



Operations Manual

Texas Vaccines for Children
and Adult Safety Net Program

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Chapter One: General Information

I. Introduction

The Texas Department of State Health Services (DSHS) Immunization program 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.

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 program will distribute new policies to staff at enrolled facilities via official policy letters, memorandums, and the monthly newsletter, “TVFC/ASN Digest”. All policy updates from the previous year are incorporated during the annual update of the Operations Manual. Both the manual and the latest updates are on the DSHS Immunization program 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 more than 4.5 million Texas children 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 program

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 program

- 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

- Immunization services are readily available
- No barriers or unnecessary prerequisites to the receipt of vaccines exist
- Immunization services are available free or for a minimal fee
- Providers utilize all clinical encounters to screen and, when indicated, immunize children
- Providers educate parents and guardians about immunization in general terms
- Providers question parents or guardians about contraindications and, before immunizing a child, inform them in specific terms about the risks and benefits of the immunizations their child is to receive
- Providers follow only true contraindications
- Providers administer simultaneously all vaccine doses for which a child is eligible at the time of each visit
- Providers use accurate and complete recording procedures
- Providers co-schedule immunization appointments in conjunction with appointments for other child health services
- Providers report adverse events following immunization promptly, accurately and completely
- Providers operate a tracking system
- Providers adhere to appropriate procedures for vaccine management
- Providers conduct semi-annual audits to assess immunization coverage levels and to review immunization records in the patient populations they serve
- Providers maintain up-to-date, easily retrievable medical protocols at all locations where vaccines are administered
- Providers operate with patient-oriented and community-based approaches
- Vaccines are administered by properly trained individuals
- Providers receive ongoing education and training on current immunization recommendations

VII. Adult Immunization Standards

- Assess immunization status for all patients at every clinical encounter
- Strongly recommend all vaccines that patients need
- Administer needed vaccines or refer patients to a vaccinating provider
- Document vaccines received by your patients in their health records and immunization registry

Chapter Two: Standards and Policies

Policy

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

Purpose

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

I. Facility Eligibility

A. Facility Participation

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

- **Behavioral health clinic** – 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 vaccinator (non health department)** – Community-wide vaccinators that are external to public or private conventional health care providers, offer vaccination services only, and conduct vaccination clinics in mobile, temporary, or offsite locations exclusively (e.g., non-permanent school-located vaccination clinics).
- **Correctional facility** – Juvenile and adult correctional facilities where juveniles are confined and on-site vaccination services are provide. Unlike juvenile detention centers, confinement in correctional facilities is generally long-term in nature; youths are confined in secure correctional facilities for periods generally ranging from a few months to years.
- **DSHS Public Health Department Clinic** – State public health clinics that provide vaccination services. This category includes public health-run STD/HIV clinics, family planning clinics, and teen health centers.

NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., public health clinic personnel) is administering vaccines.

- **DSHS Public Health Department Clinic as agent for FQHC/RHC - Deputized** – A state public health clinic deputized provider has been delegated by a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (RHC) as an agent to vaccinate underinsured children. This provider type is used for deputized state public health clinics that provide vaccination services.

NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., deputized public health clinic personnel) is administering vaccines.

- **EMS Facility** – Emergency Medical Services (EMS) or fire department facilities where vaccination services are provided.

NOTE: The EMS Facility provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., EMS Facility or EMS Facility-contracted personnel) is administering vaccine.

- **Family Planning Clinic (non-health department)** – Clinics that provide contraceptive services for clients who want to prevent pregnancy and space out 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 or mental health). This provider type is used for family planning clinics providing vaccination services.

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 and Resources Administration (HRSA) to provide health care to a medically underserved population. Community-based health care providers that offer primary care services in underserved areas and meet the criteria for “Federally Qualified Health Center (FQHC)” certification as set by the Centers for Medicare and Medicaid Services (CMS). FQHCs include HRSA Health Center Program look-alikes, which are health centers that meet Health Center Program requirements but do not receive federal award funding.

NOTE: Certain tribal organizations are also FQHCs. However, for tribal or urban Indian health clinics enrolled as FQHCs, use the “Indian Health Service, Tribal, or Urban Clinic” designation. The FQHC provider type includes any satellite, temporary, or off-site locations where provider of record (i.e., FQHC personnel) is administering vaccine.

- **Harris Health System Clinic** – Part of the network of health care facilities in Harris County.
- **HHSC Family Planning Clinic** – A state clinic whose purpose is to prescribe contraceptives or treat STDs. Do not use this designation if your main services are primary or acute care services.
- **Hospital (non-publicly funded)** – All hospitals, including medical school or university-affiliated hospitals, but excluding birthing hospitals, where on-site vaccination services are provided.

NOTE: For birthing hospitals, use the “Birthing Hospital or Birthing Center” designation. The hospital provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., hospital or hospital-contracted personnel) is administering vaccine.

- **Indian Health Service, Tribal, or Urban Clinic** – Indian Health Service (IHS), Tribal, or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated FQHCs and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.

NOTE: Certain tribal organizations are also FQHCs. However, for tribal or urban Indian health clinics enrolled as FQHCs, use the “Indian Health Service, Tribal, or Urban Clinic” designation.

- **Juvenile Detention Center** – Juvenile detention centers where on-site vaccination services are provided. Juvenile detention is defined as the temporary and safe custody of juveniles who are accused of conduct subject to the jurisdiction of the court who require a short-term restricted environment for their own or the community’s protection while pending legal action or dispositional placement in a correctional facility.
- **Local Health Department (LHD) clinic** – A city/country public health clinic contracted by the state that provides vaccination services. This category includes public health-run STD/HIV clinics, family planning clinics, and teen health centers.

NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., public health clinic personnel) is administering vaccines.

- LHD clinic as agent for FQHC/RHC-deputized A city or county public health clinic deputized provider has been delegated by a FQHC or a RHC as an agent to vaccinate underinsured children. This provider type is used for deputized city/county public health clinics that provide vaccination services.

NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., deputized public health clinic personnel) is administering vaccine.

- **Migrant Health Facilities** – Centers that provide health services, including on-site vaccination services, to migratory and seasonal agricultural workers and their families.
- **Mobile Provider** – Providers who offer vaccination and other health care services exclusively out of a mobile facility. This designation should not be used for providers with a mobile unit associated with their facility, but the unit is not the primary location for vaccine storage and administration.
- **Pharmacy** – Stand-alone retail pharmacies (e.g., CVS, Duane Reade, Walgreens, independently owned pharmacies, etc.) 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.

NOTE: This provider does not include retail health clinics (e.g., Minute Clinic) or centralized pharmacies within a hospital or health care facility that dispense vaccines to be administered by facility staff. In those cases, the provider type is determined by who administers the vaccine. The Pharmacy provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., pharmacy personnel) is administering vaccines.

- **Private Practice (e.g., family practice, pediatric, primary care):** – Private practice locations, including solo, group, or HMO practitioners, that provide vaccination services.
- **Refugee Health Clinic** – 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.

- **Residential/Congregate Care Facility** – Out-of-home settings, including group homes, childcare institutions, congregate foster care facilities, where onsite vaccination services are provided.

NOTE: If children in these settings receive vaccinations from a mobile provider or community vaccinator, then that provider type should be used.

- **Retail Health Clinic** – Health clinics located within grocery, drug, or retail stores that provide onsite vaccination services. Retail health clinics generally provide a focused range of protocol-driven health care services, such as the treatment of minor illnesses or injuries and vaccination services (e.g., Minute Clinic, Take Care Clinic).
- **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 also meet requirements of 42 CFR 405 and 491 and are able to supply a PDF version of a Centers for Medicaid Services (CMS) letter.
- **School-Based Clinics** – Permanent school-based clinics that provide vaccination services through 12th grade.

NOTE: For non-permanent school-based clinics, use the “Community Vaccinator” designation. The school-based clinic (permanent clinic location) provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., school-based clinic personnel) is administering vaccine.

- **State Hospital** – State-run hospital where on-site vaccination services are provided.

NOTE: For birthing hospitals, use the “Birthing Hospital or Birthing Center” designation. The Hospital provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., hospital or hospital-contracted personnel) is administering vaccine.

