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

# Texas Vaccines for Children and Adult Safety Net Operations Manual for Responsible Entities 2023

## Texas Department of State Health Services


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# Section One: General Information

## I. Introduction

The Texas Department of State Health Services (DSHS) Immunization Section prepared the Texas Vaccines for Children (TVFC) and Adult Safety Net (ASN) Program Operations Manual for use by DSHS Public Health Region (PHR) and contracted Local Health Department (LHD) staff who are responsible for overseeing program requirements. Consultations 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 TVFC and ASN Operations Manual is for use by DSHS PHR and contracted LHD staff who are responsible for over-seeing the program requirements in facilities under their jurisdiction.*

The purpose of the Operations Manual is to consolidate TVFC/ASN policies and information into one source document for DSHS PHR and contracted LHD staff. The contents are intended only for those entities and not for clinics or facilities enrolled in the TVFC/ASN Programs. Throughout the year, the DSHS Immunization Section will distribute new policies to staff at enrolled facilities via official policy letters, memorandums, and the monthly newsletters, "RE: News and the TVFC/ASN Digest". During the annual update of the Operations Manual, all policy updates from the previous year will be incorporated. Both the manual and the latest updates can be found on the DSHS Immunization Section website.

## II. Public Health Law Establishing the VFC Program

The federal Vaccines for Children (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 4.5 million Texas children to have access to immunizations. This is accomplished through a network of support provided by the DSHS PHRs and contracted LHDs. These organizations function as Responsible Entities (RE) to ensure compliance with State and Federal standards and effective vaccine distribution. Enrolled sites will contact their REs for information and details about required vaccine reporting.

## III. Vision and Mission of the DSHS Immunization Section

### 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 Section

- 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
- Ensure accountability of all program components

## V. Goals of the TVFC/ASN Programs

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

## VI. Childhood Immunization Standards

- Vaccination services are readily available
- Assess immunization status for all patients at every clinical encounter
- Effective communication about vaccine benefits and risks are discussed with the parent/guardians
- Vaccines are stored, administered properly, and documented correctly
- Strategies are implemented to improve vaccination coverage rates

## VII. Adult Immunization Standards

- Assess immunization status for all patients at every clinical encounter
- Strongly recommend all vaccines that patients need
- Administer vaccines that patient chooses to receive
- All vaccines administered must be documented and included in the patient's medical records

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# Section Two: Standards and Policies

## Policy

All agencies that offer and utilize TVFC/ASN vaccines must abide by the policies outlined in the TVFC/ASN Manual.

## Purpose

The purpose of this TVFC/ASN Programs Operations Manual is to provide instruction to REs about the programs and to ensure consistency and adherence to TVFC/ASN activities and standards. LHD REs report activities to PHR staff who report activities to the DSHS Immunization Section staff.

> ***NOTE:***
>
> *LHD REs report activities to PHR staff who report activities to the DSHS Immunization Section staff.*

## I. Facility Eligibility

### A. Facility Participation

**The following types of organizations are eligible to participate in the TVFC Program.**

- Addiction Treatment Facility – Locations that provide counseling, behavioral therapy, medication, case management, and other types of services to persons with substance use disorders. This provider type is used for addiction treatment centers where on-site vaccination services are provided.
- Birthing Hospital – Birthing centers or birthing hospitals where on-site vaccination services are provided.
- Community Health Center (CHC) – Community-based and patient-directed organizations that serve populations with limited access to health care. This provider type is used for community health centers that provide vaccination services.

- Community Vaccinator (non—health department) – Community-wide vaccinators that are external to health departments and conduct vaccination clinics in satellite, temporary, or off-site locations exclusively.
- DSHS Public Health Clinics – Clinics that are a government agency on the front lines of public health. Public health department clinics are staffed by state employees who report to the DSHS Health Commissioner.
- Emergency Medical Services (EMS) facilities – Sites that administer vaccines to children in a fire department facility.
- Family Planning Clinic (non-health department) – Clinics that provide contraceptive services for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and/or mental health). This provider type is used for family planning clinics where vaccination services are provided.

  **NOTE:** Non-health department clinics that offer only STD/HIV screening and treatment services should be categorized as "STD/HIV Clinic".
- Federally Qualified Health Centers (FQHC) – Centers that are designated by the Bureau of Primary Health Care (BPHC) of the Health Services & Resources Administration (HRSA) to provide health care to a medically underserved population.
- Hospital (non-publicly funded) – All hospitals, exception for birthing hospitals, where on-site vaccination services are provided.

  **NOTE:** For birthing hospitals, use the "Birthing Hospital or Birthing Center" designation.
- Juvenile Detention Center – Juvenile detention centers where on-site vaccination services are provided to individuals younger than 19 years of age. Juveniles in these facilities are considered UNinsured and are therefore eligible for the TVFC Program. Eligibility must be documented at every encounter.

- Local Health Department (LHD) clinic sites – A government agency on the front lines of health. LHDs often report to a mayor, city council, county board of health, or county commission.
- Migrant Health Facilities – Centers that provide health services, including on-site vaccination services, to migratory and seasonal agricultural workers and their families.
- Pharmacies (non-DSHS) – Stand-alone retail pharmacies or retail pharmacies within a hospital or health system where on-site vaccination services are provided. This category also included retail pharmacies that conduct community vaccination clinics at off-site or mobile locations.
- Private Provider Offices – Private practice locations, including solo, group, or HMO practitioners, that provide vaccination services.
- Public and private hospitals, including State hospitals – Publicly and privately funded institutions that provide Hepatitis B vaccine to newborns or one that provides medical and surgical treatment and nursing care for the sick and injured people. A state hospital is funded and operated by the State of Texas.
- Refugee Health Facilities – Clinics that are designated to improve the health care and monitor medical conditions of refugees who have relocated to the United States. This provider type is used for refugee health clinics that provide vaccination services.

  **NOTE:** If vaccination services are provided in a location that is co-located in a physical facility with a refugee health clinic, but are not administered by refugee health staff, select the category of the provider with oversight of vaccination services.
- Rural Health Clinics (RHC) – Clinics located in a non-urbanized Health Professional Shortage Area, Medically Underserved Area, or governor-designated and secretary-certified shortage area. This provider type is used for rural health clinics that provide vaccinations services. RHCs must supply a PDF version of your Centers for Medicaid Services (CMS) letter.

- State Supported Living Centers – A collection of residential facilities run by the State of Texas for people with intellectual disabilities.
- School-Based Clinics – Permanent school-based clinics that provide vaccination services.

  **NOTE:** Non-permanent school-based clinics should be categorized as "Community Vaccinator (non-health department).*
- STD/HIV Clinic Sites – Clinics that provide timely STD/HIV diagnosis, testing with on-site treatment, and partner services. This provider type is used for STD/HIV clinics NOT located within a health department where on-site vaccination services are provided.

  **NOTE:** This category should be used by non-Health Department (HD) clinics that exclusively offer STD/HIV screening and treatment services.
- Teen Health Centers or Adolescent-Only – Health centers that are NOT public health department-sponsored and provide on-site vaccination services to teens/adolescents.
- Tribal/Indian Health Services – Indian Health Service (IHS), Tribal, or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated Federally Qualified Health Centers and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.
- Women, Infants, and Children (WIC) Clinic – Locations that serve low-income pregnant, postpartum, and breastfeeding women, infants, and children up to age 5 who are at nutritional risk by providing nutritious foods to supplement diets, information on healthy eating including breastfeeding promotion and support, and referrals to health care. This provider type is used for WIC clinics that also provide vaccination services.

  **NOTE:** If vaccination services are provided in a location that is co-located in a physical facility with a WIC clinic, but are not administered by WIC

staff, select the category of the provider with oversight of vaccination services.

The ASN Program was developed to ensure that adults who ordinarily seek services through PHR or LHD clinics have access to recommended adult vaccines.

**The following types of organizations may enroll in the ASN Program:**

- DSHS Public Health Clinics,
- LHD Clinic Sites,
- FQHCs,
- RHCs, and
- Federally Recognized Indian Tribes.

## B. Signing Clinician Participation

To be eligible to enroll in TVFC/ASN, the signing clinician must be one of the following:

- Medical Doctor (MD),
- Doctor of Osteopathy (DO),
- Nurse Practitioner (NP) or Advanced Practice Nurse (APN),
- Physician Assistant (PA),
- Certified Nurse Midwife (CNM), or
- Registered Pharmacist (RPh).

## C. Recruitment

DSHS PHRs and contracted LHDs must conduct recruitment activities to enroll new providers into the TVFC/ASN Programs. This includes identifying and recruiting:

- Newly licensed medical professionals serving children and adolescents in Texas,
- Newly enrolled Medicaid and CHIP providers,
- Non-traditional immunization provider sites,
- Pharmacies,
- Birthing hospitals, and
- School-based clinics.

## D. Enrollment/Re-Enrollment

A TVFC/ASN Agreement Form must be completed at the initial enrollment and updated annually during re-enrollment. A signed agreement must be on file with DSHS. A new agreement must be submitted when the original signing clinician is no longer associated with the clinic.

Clinics must also enroll in the Texas Immunization Registry, ImmTrac2, before a Provider Identification Number (PIN) is assigned to participate in the TVFC/ASN Programs. Texas Health and Safety Code §§161.007-161.009 **requires** all medical providers and payors to report all immunizations administered to clients who are 17 years of age and younger.

***Enrollment/Re-Enrollment:***

*A TVFC/ASN Agreement Form must be completed at initial enrollment and updated annually during reenrollment. A signed agreement must be on file with DSHS.*

Although ASN providers are not required to report to ImmTrac2, it is **imperative** for ASN Program providers to actively consent adult patients and report vaccine doses to Immtrac2. All ASN Program providers are **required** to report adult vaccine doses administered in a timely and accurate manner into the Vaccine Allocation and Ordering System (VAOS).

Sites that are co-located at a single address are expected to enroll as one entity. Exceptions to this include the following situations:

- A co-located clinic with more than one signing clinician whose staff are exclusive to each signing clinician should not enroll under one PIN,
- A co-located clinic with more than one refrigerator or freezer unit that contains TVFC/ASN vaccines that are used by exclusive staff should not enroll under one PIN, and
- A co-located clinic with "pods" where each pod contains refrigerator or freezer units that store TVFC/ASN vaccines with specific staff assigned to the "pod" should not enroll under one PIN.

Clinics that accept Medicaid and Children's Health Insurance Program (CHIP) must enroll in TVFC. They may not refer children to DSHS PHR clinics, LHD sites, or other entities.

### 1. New Enrollment Visit

The RE must provide education to new or returning clinic staff about the TVFC/ASN Programs using the most current TVFC/ASN Provider Manual. All new or returning clinics to the TVFC/ASN Programs must receive an initial contact visit.

All new enrollment visits must be completed within 90 days of the date on the provider agreement form. If the new enrollment visit has not been conducted within 90 days, the provider will be required to complete a new enrollment.

***NOTE:***

*New Enrollment Checklist is a comprehensive list of available supplies from DSHS and a list of documents that will ensure success when new clinics join the TVFC/ASN Program. The checklist also includes all elements of the TVFC/ASN Program that the RE must review with the staff at newly enrolled sites.*

To prepare a new TVFC/ASN site for the program(s), the RE must accomplish the following steps:

- Contact clinic staff within two (2) weeks of receipt of the enrollment form,
- Verify the identification of two (2) clinic staff members as one (1) primary and one (1) backup vaccine coordinator,
- Verify that at least the two (2) coordinators completed the current TVFC Provider Policy Training module (available at immunizetexas.com), the Centers for Disease Control and Prevention's (CDC) "You Call the Shots" Modules 10 and 16 (available at https://www.cdc.gov/vaccines.ed/youcalltheshotes.html), and the Vaccine Allocation and Ordering Training (available at https://dshs.texas.gov/immunize/Vaccine-Management-Resources-for-TVFC-and-ASN.doc). If needed, provide assistance on how to accomplish these trainings. Other staff at the enrolling site should also be encouraged to complete the trainings. Refer to Section Seven: Site Coordinator Responsibilities for enrolled site vaccine coordinator responsibilities; and
- Schedule and provide education using the "New Enrollment Checklist", stock no. 11-15016, available at www.dshs.texas.gov/immunize/Responsible-Entities/Managing-TVFC---ASN-Providers/.

The primary and backup vaccine coordinators are required to attend the initial enrollment visit. It is recommended that the signing clinician is also present.

It is imperative to review each bullet on the enrollment checklist and the enrollment form with the staff to facilitate understanding of the program(s).

Verify with staff the following information provided on the enrollment form and offer feedback or make changes on a paper copy, if necessary.

- Correct shipping address (not a PO Box)
- Phone numbers

- Email address of signing clinician (DSHS communicates with enrolled sites via email)

**NOTE:** Email address must not exceed 40 characters.

- Medical license number and National Provider Identifier (NPI) of signing clinician
- Name and email address of primary and backup vaccine coordinators

**NOTE:** Email addresses must not exceed 40 characters.

- Completion of required trainings by primary and backup vaccine coordinators
- Complete information on additional clinicians that have prescribing authority (ensure the signing clinician is also listed)
- Correct selection of public or private clinic site
- Correct selection of type of clinic site
- Submission of CMS letter for sites that are FQHC or RHC
- Sites must offer all vaccines. However, those that are designated as any of the following may offer only select vaccines:
    - Addiction treatment facility,
    - Correctional facility,
    - EMS facility,
    - Hospital,
    - Juvenile justice program,
    - OB/GYN clinic,
    - Pharmacy,
    - School-based clinic,

- State-supported living center,
- STD/HIV clinic; or
- Teen/adolescent health clinic.

- The patient-profile section on the enrollment form for the TVFC Program is split into two categories.
  - The **FEDERAL VFC Program** provides vaccines for children who receive Medicaid (or are Medicaid-eligible), are UNinsured, American Indian/Alaskan Native, and/or UNDERinsured and seen in clinics designated as FQHC/RHC, or deputized PHR or LHD clinics.
  - The **TEXAS VFC (TVFC) Program** adds State and federal dollars to provide vaccines for children who are on CHIP and those who are UNDERinsured and seen in PRIVATE offices. (UNDERinsured children have private health insurance that does not cover any vaccines or covers only certain vaccines or places a dollar limit or cap on vaccines.)
- The RE must review the following information contained in the patient-profile sections (VFC and TVFC) of a TVFC enrollment form.
  - Medicaid numbers must be documented if the clinic will see Medicaid children.
  - UNinsured numbers must be documented if the clinic will see UNinsured children.
  - American Indian/Alaskan Native numbers must be documented, if applicable.
  - Only FQHCs, RHCs, PHR, and LHD clinics document numbers in the UNDERinsured category of the **Federal VFC Program**.
  - INSURED numbers must be documented. The following sites may document that they do not see privately insured patients:

- Addiction treatment facilities,
- DSHS public health clinics,
- Juvenile justice facilities or correctional facilities,
- Some LHDs,
- Migrant health facilities,
- Refugee health centers,
- Some school-based clinics,
- State-supported living centers,
- STD/HIV sites,
- Tribal/Indian health services, and
- WIC clinics.

> ***NOTE:***
>
> *Patient population data must be specific to the clinic site where a child will be vaccinated and not combined with other clinics' patient numbers.*

- CHIP numbers must be documented if the clinic will see CHIP children.
  - For a site to offer vaccines to children enrolled in CHIP, the clinic must bill CHIP for vaccine administration fees. If the site does not bill CHIP, it is not eligible to vaccinate CHIP children.

**NOTE:** There are less than 100 children younger than one (1) years-old enrolled in CHIP in Texas.

- Most children younger than one (1) years-old receive Medicaid.
- The Immunization Section provides DSHS PHR staff with the number of CHIP children younger than one (1) years-old in each Texas county.
- If the site lists more than just a few children on CHIP, provide this information and request a reassessment.

- In the TVFC section of the patient profile on the TVFC enrollment form, clinic sites that are **not** FQHCs, RHCs, or deputized DSHS PHR or LHD clinics must document numbers in the UNDERinsured category.
- The RE must verify the numbers in each age group and category and ensure the totals are calculated correctly.
- Patient population data must be specific to the clinic site where a child will be vaccinated and not combined with other clinics' patient numbers. During re-enrollment, the numbers must be based on real data (e.g., registry or billing data). During initial enrollment, the clinic should project the number of patients that will be served in the upcoming year, including insured patients.
- If the clinic is applying to participate in the ASN Program, REs must ensure that the patient-profile section for the ASN Program is completed with the number of expected insured and UNinsured adults that will be or have been vaccinated.
- The RE must verify the appropriate boxes have been checked on the agreement form for the TVFC/ASN Program enrollment process. If not, use the paper version of the form and request the signing clinician check and initial the appropriate box or boxes. The following statements apply to TVFC only, ASN only, or both programs.

    1. **(BOTH)** We will allow staff of DSHS, LHD, or DSHS Quality Assurance (QA) contractors to conduct on-site visits. These are required by DSHS regulations and include unannounced visits and other educational opportunities associated with program requirements.

    2. **(BOTH)** We will identify primary and backup vaccine coordinators at our facility who are authorized to order vaccines. We will inform DSHS of all status changes of current staff members or representatives who are no longer authorized to order vaccines, or the addition of new staff authorized to order vaccines.

3. **(TVFC ONLY)** We will screen patients and document eligibility statuses at every immunization encounter and administer vaccines only to eligible patients who are 18 years of age or younger and meet one or more of the following categories.

   - **FEDERAL VFC** includes Medicaid; American Indian or Alaskan Native; UNinsured; UNDERinsured (a child who has health insurance, but the coverage does not include vaccines, covers only selected vaccines, or sets a fixed dollar limit or cap on vaccine coverage. In this case, the child is eligible for only the non-covered vaccines. The patient must be vaccinated at an FQHC, RHC, or deputized DSHS PHR or LHD clinic.).

   - **TEXAS VFC (TVFC)** includes CHIP (if the clinic bills CHIP) and UNDERinsured (a child who has health insurance, but the coverage does not include vaccines, covers only selected vaccines, or sets a fixed dollar limit or cap on vaccine coverage. In this case, the child is eligible for only the non-covered vaccines and is vaccinated at a private clinic site).

4. **(ASN ONLY)** We will screen patients for ASN eligibility at all immunization encounters and administer State-purchased vaccines only to adults 19 years of age and older who do not have any health insurance.

5. **(BOTH)** For the vaccines identified in my profile, we will comply with immunization schedules, dosages, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) unless one of the following is true.

   - In my medical judgment, and in accordance with accepted medical practice, I deem such compliance to be medically inappropriate.

   - The particular requirements contradict State law, including laws pertaining to religious and other exemptions.

