



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Texas Vaccines for Children and Adult Safety Net Provider Manual



Texas Department of State Health Services

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Table of Contents

Introduction to the 2018 Provider Manual and the Texas Vaccines for Children (TVFC) Program	9
I. Provider Manual Information	9
II. Public Health Law Establishing the Vaccines for Children (VFC) Program	9
III. Vision and Mission of the DSHS Immunization Unit	10
IV. Goals of the DSHS Immunization Unit	11
V. Goals of the TVFC Program	11
CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT	13
I. Provider Eligibility Requirements	13
II. Provider Enrollment Requirements	13
A. Specific Terms of Agreement	13
B. Initial Enrollment	15
C. TVFC Enrollment Visit	18
D. TVFC Site Set-up	21
E. Vaccine Accountability	22
F. Provider Identification Number	23
G. Provider Change of Information	24
H. Annual Re-Enrollment	24
I. Deputization of Clinics	25
III. Provider Withdrawal from TVFC	26

IV. Provider Suspension from TVFC _____	26
V. Provider Termination from TVFC _____	27
VI. Re-enrollment after Termination _____	27
CHAPTER 2: TVFC PATIENT ELIGIBILITY AND SCREENING ____	29
I. Patient Eligibility Requirements _____	29
A. TVFC Patient Eligibility Criteria _____	29
B. Children's Health Insurance Program _____	30
C. Medicaid as Secondary Insurance _____	31
D. Nineteen-year Olds _____	31
II. Patient Eligibility Screening Record _____	31
CHAPTER 3: VACCINE MANAGEMENT _____	35
I. Approved Vaccines _____	35
II. Vaccine Ordering _____	36
A. Vaccine Choice _____	36
B. Vaccine Inventory Plan and Maximum Stock Levels ____	38
C. Increasing and Decreasing Maximum Stock Levels ____	39
D. Short-Dated Vaccine _____	40
E. Storage Capacity for Vaccine Orders _____	41
F. Vaccine Ordering in the Electronic Vaccine Inventory (EVI) System _____	41
G. Vaccine Ordering for TVFC Providers without Internet Access _____	45

H.	Vaccine Ordering for Newly Enrolled TVFC Providers__	45
I.	Ordering Influenza Vaccine _____	46
J.	Vaccine Ordering for Mass Vaccination Clinics _____	48
III.	Vaccine Distribution _____	49
A.	Vaccine Distributors _____	49
B.	Receiving Vaccine Orders _____	49
C.	Manufacturer and Distributor Maintenance of the Cold Chain _____	52
D.	Vaccines Received Warm or Questionable _____	53
E.	Vaccines Received in Error _____	54
IV.	Vaccine Loss _____	55
A.	Expired, Spoiled, and Wasted Vaccine _____	55
B.	Procedures for Vaccine Loss _____	57
C.	Negligent Vaccine Loss _____	60
V.	Vaccine Storage and Handling _____	61
A.	Refrigerator and Freezer Requirements _____	62
B.	Data Logger Requirements _____	70
C.	Vaccine Storage Requirements _____	77
D.	Protective Equipment _____	78
E.	Personnel _____	78
F.	Mass Vaccination Clinic Requirements _____	80
G.	Routine and Emergency Storage and Handling Plan __	81

H. Vaccine Protection in the Event of an Emergency _____	84
I. Cold Chain Management and Vaccine Transport _____	86
VI. Vaccine Transfers _____	95
VII. Vaccine Borrowing _____	97
VIII. Reporting Requirements _____	99
A. Reports Summary _____	100
B. Monthly Requirements _____	103
CHAPTER 4: BILLING AND ADMINISTRATION _____	105
I. Billing for Vaccine _____	105
II. Administration Fee _____	105
CHAPTER 5: PROGRAM EVALUATION _____	109
I. Provider Site Visits _____	109
A. Compliance Site Visits _____	109
B. AFIX Site Visits _____	110
II. Common Site Visit Structures _____	112
A. Combined TVFC Compliance and Initial AFIX Site Visit _____	112
B. TVFC Compliance Site Visit Only _____	113
C. Initial AFIX Site Visit Only _____	113
D. AFIX Follow-up Site Visit Only _____	113
E. Unannounced Storage and Handling Visit _____	113
III. Follow-Up Activities _____	114

IV. Electronic Medical Records (EMRs)_____	116
V. Annual TVFC Provider Feedback Survey_____	116
CHAPTER 6: FRAUD AND ABUSE _____	119
I. Fraud and Abuse _____	119
II. Definitions _____	119
III. Examples _____	120
IV. Failure to Comply with TVFC Requirements _____	121
V. Fraud and Abuse Prevention _____	122
VI. Reporting Fraud and Abuse _____	122
CHAPTER 7: DOCUMENTATION REQUIREMENTS _____	125
I. Vaccine Record Keeping Requirements _____	125
II. The Texas Immunization Registry (ImmTrac2) _____	127
III. Addressing Vaccine Hesitancy _____	128
IV. Vaccine Adverse Events _____	129
CHAPTER 8: ADULT SAFETY NET PROGRAM _____	131
I. Adult Safety Net (ASN) Overview _____	131
II. Provider Types _____	132
III. ASN Enrollment _____	132
IV. ASN Patient Eligibility _____	133
A. Eligibility Criteria _____	133
B. Nineteen year Olds _____	134
C. Patient Eligibility Screening Record _____	134

V.	ASN Vaccine Formulary _____	136
VI.	Provider Enrollment Requirements _____	136
A.	Specific Terms of Agreement _____	136
B.	Initial Enrollment _____	139
C.	ASN Enrollment Visit _____	139
D.	ASN Site Set-up _____	139
E.	Vaccine Accountability _____	140
F.	Provider Identification Number _____	140
G.	Provider Change of Information _____	141
H.	Annual Re-Enrollment _____	141
VII.	Vaccine Ordering _____	141
A.	Vaccine Choice _____	141
B.	Vaccine Inventory Plan and Maximum Stock Levels _	143
C.	Increasing and Decreasing Maximum Stock Levels __	144
D.	Short-Dated Vaccine _____	144
E.	Storage Capacity for Vaccine Orders _____	144
F.	Vaccine Ordering in the Electronic Vaccine Inventory (EVI) System _____	144
G.	Vaccine Ordering for ASN Providers without Internet Access _____	145
H.	Vaccine Ordering for Newly Enrolled ASN Providers _	146
VIII.	Vaccine Storage _____	146