- **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.

- **Student Health Services** – Permanent school-based clinics that provide vaccination services for college/university students (e.g., Job Corps).
- **Teen Health Centers** – Health centers that are not public health department-sponsored and provide on-site vaccination services to teens/adolescents.
- **University Health System Clinic** – A clinic part of the University Health System.
- **Urgent/Immediate Care Center** - Locations that provide immediate medical outpatient care for the treatment of acute and chronic illness and injury. This provider type should be used for urgent care centers or walk-in clinics where on-site vaccination services are provided.
- **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.

- **Other** – Any provider type not captured in one of the other provider type options.

The ASN program was developed to ensure that adults who ordinarily seek services through DSHS 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
- 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)
- 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
- Providers enrolled in ImmTrac2
- FQHCs/RHCs
- Pharmacies
- Birthing hospitals
- Non-traditional immunization provider sites

D. Enrollment/Re-Enrollment

A TVFC/ASN Agreement Form must be completed at the initial enrollment and annually updated during re-enrollment in October. 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 all medical providers and payors to report all immunizations administered to clients who are 18 years of age and younger.

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 program 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 program 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 the TVFC program. 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 clinics enrolling in the TVFC/ASN programs must receive an initial site visit.

The purpose of the initial enrollment site visit is to educate providers on implementing TVFC program requirements and supply appropriate resources, as well as to confirm the provider can store and monitor vaccine supply according to program requirements. 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 anew enrollment.

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

- Contact clinic staff within two weeks of receipt of the enrollment form.
- Verify the identification of two clinic staff members as one primary and one backup vaccine coordinator.
- Verify that at least the two coordinators completed the current TVFC Provider Policy Training module (available at immunizetexas.com), the CDC “You Call the Shots” Modules 10 and 16 (available at cdc.gov/immunization-training/hcp/you-call-the-shots/), and the VAOS Training (available at dshs.texas.gov/immunizations/health-departments/training). If needed, provide assistance on how to accomplish these trainings. Other staff at the enrolling site are encouraged to complete the trainings. Refer to Chapter Seven: Site Coordinator Responsibilities for enrolled site vaccine coordinator responsibilities.
- Schedule and provide education using the “New Enrollment Checklist”, stock no. 11-15016, available at dshs.texas.gov/immunizations/health-departments/materials.

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:

- | | |
|----------------------------|---------------------------------|
| • Behavioral Health Clinic | • OB/GYN clinic |
| • Correctional facility | • Pharmacy |
| • EMS facility | • School-based clinic |
| • Hospital | • STD/HIV clinic; or |
| • Juvenile justice program | • 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, 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.



Note: 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 program enrollment form.

Federal VFC Patient Profiles

- 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.
- Uninsured numbers must be documented under the Federal VFC section.

TVFC Patient Profiles

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 be enrolled in the CHIP program. The clinic must bill CHIP for vaccine administration fees.
- Most children younger than one year-old receive Medicaid and not CHIP.
- The Immunization program provides DSHS PHR staff with the number of CHIP children younger than one year-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 program enrollment form, clinic sites that are not FQHCs, RHCs, or deputized DSHS PHR or LHD clinics must document numbers in this underinsured category.
- The RE must verify the numbers in each age group.
- Patient population data must be specific to the clinic site where a child will be vaccinated and not combined with other clinics' patient numbers. The numbers must be based on real data (e.g., registry or billing data) during re-enrollment. During initial enrollment, the clinic should project the number of patients that will be served in the upcoming year, including insured patients.
- Insured numbers must be documented.



Note: There are fewer than 100 children younger than one year-old enrolled in CHIP in Texas.

The following sites may document that they do not see privately insured patients:

- | | | |
|--|--|--|
| • Behavioral health clinic | • Hospital | • Rural Health Clinic (RHC) |
| • Birthing hospital | • Indian Health Service, Tribal, or Urban Clinic | • Some school-based clinics |
| • Community Vaccinator | • Juvenile Detention Center | • State Hospitals |
| • Correctional Facility | • Some LHDs | • Student Health Services |
| • DSHS public health clinics | • Migrant health centers | • STD/HIV sites |
| • EMS Facility | • Mobile providers | • Teen Health Center (non-health department) |
| • Family Planning Clinic (non-health department) | • Refugee health clinics | • University Health System |
| • Federally Qualified Health Center | • Residential/Congregate Care Facility | • Urgent/Immediate Care Center |
| • HHSC Family Planning Clinic | | |
- All patient profiles must be updated annually during re-enrollment or through a Changes to Enrollment form when population changes occur.
 - WIC clinics 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 following statements apply to TVFC only, ASN only, or both programs.

1. **(BOTH)** We will allow staff of DSHS, LHD, or DSHS Quality Assurance and Improvement (QAI) 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. **(BOTH)** We will maintain all records related to the TVFC/ASN program for five years, and upon request make these records available for review by DSHS, LHD, the DSHS QAI 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.
4. **(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.

5. **(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).
6. **(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.
7. **(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 ice maker 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 program vaccines is strictly prohibited. There are compact, purpose-built storage units for biologics that are not considered 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 months of spoilage/expiration.

8. **(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 (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.

9. **(BOTH)** This agreement may be terminated at any time by either party for failure to comply with these requirements. If the agreement is terminated for any reason, we agree to properly return all unused vaccines.

10. **(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)
- Report required data monthly (number of underinsured patients vaccinated, and number of doses administered, by age category)

11. **(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.

12. **(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.
13. **(TVFC ONLY)** For Medicaid patients, we will accept the reimbursement for an administration fee set by the State Medicaid agency or the contracted Medicaid health plans. We will not charge a TVFC program 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.
14. **(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.
15. **(TVFC ONLY)** We will not charge for the vaccines supplied by DSHS and administered to TVFC-eligible patients.
16. **(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 is enrolled in CHIP) and underinsured seen in public non-deputized sites and private clinics (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).
17. **(ASN ONLY)** We will screen patients for ASN program 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.
18. **(ASN ONLY)** We will not charge for the vaccines supplied by DSHS and administered to uninsured adults.
19. **(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.

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 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 (MSL), pre-filled syringes, single-dose vials, combination vaccines, etc. Maximum Stock Levels 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 program 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 PIN will be assigned by DSHS 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 Immunization 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, Immunization 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 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 shipping address (Complete Sections A and B)
- Facility shipping hours (Complete Sections A and C)
- Signing clinician (Complete Sections A and D)
- Primary or backup vaccine coordinator (Complete Sections A and E)
- TVFC patient population data change (Complete Sections A and F)
- ASN patient population data change (Complete Sections A and G)

NOTE: Providers who need to change their facility name or prescribing authorities must do so by completing an ImmTrac2 renewal in Syntropi.

LHD staff must assist providers with completing 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 submits the updated information via email to the designated DSHS Immunization program consultant. Depending on the changes made, providers or LHDs may be asked by the designated DSHS Immunization program consultant to take additional actions. During annual re-enrollment, all changes to a facility's information will be updated when completing the provider agreement.

3. Annual Re-Enrollment

TVFC/ASN program re-enrollment takes 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 time frame. 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 as part of the withdrawal process. 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 number.
- Facility names and addresses must not include periods (.), commas (,), question marks (?), asterisks (*), percentage symbol (%), ampersand (and), equals (=) symbol, or greater than (>) or less than (<) symbol.
- Shipping address is 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 clinician's, and the primary and backup vaccine coordinator's information must not include periods (.), commas (,), question marks (?), asterisks (*), percentage symbol (%), ampersand (and), 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:

- Behavioral Health Clinic
- Birthing Hospital or Birthing Center
- Community Vaccinator (non-health dept)
- Correctional Facility
- EMS Facility
- Family Planning Clinic (non-health department)
- Hospital
- Juvenile Detention Center
- Mobile Provider
- Pharmacy
- Private Practice (e.g., family practice)
- Residential/Congregate Care Facility
- Retail Health Clinic
- School-Based Clinic (permanent clinic location)
- STD/HIV Clinic (non-health department)
- Student Health Services
- Teen Health Center (non-health department)
- Urgent/Immediate Care Center
- Public facility types include:
 - Behavioral Health Clinic
 - Birthing Hospital or Birthing Center
 - Community Vaccinator (non-health dept)
 - Correctional Facility (DSHS Public Health Department clinic)
 - EMS Facility
 - Family Planning Clinic (non-health department)
 - Federally Qualified Health Center (FQHC)
 - Harris Health System
 - HHSC Family Planning Clinic
 - Hospital
 - Indian Health Service, Tribal, or Urban Clinic
 - Juvenile Detention Center
 - Local Health Department (LHD)
 - Migrant Health Center
 - Mobile Provider
 - Residential/Congregate Care Facility
 - Refugee Health Clinic
 - Rural Health Center (RHC)
 - School-Based Clinic (permanent clinic location)
 - State Hospital
 - STD/HIV Clinic (non-health dept)
 - Student Health Services
 - Teen Health Center (non-health dept)
 - University Health System
 - Urgent/Immediate Care Center
 - Women, Infants, and Children (WIC) Clinic

Verify CMS letter for sites that choose FQHC or RHC.