6. **(BOTH)** We will maintain all records related to the TVFC/ ASN Program for five (5) years, and upon request make these records available for review by DSHS, LHD, the DSHS QA contractor, and the U.S. Department of Health and Human Services. Records include, but are not limited to screening and eligibility documentation, billing records, medical records verifying receipt of vaccines, vaccine ordering records, and vaccine purchase and accountability records.

7. **(TVFC ONLY)** We will annually submit a patient-population profile representing populations served by my practice/ facility. We will submit the patient-population profile more frequently if the number of children served at a clinic changes or the status of the facility changes during the calendar year.

8. **(TVFC ONLY)** We will not charge a TVFC vaccine administration fee to Medicaid or CHIP patients. We may charge an administration fee that does not exceed $13.75 per vaccine dose to American Indian/Alaskan Native, UNinsured and UNDERinsured patients. For Medicaid patients, we will accept the reimbursement for an administration fee set by the State Medicaid agency or the contracted Medicaid health plans.

9. **(TVFC ONLY)** We will not deny administration of public and State-supplied vaccines to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

10. **(TVFC ONLY)** We will not charge for vaccines supplied by DSHS and administered to TVFC-eligible patients.

11. **(ASN ONLY)** We will not charge for vaccines supplied by DSHS and administered to UNinsured adults.

12. **(ASN ONLY)** We may charge a vaccine administration fee (not to exceed $25.00 per dose) to UNinsured patients that receive ASN vaccines. However, we will not deny administration of a State-supplied vaccine to an UNinsured adult because of an inability to

pay an administration fee. We agree that unpaid administration fees will be waived and not submitted for collection actions.

13. **(BOTH)** We will distribute the current Vaccine Information Statements (VIS) every time a vaccine is administered and will maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

14. **(BOTH)** We will comply with the requirements for vaccine management in accordance with DSHS rules and the manufacturer's specifications. State-supplied vaccines will only be at the facility listed in this agreement and will not be transferred to another facility without approval of DSHS. We may be required to purchase a new refrigerator, freezer, or temperature monitoring equipment if the equipment at our facility is deemed inappropriate for vaccine storage or unable to maintain appropriate temperatures.

15. **(BOTH)** We will comply with the following requirements for vaccine management.

    - Order vaccines and maintain appropriate vaccine inventories.

    - Not store vaccines in a dormitory-style unit at any time. A dormitory style refrigerator is defined as a small combination refrigerator/freezer unit outfitted with one exterior door and an evaporator plate (also known as a cooling coil), which is usually located inside an icemaker compartment or freezer in the refrigerator. In testing, a dormitory style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed in the unit. This type of unit exhibits severe temperature-control and stability issues.

Dormitory-style units pose a significant risk of freezing vaccine even when used for temporary storage.

**NOTE:** The use of dormitory style units for storage of TVFC/ASN vaccines is strictly prohibited. There are compact, purpose-built storage units for biologics that are not considered to be dormitory style.

- Store vaccines in proper storage conditions always. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet DSHS storage and handling requirements.
- Return all spoiled/expired TVFC- or ASN-supplied vaccines to DSHS's vaccine distributor within six (6) months of spoilage/expiration.

16. **(BOTH)** We agree to operate the TVFC/ASN Programs in a manner intended to avoid "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2:

    - Fraud is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act constituting fraud under applicable federal or State law.
    - Abuse includes methods inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or actions resulting in an unnecessary cost to the 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 resulting in unnecessary cost to the Medicaid program.

17. **(TVFC ONLY)** Public health clinics and LHD clinics that have a delegation of authority to vaccinate UNDERinsured patients agree to the following:

    - Vaccinate "walk-in" TVFC-eligible UNDERinsured children ("Walk- in" refers to any UNDERinsured child who presents

requesting a vaccine - not just established patients. "Walk-in" does not mean you must serve UNDERinsured patients without an appointment. If your office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to UNDERinsured patients as well); and

- Report required data monthly (number of UNDERinsured patients vaccinated, and number of doses administered, by age category).

18. **(TVFC ONLY)** For pharmacies and school-based clinics, we agree we will do the following:

    - Vaccinate all "walk-in" TVFC-eligible children. ("Walk-in" refers to any TVFC-eligible child who presents requesting a vaccine not just established patients.)"Walk-in" does not mean you must serve TVFC patients without an appointment. If your office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to TVFC patients as well); and

    - Not refuse to vaccinate TVFC-eligible children based on a parent's inability to pay the administration fee.

19. **(BOTH)** We or the State may terminate this agreement at any time for failure to comply with these requirements. If the agreement is terminated for any reason, we agree to properly return all unused vaccines.

The RE must verify the signature on the enrollment form is that of the signing clinician.

When all items on the “New Enrollment Checklist”, stock no. 11-15016, have been reviewed with staff and seven (7) operational days of within-range temperature recording have been collected, the RE must assist staff in completing an initial order in VAOS, explaining vaccine choice, maximum stock levels, pre-filled syringes, single-dose vials, combination vaccines, etc. Maximum Stock Levels (MSL) at new clinic sites should be set to a minimal

level to prevent overstocking while the patient population is being established.

The following items must be submitted to the Immunization Section to assign a PIN to a new site. All items must be checked as completed and the detailed information must be filled in on the "New Enrollment Checklist", stock no. 11-15016, or a PIN assignment will be delayed.

- The applicable pages of stock no. 11-15016 with an asterisk (*) on Provider Education Assessment and Reporting (PEAR) requirements.
- The applicable page of stock no. 11-15016 with the signatures of the staff in attendance at the initial enrollment visit. The primary and backup vaccine coordinators are required to attend.
- The applicable page of stock no. 11-15016 with the signature of the IPOS or RE staff who verified the ImmTrac2 Organization Code.
- The applicable page of stock no. 11-15016 with the signature of the RE who provided the initial enrollment visit training.
- A paper copy of the submitted enrollment form with necessary changes documented, if applicable.
- Place first order in VAOS.

A PIN will be assigned by Immunizations staff within 24 hours of receipt of all completed documents. Staff at the new clinic site and DSHS PHR will receive the newly assigned PIN via email with login information for the Vaccine Allocation and Ordering System (VAOS). The PHR is responsible for notifying the LHD of the PIN assignment and VAOS login information, if applicable.

In addition to adding the new clinic information in VAOS, the Immunizations staff will add the new clinic information in PEAR and the Vaccine Tracking System (VTrckS), a CDC program used by Immunizations staff.

Upon assignment of a PIN, Immunizations staff will document in PEAR that the initial enrollment visit was completed.

There are additional contact/visit requirements for a newly enrolled site. See the "New Enrollment Checklist", stock no. 11-15016, for a listing of the additional contact/visit requirements.

In accordance with TVFC/ASN Program requirements, the "New Enrollment Checklist", stock no. 11-15016, must be maintained by the RE for five (5) years.

## 2. Changes to Enrolled Facility's Information

Staff at enrolled sites are responsible for notifying their REs when there are changes to site information.

Providers should fill out a "Changes to Enrollment Form", stock no. 11-15224, when the following changes occur:

- Facility name (Complete sections A & B)
- Facility shipping address (Complete sections A & C)
- Facility shipping hours (Complete sections A & D)
- Signing clinician (Complete sections A & E)
- Prescribing authorities (Complete sections A & F)
- Patient population data change (Complete sections A & G)
- Primary and/or backup vaccine coordinator (Complete sections A & H)

> ***NOTE:***
>
> *Re-Enrollment for TVFC/ASN Programs will occur in October to ensure all sites are ready for the following year.*

LHD staff must assist providers with filling out the appropriate sections of the form as needed and submit the "Changes to Enrollment Form", stock no. 11-15224, to regional staff via email. Regional staff will submit the updated information via email to the designated DSHS Immunization Section consultant. Depending on the changes made, providers and/or LHDs may be asked by the designated DSHS Immunization Section consultant to take additional actions.

## 3. Annual Re-Enrollment

TVFC/ASN re-enrollment will take place in October in preparation for the following year. Vaccine shipments may be interrupted if TVFC/ASN-enrolled clinics do not complete re-enrollment activities within the required timeframe. Providers who do not successfully re-enroll for the following calendar year will be suspended from ordering vaccines on the first working day of December to prevent receipt of vaccines in January.

Clinics that do not complete re-enrollment must be withdrawn by the end of the second week of January and the RE must pick-up vaccine by this time. These clinics can re-enroll into the program, determined by RE timelines. A "New Enrollment Checklist", stock no. 11-15016, must be completed to reinstate the site.

The PHR is responsible for verifying the following items listed below on the re-enrollment forms by November 30. The PHR may forward requests to LHD RE for assistance in obtaining corrected information.

- Ensure the staff chose the correct program in which to re-enroll.
- Verify the correct PIN is listed.
- Verify facility demographic information was entered correctly. This includes facility name, address, city, zip, county, phone, and fax.
    - Facility names and addresses must not include periods (.), commas (,), question marks (?), asterisks (*), percentage symbol (%), ampersand (&), equals (=) symbol, or greater than (>) or less than (<) symbol.
    - Shipping address must not be a PO Box.
- Verify correct ImmTrac2 organization code was entered and is accurate for that site.
- Verify the signing clinician's, and the primary and backup vaccine coordinator's information is supplied.

  - The signing clinicians', and the primary and backup vaccine coordinator's information must not include periods (.), commas (,), question marks (?), asterisks (*), percentage symbol (%), ampersand (&), equals (=) symbol, or greater than (>) or less than (<) symbol.

- Review the uploaded training certificates for the primary and backup vaccine coordinator to ensure the correct names are listed.

- Review the list of prescribing authorities at the site to ensure the signing clinician is listed.

**NOTE:** DSHS Immunizations staff will verify the medical license numbers of all prescribing authorities listed on all re-enrollment forms.

- Verify the staff chose the correct type of facility (private or public).

- Verify the correct clinic type was chosen for the facility.

  - Private facility types include EMS facilities; hospitals (not publicly funded); pharmacies (not DSHS Pharmacy); private offices (solo/ group/HMO); school-based clinics (on school premises, operated by a private group); and teen/adolescent health clinics.

  - Public facility types include community health centers; correctional facilities; addiction treatment facilities; DSHS public health clinics, including those with a delegation of authority to vaccinate UNDERinsured children; FQHC, HHSC family planning clinics; hospitals (publicly funded, including state hospitals); juvenile detention centers, local health department clinics, including those with a delegation of authority to vaccinate UNDERinsured children; migrant health facilities; pharmacies (DSHS Pharmacy only); refugee health facilities; RHC; school-based clinics on school premises, operated by school staff; state supported living centers; STD/HIV clinics; tribal/Indian health clinics; and WIC clinics.

> ***NOTE:***
>
> *At the discretion of DSHS, mass vaccinators or those with special grants may offer only influenza or HPV vaccine.*

- Verify CMS letter for sites that choose FQHC or RHC.
- Ensure staff selected the appropriate category of offering all vaccines or select vaccines. Only specialty clinics can offer select vaccines. Specialty clinics include those that serve a defined population such as addiction treatment facilities; correctional facilities; EMS facilities; family planning clinics; hospitals (including state hospitals); juvenile detention facilities; OB/GYN; pharmacies; school-based clinics; state supported living centers; STD/HIV clinics; and teen/adolescent health clinics.

**NOTE:** At the discretion of DSHS, mass vaccinators or those with special grants may offer only influenza or HPV vaccine.

- Verify the information provided in the patient-profile section.
  - The **FEDERAL VFC Program** provides vaccines for children who receive Medicaid (or are Medicaid-eligible), are UNinsured, American Indian/Alaskan Native, and/or UNDERinsured and seen in clinics designated as FQHC/RHC, or deputized PHR or LHD clinics.
  - The **TEXAS VFC (TVFC) Program** adds State and federal dollars to provide vaccines for children who are on CHIP and those who are UNDERinsured and seen in PRIVATE offices. (UNDERinsured children have private health insurance that does not cover any vaccines, covers only certain vaccines, or places a fixed dollar limit or cap on vaccines).
  - **INSURED** patient information is also required to be documented.
- Review the numbers documented in the patient-profile sections using the following information. Sites must gather this information based on real data such as Medicaid claims, encounter or billing system data, or doses administered for the previous six (6) months. Sites that record whole numbers such as 100 for each category must be contacted to gather real data instead of estimates.
  - Medicaid and UNinsured numbers must be documented if the clinic will see Medicaid and UNinsured children.

- American Indian/Alaskan Native numbers must be documented, if applicable.
- Only FQHCs, RHCs, PHR and LHD clinics document numbers in the UNDERinsured category of the **Federal VFC Program**.
- **INSURED** numbers must be documented. The following sites may document that they do not see privately insured patients:
  - Addiction treatment facilities
  - DSHS Public Health Clinics
  - Juvenile justice facilities or correctional facilities
  - Some Local Health Departments (LHDs)
  - Migrant Health Facilities
  - Refugee Health Facilities
  - Some school-based clinics
  - State-Supported Living Centers
  - STD/HIV sites
  - Tribal/Indian Health Services
  - WIC clinics
- CHIP numbers must be documented if the clinic will see CHIP children.
  - For a site to offer vaccines to CHIP children, the clinic must bill CHIP for vaccine administration fees. If the site does not bill CHIP, it is not eligible to vaccinate CHIP children.

**NOTE:** There are less than 100 children younger than one (1) year of age enrolled in CHIP in Texas. If a site documents more than just a few children younger than one (1) year of age in the CHIP category, they must be contacted for a reassessment.

  - In the **TVFC** section of the patient profile, clinic sites that are not FQHCs, RHCs, or deputized DSHS PHR or LHD clinics should document numbers in the UNDERinsured category.
  - The RE must ensure totals are calculated correctly.
- If the clinic participates in the ASN Program, the patient-profile section for the ASN Program must be completed with the number of insured and UNinsured adults that have been vaccinated in the previous year.
- Verify the information provided regarding data loggers at the site. Contact the site immediately if it is stated there are no data loggers or no-backup data logger in place.
- Ensure that data logger certificate of calibrations have been entered and that there are none expired.
- Verify the appropriate boxes have been checked on the agreement form for the TVFC/ASN Program enrollment process. See Section Two, I. Facility Eligibility, D. Enrollment/Re-enrollment, New Enrollment Visit for the listing. If a box has not been checked, RE must request the signing clinician's initials on a paper copy of a re-enrollment form.
- Verify the signature is the signing clinicians'. If not, RE must request the signing clinician's signature on a paper copy of a re-enrollment form.

REs are responsible for reviewing all re-enrollments to verify the medical license numbers of all prescribing clinicians listed on the re-enrollment forms. Upon completion, the DSHS Immunization Section staff uploads patient population information to VTrckS; uploads facility demographics to PEAR; and uploads facility name and contact information on the signing clinician and the primary and backup coordinator to Syntropi.

## E. 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 (e.g., school located clinics) require enhanced storage and handling practices. Providers who conduct off-site and mass vaccination clinics are not allowed to operate outside of their jurisdiction. For example, a provider may not transport vaccines from Region 7 to Region 8 to conduct an off-site or mass vaccination clinic.

Prior to initiation of the mass vaccination clinic REs must review and approve the enrolled site's mass vaccination protocols to ensure outreach efforts meet all the TVFC/ASN requirements, including:

- Showing the established vaccines needs (e.g., population 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/ASN vaccine 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 be documented on a "Temperature Recording Form", stock no. EC-105.

Specific storage and handling requirements for mass vaccination clinics is discussed in the storage and handling section of this manual, in Section Three: Vaccine Management, V. Storage and Handling, subsection C. Off-Site and Mass Vaccination Clinic Storage and Handling Requirements.

## F. Program Exclusion

The DSHS Immunization Section staff verify signing clinicians and those with prescribing authority with the Medicaid Exclusion List and other sources to

ensure they are allowed to participate in the TVFC/ASN Programs. A signing clinician excluded from participation in Medicaid will be denied participation in the TVFC/ASN Programs. If the signing clinician is listed as excluded, the enrollment form can be signed and resubmitted by another MD, DO, NP/APN, PA, CMN, or RPh at the site.

**NOTE:** A signing clinician that is on an excluded list is not eligible to receive or administer TVFC/ASN vaccines and must not be included on the list of prescribing authorities.

## G. Withdrawal

The following steps must be completed by the assigned RE within five (5) days of the clinic's expected withdrawal date from the TVFC/ASN Program.

- Complete a "Provider Withdrawal Form", stock no. F11-11443, or have staff at the withdrawing clinic complete it.
- Arrange to pick up all vaccines – viable and non-viable (expired/ruined).
- To request a shipping label to return non-viable vaccines that were picked up from a withdrawn facility, it is important to do one of the following:
    - Transfer all doses to the RE's PIN including non-viable doses. This method will require completion of a "Vaccine Loss Report Form", stock no. C-69, by the RE for the non-viable doses. The "Vaccine Loss Report Form", stock no. C-69, will be emailed to the DSHS Immunization Section with a note to send the shipping label via email. This is the preferred method.

> ***NOTE:***
>
> *It is important to submit a withdrawal form to DSHS Immunization Section within three (3) days of picking up the vaccine.*

- Complete the final entry in VAOS. Document doses administered, vaccine losses, and doses transferred.
- Ensure that the provider's vaccine inventory is zeroed out in VAOS.

- Appropriately pack viable vaccine, complete a "Transfer Authorization Form", stock no. EC-67, in VAOS and transfer it to another site that has agreed to accept it or return it to the RE site for redistribution.
- In PEAR and the Immunization Quality Improvement for Providers (IQIP) Database (RedCap) Program, finalize all outstanding items.
- Within three (3) days of picking up the vaccine, the RE must submit the "Provider Withdrawal Form", stock no. F11-1144, to the DSHS Immunization Section via email to the assigned consultant.

The DSHS Immunization Section will verify that VAOS has been zeroed out and that all PEAR and IQIP items have been completed. Syntropi will then be updated to reflect the withdrawal of the clinic.

It is important to submit a "Provider Withdrawal Form", stock no. F11-11443, to the DSHS Immunization Section within three (3) days of picking up the vaccine. Providers must return state-issued room temperature thermometers, data loggers, docking stations, and accompanying certificates of calibration to their REs if withdrawing from the TVFC/ASN Programs. This alerts DSHS QA contractors to remove the PIN from the list of sites on which to conduct a review. It also ensures that DSHS staff provide correct data on the number of enrolled sites to senior management and other stakeholders.

## H. Program Suspension

Clinics enrolled in the TVFC/ASN Programs are expected to follow program requirements. If a RE discovers a clinic operating outside of program requirements, the clinic may be suspended. Suspension does not prevent the staff from continuing to use TVFC/ASN vaccine, but it does prevent additional vaccine orders. Suspension must not exceed 90 days. If an enrolled site does not correct identified issues within 90 days, the clinic must be terminated from the program.