IX: Vaccine Management _____	146
X. Vaccine Transfers _____	147
XI: ASN Billing and Administration _____	147
A. Billing for ASN Vaccine _____	147
B. ASN Administration Fee _____	148
XII: ASN Site Visits _____	148
A. Adult Immunization Standards _____	148
B. Types of Adult Site Visits _____	151
C. Site Visit Scheduling and Clinic Access _____	152
D. Components of the ASN Site Visit _____	153
E. Electronic Medical Record (EMR) Review _____	154
XIII. Mobile Vaccination Clinics _____	155
XIV. Reporting Doses Administered _____	156
XV. Fraud and Abuse _____	156
A. Definitions _____	156
B. Examples _____	156
C. Failure to Comply with ASN Requirements _____	158
D. Fraud and Abuse Prevention _____	158
E. Reporting Fraud and Abuse _____	159
CHAPTER 9: VACCINE INFORMATION STATEMENT (VIS) _____	161
CHAPTER 10: ORDERING FORMS AND LITERATURE _____	163
CHAPTER 11: IMMUNIZATION RESOURCES _____	165
TVFC Program Contact Information _____	167

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Vision: 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.

Introduction to the 2018 Provider Manual and the Texas Vaccines for Children (TVFC) Program

I. Provider Manual Information

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

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

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

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

Funding from the federal VFC Program is supplemented with federal 317 funds that allow the federal purchase of vaccines and State General Revenue funds to support TVFC, and all immunization activities across Texas. Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels.

TVFC enables over 4.3 million Texas children to have access to immunizations. This is accomplished through a network of support provided by the Department of State Health Services (DSHS) and with assistance from DSHS Health Service Regions (HSRs) and contracted Local Health Departments (LHDs). These organizations function as Responsible Entities to ensure compliance with state and federal standards and the effectiveness of vaccine distribution. As a provider, you will contact your **Responsible Entity (DSHS HSR or LHD)** for more information and for the details about required vaccine reporting.

III. Vision and Mission of the DSHS Immunization Unit

Vision: A Texas free of vaccine-preventable diseases.

Mission: To remove barriers to complete and timely vaccination, increase vaccine coverage levels, and reduce the

burden of vaccine-preventable diseases for all Texas infants, children, adolescents, and adults.

IV. Goals of the DSHS Immunization Unit

- Raise and sustain vaccine coverage levels for infants and children;
- Improve adolescent vaccine coverage levels;
- Improve adult vaccine coverage levels;
- Prevent and reduce cases of vaccine-preventable diseases;
- Maintain and improve public health preparedness; and
- Promote and practice the safe handling of vaccines and ensure the accountability of all program components.

V. Goals of the TVFC Program

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

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CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT

I. Provider Eligibility Requirements

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

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

II. Provider Enrollment Requirements

A. Specific Terms of Agreement

In order to participate in the TVFC Program, each provider must agree to follow all program requirements. By signing the Texas Vaccines for Children (TVFC) Program Provider Agreement, the office and all practitioners associated with the medical office agree to the following:

- Submit a provider profile representing populations served by the facility annually;
- Screen for and document TVFC eligibility of all children at each immunization encounter;

CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT

- Administer TVFC vaccine to all children 18 years of age or younger who meet the established eligibility criteria;
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP);
- Maintain all records related to the TVFC Program for at least five years and upon request, make these records available for review;
- Immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine;
- Not charge an administration fee in excess of \$14.85 per vaccine dose;
- Not charge an administration fee to Medicaid or Children's Health Insurance Program (CHIP) patients;
- Not deny administration of a TVFC vaccine to an eligible child because of the inability of the child's parent or guardian to pay the administration fee;
- Not send a patient to collections or charge additional fees for non-payment of a TVFC administration fee;
- Provide a copy of the most current Vaccine Information Statements (VIS) for each vaccine at the time of administration;
- Comply with the TVFC Program requirements for vaccine management, including ordering and proper storage and handling practices;

CHAPTER 1: TVFC PROVIDER ELIGIBILITY AND ENROLLMENT

- Not be cited or terminated from Medicaid or CHIP;
- Operate within the TVFC Program in a manner intended to avoid fraud and abuse;
- Participate in TVFC compliance site visits, including unannounced visits and other educational opportunities, as required; and
- Acknowledge that the DSHS Immunization Unit may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office and/or facility agrees to return all TVFC vaccines.

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

B. Initial Enrollment

The first step in becoming a TVFC Provider is completing the TVFC Program Provider Agreement (E6-102) form. If you need assistance, you can call your Responsible Entity, Department of State Health Services Health Service Region (DSHS HSR) or

Local Health Department (LHD). The TVFC Program Provider Agreement is available on the DSHS Immunization Unit website at:

<http://www.dshs.texas.gov/immunize/tvfc/ProviderResources.shtm>.

The TVFC Program Provider Agreement must be completed and updated each year. The agreement includes basic information about the facility and responsible provider. It also outlines the provider's responsibilities. The signed provider agreement must be received and processed by the TVFC Program prior to the clinic receiving state and federally funded vaccines.

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

Information required for the health care providers include:

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

If the primary provider who signed the TVFC Program Provider Agreement leaves the practice, the program agreement must be updated at that time and signed by the new primary health care provider.

The Provider Profile section of the TVFC Program Provider Agreement requests information about the provider's patient population, which includes the projection and identification of clients the clinic will serve in the upcoming year. Existing providers must provide accurate data from the previous 12 months and include the number of insured patients. These numbers must be specific to the clinic site and not combined with other clinics' patient numbers. Data sources must include, but are not limited to:

- Immunization registry;
- Benchmarking;
- Number of Medicaid Claims or other billing data; and
- Client encounter data.

The Responsible Entity will assist the provider through the enrollment process. The provider must designate two staff members as the primary and back-up TVFC vaccine coordinators. The two staff members will be informed by the Responsible Entity on how to complete the two (2) required CDC "You Call the Shots" training modules and the 2018 TVFC Provider Policy Training module upon initial enrollment. After completing the modules, the Certificates of Completion must be included with the TVFC Program Provider Agreement when it is returned to the DSHS HSR responsible for the county in which the provider is located.

The provider may also choose to enroll in the Texas Immunization Registry (ImmTrac2) at this time. If the provider chooses to enroll, they will be provided information on how to submit the ImmTrac2 Registry form online.

The TVFC Program checks the Office of the Inspector General's (OIG) List of Excluded Individuals or Entities to ensure that a pending provider is eligible to participate in the TVFC Program.