Ensure staff selected the appropriate category for offering all or select vaccines. Only specialty clinics can offer select vaccines. A “Specialty Provider” is defined as a provider that only serves:

1. a defined population due to the practice specialty (e.g., OB/GYN, STD, family planning, etc.)
2. a specific age group within the general population of children ages 0–18. Local health departments and pediatricians are not considered specialty providers.

NOTE: At the discretion of DSHS, mass vaccinators or those with special grants may offer only influenza 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, 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 clinics that are not designated as an FQHC/RHC or deputized DSHS PHR or LHD (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 12 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:

- Behavioral Health Clinic
- Birthing Hospital or Birthing Center
- Community Vaccinator
(non-health department)
- Correctional Facility
- DSHS Public Health Department Clinic
- EMS Facility
- Family Planning Clinic (non-health department)
- Federally Qualified Health Center
- Harris Health System
- HHSC Family Planning Clinic
- Hospital
- Indian Health Service, Tribal, or Urban Clinic
- Juvenile Detention Center
- Local Health Department (LHD)
- Migrant Health Center
- Mobile Provider
- Residential/Congregate Care Facility
- Refugee Health Clinic
- Rural Health Center (RHC)
- School-Based Clinic (permanent clinic location)
- State Hospital
- STD/HIV Clinic (non-health department)
- Student Health Services
- Teen Health Center (non-health department)
- University Health System
- Urgent/Immediate Care Center
- Women, Infants, and Children (WIC) Clinic
- 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 year of age enrolled in CHIP in Texas. If a site documents more than just a few children under one 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 deputed DSHS PHR or LHD clinics should document numbers in the underinsured category.
- 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 signature is the signing clinician's. If not, RE must request the signing clinician's signature on the re-enrollment.

Upon completion, the DSHS Immunization program staff uploads patient population information to VTckS; 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 program 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
- Each site location must be documented on a "Temperature Recording Form", stock no. EC-105.

Vaccines must be taken back to the vaccine home after the event.

NOTE: When a provider chooses to use a portable vaccine refrigerator/freezer unit to transport vaccines, they're required to follow the manufactures requirements regarding the use of use packing material, i.e., bubble wrap or cardboard. If it is found that the provider is not following the manufactures recommendations, they are out of TVFC program compliance.

Specific storage and handling requirements for mass vaccination clinics is discussed in the storage and handling section of this manual, in [Chapter 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 program staff verifies 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 program 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 days of the clinic's expected withdrawal date from the TVFC/ASN program.

- Complete a "Provider Withdrawal Form", stock no. F11-11443, or have withdrawing clinic complete it.
- Awardees must document the reason for unenrollment and who initiated the unenrollment in PEAR.
- Arrange to pick up all vaccines – viable and non-viable (expired/ruined).
- 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.
- 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:
 - 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. 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 program with a note to send the shipping label via email. This is the preferred method.
- In PEAR and the Immunization Quality Improvement for Providers (IQIP) Database (RedCap) Program, finalize all outstanding items.
- Within three business days of picking up the vaccine, the RE must submit the "Provider Withdrawal Form", stock no. F11-1144, to the DSHS Immunization program via email to the assigned consultant.

The DSHS Immunization program 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 program within three business 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 QAI 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 program 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 program 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 program 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 program Director. Terminated sites or clinicians are removed from the program for a period of at least one year.
- Those seeking re-enrollment following termination must seek approval from the DSHS Immunization program’s Vaccine Operations Group (VOG) Manager who will consult with the DSHS Immunization program Director, the PHR, and the RE.

J. Fraud and Abuse Reporting

All RE staff, DSHS Immunization program staff, and DSHS QAI contractor staff must immediately report all allegations of fraud, abuse, and other unlawful activities to the DSHS Immunization program who may notify the Office of Inspector General (OIG), as directed by OIG procedures. These procedures are located at oig.hhs.gov/fraud/report-fraud/.

The DSHS Immunization program 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.

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 program 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 QAI 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 program vaccine.
- Billing a patient or a third party for TVFC/ASN program vaccine (other than for an administration fee).
- Failing to meet licensure requirements for signing clinicians or those with prescribing authority.
- Providing TVFC/ASN program vaccine to patients that are not eligible.
- Failing to screen for and document TVFC/ASN program eligibility at every visit.
- Charging more than \$13.75 for administration of a TVFC program vaccine to an eligible child or more than \$25.00 for administration of an ASN program 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 program 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 program records for five years.
- Failing to fully account for TVFC/ASN program vaccine.
- Failing to properly store and handle TVFC/ASN program vaccines.
- Ordering TVFC/ASN program vaccines in quantities that do not match the clinic's population profile or otherwise over-ordering TVFC/ASN program vaccine doses.
- Loss of TVFC/ASN program vaccines due to negligence.

Responsible Entity (RE)

If there is an allegation of fraud or abuse against an enrolled TVFC/ASN program 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 training (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 to six 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 program.

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 program vaccines are used only for TVFC/ASN-eligible patients.

The TVFC/ASN “Patient Eligibility Screening Record”, stock no. C-10, for children and the ASN “Adult Eligibility Screening Record”, stock no.F11-12842 for adults, may be used to document the category of eligibility. Clinic staff must document the eligibility category of each client receiving TVFC/ASN program 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 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 program 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 or residency does not affect a child's eligibility for the TVFC program.

Additionally, while citizenship is not a requirement for TVFC eligibility, TVFC vaccines are not intended for children who are simply visiting the United States, temporarily traveling in the United States, or tourists.

Insured children that have Medicaid as their secondary insurance are eligible for TVFC program 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)
- Direct primary care

Visit the Texas Department of Insurance website for status of an insurance plan by the state of Texas.

C. ASN program Eligibility

Eligibility for all ASN program vaccines are only for uninsured adults aged 19 years and older.

Adult patients with insurance, including Medicare or Medicaid, are not eligible for ASN vaccines. 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.

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 Immunization program 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 seeking 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 must submit a Delegation of Authority (DOA) addendum form. REs must submit DOA addendum forms to the DSHS Immunization program 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 program monthly by the fifteenth. Reports must come through the online survey created by the DSHS Immunization program.

Chapter Three: Vaccine Management

Policy

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

Purpose

The purpose is to ensure vaccine confidence of all who receive TVFC/ASN program 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)
- Coronavirus (COVID-19)
- 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 groups A, C, W, and Y (MCV4)
- Meningococcal Conjugate groups A, B, C, W, and Y-135 (MCV5)
- Meningococcal type B (MenB)
- Mpox
- Pneumococcal Conjugate Vaccine (PCV)
- Pneumococcal Polysaccharide Vaccine (PPSV)
- Rotavirus (RV)
- Respiratory Syncytial Virus (RSV)
- Tetanus and diphtheria (Td)
- Tetanus, diphtheria, acellular pertussis (Tdap)
- Varicella (Chickenpox)

The ASN program supplies the 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.

- Coronavirus (COVID-19)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Measles, Mumps, and Rubella (MMR)
- Meningococcal Conjugate Vaccine (MCV4)
- Tetanus and diphtheria (Td)
- Tetanus, diphtheria, acellular pertussis (Tdap)

It may be necessary for the DSHS Immunization program 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.