Clinics may also be suspended during times of emergencies, such as hurricanes or other disasters, if their facilities sustain damage. The clinic should be suspended if they are expected to be operational within 90 days.

If the damage is expected to take longer than 90 days to repair, the site must be withdrawn from TVFC/ASN Programs.

The DSHS Immunization Section will monitor the list of suspended clinics to ensure suspension does not exceed 90 days.

## I. Termination

Clinic sites can be terminated from the TVFC/ASN Programs for continued non-compliance with program requirements. A TVFC/ASN signing clinician may be terminated for instances of fraud and abuse as described below.

An official notice of termination is sent as a signed letter from the DSHS Immunization Section Director. Terminated sites and/or clinicians are removed from the program for a period of at least one (1) year.

Those seeking re-enrollment following termination must seek approval from the DSHS Immunization Section's Vaccine Operations Group (VOG) Managers who will consult with the DSHS Immunization Section Director, the PHR, and the RE.

## J. Fraud & Abuse Reporting

All RE staff, DSHS Immunization Section staff, and DSHS QA contractor staff must immediately report all allegations of fraud, abuse, and other unlawful activities to the DSHS Immunization Section who may notify the Office of Inspector General (OIG), as directed by OIG procedures. These procedures are located at https://oig.hhsc.texas.gov/report-fraud-waste-or-abuse.

The DSHS Immunization Section is currently working with the CDC and OIG to improve the process for prevention, identification, investigation, and resolution of suspected cases of fraud and abuse.

> ***NOTE:***
>
> *CDC requires program termination for facilities with staff member or subcontractor on the List of Excluded Individuals/Entities.*

OIG investigations should not be a reason to keep a clinic out of the program(s). They are innocent, unless found guilty; however, if vaccine is

mishandled, administered to ineligible patients, eligibility forms were not collected, or failure to do other program requirements, these can be reasons to suspend or withdraw.

The clinic must be monitored closely to identify improvements/compliance. This requires continued monitoring to ensure compliance with program requirements. CDC requires DSHS to terminate facilities from the program if Medicaid notifies Immunizations of a signing clinician, staff member, or subcontractor on the List of Excluded Individuals/Entities.

It is important that RE staff understand the program is subject to all federal fraud and abuse laws, and that even unintentional abuse or error is unacceptable. Education to prevent fraud or abuse is critical. To prevent unintentional fraud or abuse situations, clinic staff must be educated at every opportunity, such as during site visits, trainings, and phone calls.

Education should cover the appropriate use of TVFC/ASN vaccines and reminders that federal fraud and abuse laws apply to the TVFC/ASN Programs.

Fraud and abuse can occur in many ways, and some types of fraud and abuse are easier to prevent or detect than others. All RE staff, DSHS Immunizations staff, and DSHS QA contractor staff must be familiar with the examples listed below. They illustrate common errors that could result in fraud or abuse allegations.

The following definitions and examples are provided so DSHS can better identify and intervene in activities that could be defined as fraud or abuse.

**Fraud**

Fraud is defined as an intentional deception or misrepresentation made with the knowledge that the deception could result in an unauthorized benefit. It includes any act that constitutes fraud under applicable federal or State laws.

**These are examples. This should not be considered an exhaustive list of situations constituting fraud.**

## Examples of Fraud

- Selling or otherwise misdirecting TVFC/ASN vaccine.
- Billing a patient or a third party for TVFC/ASN vaccine (other than for an administration fee).
- Failing to meet licensure requirements for signing clinicians or those with prescribing authority.
- Providing TVFC/ASN vaccine to patients that are not eligible.
- Failing to screen for and document TVFC/ASN eligibility at every visit.
- Charging more than $13.75 for administration of a TVFC vaccine to an eligible child or more than $25.00 for administration of an ASN vaccine to an uninsured adult.

**NOTE:** Medicaid and CHIP patients must not be charged any out-of-pocket expenses.

### Abuse

Abuse is defined as practices that are inconsistent with sound fiscal, business, or medical practice and results in an unnecessary cost to the Medicaid Program. Abuse may include actions that result in an unnecessary cost to the TVFC/ASN Programs, 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.

**These are examples. This should not be considered an exhaustive list of situations constituting abuse.**

## Examples of Abuse

- Denying eligible children/adults TVFC/ASN vaccines because of inability to pay the administration fee.

- Sending a parent/guardian or patient to collections or charging additional fees for non-payment of the administration fee.
- Failing to implement TVFC/ASN Programs enrollment requirements.
- Failing to maintain TVFC/ASN records for five (5) years.
- Failing to fully account for TVFC/ASN vaccine.
- Failing to properly store and handle TVFC/ASN vaccines.
- Ordering TVFC/ASN vaccines in quantities that do not match the clinic's population profile or otherwise over-ordering TVFC/ASN vaccine doses.
- Loss of TVFC/ASN vaccines due to negligence.

> ***Abuse:***
>
> *Practice that is inconsistent with sound fiscal, business, or medical practice that results in unnecessary cost to the Medicaid Program, TVFC/ASN, a health insurance company, or a patient.*

**Responsible Entity (RE)**

If there is an allegation of fraud or abuse against an enrolled TVFC/ASN provider, an investigation must be conducted. LHD REs must collaborate with their PHR RE to provide any documentation necessary so that a full investigation of the allegation can be completed. At a minimum, the RE should conduct an unannounced storage and handling (USH) visit to review items specifically related to the allegation. The provider must be advised of the specific allegation.

If the findings of the USH supports unintentional fraud or abuse, it may be necessary to provide education to the clinic staff on TVFC/ASN Programs requirements. In other cases, the clinic staff may be asked to submit a corrective action plan outlining the activities they will institute to stop the practice(s) leading to suspicions of fraud/abuse. In addition, the staff may be asked to retake required trainings (TVFC/ASN Provider Policy Training, the CDC's "You Call the Shots", Modules 10 and 16, and the VAOS Training). The clinic may be placed on suspension during this time (Suspension not to exceed 90 days).

As a follow-up, an in-person visit should be conducted three (3) to six (6) months later, or after the clinic has implemented the corrective action plan. The visit will assess the staff's compliance with the TVFC/ASN Programs requirements.

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

# II. Patient Eligibility

## A. Patient Eligibility Screening

Screening all patients at every immunization encounter and documenting eligibility screening at every visit is the only way to ensure that TVFC/ASN vaccines are used only for TVFC/ASN-eligible patients.

The "TVFC/ASN Patient Eligibility Screening Record", stock no. C-10 for children and EF11-12842 for adults) may be used to document the category of eligibility. Clinic staff must document the eligibility category of each client receiving TVFC/ASN vaccines at every encounter.

Clinics may use their electronic medical record (EMR) systems to capture the information listed on the Patient Eligibility Screening Records if the EMR captures all required eligibility elements. Documentation of eligibility must be kept on file for a minimum of five (5) years after the last date of service and must be easily retrievable.

All TVFC/ASN enrolled clinics must conduct patient eligibility screenings. The screening form is filled out by the parent/guardian, adult patient, or by a health care provider and is a self-declaration. Clinic staff are not required to verify that the self-declaration is accurate.

## B. TVFC Program Eligibility

Children who meet these categories and are 18 years of age or younger are eligible to receive TVFC vaccine.

- Enrolled in Medicaid (or Medicaid-eligible)
- UNinsured
- American Indian or Alaskan Native
- UNDERinsured
    - Those with private health insurance that does not cover vaccines; or
    - Those with private health insurance that covers only selected vaccines (the child is eligible for TVFC vaccines for those that are not covered by his/her plan).
    - Those with private insurance that has a fixed dollar limit or cap for vaccines. Once the fixed dollar amount is reached, a child is then eligible.
- Enrolled in CHIP (only clinics that bill CHIP are eligible to vaccinate CHIP children)

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

Insured children that have Medicaid as their secondary insurance are eligible for TVFC vaccine and must not be refused vaccines 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. If a patient has one of the following type of insurances, they may be considered UNinsured or UNDERinsured for the purpose of TVFC eligibility:

- Short-term major medical,

- Limited benefit health insurance,
- Supplemental health insurance,
- Health care sharing ministries (HCSM), or
- Direct primary care.

For status of an insurance plan by the state of Texas, please see the Texas Department of Insurance website.

> ***NOTE:***
>
> *A local FQHC/RHC in each region deputizes DSHS PHR and LHD clinics. The FQHC/RHC signs an MOU with DSHS that allows UNDER-insured children to be vaccinated at DSHS PHR and LHD clinics.*

## C. ASN Program Eligibility

Eligibility for the ASN Program is only for UNinsured adults aged 19 years and older.

Adult patients with insurance, including Medicare or Medicaid, are not eligible for ASN vaccines. Adult patients with insurance that does not cover vaccines, such as some Medicare plans, are not eligible for ASN vaccines. Adults who are enrolled with Medical Access Program (MAP) are eligible to receive vaccines from ASN-enrolled providers. Insured or underinsured adults must be referred to a physician or an agency, such as a pharmacy, for vaccines.

Some ASN providers may see patients enrolled in the Healthy Texas Women (HTW) program. Patients enrolled in HTW are considered insured and do not qualify to receive vaccines under the ASN Program. Some LHD clinics, FQHCs, and RHCs purchase vaccines to administer to insured adults. Vaccines purchased with LHD, FQHC, and RHC funds can be used at the discretion of the site.

Patients who are 19 years of age and previously initiated a vaccination series under the TVFC Program are eligible to complete the series using ASN vaccines regardless of current health insurance status. These patients must have started the vaccine series when the patient was 18 years of age or younger and the vaccine must be administered at a DSHS PHR or LHD clinic and must be completed by the time the patient turns 20 years of age.

**NOTE:** A "series" in this case is specific to two (2) doses of Hepatitis A (HepA); three (3) doses of Hepatitis B (HepB); two or three (2 or 3) doses of Human Papillomavirus (HPV); two (2) doses of Meningococcal Conjugate (ACWY); two (2) doses of Measles, Mumps, and Rubella (MMR); three (3) doses of Tetanus, Diphtheria/Tetanus, Diphtheria, Pertussis (Td/Tdap); and two (2) doses of Varicella (Chickenpox). This policy does not apply to Meningococcal B (MenB), Polio, *Haemophilus influenzae* (Hib) or Influenza vaccines. This policy also does not apply to booster doses.

All adult vaccine doses administered at eligible sites should be reported on the "Enter Doses Administered" page in VAOS. It is important to accurately report doses administered to adults. The DSHS Immunizations uses this information to account for adult vaccine usage and to project and maintain supply.

## D. Deputization of Clinics

A local FQHC/RHC in each region deputizes DSHS PHR and LHD clinics. The FQHC/RHC signs a Memorandum of Understanding (MOU) with DSHS that allows UNDERinsured children to be vaccinated at DSHS PHR and LHD clinics. With very few exceptions, all PHR and LHD clinics must be enrolled in both TVFC and ASN Programs. The **Federal VFC Program** pays for the vaccines. This MOU allows UNDERinsured children to continue to receive vaccines at a DSHS PHR or LHD clinic instead of having to seek care at an FQHC or RHC. The vaccines for UNDERinsured children that are seen in clinics other than DSHS PHR or LHDs is paid for by the **TVFC Program**.

Annually, all DSHS PHR and LHD authorized sites are required to submit a Delegation of Authority (DOA) addendum form. REs must submit DOA addendum forms to the DSHS Immunization Section for each DSHS PHR and LHD clinic. The signing clinician's signature on the DOA addendum constitutes an agreement to track the number of UNDERinsured children and the number of doses administered to them, and report this to the DSHS Immunization Section monthly on the 15th. Reports must come through either the Texas Wide Integrated Client Encounter System (TWICES) or the online survey created by the DSHS Immunization Section.

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# Section Three: Vaccine Management

## Policy

All agencies offering and utilizing TVFC/ASN vaccine must institute proper vaccine management.

## Purpose

The purpose is to ensure vaccine confidence of all who receive TVFC/ASN vaccines.

## I. Approved Vaccines

The TVFC Program supplies all ACIP-recommended vaccines to enrolled sites. The signing clinician can choose vaccine brands and presentations, as listed on the pediatric formulary, the "Texas Vaccine for Children (TVFC) - Available Vaccines", stock number 11-16604. Some vaccines are available as combination vaccines. The TVFC vaccines available to enrolled sites include the following:

- Diphtheria, Tetanus, and acellular Pertussis (DTaP)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- *Haemophilus influenzae* type b (Hib)
- Human Papillomavirus (HPV)
- Inactivated Polio Vaccine (IPV)
- Influenza (Flu)
- Measles, Mumps, and Rubella (MMR)
- Meningococcal Conjugate Vaccine (MCV4)

- Meningococcal type B (MenB)
- Pneumococcal Conjugate Vaccine (PCV13)
- Pneumococcal Polysaccharide Vaccine (PPSV23)
- Rotavirus (RV)
- Tetanus and diphtheria (Td)
- Tetanus, diphtheria, acellular pertussis (Tdap)
- Varicella (Chickenpox)

The ASN Program supplies the following vaccines listed below to enrolled sites. The signing clinician can choose vaccine brands and presentations, as listed on the adult formulary, the "Adult Safety Net (ASN) - Available Vaccines", stock number 11-16658.

- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Human Papillomavirus (HPV)
- Measles, Mumps, and Rubella (MMR)
- Meningococcal Conjugate Vaccine (MCV4)
- Pneumococcal Conjugate Vaccine (PCV20)
- Pneumococcal Polysaccharide Vaccine (PSV23)
- Tetanus and diphtheria (Td)
- Tetanus, diphtheria, acellular pertussis (Tdap)
- Varicella (Chickenpox)

It may be necessary for the DSHS Immunization Section to make changes to the ASN vaccine list based on available funding. Official memos will be

distributed to enrolled ASN sites if changes to the vaccine formulary are necessary.

# II. Vaccine Ordering

## A. Vaccine Distributors

There are two vaccine distribution centers that service Texas.

- McKesson Specialty ships refrigerated TVFC/ASN vaccines.
- Merck ships frozen TVFC/ASN vaccines.

## B. Routine Order Processing Timeline

There are five parties that must work together to make the ordering process successful. They include the following:

- Staff at the enrolled site,
- REs,
- DSHS Immunization Section staff,
- CDC staff, and
- Staff of the vaccine distributor/manufacturer.

**Staff at Enrolled Site**

It is the enrolled site's responsibility to ensure that the accurate clinic address and delivery hours are entered in Syntropi. For sites to receive vaccine shipments, appropriate staff must be on site and available at least one day a week other than Monday for at least four consecutive hours during the hours of 8:00 a.m. – 5:00 p.m. The enrolled site will establish the hours available to accept vaccine orders when enrolling or re-enrolling in Syntropi.

## Responsible Entity (RE)

Throughout the month, REs should frequently check VAOS for pending vaccine orders to ensure they are reviewed and approved for further processing. The recommend interval is twice daily. When a vaccine order is submitted in VAOS, it is automatically in "Pending" status for review by the RE. It is important that REs monitor VAOS to ensure orders are not processed until they have reviewed the appropriate details, such as temperature recording forms, vaccine loss forms, comments to increase/decrease vaccine requests, etc. Orders must not be left on hold or pending for more than three (3) days.

Vaccines that are on allocation by the CDC require a strict allocation process and must NOT be approved over the suggested quantity amount. All orders approved over the suggested quantity will be reduced by DSHS Immunization Section if the vaccine is on allocation.

## DSHS Immunization Section

The DSHS Immunization Section will review requests in VAOS prior to submitting the vaccine orders to CDC via VTrckS. Vaccine orders are submitted to the CDC daily. Orders left on hold by the REs for more than 45 days will be cancelled by DSHS Immunization Section.

## CDC

The CDC receives vaccine orders daily through VTrckS and forwards the order information to the distributor.

## Distributor

The distributor(s), McKesson and/or Merck, ships vaccine on Mondays, Tuesdays, Wednesdays, and Thursdays. McKesson has five (5) business days from the day the order was uploaded into VTrckS to ship vaccines to the enrolled site and Merck has up to 15 business days from the day the order was uploaded into VTrckS to ship frozen vaccines. As a result, vaccine may take more than two (2) weeks to be received at a facility after the enrolled site placed a vaccine order in VAOS to arrive at a facility. In many cases, sites will receive vaccines sooner.

## C. Ordering Influenza Vaccine

Pre-booking influenza vaccine usually occurs in the first quarter of each year, prior to flu season. Pre-booking is a commitment by the signing clinician to order doses for their patients for the upcoming flu season.

An official memo containing instructions for placing Flu Pre-book orders in VAOS is distributed to all enrolled TVFC sites to inform staff that pre-book for flu vaccine is open. The memo includes a brief description of all influenza vaccines available for the upcoming flu season.

The DSHS Immunization Section will supply REs with a list of TVFC-enrolled sites that did not pre-book influenza vaccine. The RE is expected to contact the sites to remind the staff of the need to provide all routine immunizations to all their patients.

> ***NOTE:***
>
> *All approved orders will be processed the following business day after approval by the RE.*

The TVFC Program orders a limited quantity of additional doses to account for new sites that enroll after the closing of the pre-book deadline. Providers in need of additional flu vaccine once seasonal pre-book doses have been utilized, may also request additional doses, or wait until open ordering begins.

Influenza vaccine will be distributed to enrolled sites as doses are allocated to Texas by the CDC. When flu vaccine is available, the DSHS Immunization Section distributes the vaccine to sites that completed pre-book activities. It is important for sites that pre-booked flu vaccine to not change the allocated weekly amount unless vaccine storage is an issue. The DSHS Immunization Section makes influenza vaccine allocations based on the following criteria:

- Presentations available,
- Pre-orders including all presentations,
- Number of doses, and
- Orders already received.

The DSHS Immunization Section sends an email notification every Monday to the primary vaccine coordinator at TVFC-enrolled sites that completed pre-book activities to notify the staff that influenza vaccine is available. Staff at the enrolled sites have until noon Friday of the same week to accept the allocation in VAOS.

Vaccine amounts that are not accepted in VAOS will be cleared by the DSHS Immunization Section on Friday afternoon. Additional flu vaccine allocation will occur again the following Monday until all pre-booked doses are filled. If a facility fails to accept the allocated amounts two (2) weeks in a row, amounts must be re-assessed by the RE.

When flu vaccine has been distributed to all sites that completed pre-book activities and all newly enrolled sites, the DSHS Immunization Section opens influenza vaccine ordering to all TVFC-enrolled clinics.

## D. Vaccine Ordering for Providers without Internet Access

Enrolled sites in TVFC/ASN Program without internet access must contact their responsible entity for assistance with ordering vaccines. The RE must review the following forms for accuracy and place the clinic's vaccine ordering in VAOS:

- Equivalent to Physical Inventory in VAOS,
- Equivalent to Open Ordering in VAOS, and
- Temperature Recording Form(s), stock no. EC-105.