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

The PIN is required to be included on all TVFC forms and communications. Providers should enter their TVFC PIN into their ImmTrac2 user account. Information regarding ImmTrac2 may be found in [Chapter 7: Documentation Requirements](#) and on the ImmTrac2 webpage:

<http://www.dshs.texas.gov/immunize/immtrac>. The provider's office will be contacted by the Responsible Entity at this time, to schedule New Provider Training.

C. TVFC Enrollment Visit

All providers enrolling in the TVFC Program must receive an enrollment visit prior to receiving any vaccine through the TVFC Program. When the Responsible Entity visits the provider's office, a review of all storage units in the provider's office is

The primary vaccine coordinator and back-up vaccine coordinator must both be available to meet with the Responsible Entity on-site for the duration of the initial enrollment visit.

performed to ensure adequate and approved storage units are being used. A certified and calibrated data logger is placed in all units that will store the TVFC vaccine at this time, and logged for 10 business days before any TVFC vaccine is supplied. New Provider Training is also conducted on all TVFC Program policies to ensure that they are understood and followed.

The initial enrollment visit typically takes a minimum of three (3) hours. The primary vaccine coordinator and back-up vaccine coordinator must both be available to meet with the Responsible Entity on-site for the duration of the initial enrollment visit.

Information for new providers is available electronically at:

<http://www.dshs.texas.gov/immunize/tvfc/provider-enrollment.aspx>.

New Provider Training includes:

- Review and confirmation that the provider and staff understand and can implement all TVFC Program requirements.
- Confirmation of the following:
 - The provider has the proper equipment to maintain the TVFC vaccine;
 - The staff understands how to properly store, handle, and monitor the TVFC vaccine; and
 - The staff knows who to contact if problems arise.

- Verification of the following:
 - The provider has identified a primary and back-up vaccine coordinator;
 - The provider has a plan for routine vaccine management;
 - There are adequate water bottles in the refrigerator and frozen water bottles in the freezer; and
 - Vaccine storage units have enough storage space to accommodate the provider's maximum capacity of vaccine.
- Review of the following forms:
 - Vaccine Choice Selection; and
 - Vaccine Management Plans.
- Training also includes review of the following:
 - TVFC Program Provider Manual;
 - Vaccine Ordering & Accounting (Electronic Vaccine Inventory [EVI] System);
 - Vaccine Storage and Handling;
 - Vaccine Quarantine Bag;
 - Immunization Guidelines/Schedules;
 - School/Day Care requirements;
 - ImmTrac2;
 - Forms and Literature;
 - Vaccine Information Statements (VIS);
 - Vaccine Adverse Events Reporting System (VAERS);

- Vaccine Safety and other resources;
- Standards of Child & Adolescent Immunization Practices;
- Standards of Adult Immunization Practices (for providers who also administer an ASN Program site);
- Vaccine types;
- Administering vaccines;
- Schedule and intervals of vaccines;
- Anatomic sites;
- Needle sizes; and
- Contraindications and precautions.

D. TVFC Site Set-up

Once temperature charts are logged for 10 business days and temperatures are within the required range, the Responsible Entity begins the TVFC Program site set-up process and performs the following activities to ensure that vaccines are stored and handled appropriately:

- Checks the equipment:
 - Placement of data loggers and their calibration certificates; and
 - Verifies that plug guards are installed.
- Trains the new provider on essential processes:
 - Vaccine choice options;
 - Establishing maximum stock levels (MSLs);
 - Online vaccine management in EVI;

- Setting up the initial order;
- Creation of a Vaccine Management Plan; and
- Completion of the Temperature Recording Form.
- Checks that the following signage is displayed prominently within the clinic:
 - “Vaccine Management - Recommendations for Storage and Handling of Selected Biologicals” Poster;
 - “How to Administer Injections” Poster;
 - “Guide to Contraindications” Poster;
 - “Giving All the Doses” Chart;
 - Refrigerator Warning Signs; and
 - “Do Not Unplug” stickers on wall outlet and circuit breaker.
- Provides Recommended Immunization Schedules, Catch-up Schedules, Resource Lists, and other materials to the provider.

If any of the items above were not provided to you as a new TVFC provider, please contact your Responsible Entity to have any missing items sent to you.

E. Vaccine Accountability

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

As of 2017, provider re-enrollment takes place each November for the following year.

All TVFC providers must ensure:

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

F. Provider Identification Number

A Provider Identification Number (PIN) will be assigned to the provider upon initial enrollment into the TVFC Program. The PIN will be the clinic's vaccine account number for the duration of the clinic's enrollment in the TVFC Program.

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

Providers should enter their TVFC PIN into their ImmTrac2 user account. Information regarding ImmTrac2 may be found in [Chapter 7: Documentation Requirements](#) and on the ImmTrac2 website: <http://www.dshs.texas.gov/immunize/immtrac>.

G. Provider Change of Information

It is the TVFC provider's responsibility to maintain correct demographics, days and hours available to receive vaccine shipments, and profile information in the EVI system. The TVFC Program requires that when a provider changes location or if there is a new provider staff member acting as the primary and/or back-up vaccine coordinator, the Responsible Entity must be contacted immediately to inform them of the change. In addition, the TVFC Program requires that the provider update the information in EVI. New primary or back-up contacts are required to complete the CDC "You Call the Shots" and TVFC Provider Policy Training modules.

The TVFC Program Provider Agreement and Provider Profile must also be updated if the provider's patient population changes and/or when the provider who signed the form is no longer associated with the clinic.

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

H. Annual Re-Enrollment

As of 2017, provider re-enrollment will take place in November for the following year. The TVFC Program requires that the TVFC Program Provider Agreement and Provider Profile be updated annually. These forms are required for continued enrollment in the TVFC Program. TVFC providers that are a

Federally Qualified Health Center (FQHC) or a Rural Health Center (RHC) should also submit a copy of the Centers for Medicare & Medicaid Services (CMS) letter.

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

Certificates of Completion for the TVFC Provider Policy Training module must be included with the signed enrollment form and will be submitted to their Responsible Entity electronically as part of the re-enrollment process.

Vaccine shipments may be interrupted for TVFC providers who do not have current enrollment information on file.

Note: For TVFC providers who are also enrolled in ASN, the TVFC and ASN re-enrollment forms have been combined into a single re-enrollment form for your convenience.