The COVID-19 vaccine will remain available to enrolled ASN program providers on a temporary basis, and updates will be provided as they become available.

II. Vaccine Ordering

A. Vaccine Distributors

There are three vaccine distribution centers that service Texas.

- McKesson Specialty ships refrigerated TVFC/ASN program vaccines.
- Merck ships frozen TVFC/ASN program vaccines.
- Pfizer ships some TVFC/ASN program COVID-19 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 program staff
- CDC staff
- 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. Ad-hoc site closures that are outside of the site's usual hours must be listed on the provider's Closure Dates when placing an order in VAOS.

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 approved until they have reviewed the appropriate details, such as temperature recording forms, doses administered records, accuracy of physical to electronic inventory, vaccine loss forms, comments to increase/decrease vaccine requests, etc. Orders must not be left on hold or pending for more than three business days.

Vaccines that are on allocation by the CDC require a strict allocation process and must not be approved over the suggested quantity amount. DSHS Central Office will alert REs in the event that a TVFC/ASN vaccine is placed on allocation. In these events, all orders approved over the suggested quantity will be reduced by DSHS Immunization program if the vaccine is on allocation.

DSHS Immunization Program

The DSHS Immunization program 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 denied by the DSHS Immunization program.

CDC

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

Distributor

The distributor(s), McKesson, Merck, or Pfizer ships vaccine on Mondays, Tuesdays, Wednesdays, and Thursdays. McKesson has five business days from the day the order was uploaded into VTrckS to ship vaccines to the enrolled site. Pfizer and Merck have up to 15 business days from the day the order was uploaded into VTrckS to ship frozen vaccines. As a result, vaccine shipments may take more than two weeks to arrive at a facility after the provider's order is approved in VAOS. In many cases, sites will receive vaccines sooner. If any distributor experiences a disruption that delays orders, DSHS Central Office will communicate the reason and resolution to REs.

C. Ordering Influenza Vaccine

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

An official memo containing instructions for placing Flu Pre-book orders in VAOS is distributed to all TVFC-enrolled 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 program 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 requirement to provide all routine immunizations to all their patients.

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 program 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 program makes influenza vaccine allocations based on the following criteria:

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

The DSHS Immunization program sends an email notification every Monday to the primary and backup vaccine coordinators 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 swept by the DSHS Immunization program on Friday afternoon. Additional flu vaccine allocation will occur again the following Monday until all pre-booking requests are fulfilled. If a facility fails to accept the allocated amounts two weeks in a row, the RE must reassess the provider's allocation quantities.

When flu vaccine has been distributed to all sites that completed pre-book activities and all newly enrolled sites, the DSHS Immunization program opens influenza vaccine ordering of the remaining influenza vaccine inventory 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:

- Temperature Logs
- Doses Administered
- Physical Inventory

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 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 year of age during a 12-month period, compare the amount of DTaP doses ordered against this 100-patient estimate (three 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-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 ‘Sent to VTrckS’ or ‘Shipped’ status. Enrolled sites may override the suggested quantity but must provide a reason for the 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 deny the order. When an RE sees 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 consistently order the suggested quantity in VAOS, this may indicate a need to reduce MSLs.

Upon 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 each month automatically at the DSHS Immunization program level using doses administered data that is recorded in VAOS. Newly enrolled providers may have their MSLs manually reassessed by their RE after six 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.

DSHS Determines Automated MSL Calculations Are Determined With The Following:

- Twelve months of doses administered data from the previous year
- Divided by 12
- Multiplied by 2.5

Automated MSLs are then rounded up to appropriate pack size.

During Back-to-school, DSHS Calculates MSLs With The Following:

- Twelve months of doses administered data from the previous year
- Divided by 12
- Multiplied by 2.8

Back-to-school MSLs are then rounded up to the appropriate pack size.

DSHS Includes The Following Vaccines In MSL Calculations:

- | | |
|------------|-------------|
| • IPV | • MMRV |
| • DTAP | • HEP-A/B |
| • MCV4 | • TDAP |
| • DTAPHBIP | • HEP-A |
| • MENB | • TD |
| • DTAPHIPI | • HEP-B |
| • MMR | • VARICELLA |
| • DTAPIPV | • HPV |

Influenza, Hib, PCV15, PPSV23, and Rotavirus vaccines are not included in the back-to-school MSL calculation.

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 used 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 [Chapter Three: Vaccine Management, II. Vaccine Ordering, subsection E. Patient Profile Estimates and Provider Ordering](#).

Initial MSL

Upon 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. REs should regularly update their providers on formulary changes and product updates, which will be communicated by the DSHS Immunizations program. See the example paragraph under [Chapter Three: II. Vaccine Ordering, F. 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 complete monthly reporting prior to submitting their order for RE review and approval. If the provider expects to be closed or otherwise unavailable to receive deliveries at any point in next 2 months during their listed business hours, they must list these dates on the 'Facility' page when placing their order in VAOS. It is the RE's responsibility to review these Closure Dates when approving providers' orders to ensure that vaccines are not delivered while the Provider's staff are absent. Reviewing the provider's monthly reporting for accuracy applies even if no vaccines were ordered or administered. (See Chapter 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 provider's electronic inventory.
- 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.

NOTE: Vaccine that is not received in VAOS will impact suggested quantities that are available to the site when placing future orders.

C. Vaccine Received Warm or Questionable

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

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.

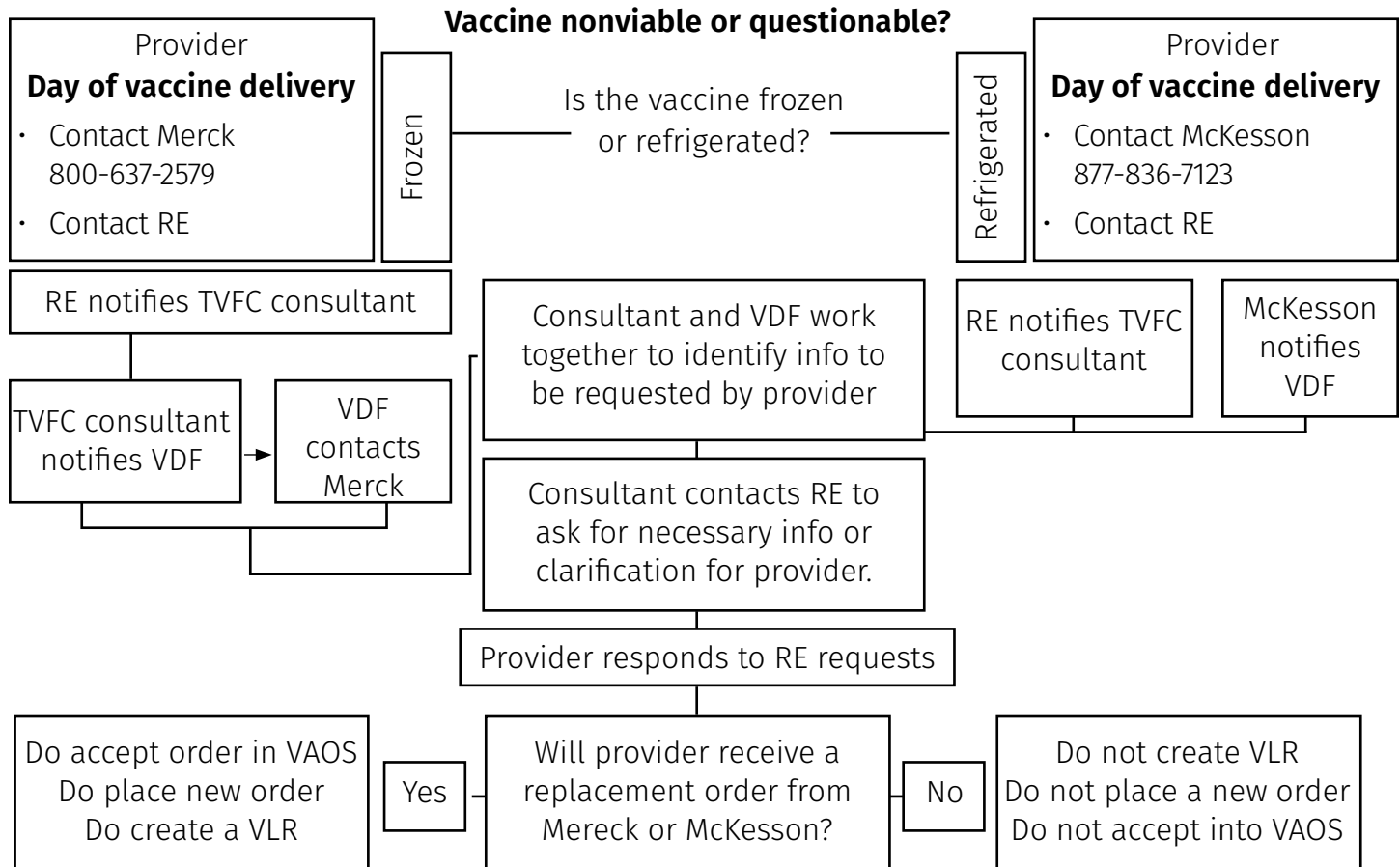
- Vaccine shipment with the temperature indicator strip showing that an out-of-range temperature occurred.
- A cooler that does not contain ice packs.
- A cooler that contains ice packs that are warm.
- Vaccine that is warm to the touch.
- Vaccine that is received damaged.
- Receiving vaccine not ordered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