It is imperative to review the Monthly Biological Report, stock no. C-33, in VAOS to ensure that the beginning inventory matches the last month's ending inventory. Any corrections needed are reported to the clinic site, so the records can be corrected prior to ordering.

## E. Patient Profile Estimates and Vaccine Ordering for Providers

The patient profile captures the number of Federal VFC- and Texas VFC-eligible children served in each facility. Information reported on the patient profile represents the populations served during the most recent 12-months.

During initial enrollment and annual re-enrollment in the TVFC/ASN Programs, DSHS requires that all enrolled sites complete their patient profile.

The population estimates are used to justify the site's need for the doses ordered and administered. This also ensures that vaccine orders are in the appropriate amounts and vaccine inventories are properly maintained.

Staff at enrolled sites may use any of the following sources to determine the patient population estimates:

- Benchmarking – A process whereby providers maintain logs in which they record all vaccines administered by type and number of doses, and by patient VFC program eligibility category over a predetermined period, e.g., one to three (1-3) months. This data is used to establish projections of vaccine needs over a 12-month period and assess the appropriateness of vaccine orders placed.
- Medicaid Claims – Medicaid billing data reflecting the services provided to Medicaid-enrolled patients. Data collected using this method should be deduplicated.
- Immunization Information System Data (ImmTrac2) – Data submitted to ImmTrac2, a secure and confidential database that safely consolidates and stores immunization records from multiple sources in one centralized system.
- Doses Administered – Data collected each time vaccine doses are administered for patients. Data collected using this method should be deduplicated.
- Encounter Data – Data that counts each individual patient encounter once. This data is deduplicated from the total number of patient visits for each individual patient.
- Billing System – The site's method of billing patients for services. Data collected using this method should be deduplicated.
- Other Methods including forecasting) – Any method not listed above, including future predictions based on current patient populations.

To ensure the quality and integrity of the TVFC/ASN Program, REs must validate the provider populations served to ensure that vaccines orders are representative of the patients served. To accomplish this, REs can compare:

- Patient population estimate with the birth cohort for the state.
- Vaccine ordering habits of the enrolled facility with the provider profile estimate. For example, if the provider profile estimates serving 100 patients younger than one (1) year of age during a 12-month period, compare the amount of DTaP doses ordered against this 100-patient estimate (three (3) doses per eligible child, 300 doses during the year, or 75 doses quarterly).
- Doses administered as reported with ImmTrac2 with the amount of vaccines ordered.

In instances where comparisons show significant discrepancies from patient-profile estimates, REs should discuss with the staff at the facility to determine the reasons for the differences. It may be discovered that the provider profile may need to be updated using the "Changes to Enrollment Form", stock no. 11-15224.

## F. Vaccine Inventory Plan and Maximum Stock Level (MSL)

The vaccine inventory plan allows all enrolled clinic sites to maintain a 75-day supply of vaccine inventory. The 75-day supply of vaccine allows for 2.5 times the monthly vaccine inventory while waiting for the arrival of the next vaccine order. Clinic staff are required to conduct monthly reporting of vaccine usage, regardless of whether vaccine is ordered. Although staff are not required to order vaccine every month, it is best practice for providers to place an order as needed to maintain a 75-day supply of vaccine. REs should establish contact with providers that have not placed a vaccine order within a six (6) month time frame. Providers who have not ordered within the past 12 months, may need to be terminated from the TVFC/ASN Programs.

MSL is a calculated peak dose inventory per vaccine type based on doses administered. When clinic staff conduct monthly reporting activities, VAOS generates a suggested amount of vaccine to order. This is the number of

doses needed to maintain a 75-day inventory. The suggested quantity is impacted by the number of vaccine doses currently on-hand at the site and all outstanding vaccine orders that are in packed or shipped status. Enrolled sites may override the suggested quantity but must provide a reason for deviation. REs must review all monthly reporting activities for facilities in their jurisdictions. When it is noted that staff have requested additional vaccine over the suggested quantity, the RE must review and approve or disapprove the order. When it is noted that staff have decreased the amount of vaccine suggested, REs must ensure the clinic has conducted monthly reporting correctly and that the doses on hand equal the number of doses documented in VAOS. If the staff at the site do not accept the suggested quantity in VAOS, this may indicate a need to reduce MSLs.

At initial enrollment, VAOS will calculate MSLs automatically based on the patient population. These MSLs are used to establish provider vaccine ordering, and after 12 months of enrollment, MSLs are recalculated automatically monthly at the DSHS Immunization Section level using doses administered data that is recorded in VAOS. Newly enrolled providers may have their MSLs manually reassessed by their RE after six (6) months with the TVFC/ASN Program, or sooner, if necessary.

Special circumstances (e.g., increase in patient population, merging clinic locations, community event, back-to-school, added vaccinators, etc.) are reasons to request MSL adjustments.

Automated MSL calculations are determined with the following:

- Six (6) months of doses administered data from the previous year,
- Divided by ~~12~~, and
- Multiplied by 2.5.

Automated MSLs are then rounded up to appropriate pack size.

***NOTE:***

*Maximum Stock Levels are calculated using the previous six (6) months of doses administered data from VAOS, divided by six (6), multiplied by 2.5.*

During back-to-school, MSLs are calculated with the following:

- 4 months of doses administered data from the previous June, July, August, and September,
- Divided by 4, and
- Multiplied by 2.5.

Back-to-school MSLs are then rounded up to the appropriate pack size. Vaccines that are included in the back-to-school MSL calculation are:

- IPV
- DTAP
- MCV4
- DTAPHBIP
- MENB
- DTAPHIPI
- MMR
- DTAPIPV
- MMRV
- HEPAB
- TDAP
- HEPA
- TD
- HEPB
- VARICELLA
- HPV

**Influenza, Hib, PCV13, PPSV23, and Rotavirus vaccines are NOT included in the back-to-school MSL calculation.**

***NOTE:***

*Back-to-School MSLs are calculated using doses administered from the previous June, July, August, and September, divided by 4 and multiplied by 2.5.*

Additional vaccine orders may be placed during the month, if needed, if all required reporting has been completed. This includes submission of temperature recording forms. If a clinic submits additional orders for several consecutive months, REs should conduct a reassessment of the site's MSLs.

The TVFC/ASN Program strives to ensure clinics have enough vaccine on hand to vaccinate their patients. If sites are running out of vaccine, a review of the patient population estimates provided on the patient-profile can be reviewed to determine if the amounts of vaccine ordered is representative of populations served. A review of this information could determine that a reassessment of the MSLs is necessary. For more information on how to assess the patient population estimates refer to Section Three: Vaccine Management, II. Vaccine Ordering, subsection E. Patient Profile Estimates and Provider Ordering.

**Initial MSL**

At initial enrollment, VAOS will calculate MSLs automatically based on the patient population. These MSLs are used to establish provider vaccine ordering. Initial MSLs at new clinic sites should be set at a minimal level to prevent overstocking while patient populations are being established.

Ensure the total amount ordered for each vaccine family equals the MSL.

In the event products or presentations are not available from the manufacturer, it may be necessary for DSHS to substitute products or presentations without notice.

### G. Vaccine Choice

DSHS allows TVFC/ASN-enrolled sites to make changes to the vaccine brands and presentations they receive as needed. It is important for staff at enrolled sites to understand when changes are made to the vaccines/brands they choose. See the example paragraph under Section Three: II. Vaccine Ordering, D. MSLs, Initial MSL. It also applies to vaccine choice.

## III. Vaccine Distribution

### A. Vaccine Order Approval

REs are responsible for reviewing/approving vaccine orders to ensure all outstanding issues are resolved. All TVFC/ASN enrolled sites must report monthly prior to vaccine orders being approved by the RE. This applies even

if no vaccines were ordered or administered. (See Section Four: Data Reporting for instructions on reviewing documentation for vaccine order approval.)

## B. Receiving Vaccine

Enrolled sites must receive vaccine in VAOS before doses are administered. To receive vaccine in VAOS, perform the following steps:

- Upon receipt, the enrolled site must compare the vaccine in the cooler(s) to information on the packing slip. This includes vaccine type, lot number, expiration date, National Drug Code (NDC), and amount received,
- Clinic staff must then accept the vaccine order in VAOS, comparing the packing slip with the information contained in VAOS,
- When the shipment is accepted in VAOS, the vaccines are added to the inventory, and
- If the information on the packing slip does not match the products received or the information in VAOS (i.e., missing vaccine or missing diluent) staff are to contact the RE immediately.

***Purpose:***

*DSHS allows TVFC/ ASN-enrolled sites to make changes to the vaccine brands and presentations they receive as needed. It is important for staff at enrolled sites to understand when changes are made to the vaccines/brands they choose.*

**NOTE:** Vaccine that is not received in VAOS will impact suggested quantities that are available to the site.

## C. Vaccine Received Warm or Questionable

Staff at enrolled clinic sites must be educated to always accept vaccine shipments. Shipments must not be refused or returned without instructions from the DSHS Immunization Section.

If there are suspicions that vaccine packages were improperly handled during transit, the vaccine still must be accepted from the carrier.

The following are examples of when shipments of vaccines must be investigated.

- Vaccine shipment with the temperature indicator strip showing that an out-of-range temperature occurred.
- A cooler that does not contain ice packs.
- A cooler that contains ice packs that are warm.
- Vaccine that is warm to the touch.
- Vaccine that is received damaged.

> ***Receipt of Vaccines:***
>
> *Vaccine shipments must not be refused or returned even if there are suspicions that the package was handled improperly.*

REs must be notified on the same day the vaccine arrived if the clinic staff are concerned about vaccine viability in a vaccine shipment. Clinic staff must be instructed to place the backup data logger probe in the shipment to obtain the current temperature. The probe should be placed near the vaccine with the lid of the shipping container closed until the temperature stabilizes. Inform staff that vaccine temperatures may be requested when contacting the distributor.

The RE must collect details of the occurrence and determine if a shipping issue has occurred. If the RE determines that a shipping issue is the cause, the RE must direct clinic staff to contact McKesson or Merck on the **day of delivery** for further instructions.

### When Clinic Staff are to Contact McKesson and/or Merck Directly

Clinic staff may only contact the distributor(s) (McKesson/Merck) when there is a questionable temperature in a shipment. Clinic staff must contact the distributor **on the same day** that the shipment arrives. If the vaccine is non-viable or questionable (e.g., spoiled in transit) and the clinic staff

contacts the distributor on the same day as the shipment's arrival, there will not be an issue with replacement. Direct contact with the distributor prevents delays and allows for replacement orders. McKesson will notify DSHS as a courtesy and will contact CDC to request a replacement.

**When Clinic Staff are to Contact the RE**

For all other issues (besides temperature problems in a received shipment), clinic staff should contact the RE. Clinic staff must be educated not to write "DO NOT USE" on the individual vaccine boxes. A box or quarantine bag(s), supplied by the TVFC/ASN Programs, should be used to keep the vaccines together in the appropriate vaccine storage unit. Document "DO NOT USE" on the outside of the box or quarantine bag. If the vaccine is deemed viable, the clinic site must accept the vaccine shipment in VAOS and remove them from quarantine.

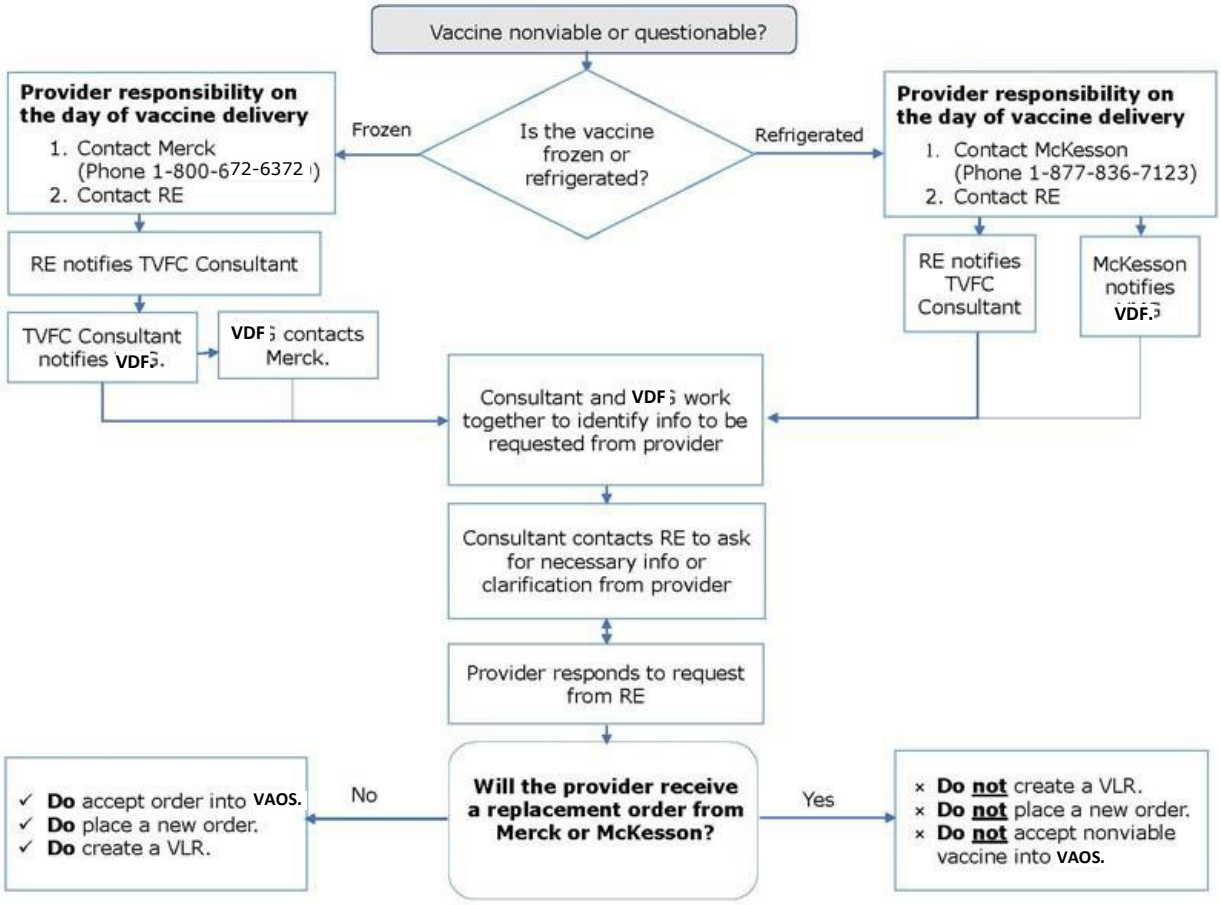
If the vaccine is deemed ruined because it was mishandled during shipment, the clinic staff must not receive the vaccine shipment in VAOS until a replacement shipment is received.

If the vaccine was received in VAOS, the clinic staff must correct this in their "Monthly Biological Report", stock no. C-33. The staff need to update their "Monthly Biological Report", stock no. C-33 while zeroing out only the ruined vaccine on their "Monthly Biological Report", stock no. C-33, which will remove it from their inventory. Once a replacement order is received, the clinic staff will need to update the lot number and other information related to the new shipment in VAOS, or they may have to add-line the replacement vaccine in VAOS.

Clinic staff must contact their RE when vaccine is received damaged (e.g., broken vials, leaking syringes, missing protective caps, etc.). The RE must contact the DSHS Immunization Section for information on how to proceed with damaged vaccines. Refer to Figure 1, to identify steps to handle calls regarding vaccine shipments received warm or questionable.

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

**Figure 1.** Flowchart to calls regarding vaccines received questionable.




## D. Vaccine Received in Error

If vaccine is received that was not ordered, the staff at the enrolled clinic must contact their RE immediately. The RE is to contact the DSHS Immunization Section who will research the issue and provide the required next steps. It may be necessary for the RE to pick up and redistribute vaccine that was sent in error to a clinic site.

If the clinic staff ordered vaccine in error, the site may keep the vaccine and use it. The reasons for the redistribution of vaccine are limited and do not include unintended orders. However, if the clinic is unable to store the vaccine due to restricted refrigerator/freezer capacity, the RE must pick up the vaccine and store it or redistribute it.

# IV. Vaccine Loss

## A. End-of-Month Inventory

In accordance with TVFC/ASN requirements, staff at enrolled sites must notify their RE 60 to 90 days prior to the expiration date of the vaccine. If the vaccine will not be used before the expiration date, the RE is responsible for assisting with redistribution of the soon-to-expire vaccine if another enrolled clinic is able to take possession of the vaccine and is able to use it before the expiration date.

**Negligent Vaccine Loss**

Staff at enrolled TVFC/ASN sites are responsible for vaccine losses due to negligence. Negligence includes the following:

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

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

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

**Non-Negligent Vaccine Loss**

Non-negligent vaccine losses include the following:

- Damaged needle or seal, particulate in the vial, discolored liquid, etc.,
- Expired flu, pedi PPSV,
- Expired – notified RE 60-90 days before expiration,
  - RE was unable to transfer.
- Mechanical failure of refrigerator or freezer,
- Natural disaster or power outage,

- Unable to transfer open multi-dose vial, and
- Vaccine spoiled in shipment due to shipper error.

## B. Expired/Ruined/Wasted Vaccine

The TVFC/ASN Program requires that all unopened vials or syringes of expired/ruined/wasted vaccines be returned to the third-party distributor within six (6) months of expiration or the date the vaccine was ruined/wasted.

Discard in a sharps container (do not return) all expired/ruined/wasted vaccine when any of the following apply:

- The cap has been removed from a vial,
- A multi-dose vial has been opened but not all doses have been used after 28 days,
- A needle has been attached to a pre-filled syringe,
- Vaccine has been drawn into the syringe but was not administered, or
- Vaccine was reconstituted with incorrect diluent.

Expired/ruined/wasted vaccines must be removed from the unit(s) and stored until a label for return to the distributor is received. For guidance on returning vaccines, see Section Four: Data Reporting.

Expired/ruined/wasted vaccine to be returned to the distributor includes the following:

- A vial that was dropped and was determined to be ruined (if the vial is unbroken),
- Vaccine that has been left out of an appropriate refrigerator/freezer and was determined to be ruined by the vaccine manufacturer,
- Vaccines that were transported inappropriately and were determined to be ruined by the vaccine manufacturer,

- Vaccines that were in a refrigerator/freezer that failed to maintain appropriate temperature ranges and were determined to be ruined by the vaccine manufacturer,
- Refrigerated vaccine doses that were stored under freezer conditions and were determined to be ruined by the vaccine manufacturer, and
- Frozen vaccine doses that were stored under refrigerator conditions and determined to be ruined by the vaccine manufacturer.