I. Deputization of Clinics

Deputization is used to support areas where an FQHC/RHC is unable to serve an underinsured population. If an FQHC/RHC is unable to serve a specified population, then DSHS HSRs and LHDs are the second line to serve as a "safety net" for the underinsured. Texas has implemented deputization of public health department clinics and LHDs. Delegation of Authority

(DOA) or deputization, allows Texas FQHCs and RHCs to delegate authority for vaccinating underinsured children. Underinsured children served in FQHC, RHC, or deputized sites are eligible for federal VFC vaccine according to federal guidance.

III. Provider Withdrawal from TVFC

Any TVFC provider wanting to withdraw from the TVFC Program must contact their Responsible Entity to arrange for vaccine pick-up and assistance with final paperwork. Prior to withdrawal, the provider must complete a Provider Withdrawal Form and submit the form to their Responsible Entity.

IV. Provider Suspension from TVFC

If a provider violates the agreement and accountability requirements that are part of participating in TVFC, they may temporarily lose their ordering privileges. Suspension is dependent upon the severity of the non-compliance issues and/or failure to complete the TVFC required corrective action plans. TVFC corrective action plans are set in place to correct failures in vaccine management and non-compliance issues, including, but not limited to, failure to complete re-enrollment in a timely manner, failures in vaccine management, improper storage and handling practices, and failure to complete monthly reporting requirements. Providers may be asked to complete additional training as part of the corrective action plan.

V. Provider Termination from TVFC

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

A TVFC provider may also be terminated for instances of fraud and abuse, as described in [Chapter 6: Fraud and Abuse](#), of this manual.

All TVFC providers are notified of their termination from the program via a signed letter from the Immunization Unit Director. Terminated TVFC providers are removed from the TVFC Program for a period of at least one year. Providers seeking re-enrollment following the minimum termination period must seek approval to re-enroll from the Immunization Unit's Vaccine Operations Group (VOG) Manager.

VI. Re-enrollment after Termination

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

TVFC providers terminated for instances of fraud and abuse may be considered for re-enrollment after one year, and only if

the provider is actively enrolled in Medicaid at that time and is not listed on OIG's List of Excluded Individuals and Entities (LEIE).

The Immunization Unit Vaccine Management Group (VMG) Manager and Vaccine Operations Group (VOG) Manager, in consultation with the Immunization Unit Director, have the authority to determine whether or not a provider is eligible to re-enroll in the TVFC Program.

CHAPTER 2: TVFC PATIENT ELIGIBILITY AND SCREENING

I. Patient Eligibility Requirements

A. TVFC Patient Eligibility Criteria

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

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

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

If a child is TVFC-eligible in more than one eligibility category, the provider must select and document the eligibility category

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

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

that will require the least out-of-pocket expense for the parent or guardian.

Immigration status does not affect a child's eligibility for the TVFC Program.

B. Children's Health Insurance Program

Texas has an insurance program called the Children's Health Insurance Program (CHIP). An agreement between the DSHS Immunization Unit and CHIP stipulates that vaccines for eligible CHIP enrollees are purchased through the federal contract. Since children with CHIP are not eligible for the federal VFC Program, the DSHS Immunization Unit is reimbursed for doses administered to CHIP children based on CHIP enrollment data. The Vaccine Purchase Estimator Tool (VPET) is a tool provided by the CDC, which is used to estimate the number of vaccine doses required to fully vaccinate the state of Texas' enrolled CHIP population with all applicable vaccines that are given quarterly. Each TVFC provider who administers VFC vaccines to CHIP children are required to bill CHIP for the vaccine administration fees. The CHIP pays the provider an administration fee and reimburses the DSHS Immunization Unit for the cost of the vaccines that were administered to CHIP children.

C. Medicaid as Secondary Insurance

If a child has private health insurance and Medicaid as secondary insurance, the child is TVFC-eligible. The provider can administer TVFC vaccine to the child and bill Medicaid for the administration fee. The parent or guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine administration fee.

D. Nineteen-year Olds

Patients who are 19 years of age and who previously initiated a vaccination series under the TVFC Program, but have not completed the series, may complete the series using ASN vaccines regardless of their current health insurance status. The vaccine must be administered by an ASN provider at a DSHS HSR or LHD clinic. This provision only applies to patients that have not yet reached their 20th birthday.

II. Patient Eligibility Screening Record

Screening for patient eligibility is the foundation of provider-level accountability. Screening all children at every immunization encounter and documenting eligibility screening at every visit is the only way to ensure that TVFC vaccine is used only for TVFC-eligible children. As such, full compliance on screening for eligibility is required. In the event improper screening results in the administration of TVFC vaccine to a

non-TVFC-eligible child, providers are responsible for replacing the improperly used TVFC vaccine with private stock.

Providers are required to document the eligibility of each child receiving TVFC vaccine at every visit. During a child's initial visit to the provider site, the provider must document the child's eligibility category per the TVFC Program guidelines and update the child's eligibility information during each future visit.

Providers may use the Patient Eligibility Screening Record (C-10) or may electronically store patient demographic information. Eligibility screening must be completed/updated for all children at every visit, even including children with a previous record on file. A child's eligibility must be documented at every visit prior to vaccine administration. The parent, guardian, or provider may complete the Patient Eligibility Screening Record. Verification of parent/guardian response is not required.

Documentation of eligibility screening must include the following elements:

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

The Patient Eligibility Screening Records must be kept on file with the patient's record, by all providers, for a minimum of five years after the last date of service to the patient and must be easily retrievable.

It is also acceptable for providers to utilize electronic medical records (EMR) system to capture and save the information from the Patient Eligibility Screening Records as long as the EMR captures all the required eligibility elements.

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CHAPTER 3: VACCINE MANAGEMENT

I. Approved Vaccines

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

- Diphtheria and Tetanus toxoids, adsorbed (DT)
- Diphtheria-Tetanus toxoids and acellular Pertussis (DTaP)
- Diphtheria-Tetanus toxoids and acellular Pertussis, Hepatitis B, and inactivated polio (DTaP-Hep B-IPV)
- Diphtheria-Tetanus toxoids and acellular Pertussis, inactivated polio, and *Haemophilus influenzae* type b (DTaP-IPV/Hib)
- Diphtheria-Tetanus toxoids and acellular Pertussis and inactivated polio (DTaP-IPV)
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Hepatitis A and Hepatitis B (Hep A - Hep B) combination
- *Haemophilus influenzae* type b (Hib)
- Human Papillomavirus (9vHPV)
- Influenza (Flu)
- Inactivated polio (IPV)
- Measles, Mumps, and Rubella (MMR)
- Measles, Mumps, Rubella, and Varicella (MMRV)

- Meningococcal groups C and Y and *Haemophilus influenzae* b (tetanus toxoid) (HIBMENECY)
- Meningococcal Conjugate (MCV4)
- Meningococcal Serogroup B (MenB)
- Pneumococcal Conjugate (PCV13)
- Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
- Rotavirus (RV)
- Tetanus and diphtheria toxoids, adsorbed (Td)
- Tetanus and diphtheria toxoids and acellular Pertussis (Tdap)
- Varicella

II. Vaccine Ordering

A. Vaccine Choice

The TVFC Program supplies all ACIP recommended vaccines and toxoids to enrolled providers. Providers participating in the TVFC Program are required to offer all ACIP recommended vaccines to the eligible populations they serve, including influenza vaccine. House Bill 448 from the 81st Texas Legislature gives TVFC providers the opportunity to choose their preferred brands and presentations of vaccines from their available formularies.