REs, DSHS Central Office, and McKesson 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 Or Merck Directly

Clinic staff may only contact the distributor(s) (McKesson/Merck) when a shipment has a questionable temperature. 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 does not contact the distributor on the same day as the shipment's arrival, there will not be a replacement shipment. 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. Clinic staff must notify the RE of the situation.



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 marked as received in VAOS when it was in fact non-viable, the clinic staff must correct this in their “Monthly Biological Report”, and Physical Inventory. The staff need to update their “Monthly Biological Report”, by creating vaccine loss records for only the ruined vaccine on their “Monthly Biological Report”, 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 if the original Vaccine Shipment Number (VSN) was left unreceived, 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 program 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.

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 program 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 must 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 program 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.



Note: Do not return
expired/ruined/wasted vaccine

Negligent Vaccine Loss

Staff at enrolled TVFC/ASN-enrolled 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,
- Not stored properly upon receipt.

TVFC/ASN-enrolled sites may be required to reimburse the DSHS Immunization program 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 months of expiration or the date the vaccine was ruined/wasted.

Discard in a sharps container 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
- A needle has been attached to a pre-filled syringe
- Vaccine drawn into the syringe but not administered
- 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 [Chapter 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 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 deemed non-viable 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

Vaccine transfers are permitted between TVFC/ASN-enrolled 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. The routine re-distribution of TVFC/ASN program vaccine, flu vaccine as well as short-dated flu vaccine is not allowed. If a transfer must occur, TVFC/ASN program 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 vaccine coordinator, backup vaccine 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
- Number of doses that are being transferred

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 years, in accordance with TVFC/ASN programs requirements.

The RE must do the following:

- Educate clinic staff on the importance of cold-chain management as detailed in the TVFC/ASN Provider Manual
- 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 program 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 [Chapter 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 program 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 program Consultant to unsuspend the PIN.
- Request temperature logs documenting seven 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 occasionally provides 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 handle TVFC/ASN program vaccines 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 program 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.

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.

Any currently enrolled provider using both compartments of a household combination unit that is maintaining the required temperature ranges, may continue using the unit. If temperature excursions occur that can't be attributed to another cause (e.g., power outage), the provider must discontinue use of one of the compartments.

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

Auto-Dispensing Units

DSHS has approved the use of auto-dispensing or door-less units to store TVFC/ASN program 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.

A service record is required for auto-dispensing units if a certificate of calibration is not available. Servicing must be completed on auto-dispensing units as specified by the manufacturer. Monthly temperature logs must be recorded and submitted each month by the seventh. 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 immunizetexasorderform.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 program vaccine.

In addition, clinic sites are also required to have a certified, calibrated backup data logger that is unique from the primary device. It is required 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 QAI 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 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 years to the date of calibration. All certificates of calibration must be sent to your RE. Enrolled clinic sites with expired data logger certificates of calibration will be suspended until current certificates are received.

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; record the numbers on both sides of the decimal point and do not round (Ex: for 46.1F or 8.1C, note that the numbers to the right of the decimal meet the criteria for a temperature excursion. Similarly, 35.9F or 1.9C are also temperature excursions). If a temperature excursion occurs, TVFC/ASN program providers must reach out to the vaccine manufacturer to obtain guidance on vaccine viability.

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 program vaccine must have temperatures recorded for seven operational days with the min/max (twice daily) before a vaccine order is approved.

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

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 program vaccines. If other biologics must be stored in the same unit as TVFC/ASN program 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 program 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.

Refer to the CDC Storage and Handling Toolkit for more information.

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 program vaccine must be ordered and shipped directly to a location within the ordering site's DSHS PHR jurisdiction.
- 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 program 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 hour each way, the clinic may run for up to six 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
- Expiration dates

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 program 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 program 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 Chapter Five: Program Evaluation.

The completed document must be posted on or near the refrigerator/freezer units that contain TVFC/ASN program 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 program 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.

Chapter 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 7th 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 request corrections. Documentation of the contact/education must be documented in PEAR.

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.

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								

Figure 2. Example of Tracking Spreadsheet

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 program, 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 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 or four days .
- 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 program staff.

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 program staff			
		3. Order shipped	4. Order received	
	1. Order placed by clinic staff OR opened by RE	2. Order dropped by Immunization program staff		
			3. Order shipped	4. Order received
		1. Order placed by clinic staff OR opened by RE	2. Order dropped by Immunization program 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 3. Vaccine shipping schedule (not including flu) 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 program Staff			
3. Order shipped	4. Order received			
	1. Order placed by clinic staff OR opened by RE	2. Order dropped by Immunization program staff		
	3. Order shipped	4. Order received		
		1. Order placed by clinic staff OR opened by RE	2. Order dropped by Immunization program 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.

Merck Shipping Schedule (non-flu)				
Monday	Tuesday	Wednesday	Thursday	Friday
1. Order placed by clinic staff or opened by RE	2. Order dropped by Immunization program 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.

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 program 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 program 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 four, "Vaccine Storage Troubleshooting Record) of the temperature recording form was submitted. It contains information about the excursion. If page four 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 program staff.

- 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 program 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 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 program 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 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 and uploaded to VAOS.

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 program 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 program 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.

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 Chapter 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
- 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 Program

The DSHS Immunization program will review VLRs for potential vaccine restitution (dose-for-dose replacement of the vaccines). See [Chapter 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 program 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. In addition, borrowing between TVFC and ASN requires a vaccine borrowing report. Planned borrowing between the TVFC and ASN programs is not permitted. A vaccine borrowing form must be completed for the following reasons:

A dose of TVFC vaccine is administered to a non TVFC-eligible child.

- A dose of privately-purchased vaccine is administered to a TVFC-eligible child or an ASN-eligible adult.
- A dose of ASN vaccine is administered to a TVFC-eligible child.
- A dose of ASN vaccine is administered to a non ASN-eligible adult.
- A dose of TVFC vaccine is administered to an ASN-eligible patient.

If a TVFC/ASN program dose(s) is 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 program 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 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 seventh of each month, all ASN-enrolled sites must document the number of uninsured female veterans who received ASN program vaccines for the previous month using the Uninsured Female Veterans Reporting Form located online at dshs.texas.gov/immunizations/health-departments/materials. 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 program vaccine the previous month, the site staff must report zero in the survey.

Chapter Five: Program Evaluation

Policy

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

By signing the TVFC/ASN programs Agreement, the signing clinician agrees to allow PHRs, LHDs, and DSHS QAI 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 program 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 program 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 program policies.

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, six, nine, 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 program 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.