## C. Vaccine Disposal

The Centers for Disease Control and Prevention (CDC) advises providers to dispose of wasted vaccines in accordance with local regulations. The Texas Department of State Health Services (DSHS) follows the Texas Commission on Environmental Quality's (TCEQ) guidance on proper medical waste disposal of wasted vaccine. The TCEQ and DSHS define medical waste as special waste from health care-related facilities (25 TAC 1.132(46) and 30 TAC 326.3(23)), which includes: treated and untreated animal waste, bulk human blood and body fluids, microbiological waste, pathological waste, and sharps.

Following TCEQ's guidance on the disposal of medical waste, dispose of needles and associated vials in a clearly labeled sharps container, treating it as a contaminated biohazard container. Wipe down and sanitize work areas. After disposing of vaccine, take off and dispose gloves, and thoroughly wash hands with soap and water for at least 20 seconds or use an alcohol-based hand sanitizer that contains at least 60% alcohol.

Additional information on local regulations for how to treat and dispose of medical waste in Texas, can be found on TCEQ's website or by emailing info@tceq.texas.gov.

## D. Vaccine Transfer

The routine re-distribution of TVFC/ASN vaccine, flu vaccine as well as short-dated flu vaccine is not allowed. However, vaccine transfers can be allowed between TVFC/ASN sites when necessary to avoid vaccine loss if the expiration date is within 60 to 90 days, if the provider's storage unit is

overstocked, and if the provider withdraws, is suspended, or is terminated from the TVFC/ASN Programs. If a transfer must occur, TVFC/ASN staff at enrolled sites are required to submit a "Vaccine Transfer Authorization Request Form", stock no. EC-67, to their RE. Only PHR staff can authorize a vaccine transfer.

**NOTE:** Vaccine must never be transferred between the programs (from TVFC to ASN or ASN to TVFC).

**Staff at Enrolled Sites**

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

- Ensure that the vaccine transfer is occurring for one of the following reasons:
  - Short-dated vaccine (within 60 to 90 days of expiration),
  - Provider's storage unit is overstocked,
  - Withdrawal, suspension, or termination of a clinic from the TVFC/ASN Program, or
  - Other (emergency situations).
- The primary coordinator, backup coordinator, or signing clinician must complete and sign the "Vaccine Transfer Authorization Request Form", stock no. EC-67, agreeing that the vaccine will be transferred in accordance with "TVFC/ASN Vaccine Storage and Handling Guidelines" to ensure the proper cold chain will be maintained throughout the transfer process.

  Each vaccine transferred must be listed on a separate row on the "Vaccine Transfer Authorization Request Form", stock no. EC-67, and include the following details:
  - vaccine type,
  - NDC,

  - lot number,
  - expiration date, and
  - number of doses that are being transferred; and
- The completed form must be forwarded to the RE via fax or email, or it may be uploaded to VAOS. The RE must ensure the transfer is approved by the PHR, which must be done prior to the transfer of the vaccine. For emergency situations, clinic staff must call the RE prior to faxing the form or the next business day, if the emergency occurred on a weekend or holiday.

**Responsible Entity (PHR and LHD)**

When a "Vaccine Transfer Authorization Request Form", stock no. EC-67, is submitted, the PHR staff must approve or deny the transfer within two business days. The PHR must follow these steps:

- Review the transfer request in VAOS and approve or deny within 14 days.
- If the transfer is approved, fax or email the clinic staff and LHD, if applicable, a signed copy of the transfer form.
- Maintain a copy of the "Vaccine Transfer Authorization Request Form", stock no. EC-67, for five (5) years, in accordance with TVFC/ASN Programs requirements.

***Vaccine Transfers:***

*Transfers are only allowed for vaccine that is going to expire within 60 to 90 days, when a facility is withdrawing from the TVFC/ASN Program or due to emergency situations such as a flood or loss of electrical power.*

The RE must do the following:

- Educate clinic staff on the importance of cold-chain management as detailed in the TVFC/ASN Provider Manual, and
- Review VAOS to ensure clinic staff properly documented the vaccine transfer.

## End of School Year Transfers

At the end of a school year, it is necessary for vaccines to be transferred to the RE or another facility as the unit temperatures will not be monitored during the summer. The following procedures must be followed when school clinics close for the summer.

- Notify DSHS Immunization Section to suspend the PIN. Suspension must not exceed 90 days.
- Facilities that are out of the TVFC/ASN Programs for more than 90 days must be withdrawn. Withdrawing will require the facility to fill out a new agreement form to return to the TVFC/ASN Programs at the beginning of the next school year. For withdrawal procedures, see Section Two: I. Facility Eligibility, F. Withdrawal.
- Arrange to pick up all vaccines – viable and non-viable (expired/ruined).
- If necessary, complete VAOS to include doses administered and vaccine losses.
- If staff at the site have not previously documented a vaccine loss for ruined/expired/wasted vaccine currently on hand, the RE must report it in VAOS.
- The RE must request a shipping label to return non-viable vaccines that are picked up from a school that is closing for the summer. It is important to do the following:
    - In VAOS, document the RE's email address in place of the primary vaccine coordinator. The shipping label will be emailed to the RE. This is the preferred method.
    - However, in the event non-viable doses have already been transferred, a vaccine loss report form must be completed by the RE. The shipping label will be emailed to the RE.
    - In the event the RE failed to change the email address in Syntropi, notify the DSHS Immunization Section to request that the label be

sent to the RE and not to the email address of the primary vaccine coordinator at the school. This is the least preferred method.

- Complete in VAOS to transfer doses to the RE PIN or another PIN that has agreed to accept the doses.
- Enter vaccine inventory into VAOS to reconcile the school's on-hand inventory to zero.
- Complete a "Vaccine Transfer Authorization Request Form", stock no. EC-67.
- Appropriately pack viable vaccine and transfer it to another site that has agreed to accept it or return it to the RE site for redistribution.
- If unable to transfer the doses to another PIN, the RE may store the vaccine under appropriate conditions until the school staff returns for the next school year.
- Finalize all follow-up activities in PEAR and IQIP.

When the school staff returns for the next school year, the following procedures must be followed.

- Notify the DSHS Immunization Section Consultant to unsuspend the PIN.
- Request temperature logs documenting seven (7) operational days of within-range temperatures.
- Instruct the primary and backup coordinator to conduct vaccine reporting information in VAOS for the months of the summer when reporting was not completed.
- Instruct staff to submit a vaccine order.

### Vaccine Use after an Emergency

DSHS will occasionally provide vaccine in response to a declared emergency such as a natural disaster or an outbreak of vaccine-preventable disease (VPD). The vaccine is purchased with state funds and can be administered to

adults who are affected by the emergency, adults who are responding to the emergency or adults who could be affected by the VPD outbreak. Every emergency vaccine administered requires an "ASN Patient Eligibility Screening Form", stock no. E11-12842, to be filled out in accordance with ASN Program requirements.

When response to the outbreak is over (as declared by DSHS staff or when no other patients are seeking the vaccine), the vaccine must be transferred and accepted into the PHR's adult vaccine inventory. To accept the vaccine from the emergency response to your inventory, you must "Add Line" it in VAOS.

When a site that participates in the ASN Program requests this vaccine via an order in VAOS, you can transfer the vaccine to that clinic using "other" choice on the "Vaccine Transfer Authorization Request Form", stock no. EC-67, and follow other required procedures for moving/transporting vaccine. All transfers must be documented in VAOS.

# V. Storage and Handling

Vaccine viability depends heavily on the knowledge and habits of the clinic staff. All staff who handles TVFC/ASN vaccine must be very familiar with the proper storage and handling of vaccine.

The TVFC/ASN Programs require immediate notification to the RE if a new staff member is named as a primary or backup vaccine coordinator at an enrolled site. The RE must ensure new staff are trained on proper storage and handling of vaccines and all other elements of the TVFC/ASN Programs.

## A. Proper Equipment for Vaccine Storage

### Vaccine Storage Units

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

- Pharmaceutical/purpose-built units,

- Stand-alone, single-purpose refrigerator and stand-alone single-purpose freezer, and
- Combination household unit.

If a site must use a combination household unit, the staff must be strongly encouraged to obtain a stand-alone freezer. The household unit will contain the refrigerated vaccine and the stand-alone freezer should contain the frozen vaccine. The amount of frozen vaccine is small compared to the refrigerated stock, so the freezer may be an on-the-counter or an under-the-counter type, if appropriate temperatures are maintained. A frost-free unit with an automatic defrost cycle is preferred.

> ***NOTE:***
>
> *If a facility uses a household combination unit to store TVFC/ASN vaccine, a strong recommendation should be made to use the refrigerator section only and to obtain a stand-alone freezer for frozen vaccine.*

It is difficult to maintain appropriate temperatures in a combination household unit when both the refrigerator and freezer are used to store vaccine. Use of the freezer compartment of a household combination unit is discouraged. Most vaccine losses occur in household combination units when both sections are used. If a site must use a combination household unit to store both refrigerated and frozen vaccine, the units must have separate thermostats for each compartment.

**Auto-Dispensing Units**

DSHS has recently approved the use of auto-dispensing or door-less units to store TVFC/ASN vaccines. This type of unit is purposely built to store vaccines. Loading vaccines in this type of unit is the only time vaccines should be kept outside of their original packaging however, providers must keep all the original vaccine packaging in the event the vaccine has to be transported outside of the unit. Monthly temperature logs must be recorded and submitted each month on the 5th. Ensure that temperature logs are posted on the unit, as with other cold storage units.

**Dorm-style units (those with a freezer behind a refrigerator door) are never allowed to store TVFC/ASN vaccine.**

Refrigerator/freezer units must be large enough to hold the year's largest inventory (i.e., back-to-school or during flu season). The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C). The recommended temperature in a refrigerator is 40°F (4°C). The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C). For additional vaccine storage and handling requirements, view CDC's "You Call the Shots" module 10, the current CDC Vaccine Storage and Handling Toolkit, the TVFC Provider Policy Training, or DSHS material (such as the storage and handling poster) available at www.immunizetexas.com.

### Data Loggers

Clinics enrolled in the TVFC/ASN Programs are required to have certified, calibrated data loggers in all refrigerators and freezers that store TVFC/ASN vaccine.

In addition, clinic sites are also required to have a certified, calibrated backup data logger. It is recommended that the backup data logger have a different calibration retesting date than the primary data logger. Data loggers must be able to be reset on site by the provider. The backup data logger will be used in the following situations:

- In the event the operation of the primary data logger fails,
- To monitor the temperature of vaccine that is moved during an emergency, and
- When the primary data logger is sent for recalibration.

The certificates of calibration for all data loggers must be maintained at the site and be made readily accessible to staff at the enrolled site, RE staff, or the DSHS QA contractor during site reviews. Certificates of calibration matching the serial numbers on the data loggers will be reviewed during site visits. Photos of the data loggers do not meet certificate of calibration requirements.

Calibration testing must be completed every two to three (2-3) years or according to the manufacturer's suggested timeline. REs must also review data logger expiration dates. The RE should have in place a QA process for reviewing data logger and backup data logger expiration dates on a regular basis. If the certificate of calibration does not list an expiration date, it can be calculated by adding two (2) years to the date of calibration. All certificates of calibration must be sent to your RE who will submit them to DSHS Immunization Section for processing. Enrolled clinic sites with expired data logger certificates of calibration will be suspended until current certificates are received.

***NOTE:***

*Providers are responsible for purchasing or re-calibrating one data logger for each of their vaccine storage units. They must also maintain a backup data logger with a valid calibration date.*

It is recommended that enrolled clinic sites download data from their data loggers at least once per week, preferably on Mondays, to ensure excursions are identified and addressed in a timely manner.

When reading temperatures from 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.

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

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

- Temperature monitoring devices that are not calibrated, and
- Thermometers.

**Expired data loggers must be replaced with new certified data loggers or recalibrated at the clinic's expense.**

## B. Vaccine Storage and Handling

The RE must ensure all clinic staff are familiar with appropriate storage and handling processes.

A new or newly repaired unit that will store TVFC/ASN vaccine must have temperatures recorded for seven (7) operational days (or at the discretion of the RE) with the min/max (twice daily) before a vaccine order is approved.

Refrigerators and freezers storing TVFC/ASN vaccines must be directly wired or plugged directly into a wall outlet using a plug guard (provided by DSHS, if needed).

> ***NOTE:***
>
> *A new or newly repaired unit that will store TVFC/ASN vaccine must have temperatures recorded for seven (7) operational days (or at the discretion of the RE) with the min/max (twice daily) before a vaccine order is approved.*

Plug guards are effective tools to prevent the intentional or accidental unplugging of the unit. Do not use any of the following for refrigerators or freezers:

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

"Do Not Unplug" signs must be posted at the electrical outlets where refrigerators and freezers are plugged in and "Do Not Disconnect" signs must be posted at the circuit breakers.

Food and drinks are not to be stored in the same refrigerator or freezer as TVFC/ASN vaccines. If other biologics must be stored in the same unit as TVFC/ASN vaccines, store the biologics below the vaccines to avoid contamination.

It is recommended that crisper bins be removed from refrigerators to prevent the storage of vaccines in inappropriate areas. In place of the crisper bins, the area is recommended to be filled with water bottles.

Water bottles are required in units that contain TVFC/ASN vaccine.

The use of water bottles in refrigerators and freezers helps to maintain appropriate temperatures for longer periods of time in the event of a power failure.

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, or
- Any other coolant material that is not allowed by the CDC or TVFC/ASN Programs.

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

Review the "New Enrollment Checklist", stock no. 11-15061, and the TVFC/ASN Provider Manual for more vaccine storage recommendations and requirements.

## C. Off-site and Mass Vaccination Clinic Storage and Handling Requirements

To ensure vaccine storage and handling for 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 site'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.
- 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 includes a digital display viewed outside of the storage unit and a probe in buffered material that closely resembles vaccines.
- 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 [1] hour each way, the clinic may run for up to six [6] hours).
- The vaccine being transported must be tracked to maintain accountability for monthly reporting in VAOS. This includes:
  - Vaccine type(s) and brand names,
  - Quantity of each type,
  - NDC numbers,
  - Lot numbers, and
  - Expiration dates.

> ***NOTE:***
>
> *Clinic staff are required to verify their vaccine management plans annually and confirm that their identified backup site is still able and willing to function as their emergency site.*

- Upon arrival at the clinic site, the staff must 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. The "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.
- An assessment of the temperatures must be conducted prior to placing vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised.
- Vaccines exposed to temperature excursions (above or below the required temperature range) 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.

## VI. Routine and Emergency Storage and Handling Plan

The DSHS Immunization Section has developed "Vaccine Management Plan Templates", stock no. E11-14498, for vaccine management, including routine vaccine storage and handling and what to do with TVFC/ASN vaccine in the event of an emergency (such as loss of power, unit failure, or a natural disaster).

This document, or a similar one developed by the site (containing all the same elements), is required at all TVFC/ASN-enrolled sites and must be reviewed and signed at least annually or more frequently if staff changes occur or other changes are necessary. Clinic staff are required to annually verify their vaccine management plans and confirm their identified backup site is still able and willing to function as their emergency site.

During compliance site visits and unannounced storage and handling visits, this document will be reviewed for completeness. Materials for emergency

vaccine transport will also be checked during a compliance site visit. For more information on common site visit structures, refer to Section Five: Program Evaluation.

The completed document must be posted on or near the refrigerator/freezer units that contain TVFC/ASN vaccine, so it is easily accessible for staff, especially in the event of an emergency.

The vaccine management plan must include the following:

- The names and phone numbers of emergency contacts,
- A plan for how to move vaccines to ensure proper cold chain is monitored and maintained, and
- The address of an alternate location where vaccines will be temporarily stored.

Due to strict temperature, storage and monitoring requirements of vaccines, the Texas DSHS does not permit TVFC/ASN vaccines to be stored at a private residence.

Private residences include, but are not limited to, the part of a structure used as a dwelling, including, without limitation: a private home, townhouse, condominium, apartment, mobile home, vacation home, cabin, or cottage.

DSHS reserves the right to decline to send vaccine to providers as it deems appropriate.

# Section Four: Data Reporting

## Policy

Enrolled clinic sites are required to submit monthly reports.

## Purpose

To account for vaccine receipt, transfer, usage, wastage, and on-hand inventory.

## I. Monthly Reports

Monthly reporting is required between the 1st and 5th of each month, whether an order is placed or not. Reporting is also required each time an additional order is placed. The documents listed below must be completed and submitted in VAOS (if internet access is available) by all enrolled sites. Vaccine orders must not be approved until the following required documents are submitted.

- Temperature Logs
- Doses Administered
- Physical Inventory
- Receipt of Vaccine Shipments (if applicable)
- Vaccine Transfers (if applicable)
- Vaccine Loss (if applicable)

If clinic staff are not completing or submitting the forms correctly or on time, the RE must re-educate staff on the proper procedures and

***NOTE:***

*Vaccine orders will not be processed until the following are submitted:*

- *Temperature Logs*
- *Doses Administered*
- *Physical Inventory*
- *Receipt of Vaccine Shipments (if applicable)*
- *Vaccine Transfers (if applicable)*
- *Vaccine Loss (if applicable)*

request corrections. Documentation of the contact/education must be documented in PEAR.

**NOTE:** The DSHS Immunization Section is required to monitor those who have been granted access to PEAR and RedCap (IQIP Database), available at CDC's Secure Access Management Services (SAMS). Staff who no longer need access to PEAR/IQIP are required to notify the DSHS RE. On a quarterly basis, staff at the DSHS Immunization Section review the list of employees conducting site reviews or conduct PEAR/IQIP follow-up to ensure the list is up to date. The RE must inform the DSHS Immunization Section of employees that no longer need access to PEAR/IQIP.

It is highly recommended REs maintain a list of all enrolled facilities in their jurisdictions and monitor the submission of required monthly documents.

As enrolled sites submit reports, REs should document on a list that site reports were reviewed each month. This should prompt an immediate review of VAOS for vaccine orders. See Figure 2 for an example of a simple tracking spreadsheet to monitor report submission.

**Figure 2.** Example of Tracking Spreadsheet

| PIN TRACKING SPREADSHEET FOR MONTHLY REPORTING | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PIN | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC |
| 000001 | X | X | X | X | | | | | | | | |
| 000002 | X | X | | | | | | | | | | |
| 000003 | X | X | | | | | | | | | | |
| 000004 | X | X | X | X | | | | | | | | |

## PHR and LHD RE

Review the clinic's vaccine order in VAOS.