The provider who signs the TVFC Program Provider Agreement can choose vaccine brands and presentations. For new TVFC providers, the Responsible Entity (DSHS HSR or LHD) will create the initial vaccine order using the Pediatric Biological

Order Form (EC-68-1). The Pediatric Biological Order Form will reflect the provider's vaccine choices, their maximum stock level (MSL), and order quantity.

Each quarter, TVFC providers will have the opportunity to choose the brand and presentation for each TVFC vaccine in the Electronic Vaccine Inventory (EVI) system. They can change or adjust specific vaccine brands, presentations, and percentages within each vaccine "family" (i.e., DTaP), or take no action to maintain the current selections. Providers are encouraged to review all choice selections on a quarterly basis.

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

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

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

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

The suggested quantity is the maximum number of doses a provider needs to maintain the 75-day inventory.

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

B. Vaccine Inventory Plan and Maximum Stock Levels

The vaccine inventory plan requires all enrolled providers to maintain a **75-day supply** of vaccine inventory. All Providers should place vaccine orders monthly. The CDC recommends that providers place orders when they have a four week supply of vaccine available, to ensure there is enough vaccine in stock to allow for any potential delays. The CDC also recommends smaller, more frequent orders rather than larger orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. Providers may place additional orders. Providers are not required to order each month, but as needed to maintain a 75-day supply of vaccine.

The maximum stock level (MSL) is a calculated peak dose inventory (per vaccine type). The suggested quantity is the maximum number of doses a provider needs to maintain the 75-day inventory. Providers must take into account their current inventories and unit storage capacities when placing orders to ensure that they have adequate storage for all vaccines. **Special circumstances may allow for monthly MSL adjustments on rare occasions.** The provider must

request a review and obtain permission from their Responsible Entity prior to ordering more than their suggested MSL quantity.

Upon initial enrollment, the Responsible Entity will work with the TVFC provider to develop MSLs based on the provider's patient population. All MSLs are monitored and revised in EVI. Newly enrolled providers may have their MSL reassessed by their Responsible Entity after 6 months with the TVFC Program. MSLs are recalculated on a monthly basis based upon doses administered data. The monthly average MSL is determined from this data. Providers may not order vaccine in excess of their suggested quantity without permission from their Responsible Entity.

See [Section VIII. Reporting Requirements](#), for more detail of the monthly reporting requirements.

C. Increasing and Decreasing Maximum Stock Levels

A provider's MSL may be increased or decreased at any time if the number of TVFC-eligible children served changes, or if there are any applicable changes to the status of the facility that might impact vaccine usage. **TVFC providers can notify their Responsible Entity if they feel a change is needed.** Changes may also be made by the DSHS Immunization Unit based upon the data gathered during the calendar year.

To determine appropriate MSLs for the Back-to-School season, calculations will be done by the DSHS Immunization Unit to determine the new MSL utilizing the reporting data from the previous calendar year.

Providers that consistently order below their suggested quantity may have their MSL lowered. Providers that place multiple orders during a given month may have their MSL increased. Final determination is made depending on the frequency and duration of the provider's ordering pattern.

D. Short-Dated Vaccine

Short-dated vaccines are those vaccines that are within 90 days of expiration. Placing orders according to the established MSLs and rotating vaccines so that short-dated vaccines are used first will help to prevent losses due to expiration. Clinic staff must note vaccine expiration dates when physically counting inventory at the end of the month. Short-dated vaccine must be used first. Vaccine surplus kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of refrigerator failure. When ordering vaccines, TVFC providers must have no more than the designated MSL in stock and including the order.

Each TVFC provider is required to notify their Responsible Entity **90 days prior** to the expiration of vaccine. If the provider is unable to administer the vaccine prior to expiration, the

Monthly reporting in EVI is required for all TVFC providers, whether or not an order is placed.

Responsible Entity may assist with moving the vaccine to another provider site, provided another provider is willing to accept the vaccine.

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

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

E. Storage Capacity for Vaccine Orders

A TVFC provider must have adequate refrigeration and/or freezer space to accommodate a maximum order based on their MSL, including flu. A TVFC provider must also take into consideration the space needed for their private stock when calculating storage capacity.

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

The TVFC Program uses the EVI system for vaccine ordering. EVI allows TVFC providers to manage their vaccine inventory online. All vaccine orders will be placed in EVI unless internet

access is unavailable. A TVFC provider may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

Prior to placing an order, TVFC providers are required to enter the following information into EVI:

- Verification of days and hours of operation that the provider is available to receive the vaccine;
- The delivery address;
- Primary and back-up point of contact information;
- All vaccine received;
- All vaccine doses transferred;
- Any expired, spoiled, or wasted vaccine;
- All doses administered within the last calendar month;
- A physical count of all vaccines by brand, presentation, lot number, and expiration date within two days of placing their online order (C-33 report);
- If applicable, all doses that will expire within 90 days; and
- Any scheduled clinic closures (including holidays) must be noted in the comments section of the order.

Monthly reporting is required for all TVFC providers, whether or not an order is placed.

Providers must also submit the following reports to their Responsible Entity via fax or a scanned copy:

- Temperature logs (EC-105)
- Vaccine Loss Reports, if applicable
- Borrowing form (EF 11-14171), if applicable.

All orders placed in EVI will be reviewed and approved by the Responsible Entity pending the TVFC provider's completion and submission of the required monthly reporting forms and resolution of any outstanding issues. Incomplete or inaccurate online orders will be placed on "Hold", pending corrections by the TVFC provider, which may cause orders to be delayed.

