extremely sensitive to temperature excursions. Any exposure to out-of-range temperatures could make the vaccine non-viable. For this reason, it is important to regularly monitor the temperature of the vaccines and take quick action when

temperature excursions occur. Refer to Chapter 8: MASS VACCINATORS, for specific information regarding the transporting of vaccines for mass vaccination clinics and handling temperature excursions.

XIV. Reporting Doses Administered

Qualified ASN-enrolled sites who also participate in TVFC are required to distinguish between adult and pediatric vaccines and order and report adult vaccines separately from TVFC pediatric vaccines. The Combined Tally and Inventory Sheet in EVI is an optional form that may assist in tracking adult and pediatric doses administered.

ASN-enrolled sites are required to enroll in ImmTrac2, Texas' Immunization Registry prior to receiving ASN vaccine. Adult vaccines are encouraged to be reported into ImmTrac2. For more information about ImmTrac2, see CHAPTER 7: DOCUMENTATION REQUIREMENTS > II. The Texas Immunization Registry (ImmTrac2).

XV. Fraud and Abuse

As the complexity of immunizations and immunization-related programs grow, ASN-enrolled clinic staff may become more vulnerable to unintentionally committing acts that could be construed as fraud and/or abuse. Fraud and abuse, whether intentional or not, is subject to all federal fraud and abuse laws.

A. Definitions

A working understanding of what constitutes fraud and abuse is critical for all persons working in the ASN Program. Specific definitions of what constitutes fraud and abuse can be found in the CHAPTER 6: FRAUD AND ABUSE > II. Definitions section of this manual.

B. Examples

Fraud or abuse can occur in many ways. Some types of fraud and abuse

are easier to prevent or detect than others. All clinic staff 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 ASN vaccine to ineligible ASN patients
- Sell or otherwise misdirect ASN vaccine
- Bill a patient or third party for ASN vaccine (other than administration fees)
- Charge more than $25.00 per dose for administration of an ASN vaccine
- Failure to meet licensure requirements for enrolled sites
- Deny ASN-eligible adults ASN vaccine because of the inability to pay an administration fee
- Send a patient to collections or charge additional fees for non-payment of the administration fee
- Failure to implement program enrollment requirements of the ASN Program
- Failure to screen for and document ASN eligibility at every visit
- Failure to maintain ASN records for five years
- Failure to fully account for ASN vaccine
- Failure to properly store and handle ASN vaccine
- Order ASN vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of ASN doses
- Loss of ASN vaccine due to negligent waste

C. Failure to Comply with ASN Requirements

A signature of a signing clinician on the TVFC/ASN Program Agreement is

an agreement to comply with all ASN Program requirements. Lack of adherence to the ASN Program requirements by an enrolled site could lead to fraud and abuse of the ASN Program. Non-compliance with ASN Program requirements may occur due to an unintentional lack of understanding of the requirements. Behavior may also be intentional. If non-compliance appears intentional and a clinic has received financial benefits from the behavior, the situation may result in immediate referral for investigation of suspected ASN Program fraud and abuse.

D. Fraud and Abuse Prevention

The ASN Program actively works with enrolled clinic staff to help prevent fraud and abuse in the ASN Program. The best methods to prevent fraud and abuse are strong educational components discussed during the initial site enrollment process and during the ASN Compliance Visit. Both occasions provide an opportunity to identify and prevent situations that may develop into fraud and abuse.

E. Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to the ASN Program or the RE via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that promote potential fraudulent situations are also investigated. The RE and DSHS QA contractors must report all cases of alleged or suspected fraud or abuse.

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CHAPTER 10: VACCINE INFORMATION STATEMENT (VIS)

All immunization clinic sites 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 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. The most current version of each VIS must be provided. A list of current VIS dates for each vaccine can be found on the Immunization Action Coalition (IAC) website at www.immunize.org/vis.

A VIS may be provided 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.

A copy (which can be an electronic copy) of each appropriate VIS must be offered to take away following the vaccination.

Reasonable steps must be taken to provide information in the appropriate languages to ensure patients with limited English proficiency are effectively informed. All VISs are available in more than 20 languages and can be downloaded from the IAC website at www.immunize.org/vis.

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CHAPTER 11: ORDERING FORMS AND LITERATURE

The DSHS Immunization Unit offers various forms, literature, brochures, posters, and VIS' free of charge. Forms are available to view, download, or ship directly to clinic sites. Allow 10 business days for delivery. A complete list of forms and materials available for order is online at https://secure.immunizetexasorderform.com/default.asp.

If internet access is unavailable, clinic sites may send a request for literature directly to the DSHS Immunization Unit via fax or mail.

When placing orders in writing, include the following elements:

- Stock number and requested quantity,
- Physical address for delivery, and
- Telephone number (including area code).

The request may be sent in one of the following ways:

Mail to:

Immunization Unit

Department of State Health Services

Mail Code-1946

P.O. Box 149347

Austin, Texas 78714-9347

Fax to: (512) 776-7288, Attn: Public Information, Education & Training (PIET) Department.

If you have questions regarding forms or the ordering process, please call PIET at (512) 776-6530 or toll free at
(800) 252-9152.