- Review "Out of Office Dates" submitted by the provider for possible clinic closures. These are dates and times when the facility will not be operational. Do this before approving a vaccine order to ensure the clinic will be available to receive vaccine.
- The DSHS Immunization Section, the CDC, and the distributor are unable to see individual comments about facility closures.
- REs must refer to the shipping timeframes in Figures 3, 4, and 5 to determine if orders should be placed on hold or approved for processing using the clinic's closures as a guide.
- When the RE places an order in APPROVED status, the clinic can expect to receive vaccine up to 15 business days later.
- Vaccine orders should not be PENDING by the RE for more than three (3) days as this will result in a delay of vaccine delivery.
- Figure 4 shows that the clinic may receive an order of pre-booked flu vaccine as early as three (3) or four (4) days after the RE changes the status to APPROVED.
- The shipping schedule for frozen vaccine shipped from Merck can be determined using Figure 5. Merck is allowed 15 business days to ship vaccine from when the vaccine order is uploaded although vaccine from Merck usually arrives sooner.
- The schedules in Figures 3, 4, and 5 apply when orders are dropped by 12 noon by Immunization Section staff.

**Figure 3.** Vaccine shipping schedule (not including flu) from McKesson.

| McKesson Shipping Schedule (non-flu) | | | | |
|---|---|---|---|---|
| **Monday** | **Tuesday** | **Wednesday** | **Thursday** | **Friday** |
| 1. Order placed by clinic staff or opened by RE | 2. Order dropped by Immunization Section Staff | | | |
| | | 3. Order shipped | 4. Order received | |
| | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | | |
| | | | 3. Order shipped | 4. Order received |
| | | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | |
| 3. Order shipped | 4. Order received | | | |
| | | | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff |
| 3. Order shipped | 4. Order received | | | |

**Figure 4.** Pre-booked influenza vaccine shipping schedule from McKesson

| McKesson Shipping Schedule (pre-booked flu) | | | | |
|---|---|---|---|---|
| **Monday** | **Tuesday** | **Wednesday** | **Thursday** | **Friday** |
| 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | | | |
| 3. Order shipped | 4. Order received | | | |
| | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | | |
| | 3. Order shipped | 4. Order received | | |
| | | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | |
| | | 3. Order shipped | 4. Order received | |
| | | | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff |
| | | | 3. Order shipped | 4. Order received |

**Figure 5**. Vaccine shipping schedule from Merck.

| Merck Shipping Schedule | | | | |
|---|---|---|---|---|
| **Monday** | **Tuesday** | **Wednesday** | **Thursday** | **Friday** |
| 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | | | |
| | | | | |
| | | | | |
| | 3. Order shipped | | | |
| 4. Order received | | | | |
| | 1. Order placed by clinic staff OR opened by RE | 2. Order dropped by Immunization Section staff | | |
| | | | | |
| | | | | |
| 3. Order shipped | 4. Order received | | | |

If the site requests more vaccine than the suggested quantity, ensure a statement is included.

- Review the Vaccine Items page in VAOS for adjustments made to the inventory. If adjustments are made, this may be an indication that vaccine is unaccounted for and should trigger additional assistance to the site.

- If the order is approved, the vaccine request in VAOS will document the staff approval.

**NOTE:** If the provider's most recent VAOS update did not include all days of the previous month, the clinic staff will need to submit two doses administered reports. One is for the unreported days from the previous month, and one is for the current month.

As an example, if VAOS was last updated on March 29, the next time staff log into VAOS, doses administered for March 30 and 31 must be completed before April activities can be documented. It is imperative that clinic staff carefully watch the dates for which they report vaccine usage.

Ensure TVFC vaccine is documented in the 0 - 18 column only, and that ASN vaccine is documented in the >19 column only unless vaccine was administered incorrectly. If vaccine is documented as administered incorrectly, the RE must contact staff at the site and provide additional training/education to ensure the practice does not continue. This practice requires the site to "pay back" the TVFC/ASN Programs by adding private vaccine to the inventory.

## A. Temperature Recording Form

Enrolled sites must submit temperature recording forms for all units that contain TVFC/ASN vaccine. These forms must be reviewed by RE staff to ensure all temperatures are always within acceptable ranges and that all information is completed as required. The following steps must be taken when reviewing temperature recording forms for accuracy:

- Verify all recorded temperatures are within the required ranges,
- Verify temperatures were documented twice daily, every day the site was open,
- Review to ensure minimum/maximum temperatures were recorded every day the site was open,
- Ensure staffs' initials are documented every day the site was open,

- Ensure staff have documented the time, including hour and minutes the temperature was taken twice daily, every day the site was open, and
- In the event a temperature excursion occurred during the month, ensure page three (3) of the temperature recording form was submitted. It contains information about the excursion. If page three (3) was not submitted, the RE must contact the site to request the documentation be submitted for the excursion.

## B. Temperature Excursion, Vaccine Loss Report, and Returning Vaccine

### Staff at Enrolled Sites

If a temperature excursion occurred, the clinic staff must contact the vaccine manufacturers to receive a determination of vaccine viability.

The clinic staff must contact the vaccine manufacturers to determine vaccine viability before a VLR is generated.

Until a determination is received, the current inventory at the site must be isolated and kept under appropriate conditions. Any new vaccine orders must be placed on hold. Vaccine viability must be determined by the vaccine manufacturers only – not by the clinic staff, RE staff, or DSHS Immunization Section staff.

> ***NOTE:***
>
> *If the manufacturer concludes that vaccine viability cannot be determined, a signing clinician with prescribing authority at the clinic site is responsible for making the determination.*

- If the vaccine is deemed ruined, clinic staff must be educated on the completion of a VLR in VAOS.
- If necessary, the signing clinician, with the assistance of the vaccine manufacturers, determines whether children will need to be recalled and revaccinated. The vaccine used to revaccinate these children must be from privately purchased vaccine. TVFC vaccine must not be used to revaccinate children when a vaccine manufacturer deems the vaccine used was non-viable.

**NOTE:** If new units are obtained or existing ones are repaired, the clinic staff are required to submit seven (7) operational days of in-range temperatures before vaccine orders are approved. Additional days of temperature recordings may be required but is at the discretion of the PHR RE.

Clinic staff must provide the vaccine manufacturers with information on the temperature(s) of the unit(s) using information downloaded from the data logger. If children were immunized with vaccine that has been deemed by the manufacturer as non-viable, the signing clinician must determine which children should be revaccinated. If it is determined that revaccination is necessary, the clinic must use privately purchased vaccine not TVFC vaccine. The clinic must assume all financial responsibility for the cost of vaccines for revaccinating children when the clinic staff continued to vaccinate using vaccine that was stored in temperatures outside the required ranges. If the manufacturer concludes that vaccine viability cannot be determined, a signing clinician with prescribing authority at the clinic site is responsible for making the determination.

Enrolled clinic staff are required to adhere to the following procedures when vaccine losses occur:

- Immediately remove expired or ruined vaccine from the vaccine storage unit(s), and
- Complete the Enter Vaccine Loss page in VAOS to generate a VLR. This report must be generated within four (4) business days of the incident's occurrence. The VLR must be printed and signed by a clinician with prescribing authority listed on the agreement form.

**NOTE:** Signature stamps are not allowed on VLRs. It must be an original signature. The report must be faxed or emailed to the RE, and include the following details:

- Clinic demographics,
- Date the loss occurred or was discovered,
- Type of loss,

- Reason for the loss,
- Explanation of the loss,
- Corrective action taken to avoid a recurrence, and a
- List of vaccines by antigen, manufacturer, lot number, expiration date, and the number of doses lost.

**PHR and LHD RE**

REs may be asked to assist clinic staff to contact the vaccine manufacturer and completing the VLR in VAOS.

- When a VLR is submitted with a prescribing clinician's signature, it must be reviewed for completeness and forwarded to the DSHS PHR.

**NOTE:** Submission of VLRs to DSHS Immunization Section from PHR staff is required only when the clinic staff selects the incorrect designation (i.e., clinic staff selected non-negligent loss, but actual loss was due to negligence or vice versa). For VLRs with the incorrect designation, REs must handwrite the correct information on a copy of the VLR and emailed to their PHR REs.

The PHR RE must send the corrected VLR to their DSHS Immunization Section Consultant. The email subject must be listed as the clinic's PIN and "VLR Determination Change".

- Additional vaccine orders should occur only after safe storage for vaccines has been confirmed at the site.
- Clinic staff at the enrolled site must be notified that a shipping label will be emailed to the primary vaccine coordinator. This label will be used to send the vaccine back to the distributor.

***NOTE:***

*Submission of VLRs to Central Office is only required when clinic staff select the incorrect designation. The email subject must be listed as the clinic's PIN and "VLR Determination Change".*

- The RE must notify the clinic staff that more than one shipping label may arrive. The number of labels is based on the number of doses lost. Each box that is used to return vaccine should not weigh more than 70 pounds.

Additional information that must be shared with the clinic staff includes the following:

- Vaccines that are listed on the VLR that are not included in the box must be crossed off the list,
- Return only TVFC/ASN expired/ruined vaccine that is listed on the VLR. Refer to Section Three: IV. Vaccine Loss, B., Expired/Ruined/Wasted Vaccine to determine what vaccines should not be returned,
- If more than one box is used to return vaccine, the boxes should be marked with "box 1 of 2", etc.,
- Include a copy of the VLR in each box. Document only the contents included in that box,
- Attach the return label that the primary vaccine coordinator received via email on the outside of the box, and
- Prepare the box for shipping by securing it with tape.

Clinic staff should wait until they receive another vaccine shipment before they present the container(s) to the courier for return to the distributor. Calls to UPS to schedule a pickup will be subject to a fee set by UPS. If UPS has not picked up package within 30 days, a new shipping label must be requested by clinic staff.

### DSHS Immunization Section

The DSHS Immunization Section will review VLRs for potential vaccine restitution (dose-for-dose replacement of the vaccines). See Section Three: IV. Vaccine Loss, A. End of the Month Inventory for determination of negligence/non- negligence.

## C. Vaccine Borrowing Form

TVFC/ASN-enrolled sites must not borrow TVFC/ASN vaccine to administer to non-TVFC/ASN-eligible patients. Clinics are required to keep enough private stock on hand to cover non-eligible TVFC/ASN clients. If a TVFC/ASN dose(s) is accidently administered to a non-TVFC/ASN-eligible client, or a private dose is administered to a TVFC/ASN-eligible client, the staff must complete the following steps:

- Document the incident on a "Vaccine Borrowing Form", stock no. EF11- 14171. Each vaccine that was administered to a non-TVFC/ASN-eligible client must be listed on a separate row on the form.
- The clinic must replace the vaccine immediately. In VAOS, the vaccine used on a non-eligible patient must still be documented on the doses administered tab; and
- The replacement vaccine must be added into VAOS. Use the "add line"-feature on the Physical Inventory page to account for the replacement.

**NOTE:** If the NDC number of the private stock vaccine dose is not listed in VAOS, the "add line" feature cannot be used. In this case, when the RE is notified, a coordination with staff at DSHS Immunization Section must take place to receive instructions on how to proceed.

- The clinic staff must report the incident by faxing or emailing a copy of the vaccine borrowing form to their RE within 24 hours of the occurrence. Adherence to the Health Insurance Portability and Accountability Act (HIPAA) guidelines is mandatory when this form is submitted.
- As required by the TVFC/ASN Program, vaccine-borrowing forms must be kept for a minimum of five (5) years and be made easily available for review during site visits.

## D. ASN 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 veterans who receive ASN vaccines.

By the 5th of each month, all ASN-enrolled sites must document the number of uninsured 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 requiring access to the survey must contact their RE to receive the password. REs who are not familiar with the password must contact their DSHS PHR.

If no female veterans received ASN vaccine the previous month, the site staff must report zero (0) in the survey.

***NOTE:***

*Adult vaccines administered to female veterans are required to be reported monthly to DSHS via an online survey.*

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

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# Section Five: Program Evaluation

## Policy

REs must monitor enrolled clinic sites to ensure staff and signing clinicians comply with all TVFC/ASN requirements.

By signing the TVFC/ASN Programs Agreement, the signing clinician agrees to allow PHRs, LHDs, and DSHS QA contractors to conduct unannounced site visits and announced or unannounced storage and handling (USH) visits.

## Purpose

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

## I. Provider Accountability

As the cost of vaccines increases and the complexity of immunization programs grow, the TVFC/ASN Programs become more vulnerable to fraud and abuse.

This information will guide PHR and LHD staff to do the following:

- Identify high-risk non-compliance issues,
- Prevent recurrence through education and training, and
- Determine when referral to Texas OIG is appropriate.

### A. Primary Education

Primary education must occur during the initial TVFC/ASN enrollment or during new staff training. This education includes orientation/updates to the TVFC/ASN Programs.

## B. Secondary Education

Secondary education should include re-education and individual training. It should occur when it is necessary to address moderate compliance issues that may include initial serious non-compliance activities or repeat minor non-compliance issues. Secondary education is performed in PEAR when a site visit is conducted, and non-compliance is identified, and it requires follow-up activities to be conducted by the RE. If secondary education is unsuccessful, the RE should begin a formal intervention.

## C. Formal Intervention

Formal intervention targets education or training on how to correct areas of identified need. It is important to provide education with the current TVFC/ASN Provider Manual and associate it with the identified non-compliance issues. If a formal intervention is unsuccessful, the RE should begin tertiary education.

## D. Tertiary Education

Tertiary education occurs when immediate and significant actions must occur to correct serious compliance issues (i.e., the non-compliant behavior caused vaccine loss or placed the TVFC/ASN Programs in danger, or the signing authority received unintentional financial gain because of the behavior). RE staff must visit the site to discuss the issue(s) with the signing authority and all staff. The aim is to correct practices that were not in alignment with TVFC/ASN policies.

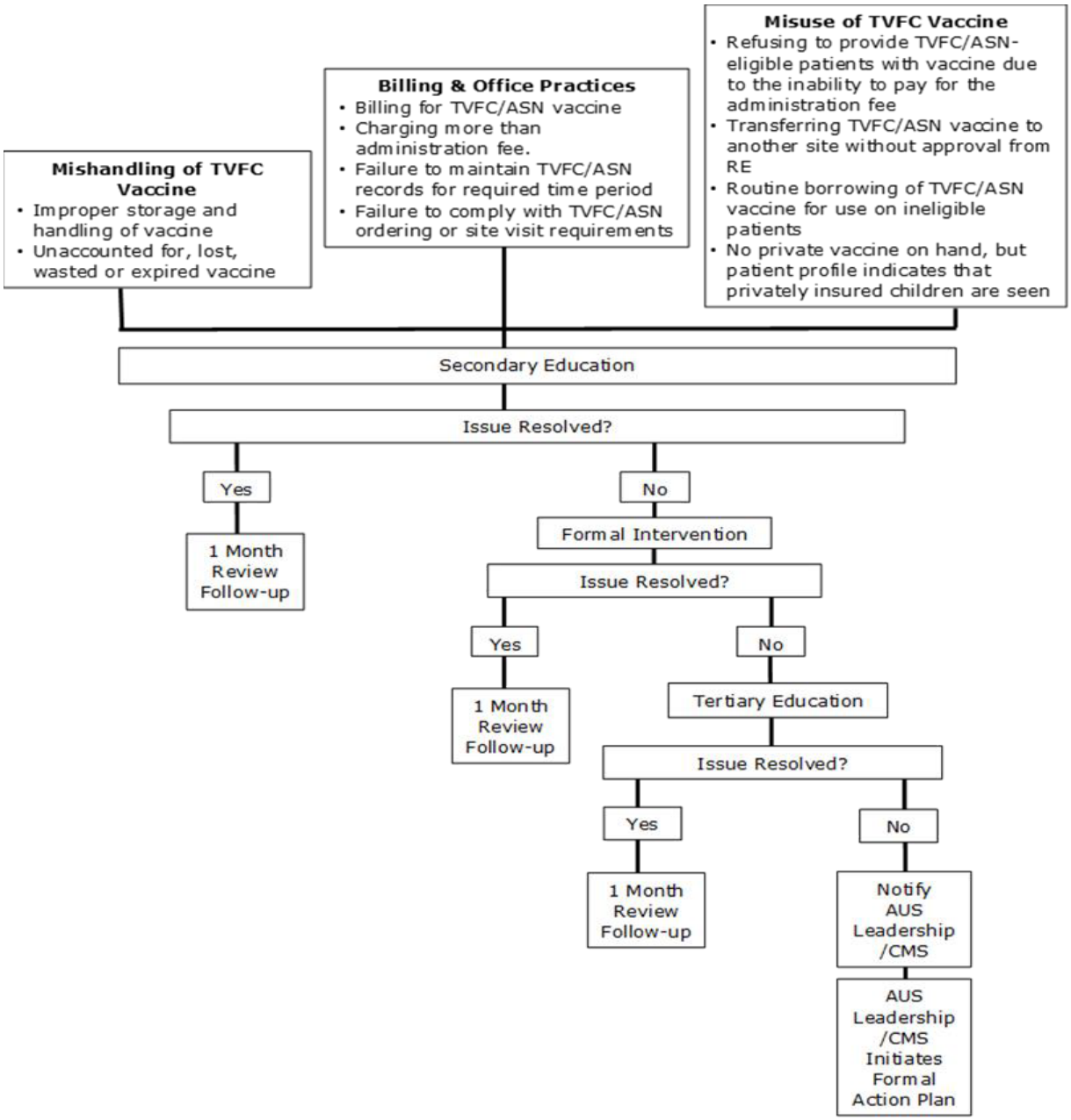
***NOTE:***

*REs must follow the levels of education when a clinic site fails to complete TVFC/ASN Program requirements.*

It is recommended that clinic staff develop a corrective action plan outlining the actions they will take to correct the issues. The primary and backup vaccine coordinators and the signing authority should sign the corrective action plan. At three (3), six (6), nine (9), and 12 months, the RE must monitor the progress of the corrective action plan to ensure full completion.

If the allegation is found to be true that TVFC/ASN vaccine was administered to ineligible patients, the education must include a dose replacement from the site's private stock and documented on the "Vaccine Borrowing Form", stock no. EF11-14171. Figure 6 identifies the level of education a RE must provide to an enrolled clinic site if clinic staff fail to comply with TVFC/ASN Program requirements.

**Figure 6.** TVFC/ASN-enrolled site fails to comply with program rules.



# II. Common Site Visit Structures

## A. Combined IQIP and TVFC Compliance Site Visit

Immunization Quality Improvement for Providers (IQIP) is a CDC quality improvement program conducted by immunization programs to support TVFC-enrolled sites. The purpose of IQIP is to promote and support the implementation of provider level quality improvement strategies. A core component of this visit is to focus on assessing provider-level vaccination coverage rates using the data reported to the Texas Immunization Registry.