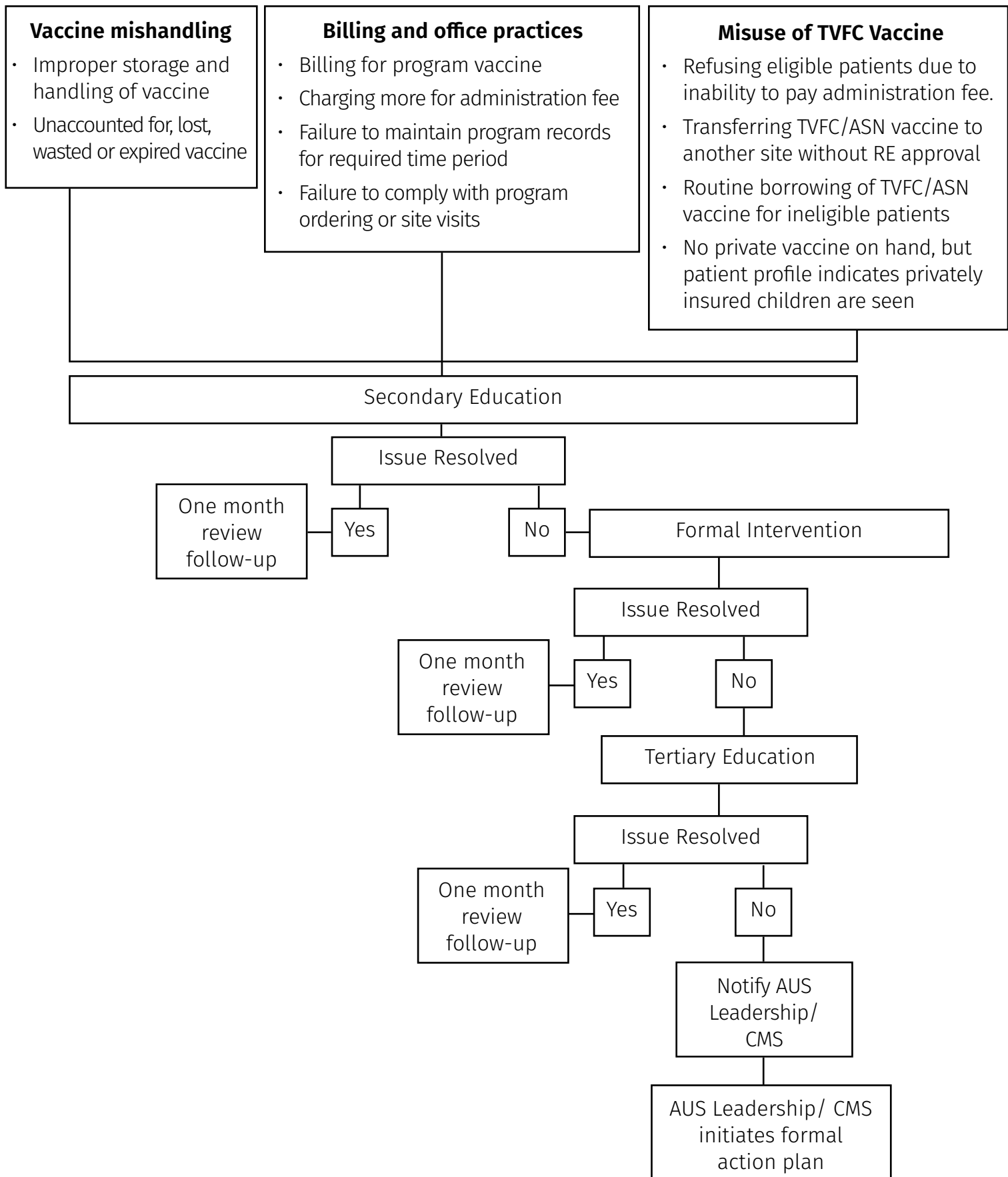


Figure 6. TVFC/ASN-enrolled site fails to comply with program rules.

II. Common Site Visit Structures: Compliance, IQIP, and Unannounced Storage and Handling

A. TVFC Compliance Site Visit

The purpose of the compliance visit is to assess, support, and educate the site regarding TVFC/ASN program policies and procedures. The purpose is not to critique. It is required that the signing clinician, primary vaccine coordinator, or backup vaccine coordinator be present and responsive for all site visit related activity.

- DSHS QAI Contractor (TMF) will conduct all annual TVFC/ASN compliance site visits
- All TVFC facilities will receive a site visit at least once every other year; however, visits may occur annually.
- DSHS QAI Contractor (TMF) 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 program 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 11 months but 12 months is ideal. Newly enrolled sites should receive a visit six to 12 months after initial enrollment.

It is required at least one of the following staff is present at all site visit related activities:

- Signing clinician
- Primary vaccine coordinator
- Backup vaccine coordinator

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 and entered into the PEAR database within 24 hours of the conducted site visit. Reports are available to the DSHS Immunization program 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 program staff will follow up to discuss the prevention of a recurrence.

At the conclusion of a compliance visit, DSHS QAI Contractor (TMF) 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.

At the end of the site visit, the vaccine coordinator or a signing clinician must sign the Acknowledgment of Receipt (AR) form, stock #s. 11-14888 or 11-14981 for compliance visits.

TVFC Compliance Follow-up Action Items

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. DSHS PHR and LHD staff (REs) must conduct all required follow-up action item activities listed in the PEAR database under the "follow-up action list" by the posted deadline. The RE must work with the clinic staff by providing education and guidance regarding corrective actions, including monitoring. REs must ensure all necessary documents are submitted in PEAR. 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 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 or email the clinic's vaccine coordinator to ensure the corrective actions have been implemented.

Not completing follow-up action items in PEAR by the listed deadline can result in a program suspension of the provider.

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 Chapter 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 Texas DSHS Immunization program staff.

B. Immunization Quality Improvement for Providers (IQIP) Site Visits

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. The IQIP site visit purpose is to also review procedures and clinic practices so that the TVFC program can assist in creating strategy improvement plans.

It is required that the signing clinician, primary vaccine coordinator, or backup vaccine coordinator be present and responsive to all site visit related activity, to include the two, six-month check-ins, and the 12-month IQIP follow-ups.

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
- Able to use available data from the registry 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.

Sites that will receive a combined IQIP and TVFC PEAR Compliance visit will be identified by DSHS Immunization program. Currently TVFC program Providers who qualify for an IQIP visit will get a visit termed as "Combination Site Visit" which will include their annual Compliance visit at the same time.

IQIP visits must be documented in the IQIP Database (REDCap) during the site visits. If internet access is not available, the visit must be entered within 24 hours of the initial visit.

IQIP Site Visit Follow-up Activities

The Texas DSHS Quality Assurance and Improvement (QAI) team will conduct all IQIP follow-up activities. Technical assistance and support are given virtually at two, six 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. IQIP check-ins at two months and six months and the 12-month follow-ups are required to be entered in the IQIP database within 10 days of their conducted date. Tentative follow-up visits will be scheduled in the IQIP database during the initial site visit.

Two And Six-Month IQIP Check-Ins

During the two and six-month check-in, the Texas DSHS QAI team will 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 the updated strategy plan, if necessary, and
- Enter data into IQIP Database (REDCap).

12-Month IQIP Follow-up

During the 12-month follow-up Texas DSHS QAI Team will 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.

For more information on conducting IQIP follow-ups, see the Texas IQIP Manual for REs.

C. Unannounced Storage and Handling (US and H) Visits

The RE conducts US and H visits that serve as “spot checks” for proper vaccine storage and handling. As with compliance site visits, US and H visits must be directly entered in PEAR within 24 hours of the visit being conducted.

The RE will prioritize sites for US and H 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 to 12 months after enrollment]
- Significant inventory adjustments, and
- Determination of the clinic’s non-compliance with corrective actions from previous visits.

If the RE identifies storage and handling issues, they must review findings 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 program clinics in their jurisdictions.

It is important for REs to monitor the list of clinics scheduled for a compliance visit from Texas DSHS QAI contractor to ensure a US and H is not conducted when a compliance visit is scheduled. The timing between a compliance visit and a USH is three to six months. Annually, Texas DSHS QAI provides a list of selected TVFC program PINs to the QAI contractor to conduct appropriate typed site visits to meet program requirements. Interrupting this process results in a delay of compliance visits.

At the end of the site visit, the appropriate TVFC program key provider staff who were present are required to sign the “Acknowledgment of Receipt (AR)” form, located in PEAR for storage and handling visits.