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CHAPTER 12: IMMUNIZATION RESOURCES

- Adult Safety Net (ASN) Website
  www.dshs.texas.gov/immunize/ASN/
- CDC Immunization Website
  www.cdc.gov/vaccines/
- CDC Immunization Schedules
  www.cdc.gov/vaccines/schedules/index.html
- CDC Vaccines for Children (VFC) Website
  www.cdc.gov/vaccines/programs/vfc/index.html
- CDC Vaccine Storage and Handling Toolkit
  www.cdc.gov/vaccines/hcp/admin/storage/toolkit/
- CDC "You Call the Shots" Training
  www.cdc.gov/vaccines/ed/youcalltheshots.html
- ImmTrac2, the Texas Immunization Registry
  www.dshs.texas.gov/immunize/immtrac/default.shtm
- Immunization Action Coalition
  www.immunize.org/
- Standards for Adult Immunization Practice
  www.cdc.gov/vaccines/hcp/adults/for-practice/standards/
- Immunization Quality Improvement for Providers Program
  dshs.texas.gov/immunize/Immunization-Quality-Improvement-for-Providers-Program/
- Texas DSHS Immunization Website
  immunizetexas.com/
- Texas Vaccines for Children (TVFC) Website
  www.dshs.texas.gov/immunize/tvfc/
- Texas Vaccine Education Online
  www.vaccineeducationonline.org/

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Vaccine Manufacturers Contact List

Vaccine manufactures should be contacted in the event of a temperature excursion to your vaccine storage unit. Refer to the vaccine manufacturer information as listed on the box.

Vaccine Manufacturers	Phone Numbers
GlaxoSmithKline	1-888-825-5249
Astra Zeneca	1-800-236-9933
Merck	1-800-627-6327
Sanofi Pasteur	1-800-822-2463
Seqirus USA, Inc	1-800-358-8966
Pfizer	1-800-438-1985
Grifols	1-888-474-3657

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TVFC Program Contact Information

DSHS Immunization Unit: 1-800-252-9152

Responsible Entity Contact

PINS Beginning with	Responsible Entity	Phone Number
00	City of San Antonio	210-207-3965
01	PHR 1	806-783-6412
02	PHR 2	325-795-5660
03	PHR 3	817-264-4790
04 or 05 **not** in Hardin, Jefferson or Orange Counties	PHR 4/5N	903-533-5310
05 **in** Hardin, Jefferson or Orange Counties, 06	PHR 6/5S	713-767-3410
07	PHR 7	254-778-6744
08	PHR 8	210-949-2067
09	PHR 9	432-571-4137
10	PHR 10	915-834-7924
11	PHR 11	956-421-5552
25	City of Houston	832-393-5188

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2021 Manual Revision History

Introduction to the 2021 TVFC Provider Manual for the TVFC Program

- Provider Manual Information: new language clarifying the announcement of policy changes.

Chapter 1 – TVFC Site Eligibility and Enrollment

- Enrollment Requirements: additional language added to clarify the requirement for reporting to ImmTrac2.
- Annual Re-Enrollment: additional language added to clarify withdrawal process for providers that do not complete re-enrollment.
- Site Eligibility: additional language added to clarify enrollment and reporting vaccine doses to ImmTrac2 to participate in the TVFC Program.

Chapter 2 – TVFC Patient Eligibility and Screening

- Nineteen-Year-Olds: additional language added to clarify vaccine series that are eligible to be completed under the ASN Program.

Chapter 3 – Vaccine Management

- Refrigerator and Freezer Requirements: additional language added to clarify requirements for vaccines used in auto-dispensing units.
- Cold Chain Management and Vaccine Transport: language added to clarify requirement having vaccine transport packing supplies on-hand during compliance site visits.

Chapter 5 – Program Evaluation

- Common Site Visit Structures: added IQIP Only Site Visit
- TVFC Provider Feedback Surveys: added subsection Annual TVFC Satisfaction Survey and Site Visit Assessment Survey

Chapter 6 – Fraud and Abuse

- Failure to Comply with TVFC Program: additional language added to clarify immediate referral for providers that commit intentional fraud and abuse.

Chapter 7 – Documentation Requirements

- The Texas Immunization Registry: added Subsection A, Reporting Vaccine Eligibility in ImmTrac2.
- The Texas Immunization Registry: added Subsection B, Reporting Requirements During Disaster Declaration.
- Vaccines Adverse Events: additional language added for reporting serious adverse events.

Chapter 8 – Off-Site and Mass Vaccinations Clinics

- Change chapter title to Off-Site and Mass Vaccination Clinics
- Vaccine Ordering for Off-Site and Mass Vaccination Clinics: added language to clarify a schedule of clinics must be submitted prior to receiving vaccine.
- Off-site and Mass Vaccination Clinic Requirements: additional language added to clarify the requirement for vaccine transport.

Chapter 9 – Adult Safety Net Program

- ASN Enrollment: additional language added to clarify ASN sites must enroll in ImmTrac2.
- Nineteen-Year-Olds: additional language added to clarify vaccine series that eligible to be completed using vaccine under the ASN Program.
- Reporting Doses Administered: additional language added to clarify reporting vaccines doses administered to ImmTrac2.

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Texas Department of State Health Services
Immunization Unit
MC-1946
P.O. Box 149347
Austin, TX 78714-9347

(800) 252-9152

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