IQIP serves to assist and support health care providers by identifying opportunities to improve vaccine uptake, determining options for improving immunizations delivery practices, and ensuring providers are:

- Aware of and knowledgeable about their vaccination coverage and missed opportunities to vaccinate,
- Motivated to try new immunization service delivery strategies and incorporate changes into their current practices,
- Capable of sustaining changes and improvements to their vaccination delivery services, and
- Able to use available data from the registry and/or EHR to improve services and coverage.

During the IQIP site visit, clinics will be evaluated on successful reporting of vaccine administrations to ImmTrac2 and on the clinic's efforts to increase coverage rates at their site. Vaccination coverage is measured at or near the time of the site visit to establish a baseline performance and again one year later to evaluate progress. REs must conduct follow-up activities at 2-, 6-, and 12-month intervals by telephone and in accordance with the IQIP Program policies. It is recommended the signing clinician and primary or backup vaccine coordinator be present during the IQIP visit. At the end of the site visit, the staff who were present are required to sign the "Acknowledgement of Receipt (AR)" form, stock nos. 11-14888 or 11-14981.

IQIP visits must be documented in the IQIP Database during the site visits. If internet access is not available, the visit must be entered within 10 days of the initial visit. Follow-up visits will be scheduled in the IQIP database during the initial visit and required to be conducted within 10 days of the scheduled date.

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

- PHR staff are responsible for conducting annual TVFC/ASN site visits at all DSHS PHR and LHD clinics within their jurisdiction. This may change if the DSHS Immunizations institutes a special project for which a contracted QA entity conducts visits at DSHS PHR and/or LHD clinics.
- Private facilities receive a site visit at least once every other year; however, visits may occur annually. The QA contractor conducts site visits at private facilities.
- The QA contractor will contact the RE point of contact (POC) immediately in the event any of the following issues are found during site visits:
    - Dorm-style refrigerator is used to store TVFC/ASN vaccines,
    - Temperature excursion occurring during the site visit,
    - Site does not have a valid data logger to monitor the units containing TVFC/ASN vaccine (contractor will provide one, if available),
    - Temperature excursions documented on the temperature recording form or identified on the data logger,
    - Vaccine borrowing that occurred and was not documented,
    - Unit is overcrowded with vaccine, preventing proper air flow, or
    - Vaccines that have expired or are within 90 days of expiration.

The required spacing between compliance site visits is a minimum of 12 months. Newly enrolled sites should receive a visit six (6) to 12 months after initial enrollment.

Compliance visits must be directly entered in PEAR while the review is being conducted. However, if an internet connection is not available, a paper version of the site visit must be used. Within one day of the conducted site visit and its documentation on paper, the information must be entered in PEAR. Reports are available to the DSHS Immunization Section on the amount of time it takes for a reviewer to enter information into PEAR after a review is conducted on paper. This information is used to identify staff who do not comply with this requirement. If determined out-of-compliance, DSHS Immunization Section staff will follow up to discuss the prevention of a recurrence.

At the conclusion of a compliance visit, the DSHS PHR or QA contractor reviewer must discuss the visit's outcomes with the vaccine coordinator. The discussion must include a review of the site visit findings and a formal

follow-up plan with a timeline addressing non-compliance issues or opportunities for improvement. Sites that will receive a combined IQIP and TVFC PEAR Compliance visit will be identified by DSHS Immunization Section.

## B. IQIP Site Visit

Some sites may receive an IQIP only visit. For more information on the IQIP portion of the visit, see the above section Combined TVFC Compliance Site Visit.

## C. TVFC Compliance Site Visit

When a clinic is not selected to receive an IQIP visit, only a compliance visit is conducted. The purpose of the compliance visit is to assess, support, and educate the site regarding TVFC/ASN policies and procedures.

At the conclusion of the compliance visit, the DSHS RE or QA contractor reviewer must discuss the visit's outcomes with the vaccine coordinator. The discussion must include a review of the site visit findings and a formal follow-up plan with a timeline that addressing any non-compliance issues or opportunities for improvement.

## D. ASN Compliance Site Visit

The purpose of the ASN compliance visit is to assess, support, and educate the site regarding ASN policies and procedures. Clinic sites that are enrolled exclusively in the ASN Program are required to be reviewed annually by the DSHS PHR reviewer. ASN site visits are not recorded in PEAR. They are recorded in the Adult Site Visit Survey found online at www.dshs.texas.gov/immunize/ASN/publications.aspx.

At the end of the compliance visit, the DSHS PHR or QA contractor reviewer must discuss the visit's outcomes with the vaccine coordinator. The discussion must include a review of the site visit findings and a formal follow-up plan with a timeline addressing any non-compliance issues or opportunities for improvement.

## E. Unannounced Storage & Handling (USH) Visits

The RE conducts USH visits that serve as "spot checks" for proper vaccine storage and handling. As with compliance site visits, USH visits must be directly entered in PEAR while the visit is being conducted.

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

- Vaccine loss,
- Improper storage of vaccine,
- Improper documentation on temperature logs,
- Orders inconsistent with suggested quantities,
- Newly enrolled sites [six (6) to 12 months after enrollment],
- Significant inventory adjustments, and
- Determination of the clinic's non-compliance with corrective actions from previous visits.

***USH Visits:***

*Annually, REs must conduct USH visits in at least 10% of the clinics under their jurisdiction.*

If the RE identifies storage and handling issues, they must review them with the clinic staff during the visit. The staff are expected to make immediate corrections to safeguard vaccines. DSHS PHR and contracted LHD staff are required to annually conduct USH visits on 10% of enrolled TVFC clinics in their jurisdictions. It is important for REs to monitor the list of clinics scheduled for a compliance visit from DSHS QA contractor to ensure a USH is not conducted when a compliance visit is scheduled.

The timing between compliance visits must be at least 12 months and the timing between a compliance visit and a USH is three to six (3-6) months.

Annually, DSHS provides a list of PINs to the QA contractor to conduct site visits on. Interrupting this process results in a delay of compliance visits.

**NOTE:** The DSHS Immunization Section or DSHS PHR may conduct unannounced reviewer-evaluation visits during which the reviewer will be evaluated while a site visit is being conducted.

## III. Follow-up Visits

Follow-up activities are conducted as necessary to address all issues and are dependent upon the severity of non-compliance issues and the follow-up action plan. The RE must conduct all required follow-up activities must work with the clinic staff by providing education and guidance regarding corrective actions, including monitoring. Follow-up activities are structured based on the type of initial visit conducted.

### A. IQIP Follow-up Activities

REs must conduct all IQIP follow-up activities. Technical assistance and support are given via telephone at 2-, 6-, and 12-month intervals to assist providers in staying on course with their strategy implementation plans. At the end of 12 months, a final discussion of the strategy plan progress and coverage rates are measured again to evaluate effectiveness. For more information on conducting IQIP follow-ups, see the Texas IQIP Manual for REs.

### Two- and Six-Month Follow-ups

During the 2- and 6-month follow-ups, REs must review notes from the previous site visit to discuss the following items with the staff at the enrolled facility:

- Review the strategy plan and discuss implementation status,
- Identify barriers and provide technical assistance,
- Establish new action items for updated strategy plan, if necessary, and
- Enter data into IQIP Database.

### 12-Month Follow-up

During the 12-month follow-up REs must review notes from the previous site visit to discuss implementation status. Vaccine coverage rates will be assessed to determine if coverage goals set during the initial site visit were reached. The 12-month follow-up must be conducted and documented to close out the IQIP cycle.

## B. TVFC Compliance Follow-up Visit

PHR and LHD staff must conduct follow-up compliance activities in PEAR within the required timeframes, regardless of who conducted the site visit. The purpose of the follow-up is to ensure that identified areas for improvement are understood by the site 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 to determine staff compliance with the corrective actions must be conducted using one of the following:

- Visit the clinic to observe corrective actions or

- Call the clinic's vaccine coordinator to ensure the corrective actions have been implemented.

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

If a clinic exhibits habitual non-compliance and does not follow corrective actions in response to education, it is recommended that vaccine ordering privileges be suspended. See Section Five: I. Provider Accountability for levels of education.

In the event it becomes necessary to suspend a clinic, suspension must not last longer than 90 days. It may also be necessary to escalate the levels of education to include the signing clinician and all clinic staff. If non-compliance continues, termination from the TVFC/ASN Program is recommended, after discussion with DSHS PHR and DSHS Immunization Section staff.

### C. ASN Compliance Follow-up Visit

PHR staff are responsible for conducting follow-up visits on all ASN-only enrolled sites, regardless of who conducted the first visit.

## IV. Documenting Site Visits

The Acknowledgement of Receipt (AR) form is a document that confirms a site visit was completed, the results of the visit were reviewed with the staff, and the vaccine coordinator or signing clinician understands the actions needed to correct/address the non-compliance issues, if applicable.

The AR must be signed by the vaccine coordinator or a signing clinician at the site at the end of the site visit. All LHDs are required to submit completed AR forms to their DSHS PHRs within three (3) operational days of the site visit. When a PHR is the RE, completed AR forms must be submitted to the DSHS Immunizations within three (3) operational days of the site visit.

REs must use most current form available in PEAR with the following sections completed:

- Facility name,
- Site visit number in the correct format (mmddyyyyTXA000000),
- Reviewer name and email address,
- Date of the visit on the AR matching what is documented in PEAR,
- Vaccine coordinator or signing clinician's signature and date, and
- Reviewer's signature and date.

***NOTE:***

*The Acknowledgement of Receipt (AR) form is a document that confirms a site visit was completed, the results were reviewed with the staff, and the vaccine coordinator or signing clinician understands the actions needed to correct/address the non-compliance issues, if applicable.*

The DSHS PHR must conduct a quality assurance check and submit the AR received from LHDs to the DSHS Immunization Section within five (5) operational days from the form receipt date.

The IQIP database records all information related to the IQIP portion of a site visit. All IQIP visits to include all follow-up visits must be documented in the IQIP database within 10 days of the completed visit. The DSHS Immunization Section will monitor documentation of completed and overdue visits.

## V. Satisfaction Surveys

Staff at TVFC/ASN-enrolled sites 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.

Staff at enrolled TVFC/ASN sites can expect at least two (2) surveys yearly.

The program satisfaction survey was created to assess overall TVFC/ASN Programs satisfaction and is an annual requirement of DSHS by the CDC. Clinic staff are required to participate in the program satisfaction survey that is conducted during re-enrollment.

The site visit assessment survey is conducted following a site 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.

# Section Six: Documentation Requirements

## I. The Texas Immunization Registry (ImmTrac2)

ImmTrac2 is operated by the DSHS Immunization Section and is an important component of Texas' strategy to improve immunization coverage rates.

> ***NOTE:***
>
> *Texas Law requires vaccinators to report all immunizations administered to children 17 years of age or younger to ImmTrac2 within 30 days of administration of the vaccine.*

Texas Health and Safety Code §§161.007-161.009 requires all medical providers and payors to report all immunizations administered to clients who are younger than 18 years of age 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.

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 https://immtrac.dshs.texas.gov/TXPRD/portalInfoManager.do.

### A. Reporting Vaccine Eligibility in ImmTrac2

TVFC/ASN eligibility 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 Children (younger than 18 years old)
- 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 Vaccines 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.

## II. Vaccine Adverse Event Reporting System (VAERS)

All staff at enrolled sites are required to report adverse events following vaccine administration. An adverse event can be reported using the VAERS online form available at vaers.hhs.gov or on the PDF form available at the same site.

Reports of adverse events are welcome from all concerned individuals, including the following:

- Patients,
- Parents,

- Healthcare providers,
- 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.

***NOTE:***

*VAERS Reports that include a serious adverse event must also be provided to the DSHS Central Office at imm.epi@dshs.texas.gov.*

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.

Providers 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), providers must send a copy of the report to their RE after the report has been submitted.

REs are required to submit a copy of the report to the DSHS Immunizations at imm.epi@dshs.texas.gov. This can be done most easily by using the "pdf upload" option on the VAERS website.

## III. Vaccine Record Keeping Requirements

The 1986 National Childhood Vaccine Injury Act (NCVIA) requires all vaccinators to record specific information in the medical record every time a vaccine is administered. The following elements are required:

- Name of the vaccine that was administered,
- Date the vaccine was administered (month/day/year),
- Date the VIS was given to the patient,
- Publication date of the VIS,
- Name of the vaccine manufacturer,
- Vaccine lot number,
- Name and title of the health care provider that administered the vaccine, and the
- Address of the clinic where the vaccine was administered.

If needed, the DSHS Immunizations provides immunization records that are designed to capture all information that is required when a vaccine is administered. Immunization records for clinics, the "Vaccine Information Documentation Form", stock no. C-100, and clients, the "Personal Immunization Record", stock no. C-102, can be ordered free-of-charge from DSHS at www.immunizetexasorderform.com.

# Section Seven: Enrolled Clinic Staff Responsibilities

REs must ensure the clinic staff (primary and backup vaccine coordinators and signing clinician) are knowledgeable of their responsibilities of the TVFC/ASN Programs. Intentional or unintentional negligence of program requirements may be considered fraud and abuse of the program.

## Primary and Backup Vaccine Coordinator

The TVFC/ASN Programs require that the signing clinician designate a primary vaccine coordinator at the clinic site who will be responsible for ensuring all vaccines are stored and handled correctly. The program also requires that a second staff member at the facility be appointed as a backup vaccine coordinator 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. Each site must have a unique primary vaccine coordinator and backup vaccine coordinator. TVFC/ASN sites with operating hours or operating days that do not overlap may share a coordinator (e.g., primary vaccine coordinator at the first PIN and secondary vaccine coordinator at the second PIN). The following are the responsibilities of the primary and backup vaccine coordinator to implement, oversee, and monitor the TVFC/ASN Programs requirements:

- Ensure only eligible patients receive TVFC/ASN vaccines,
- Set-up data loggers in storage units,
- Ensure staff are familiar with the operation of the data loggers including how to download the data (recommended weekly, on Mondays),
- Monitor and record the temperatures of units (refrigerator and freezer) twice each workday,
- Read and record the minimum and maximum temperatures at the beginning of each workday,

- Monitor the operation of storage equipment and systems,
- Maintain all documentation, such as vaccine inventory, temperature logs, and certificates of calibration,
- Document TVFC/ASN vaccine inventory information,
- Place orders for TVFC/ASN vaccine in VAOS,
- Report vaccine activities in VAOS monthly,
- Track and document doses administered,
- Oversee proper receipt and storage of vaccine deliveries,
- Organize vaccines to monitor expiration dates,
- Remove expired vaccine from storage units and document the loss in VAOS,
- Ensure TVFC/ASN 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 emergencies,
- Oversee proper vaccine transport (i.e., during an emergency),
- Ensure other clinic staff are trained in the proper storage and handling of vaccines, and
- Notify RE of staff changes to primary or backup vaccine coordinator or signing clinician.

In the event that a primary or backup vaccine coordinator is removed from a site, providers must notify their RE of the staffing update immediately. Once the notification is received, the site will have 10 business days to designate and onboard a replacement coordinator. If a new coordinator is not onboarded (including the completion of all required trainings) at the end of

the 10th business day, the site will be suspended until a new coordinator is designated.

## Signing Clinician

By signing the agreement, the signing clinician agrees to abide by the program conditions as outlined on the TVFC Program Provider Agreement and is agreeing to conditions on behalf of all the practitioners, nurses, and others associated with the health care facility.

Signing clinicians are responsible for the following items:

- Agree to allow DSHS or DSHS Quality Assurance contractors to conduct on-site visits including announced and unannounced visits and other educational opportunities associated with program requirements,
- Identify a primary and backup vaccine coordinator at the facility who will have authorization to order vaccines,
- Notify RE of staff changes (primary or backup vaccine coordinators),
- Ensure only eligible patients receive vaccine,
- Comply with immunization schedules, dosages, and contraindications established by ACIP unless:
  - Compliance is deemed medically inappropriate, or
  - The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
- Maintain records relating to the program for five (5) years and upon request, make those records available for review,
- Submit a patient population profile representing populations served annually, or if patient population and/or status of facility changes,
- Will not charge a vaccine administration fee to Medicaid or CHIP patients,

- Will not exceed the $13.75 vaccine administration fee per dose for American Indian/Alaska Native, Uninsured, and UNDERinsured patients,
- Ensure to not deny administration of public and state supplied vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay an administration fee,
- Ensure TVFC-eligible patients are not charged for vaccines supplied by DSHS,
- Ensure UNinsured adults are not charged for vaccines supplied by DSHS,
- Ensure that vaccine administration fee for UNinsured adults does not exceed $25.00 per dose,
- Ensure Vaccine Information Statements (VIS) are distributed every time a vaccine is administered and maintain records in accordance with NCVIA, which includes reporting to VAERS,
- Ensure that compliance requirements for vaccine management is in accordance with DSHS rules and manufacturer's specifications, and
- Will operate TVFC/ASN Programs in a manner intended to avoid fraud and abuse as defined in Section Two: Standard and Policies, Subsection I. Fraud and Abuse Reporting.

# Section Eight: Responsible Entity (RE) Accountability

The following are items required by REs to ensure program accountability:

**Category 1. Ensure Vaccine Availability**

- Review and approve orders on time,
- Recruitment to increase access to vaccines,
- Ensure children can remain in their medical home by maintaining clinics enrolled in the TVFC/ASN Programs, and
- Ensure RE staff are well versed in MSL calculations.

**Category 2. Ensure Vaccine Viability (no storage and handling violations)**

- Review submitted temperature recording logs thoroughly to ensure no out-of-range temperatures are recorded and documentation is correct, and
- Ensure RE staff are well versed in vaccine storage and handling procedures.