Each TVFC provider must abide by their established MSLs when ordering vaccine. EVI uses the TVFC provider's MSLs and current inventory to determine a suggested quantity of vaccine on the "Place Order" tab. Any orders exceeding the MSL will be reviewed on a case-by-case basis.

Vaccine loss is captured electronically in EVI. When a TVFC provider documents, as required, any expired, spoiled, or wasted vaccine in EVI, the system will automatically place subsequent orders on "Hold" until the nature of the loss has been determined.

All TVFC providers are able to view their order status on the “Order History” page of EVI. Status definitions are the following:

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

If any discrepancy is found between the orders placed, the packing list, the fax confirmation, or the doses received, TVFC providers are instructed to immediately contact their Responsible Entity for resolution. All vaccines must be appropriately stored immediately upon receipt regardless of any errors in the order.

G. Vaccine Ordering for TVFC Providers without Internet Access

A TVFC provider without access to the internet will contact their Responsible Entity, who will then enter the TVFC provider's order online. The TVFC provider will submit the following paper forms to their Responsible Entity so that vaccine order can be placed:

- Monthly Biological Report (C-33);
- Pediatric Biological Order Form (EC-68-1); and
- Temperature Recording Form(s) (EC-105).

The Monthly Biological Report is reviewed by their Responsible Entity to ensure that the beginning inventory matches the last month's ending inventory. Calculations must be correct and the net loss or gain must not exceed five doses of any one vaccine. Any corrections needed are reported to the TVFC provider so the records can be corrected prior to ordering.

H. Vaccine Ordering for Newly Enrolled TVFC Providers

Newly enrolled TVFC providers are set up for vaccine ordering in EVI during New Provider Training with their Responsible Entity. The order is placed by the TVFC provider as part of the training.

The Responsible Entity collects and reviews the following paper reports prior to placing the new TVFC provider's vaccine order:

- Pediatric Biological Order Form (EC-68-1); and
- Temperature Recording Form(s) (EC-105).

I. Ordering Influenza Vaccine

ACIP recommends routine annual influenza vaccination of all persons aged 6 months and older. Additionally, as a provider for the TVFC Program, you have agreed to administer all ACIP recommended vaccines to the eligible population that you serve.

The pre-book is a commitment by the TVFC provider to order doses for the upcoming flu season. Annual influenza vaccine orders are typically pre-booked by TVFC providers in the first quarter of each calendar year. TVFC providers will use an online survey tool to select their vaccine choices for the upcoming season. The link to the survey is made available to the TVFC providers in a memo and includes a brief description of the influenza vaccines available for the upcoming flu season.

If the orders exceed the expected number of eligible children from the TVFC provider profile, providers may be contacted for an explanation. If a TVFC provider who sees TVFC-eligible children does not order influenza vaccine for the upcoming season, they must complete a separate section of the survey explaining why they are not ordering the vaccine. A TVFC

provider is required to follow all ACIP recommendations, including the administration of influenza vaccine. A TVFC provider who does not order influenza vaccine will receive a follow-up phone call from their Responsible Entity or the TVFC Program.

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

Influenza vaccine will be allocated to TVFC providers as it is made available to Texas. The TVFC Program typically completes all pre-booked and new TVFC provider orders first as part of the first round allocation. A second influenza survey tool will be re-opened for TVFC providers that did not order during the pre-book period. TVFC Providers who wish to add to their original order may also order additional vaccine during this second round. When the first and second round orders are filled entirely, any remaining influenza vaccine will be added to the EVI system for general ordering by all TVFC providers. If there is an additional need for influenza vaccine, the TVFC Program will contact other TVFC providers in Texas for a possible vaccine transfer or place an additional order with the CDC.

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

J. Vaccine Ordering for Mass Vaccination Clinics

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 clinic) require enhanced storage and handling practices.

The TVFC provider must develop mass vaccination protocols to ensure outreach efforts meet all TVFC requirements, including:

- Showing the established vaccine needs (e.g., provider profile);
- A plan for overseeing vaccine ordering for each clinic site to ensure that proper amounts of TVFC stock are transported on each clinic day;
- The type of portable storage unit being used;

It is important to recognize and store vaccine shipments immediately upon receipt to ensure vaccine viability.

- How the cold chain will be maintained from the beginning to the end of the mass vaccination clinic; and
- Each site location should be documented on the Temperature Recording Form (EC-105).

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

Specific storage and handling requirements for mass vaccination clinics is discussed in the storage and handling section of this Chapter, in [Section V- Vaccine Storage and Handling, subsection F. Mass Vaccination Clinic Requirements](#).

III. Vaccine Distribution

A. Vaccine Distributors

The TVFC Program uses two vaccine distribution centers:

- McKesson Specialty, a third party distributor which ships the majority of TVFC vaccines; and
- Merck, the manufacturer of Varicella vaccines, which ships directly to providers.

B. Receiving Vaccine Orders

The TVFC Program requires that TVFC providers always accept vaccine shipments and never refuse or return the shipments without specific instructions from the TVFC Program or from

their Responsible Entity. The TVFC provider must ensure that the accurate clinic address and delivery hours are entered into EVI.

In order for TVFC providers to receive vaccine shipments, appropriate staff must be on site and available at least one day a week other than Monday and for at least four consecutive hours during the hours of 8:00 a.m. – 5:00 p.m. Each TVFC provider establishes the hours available to accept vaccine shipments when they submit their initial vaccine order in EVI. The vaccine will be shipped so that it will arrive when the provider is available to accept the order. The TVFC provider will not be able to change their available hours in EVI once an order is placed. The TVFC provider will be held responsible for incomplete or erroneous information entered into EVI which can result in vaccine loss.

The TVFC provider can expect their approved orders approximately two to three weeks after placing their online order in EVI. It is important to recognize and store vaccine shipments immediately upon receipt to ensure vaccine viability. All TVFC providers are required to train their staff on what a vaccine shipment looks like and have a vaccine management plan in place to ensure the vaccine is stored quickly and correctly upon arrival.

The following steps are required when a vaccine shipment arrives:

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

Each package shipped from McKesson comes with a temperature monitoring strip(s). If the monitor strip(s) indicates, or if staff suspects that the cold chain has been

compromised, staff must immediately follow the instructions in subsection D below, [“Vaccines Received Warm or Questionable”](#).

All TVFC providers are required to record the vaccine at the time of receipt in EVI to maintain correct online vaccine inventory.