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

D. Documenting Site Visit, AR Forms

The Acknowledgment 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 primary vaccine coordinator, backup vaccine coordinator or signing clinician understands the actions needed to correct/address the non-compliance issues, if applicable.

The RE must use the most current AR form available in PEAR (under the Documents tab) with the following sections completed:

- Provider/Facility Name
- Provider TVFC PIN Number (6 digits)
- Site Visit Number : mmddyyyyTXA000000 (visit date)(TXA PIN #)
- Site Visit Reviewer Name (first and last)
- Site Visit Reviewer Email Address
- Site Visit Date
- Name of Medical Director (or equivalent) if they are present at the visit OR if Medical Director (or equivalent) is not present, name of Primary Vaccine Coordinator, Backup Vaccine Coordinator, or Signing Clinician that was present at the visit
- Signature of Site Visit Reviewer
- Signature of provider who was present at the visit

The AR form must be signed By the primary vaccine coordinator, backup vaccine coordinator, or the signing clinician at the site at the end of the site visit.

When the LHD conducts the site visit, they are required to submit completed AR forms to their DSHS PHRs within three operational dates of the US and H and S and H site visit and the PHR manager will submit to Texas DSHS QAI team within three days of receipt. When a PHR conducts the site visit, completed AR forms must be submitted to the Texas DSHS QAI team within five operation days of the US and H and S and H site visit.

NOTE: All users who have access to Center of Disease Control (CDC) Quality Assurance and Improvement (QAI) Databases (PEAR and REDCap) must complete and submit certificates for the trainings below annually:

- Module 10 CDC You Call the Shots: Module 10
- Module 16 CDC You Call the Shots: Module 16
- VAOS Vaccine Allocation and Ordering Systems
- Current Annual Policy Training Vaccine Education Online

The DSHS Immunization program is required to monitor those who have been granted access to PEAR and RedCap, 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 program review the list of employees conducting site reviews or conduct PEAR/IQIP follow-up to ensure the list is up to date.

III. 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 surveys yearly.

Annual TVFC/ASN Provider Satisfaction Survey

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. A survey link will be sent to providers when it is time to re-enroll in the program(s)

Site Visit Assessment Survey

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 allows the clinic staff to provide feedback about their experiences during the visit.

Chapter Six: Documentation Requirements

I. The Texas Immunization Registry (ImmTrac2)

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

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 to ImmTrac2 within 30 days of administration of the vaccine. Refer to the ImmTrac2 Site Registration Guide (stock no. 11-15175) and ImmTrac2 Site Renewal Through Syntropi (stock no. 11-16804) on how to register a new site and renew an agreement.

ImmTrac2 is designed to consolidate immunization records from multiple sources throughout the state including:

- Electronic Data Exchange with ImmTrac2 from Electronic Health Record (EHR) systems
- Registered organizations have easy access to immunization records for participating clients
- Forecasts immunizations coming due or past due
- Various reports available for ImmTrac2 users including “Reminder” and “Recall” capabilities

Parent or guardian consent for ImmTrac2 participation is required for clients younger than 18 years of age. Adults may also consent to ImmTrac2, which stores their immunization information for a lifetime. Individuals who turn 18 years old and were participating in ImmTrac2 as a minor, must sign an adult consent form by their 26th birthday to keep their immunization information in ImmTrac2. At the patient's 18th birthday, the immunization record stored in ImmTrac2 will be “hidden” from view until an adult consent form is signed. If a patient does not sign an adult consent form, the record will be deleted from ImmTrac2 on the patient's 26th birthday.

TVFC-enrolled sites must register as an authorized organization with ImmTrac2 by completing a site registration in Syntropi. Call the ImmTrac2 Customer Support Line at 800-348-9158 or visit the ImmTrac2 webpage at dshs.texas.gov/immunizations/providers/overview for information about ImmTrac2 or to register.

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):

- V01 for Private Pay/Insurance: Patient is younger than 19 years old
- V02 for Medicaid: Patient is younger than 19 years old
- V03 for No Insurance: Patient is younger 19 years old
- V04 for American Indian/Alaskan Native: Patient is younger than 19 years old
- V05 for Underinsured, FQHC/RHC/Deputized: Patient is younger than 19 years old
- TXA01 for CHIP: Patient is younger than 19 years old
- TXA02 for Underinsured, Not FQHC/RHC/Deputized: Patient is younger than 19 years old
- TXA04 for Adult, No Insurance: Patient is 19 years old and older
- TXA05 for Adult, Underinsured: Patient is 19 years old and older
- TXA06 for Adult, Private Pay/Insurance: Patient is 19 years old or older

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 years following the end of the disaster declaration. In order for the information to remain in ImmTrac2 past the initial five years, the client must sign a Disaster Information Retention (DIR) Consent Form (stock no. F11-12956)

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 [texreg.sos.state.tx.us/public/readtac\\$ext.ViewTAC?tac_view=4&dti=25&pt=1&ch=100&rl=Y](http://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=4&dti=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
- Health care providers
- Pharmacists
- Vaccine manufacturers

Health care providers are encouraged to report all clinically significant adverse events after vaccination to VAERS, even if it is unclear whether the vaccine caused the event. Providers are also required by federal law to report certain adverse events found in the VAERS Table of Reportable Events. Some reporting requirements are vaccine specific.

Generally, reporting is also required for events described in a manufacturer's package insert as contraindications to additional doses of vaccine and for acute complications or sequelae including death.

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. Bilingual immunization records for clinics, the “Vaccine Information Documentation Form”, stock no. C-100, and clients, the “Personal Immunization Record”, stock no. C-102, and the “Adult Immunization Record Card”, stock no. C-104, can be ordered free-of-charge from DSHS at immunizetexasorderform.com.

Chapter 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. Both vaccine coordinators must provide a unique email address for user security and contact purposes.

Primary and backup vaccine coordinators at all TVFC/ASN-enrolled sites must complete the following trainings:

- [TVFC/ASN “Provider Policy Training” module](https://learningportal.hhs.texas.gov/course/view.php?id=354)
- [VAOS Training](https://dshs.texas.gov/immunizations/providers/training-and-Quiz) [dshs.texas.gov/immunizations/providers/training and Quiz](https://dshs.texas.gov/immunizations/providers/training-and-Quiz) survey.alchemer.com/s3/6801123/Vaccine-Allocation-and-Ordering-System-Quiz
- CDC “You Call the Shots” training module 10
- CDC “You Call the Shots” training module 16

TVFC/ASN-enrolled 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 program 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 program vaccine inventory information
- Place orders for TVFC/ASN program 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 program 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.



Note: Once the notification is received, the site will have 10 business days to designate and onboard a replacement coordinator and submit a Changes to Enrollment Form (stock no. 11-15224).

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. If a new coordinator is not onboarded (including the completion of all required trainings) at the end of the tenth 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 and Improvement (QAI) 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) immediately through a Changes to Enrollment Form (stock no. 11-15224)
- 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 years and upon request, make those records available for review
- Submit a patient population profile representing populations served annually, or if patient population 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 the vaccines supplied by DSHS
- Ensure uninsured adults are not charged for the 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 Chapter Two: Standard and Policies, Subsection I. Fraud and Abuse Reporting.

Chapter Eight: Responsible Entity 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
- 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.