**Category 3. Customer Service**

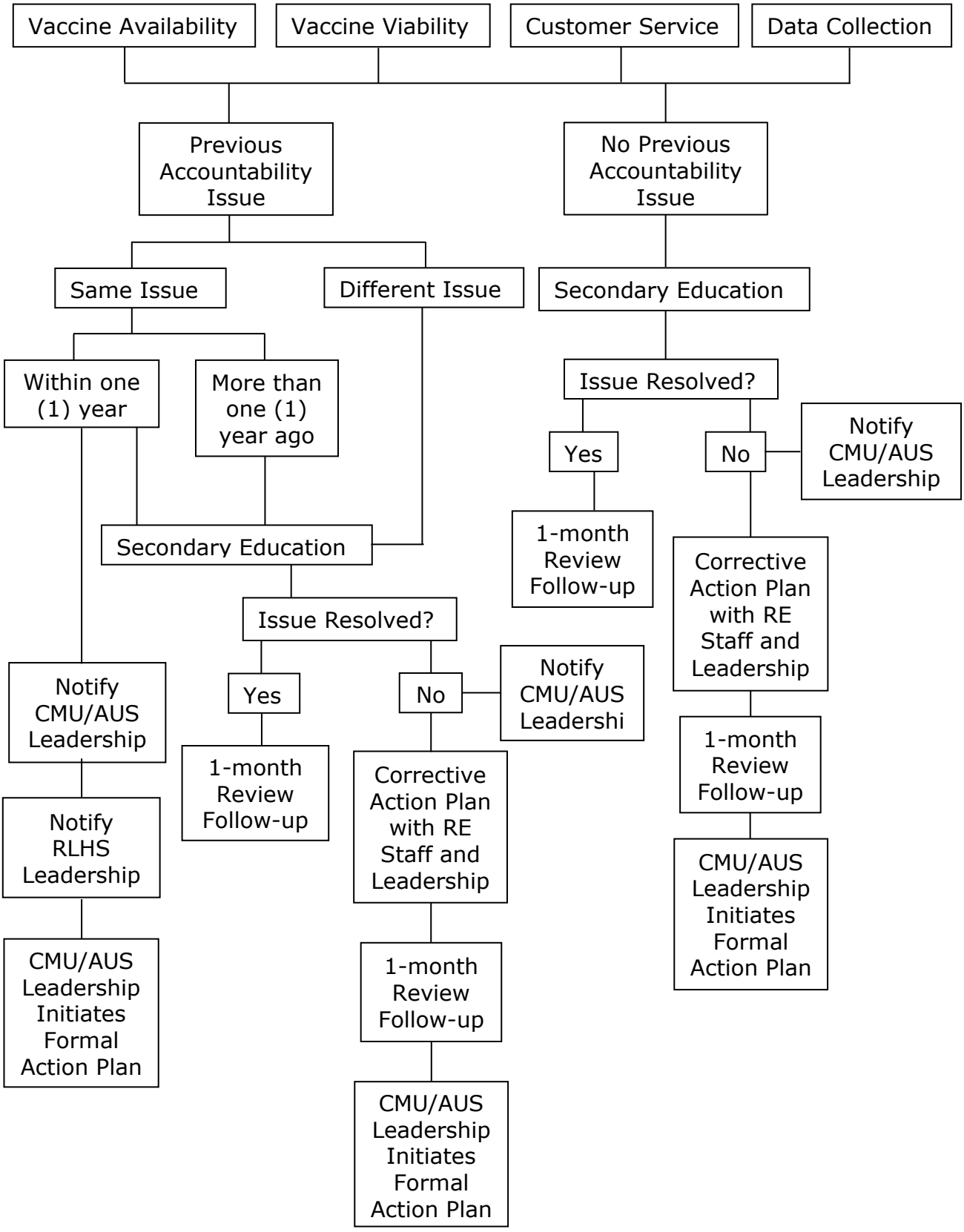
- Ensure RE staff provide uniform policies and clear directions,
- Provide timely customer service and accurate education,
- Provide accurate education on ImmTrac2,
- Provide technical assistance,
- Ensure RE staff are abiding by the program requirements (i.e., not violating vaccine transfer policy),

- Ensure RE staff provide excellent customer service by returning phone calls or emails in a short amount of time,
- Ensure RE staff attend DSHS meetings and actively participate,
- Ensure RE staff disseminate information to enrolled clinics as soon as released and retain documentation,
- Ensure RE staff are well versed in the Perinatal Hepatitis B Program, and
- Ensure RE staff are well versed in the TVFC/ASN Programs.

**Category 4. Data Collection for Action and System Improvements**

- Ensure RE staff document USH, site visits, and IQIP visits accurately and on-time in PEAR and RedCap,
- Ensure RE staff conduct USH, site visit, and IQIP visit follow-ups on-time in PEAR and RedCap,
- Ensure RE staff are actively registering sites in ImmTrac2,
- Ensure RE staff are conducting Perinatal Hepatitis B case management in accordance with the program requirements,
- Ensure RE staff conduct and complete school and daycare audits, validations, and assessments in accordance with the program requirements, and
- Ensure RE staff are conducting VPD surveillance in accordance with the program requirements.

**Figure 7.** RE fails to comply with program requirements.



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# Section Nine: Document Submission

PHRs and LHDs serve as REs to sites enrolled in the TVFC/ASN Programs. PHRs serve as the RE for LHD clinics and private-enrolled clinics within their jurisdictions. LHDs serve as the RE for private-enrolled clinic sites within their jurisdictions.

Some forms related to TVFC/ASN Programs must be forwarded to PHRs and/or to the DSHS Immunization Section. Figure 8 explains documentation submission requirements and is a guide to determine what forms must be sent from the LHD to the PHR when the LHD is the RE. Figure 9 is a guide to determine what forms the PHR must forward to the DSHS Immunization Section when the PHR is the RE. Figure 10 lists documentation submission timeframes.

**Figure 8.** Form submission from LHD to PHR.

| When LHD is the RE for Privately Enrolled Sites | |
|---|---|
| **The LHD Receives:** | **The LHD Submits Information to:** |
| Biological order form (pedi/adult) | **PHR*** |
| Clinic withdrawal form | **PHR*** |
| CMS letter from FQHCs/RHCs (new enrollments) | PHR |
| Enrollment form updates/changes | **PHR*** |
| VAOS vaccine transfer form | **PHR*** |
| New enrollment form | **PHR*** |
| New enrollment checklist | **PHR*** |
| Temperature recording form | PHR |
| Training certificate for primary/backup vaccine coordinators | PHR |
| Vaccine borrowing form | PHR |
| Vaccine loss report | **PHR**** |
| Vaccine management plan | |
| Vaccine transfer authorization form | PHR |
| * PHR must submit to the DSHS Immunization Section.<br>** VLRs must be submitted to DSHS Immunization Section only when a correction to a vaccine loss designation is necessary. | |

**Figure 9.** Form submission from PHR to DSHS Immunizations.

| When PHR is the RE for LHD Clinics or Privately Enrolled Sites | |
|---|---|
| **The PHR Receives:** | **The PHR Submits Information to:** |
| Biological order form (pedi/adult) | DSHS Immunization Section |
| Clinic withdrawal | DSHS Immunization Section |
| CMS letter from FQHCs and RHCs (new enrollments) | |
| Enrollment form updates/changes | DSHS Immunization Section |
| VAOS vaccine transfer form | |
| New enrollment form | DSHS Immunization Section |
| New enrollment checklist | DSHS Immunization Section |
| Training certificate for primary/backup vaccine coordinators | |
| Temperature recording form | |
| Vaccine borrowing form | |
| Vaccine loss report* | DSHS Immunization Section |
| Vaccine management plan | |
| Vaccine transfer authorization form | |
| * VLRs must be submitted to DSHS Immunization Section only when a correction to a vaccine loss designation is necessary. | |

**Figure 10.** Documentation submission dates.

| Documentation Submission Deadlines | | | |
|---|---|---|---|
| **Activity** | **Clinic** | **LHD to PHR** | **PHR to DSHS Immunization Section** |
| **Monthly reports** | By the 5th of each month | | |
| **Female veteran reporting** | By the 5th of each month | | |
| **Withdrawal Form** | | Within three (3) days of picking up vaccine | Within three (3) days of picking up vaccine or receipt from LHD |
| **Vaccine Loss Report Form** | Generate within four (4) days of loss | When received | When received |
| **Delegation of Authority** | | Annually, when requested | Annually, when requested |
| **Acknowledgement of Receipt (AR) Form** | | Within three (3) days of USH visit | Within three (3) days of site visit or USH or within five (5) days of receipt from LHD |
| **Vaccine Borrowing Form** | Within 24 hours of occurrence | Monthly | |
| **Re-enrollment for TVFC/ASN Programs** | Oct. 1-31 | Review completed by Nov. 30 | Review completed by Nov. 30 |
| **Underinsured Reporting** | By the 15th of each month | | |

# Section Ten: Abbreviations

**ACIP:** Advisory Committee on Immunization Practices

**AIM:** Antiviral, Immunization, and other Medications

**APN:** Advanced Practice Nurse

**AR:** Acknowledgement of Receipt

**ASN:** Adult Safety Net

**CoCASA:** Comprehensive Clinic Assessment Software Application

**CDC:** Centers for Disease Control and Prevention

**CHC:** Community Health Center

**CHIP:** Children's Health Insurance Program

**CMS:** Center for Medicare and Medicaid Services

**CNM:** Certified Nurse Midwife

**DO:** Doctor of Osteopathy

**DOA:** Delegation of Authority

**DSHS:** Texas Department of State Health Services

**DT:** Diphtheria, Tetanus

**DTaP:** Diphtheria, Tetanus, acellular Pertussis

**EMR:** Electronic Medical Record

**EMS:** Emergency Medical Services

**FQHC:** Federally Qualified Health Center

**Hib:** *Haemophilus influenzae* type b

**HIPAA:** Health Insurance Portability and Accountability Act

**HPV:** Human Papillomavirus

**IPOS:** ImmTrac2 Program Outreach Specialist

**IPV:** Inactivated Polio Vaccine

**IQIP:** Immunization Quality Improvement for Providers

**LHD:** Local Health Department

**MAP:** Medical Access Program

**MCV:** Meningococcal Conjugate Vaccine

**MD:** Medical Doctor

**MenB:** Meningococcal type B

**MOU:** Memorandum of Understanding

**MMR:** Measles, Mumps, Rubella

**MSL:** Maximum Stock Level

**NCVIA:** National Childhood Vaccine Injury Act

**NDC:** National Drug Code

**NP:** Nurse Practitioner

**NPI:** National Provider Identifier

**OBRA:** Omnibus Budget Reconciliation Act

**OIG:** Office of the Inspector General

**PA:** Physician Assistant

**PCV:** Pneumococcal Conjugate Vaccine

**PEAR:** Provider Education Assessment and Reporting

**PHR:** Public Health Region

**PIN:** Provider Identification Number

**POC:** Point of Contact

**PPSV:** Pneumococcal Polysaccharide Vaccine

**QA:** Quality Assurance

**RE:** Responsible Entity

**RHC:** Rural Health Clinic

**RPh:** Registered Pharmacist

**STD/HIV:** Sexually Transmitted Diseases/Human Immunodeficiency Virus

**Td:** Tetanus, diphtheria

**Tdap:** Tetanus, diphtheria, acellular pertussis

**TDI:** Texas Department of Insurance

**TVFC:** Texas Vaccines for Children

**TWICES:** Texas Wide Integrated Client Encounter System

**USH:** Unannounced Storage and Handling

**VAERS:** Vaccine Adverse Event Reporting System

**VAOS:** Vaccine Allocation and Ordering System

**VFC:** Vaccines for Children

**VIS:** Vaccine Information Statement

**VLR:** Vaccine Loss Report

**VOG:** Vaccine Operations Group

**VTrckS:** Vaccine Tracking System

**WIC:** Women, Infants, and Children

# Section Eleven: Forms and Tools

- Adult Biological Order Form, stock no. EC-68-2*
- Adult Eligibility Screening Record, stock no. F11-12842*
- Changes to Enrollment Form, stock no. 11-15224*
- Monthly Biological Report, stock no. C-33 (found in VAOS)
- New Enrollment Checklist, stock no. 11-15016*
- Pediatric Biological Order Form, stock no. EC-68-1*
- Pediatric Eligibility Screening Record, stock no. C-10*
- Provider Withdrawal Form, stock no. F11-11443*
- Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, United States, 2022, stock no. 6-105
- Recommended Immunization Schedule for Adults 19 Years or Older, United States 2022, stock no. 6-104
- Temperature Recording Form, stock no. EC-105 (available to record Celsius or Fahrenheit, for refrigerators and freezers)*
- TVFC/ASN Provider Agreement Form*
- Vaccine Borrowing Form, stock no. EF11-14171*.
- Vaccine Loss Report (found in VAOS)
- Vaccine Management Plan Templates, stock no. E11-14498*
- Vaccine Services to Female Veterans (online survey)*
- Vaccine Transfer Authorization Form, stock no. EC-67*

- VAERS Reporting Form

* Available at ~~www.dshs.texas.gov/immunize/Responsible-Entities/Managing-TVFC---ASN-Providers/~~

# Section Twelve: Immunization Resources

**CDC Immunization Schedules**
cdc.gov/vaccines/schedules/index.html

**CDC Immunization Website**
cdc.gov/vaccines

**CDC Vaccines for Children (VFC) Website**
cdc.gov/vaccines/programs/vfc/index.html

**CDC Vaccine Storage and Handling Toolkit**
cdc.gov/vaccines/hcp/admin/storage/toolkit

**CDC "You Call the Shots" Training**
cdc.gov/vaccines/ed/youcalltheshots.html

**IQIP Manual**
dshs.texas.gov/immunize/Responsible-Entities/Quality-Assurance-for-TVFC-Providers/

**IQIP Website**
dshs.texas.gov/immunize/Immunization-Quality-Improvement-for-Providers-Program/

**ImmTrac2, the Texas Immunization Registry**
dshs.texas.gov/immunize/immtrac/default.shtm

**Immunization Action Coalition**
www.immunize.org/

**Standards for Adult Immunization Practice**
cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html

**Texas Adult Safety Net (ASN) Website**
dshs.texas.gov/immunize/ASN

**Texas DSHS Immunization Website**
www.immunizetexas.com

**Texas Vaccine Education Online**
https://learningportal.hhs.texas.gov/course/index.php?categoryid=45

**Texas Vaccines for Children (TVFC) Website**
dshs.texas.gov/immunize/tvfc

**Vaccine Allocation and Ordering Training**
https://dshs.texas.gov/immunize/Vaccine-Management-Resources-for-TVFC-and-ASN.doc

# Section Thirteen: Program Contact Information

DSHS Immunization Section (800) 252-9152

| PINS Beginning With | TVFC/ASN Contact | Phone |
|---|---|---|
| 00 | City of San Antonio | 210-207-3965 |
| 01 | PHR 1 | 806-391-1323 |
| 02 | PHR 2 | 325-795-5660 or 817-264-4790 |
| 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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# 2023 Manual Revision History

## General Manual Revisions

- Updated Texas Vaccines for Children (TVFC) and Adult Safety Net (ASN) verbiage to specify which policies applied to each program throughout manual sections.
- Replaced DSHS Immunization Unit with DSHS Immunization Section.
- Updated Rural Health Center to Rural Health Clinic.
- Updated grammatical errors.

## Program and Policy Revisions

- Vaccine Allocation and Ordering System (VAOS): Updated vaccine ordering and management information to align with VAOS functions.
    - Aligned language relevant to the ordering process, documenting vaccine, transferring, vaccine choice, Maximum Stock Levels (MSLs), and reporting.
    - Added a requirement for all primary and backup vaccine coordinators to complete the VAOS Training Quiz.
    - Added language to specify that vaccine transfers will be auto denied in VAOS after two (2) weeks.
- Updated use of biological ordering forms and the monthly biological report.
- Removed the "Combined Tally and Physical Inventory Form", stock no. C-88, to be replaced by the VAOS Tally Sheet.
- Provider eligibility.
    - TVFC: Eligible site types added.

- ASN: Added Federally Recognized Indian Tribes to the list of eligible sites.

- Multi-dose discard: Updated date of discard to 28 days for opened or accessed multi-dose vials.

- Flu survey: Revised flu survey verbiage to specify that flu vaccine choice will be submitted through VAOS.

- "Changes to Enrollment Form", stock no. 11-15224: Facilities must submit "Changes to Enrollment Form" in the following instances:

  - Change of facility name, facility shipping address, shipping hours, signing clinician, prescribing authorities, patient population data change, primary and/or backup vaccine coordinator(s).

- Data logger requirements:

  - All certificates of calibration must be sent to Res, who send to DSHS Central Office for processing. Providers with expired data logger certificates will be suspended until current data logger certificates are received.

  - Photos of data loggers will not be accepted as valid certificates of calibration.

  - Added language that providers must return state-issued data loggers and certificates of calibration to REs if withdrawn from the program(s).

  - Added a requirement that all PINS must have data loggers that can be reset by staff on site.

- Reporting requirements:

  - Monthly reporting to be completed in VAOS.

  - Ordering will be unavailable until monthly reporting is submitted.

  - Updated timeline within which required reporting should be submitted.

- Vaccine storage:
  - Updated recommendations for the use of the freezer compartment of a household combination unit.
- Formulary updates: Changes to made to the TVFC and ASN formularies to reflect current offerings.
- Waiting period: Removed the waiting period for vaccine shipments to align with the COVID-19 shipping policy.
- VAOS training requirement: All primary and backup vaccine coordinators are required to complete and submit the VAOS Training Quiz.
- UNDERinsured reporting: Added the required monthly reporting deadline.
- CPT codes: Added a reference link to look up CPT codes on the Centers for Medicare and Medicaid Services (CMS) website.
- Primary and backup vaccine coordinators: Updated language to specify that primary and backup vaccine coordinators must be unique to each site.
- Coordinator replacement: Added language to give a window of ten (10) days for sites to replace a lost primary or backup vaccine coordinator.
- Vaccine transfers:
  - Updated language to designate appropriate signatories for transfer forms.
  - Specified the required timeframe for regions to approve or deny transfers.
- IQIP site visit attendees: Specified who should be present during site visits.
- Auto-dispensing units: A new section was added for requirements specific to auto-dispensing units.

- MSL calculations: Updated language to specify patient population data should be adjusted in Syntropi to adjust MSLs in VAOS.
- Vaccine Transfers: additional language added to clarify the routing redistribution of TVFC vaccine, including flu vaccine and short-dated flu vaccine is not allowed unless under certain circumstances.
- Vaccine Borrowing: additional language added to clarify steps to take if TVFC vaccine is administered to a privately insured patient or ASN patient.
- Reporting Requirements: additional language added to clarify the requirement of temperature recording forms to be submitted each time a vaccine order is placed.

**Chapter 5 – Program Evaluation**

- Combined IQIP and Compliance Site Visit: additional language added to clarify the staff required to be present at IQIP visits.
- Follow-Up Activities: additional language added to clarify the staff required to be present at site visits and signing of the AR form.

**Chapter 9 – Adult Safety Net Program**

- Vaccine Choice: revised language to update vaccine choice ordering for ASN Providers.
- Vaccine Transfers: additional language added to clarify the routine redistribution of ASN vaccine.
- Components of the ASN Site Visit: additional language added to clarify the staff required to be present at ASN site visits.

**Chapter 11 – Ordering Forms and Literature**

- Updated website for complete listing of forms and materials available for ordering.

## Vaccine Manufacturer's Contact List

- Updated Merck and Seqirus USA, Inc., contact phone numbers.

## TVFC/ASN Programs Contact Information

- Updated PHR 1 RE's contact phone number.

## Chapters 1 - 9

- Updated and replaced Electronic Vaccine Inventory (EVI) with Vaccine Allocation and Ordering System (VAOS) language throughout the 2022 TVFC/ASN Provider Manual.

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