C. Manufacturer and Distributor Maintenance of the Cold Chain

The manufacturer and distributor pack the vaccine using qualified pack-outs and containers that have been tested to maintain appropriate temperatures. Refrigerated vaccine is packed to maintain the cold chain for 72 hours. The vaccine will be shipped using high quality cardboard boxes with Styrofoam inserts.

Packages are imprinted with “Temperature Sensitive Product” and include red stickers reading “Refrigerate upon Arrival” to alert clinic staff to refrigerate contents immediately upon arrival.

Varicella and MMRV are directly shipped from Merck. Merck products are shipped frozen with a four-day pack-out. If the vaccine arrives within four days of the pack date on the invoice, then the vaccine is viable. The TVFC provider must immediately place all vaccines in proper storage. If the vaccine arrives outside of the four-day pack-out, then the TVFC

provider must immediately place the vaccine in a Vaccine Quarantine Bag provided by the TVFC Program, store the vaccine properly, notify their Responsible Entity, and contact the manufacturer.

D. Vaccines Received Warm or Questionable

Vaccines must always be stored properly, even if viability is questionable. If vaccines are received warm, damaged, or in an otherwise questionable state, the TVFC provider must immediately contact their Responsible Entity. Questionable vaccine cannot be identified visually and must be placed in a Vaccine Quarantine Bag provided by the TVFC Program and separated in proper storage until viability can be determined.

Examples of questionable (potentially non-viable) vaccines:

- Vaccine shipment received with temperature indicator strip showing out of range;
- Vaccine is warm to touch; or
- Vaccine is received damaged.

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

- Separate the questionable vaccine in a Vaccine Quarantine Bag and place questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine itself.

- Contact the manufacturer immediately to determine the viability of the vaccine. If the manufacturer is unable to respond, the provider must inform their Responsible Entity.
- Contact your Responsible Entity on the same day the vaccine arrived at the TVFC provider's office. Any calls received after the day of delivery will result in the CDC's liability for vaccine replacement, regardless of the cause of the temperature excursion. This documentation must be maintained with the provider's TVFC records for a minimum of five years.
- Inform the Responsible Entity of the determination of the viability of the vaccine.
- All TVFC providers must keep the vaccine quarantined and wait for the instructions for replacement, reporting loss, etc.

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.

E. Vaccines Received in Error

TVFC providers must call their Responsible Entity immediately upon receipt of vaccines that are received in error. The TVFC provider may opt to keep the vaccine if they have storage capacity and will administer the doses. If the TVFC provider cannot absorb the vaccine into their stock, then their Responsible Entity may assist in redistributing the vaccine to other TVFC providers to prevent vaccine wastage.

Spoiled and expired vaccine must be returned to the distributor within 6 months of the loss.

IV. Vaccine Loss

A. Expired, Spoiled, and Wasted Vaccine

The Immunization Unit requires all unopened or unused vials and syringes of expired TVFC vaccines be returned to the third-party distributor (McKesson). Vaccine manufacturers reimburse CDC for the federal excise tax portion of the cost of the vaccine. Therefore, providers should not discard any vaccine unless specifically directed by the DSHS Immunization Unit, DSHS HSR or LHD. Any exception to this rule will be communicated by the DSHS Immunization Unit on a case-by-case basis. Providers are to immediately notify their Responsible Entity of vaccine cold chain failure events or vaccine wastage incidents involving TVFC vaccines upon discovery of the incident.

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

- Natural disaster/power outage;
- Refrigerator being too warm or too cold;
- Freezer too warm;
- Failure to store vaccine properly upon receipt;
- Vaccine spoiled in transit;
- Mechanical failure; or
- Recall.

Wasted vaccine is any non-viable vaccine that cannot be returned for excise tax credit. This includes:

- Vaccine drawn into the syringe but not administered;
- Vaccine in open vial multi-dose vial where all doses have not been administered (partial vial);
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility);
- Lost vial;
- Vaccine drawn into the syringe but refused by the patient;
- Incorrect vaccine that has been prepared for patient; and/or
- Incorrect diluent drawn for vaccine.

Wasted and expired/spoiled vaccines should be removed from the storage unit, labeled “Do Not Use,” and stored pending return to distributor. Expired diluents do not need to be returned. Lost vials are expected to be adjusted on the provider inventory.

Vaccine loss must be documented on a Vaccine Loss Report (VLR) electronically in EVI no later than four days past the date of the incident(s). All vaccine returns to McKesson must occur within six months of the loss. The third party distributor, McKesson, will document Texas losses and return vaccines to the manufacturer for excise tax credit.

B. Procedures for Vaccine Loss

Every dose of vaccine that is lost (wasted, spoiled, or expired) must be reported to the TVFC Program on a Vaccine Loss Report electronically generated in EVI. Spoiled and expired vaccine must be returned to the distributor within 6 months of the loss.

Providers are to follow the procedures listed below when vaccine loss occurs:

- Remove expired/spoiled vaccine from the vaccine storage unit and place in a Vaccine Quarantine Bag.
- Contact your Responsible Entity immediately with the following information:
 - Antigen;
 - Lot number;
 - Expiration date; and
 - Reason for expiration/loss.
- If storage was compromised, provide the Responsible Entity with amount of time product was out-of-range and the highest and lowest temperatures recorded (this information may be gathered from the data logger download).
- Document the vaccine loss on the Vaccine Loss Report electronically generated in EVI within four days past the date of the incident of loss. Explain the cause(s) of the loss and outline the steps taken to ensure vaccines will be protected in the future.

- The Vaccine Loss Report must also be printed and signed by the medical provider who signed the TVFC Program Provider Agreement or any medical personnel with prescribing authority listed on your Provider Agreement. The report must then be emailed or faxed to the Responsible Entity within four days of the date of the loss.
- The Vaccine Loss Report includes the following sections:
 - Clinic demographics;
 - Date loss was discovered;
 - Type of loss;
 - Reason for loss;
 - Corrective action taken to avoid re-occurrence;
 - List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost.

TVFC providers will receive a shipping label from McKesson for returning non-viable vaccine, if applicable. The provider must wait until UPS returns for the pickup to avoid paying a fee.

- Providers must ensure that all vaccines listed on that Vaccine Loss Report are included in the box for return (except for dropped or broken vials/syringes).
- If more than one box is used to return non-viable vaccine, providers must indicate on the Vaccine Loss Report the number of the box in which the vaccine is being shipped (e.g., "Box 1 of 2," "Box 2 of 2," etc.).

- Any wasted vaccine listed on the Vaccine Loss Report (dropped or broken vials/syringes) should be marked through with a single line as they are not included in the box for return.