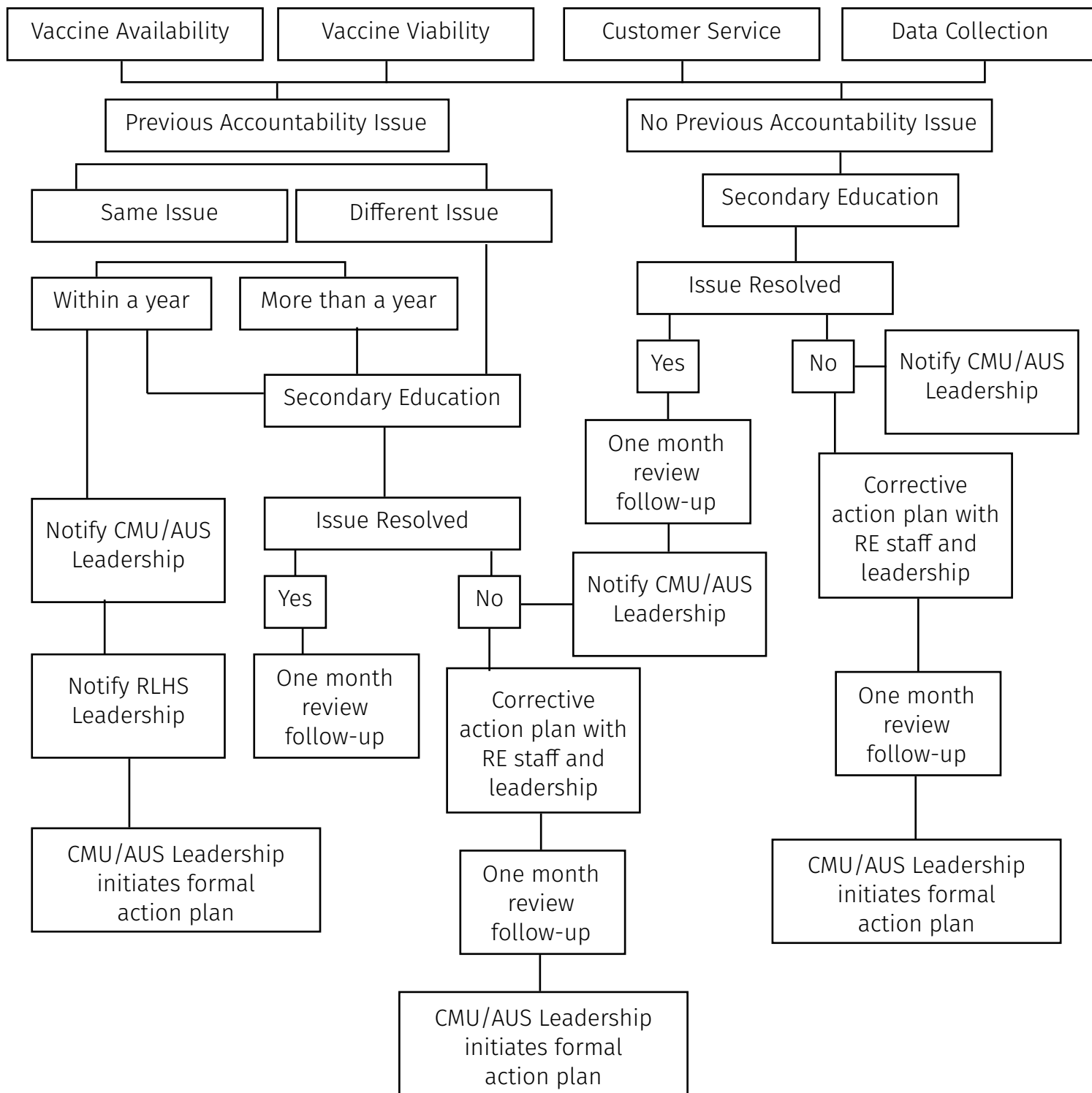


Figure 7. RE fails to comply with program requirements.

Chapter 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 or to the DSHS Immunization program. 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 program when the PHR is the RE. Figure 10 lists documentation submission timeframes.

When LHD is the RE for Enrolled Sites	
The LHD Receives:	The LHD Submits Information to:
Clinic withdrawal form	PHR*
CMS letter from FQHCs/RHCs (new enrollments)	PHR
Enrollment form updates/changes	PHR*
New enrollment form (TVFC/ASN Program Provider Agreement)	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 program.	
** VLRs must be submitted to DSHS Immunization program only when a correction to a vaccine loss designation is necessary.	

Figure 8. Form submission from LHD to PHR.

When PHR is the RE for LHD Clinics or Enrolled Sites	
The PHR Receives:	The PHR Submits Information to:
Clinic withdrawal	DSHS Immunization program
CMS letter from FQHCs and RHCs (new enrollments)	
Enrollment form updates/changes	DSHS Immunization program
New enrollment form (TVFC/ASN Program Provider Agreement)	DSHS Immunization program
New enrollment checklist	DSHS Immunization program
Training certificate for primary/backup vaccine coordinators	
Temperature recording form	
Vaccine borrowing form	
Vaccine loss report*	DSHS Immunization program
Vaccine management plan	
Vaccine transfer authorization form	

* VLRs must be submitted to DSHS Immunization program only when a correction to a vaccine loss designation is necessary.

Figure 9. Form submission from PHR to DSHS Immunizations.

Documentation Submission Deadlines			
Activity	Clinic	LHD to PHR	PHR to DSHS Immunization program
Monthly reports	By the seventh of each month		
Female veteran reporting	By the seventh of each month		
Withdrawal Form		Within three days of picking up vaccine	Within three days of picking up vaccine or receipt from LHD
Vaccine Loss Report Form	Generate within four days of loss	When received	When received
Delegation of Authority		Annually, when requested	Annually, when requested
Acknowledgment of Receipt (AR) Form		Within three days of USH visit	Within three days of site visit or USH or within five 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 fifteenth of each month		

Figure 10. Documentation submission dates.

Chapter 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

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

Chapter 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, 2024, stock no. 6-105
- Recommended Immunization Schedule for Adults 19 Years or Older, United States 2024, 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 dshs.texas.gov/immunizations/health-departments/materials

Chapter Twelve:

Immunization Resources

CDC Immunization Website	cdc.gov/vaccines/
CDC Immunization Schedules	cdc.gov/vaccines/imz-schedules/index.html
CDC Vaccines for Children (VFC) Website	cdc.gov/vaccines-for-children/about/index.html
CDC Vaccine Storage and Handling Toolkit	cdc.gov/vaccines/hcp/storage-handling/
CDC “You Call the Shots” Training	cdc.gov/immunization-training/hcp/you-call-the-shots/
ImmTrac2, the Texas Immunization Registry	immtrac.com
Immunization Action Coalition	immunize.org/
Standards for Adult Immunization Practice	cdc.gov/vaccines-adults/hcp/imz-standards/
Immunization Quality Improvement for Providers Program	dshs.texas.gov/immunizations/providers/compliance
Texas DSHS Immunization Website	immunizetexas.com
Texas Vaccine Education Online	https://learningportal.hhs.texas.gov/course/index.php
Texas DSHS Program Information for REs	dshs.texas.gov/immunizations/health-departments/overview
Vaccine Manufacturers Contact List	
Vaccine manufactures should be contacted in the event of a temperature excursion to your vaccine storage unit. Refer to the vaccine manufacturer information as listed on the box.	
Vaccine Manufacturers Phone Numbers	GlaxoSmithKline 888-825-5249 Astra Zeneca 800-236-9933 Merck 800-672-6372 Sanofi Pasteur 800-822-2463 Seqirus USA, Inc 855-358-8966 Pfizer 800-438-1985 Grifols 888-474-3657

Chapter Thirteen:

Program Contact Information

TVFC/ASN Program Contact Information	
DSHS Immunization Section	800-252-9152 vaccallcenter@dshs.texas.gov
Responsible Entity Contact	
PINS Beginning with Responsible Entity Phone Number	
00 City of San Antonio	210-207-3965
01	PHR 1 806-391-1323
02	PHR 2 325-795-5660
03	PHR 3 817-264-4790
04 or 05 not in Hardin, Jefferson or Orange Counties	PHR 4/5N 903-944-9956
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

2025 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.
- Updated grammatical errors.

Chapter 1: General Information

- Updated recruitment section (page 16)
- Clarified when patient populations need to be updated during annual re-enrollment, all changes to a facility's information will be updated when completing the provider agreement (page 20)

Chapter 2: Standards and Policies

- Updated steps for the Changes to Enrollment Form (CTEF) (page 25)
- Providers who need to update facility information and prescribing authorities must complete an ImmTrac2 renewal in Syntropi (page 25)
- While citizenship is not a requirement for TVFC eligibility, TVFC vaccines are not intended to be used for children who are simply visiting the United States, temporarily traveling in the United States or tourist (page 39)
- Reports must come through the online survey created by the DSHS Immunization program (page 41)

Chapter 3: Vaccine Management

- Updated calculation for MSLs (page 49)
- Changed MSL calculation from six-months to twelve (page 49)

Chapter 5: Program Evaluation:

- Included language for site visits (page 80)

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