Important Note: Only unbroken, sealed vaccine vials/syringes may be included for return. Broken vials/syringes, open multi-dose vials, or exposed syringe needles should NEVER be included in the box.

Providers will have to wait until UPS returns to their office with the next delivery to return the box with the non-viable vaccines. If the provider calls to schedule a pickup, the provider will be charged a pick up fee. McKesson will not schedule pickups on behalf of TVFC providers unless special arrangements are made by the DSHS Immunization Unit.

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

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

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

C. Negligent Vaccine Loss

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

- Vaccine stored improperly;
- Vaccine left out of the refrigerator or the freezer;
- Refrigerator or freezer unplugged (plug guard, that covers the outlet, is not used);
- Vaccine transported inappropriately (appropriate cold chain was not maintained);
- Improper monitoring of temperatures in refrigerator or freezer;
- Allowing vaccine to expire without notifying the Responsible Entity 90 days in advance of the expiration date;
- Refrigerator or freezer door left open (causing temperature excursion);
- Refusal of a vaccine shipment;
- Vaccine not stored properly upon receipt;
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility);
- Lost vial;
- Incorrect vaccine prepared for patient; and/or
- Incorrect diluent drawn for vaccine.

V. Vaccine Storage and Handling

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

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

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

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

A. Refrigerator and Freezer Requirements

TVFC providers are required to have appropriate equipment that can store vaccine and maintain proper conditions:

- Refrigerator and freezer units must be large enough to hold the year's largest inventory without crowding.
- Two types of refrigerator units are acceptable for storage: a stand-alone, single-purpose refrigerator or a pharmaceutical/purpose-built unit.
- The CDC recommends stand-alone freezers specifically manufactured to maintain very cold temperatures. These freezers are acceptable for the storage of Varicella, MMRV, or MMR vaccines only. A frost-free unit with an automatic defrost cycle is preferred.
- Combination units, if used, must have separate thermostats for the refrigerator and freezer compartments. The CDC recommends not using both the freezer and refrigerator section of a dual unit. Each unit should serve as either a freezer or a refrigerator.
- Dorm-style and small combination refrigerator and freezer units with a single external door are never allowed for the storage of TVFC vaccine.
- The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at midrange, 40°F (4°C).

- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C) for vaccine viability.
- An alarm system and back-up generator are recommended to help reduce vaccine loss when unexpected temperature fluctuations occur.
- Refrigerators and freezers storing vaccines must be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.

Each refrigerator or freezer must contain a sufficient number of water bottles to help maintain proper storage temperature during peak usage of the unit. Peak usage is considered when there is frequent opening and closing of unit doors or a power failure. Water bottles serve as a physical barrier to prevent placing vaccines in areas where there is greater risk for temperature excursions.

Note: The CDC recommends that water bottles should not be used in pharmaceutical/purpose-built units if the manufacturer indicates that water bottles negatively impacts the functionality of the unit.

Depending on the size of the unit, the amount of vaccine stored, and the time of year, “sufficient” may differ from one clinic to the other. However, there must be adequate water bottles in each refrigerator and adequate frozen water bottles in

each freezer to help maintain proper storage temperature during peak usage of the unit or until vaccines can be moved to another refrigerator or freezer.

For the refrigerator:

- Make sure the refrigerator door is closed completely;
- Replace crisper bins with water bottles to help maintain a consistent temperature (unless used for other medical equipment or supplies);
- Label water bottles “Do Not Drink”;
- Post “Do Not Unplug” signs on the refrigerator and by the electrical outlet;
- Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly;
- Place water bottles on the top shelf of the refrigerator;
- Do not use the top shelf for vaccine storage;
- Do not put food or beverages in the refrigerator;
- Do not put vaccines in the doors or floor of the refrigerator;
- Do not drink from or remove the water bottles;
- Leave 2-3 inches between all vaccine and the refrigerator walls;
- Store each type of vaccine or diluent in a separate container;

- Place vaccines with the earliest expiration dates in front of those with later expiration dates;
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents should never be frozen;
- Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored. If diluent is stored separately from the corresponding vaccine, label the container where it is stored;
- Store vaccines and diluents with similar packaging or names (e.g., DTaP and Tdap or Hib and HepB) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors;
- Make sure to label the formulation “pediatric” or “adult,” if applicable;
- Always store vaccines in their original packaging with lids closed until ready for administration;
- Never store loose vials or manufacturer-filled syringes outside of their packaging;
- Do not pack a storage unit too tightly. This can restrict air circulation and impact temperature;
- Vaccines should be centrally stored within the unit; and
- Store privately purchased vaccine on different shelves from TVFC to minimize the risk of administering TVFC vaccine to non-eligible patients. TVFC vaccines should be clearly marked to differentiate them from privately purchased vaccines.

- For the freezer:
 - Make sure the freezer door is closed completely;
 - Use frozen water bottles to help maintain a consistent temperature;
 - Place water bottles against the walls, in the back, on the floor, and in the door racks;
 - Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly;
 - Post “Do Not Unplug” signs on the freezer and by the electrical outlet;
 - Do not put food in the freezer;
 - Leave 2-3 inches between all vaccines and the freezer walls;
 - Do not store vaccines in the freezer doors;
 - Avoid storing vaccines in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents or shelves on the door;
 - Store each type of vaccine in a separate container;
 - Vaccines should be centrally stored within the unit;
 - Place vaccines with the earliest expiration dates in front of those with later expiration dates;
 - Attach labels to shelves and containers to clearly identify each type of vaccine;

- Store vaccines with similar packaging or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors;
- Store privately purchased vaccine in a clearly marked container separate from TVFC vaccine to ensure TVFC vaccine is not inadvertently administered to a non-eligible patient;
- Make sure to label the formulation “pediatric” or “adult,” if applicable;
- Always store vaccines in their original packaging with lids closed until ready for administration;
- Never store loose vials or manufacturer-filled syringes outside of their packaging;
- Diluents should never be frozen; and
- Arrange vaccines in rows; do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

New or Repaired Units:

Prior to using a new or newly repaired unit to store vaccines, allow 10 business days of refrigerator or freezer temperature readings/recordings (a minimum of two times each workday) on an EC-105 form. Also record the required minimum/maximum temperatures one time at the beginning of each business day to ensure temperatures are within appropriate ranges. Submit the recordings to the Responsible Entity for review and approval,

before placing vaccine in the storage unit. Minimum and Maximum temperature readings must be reset from the day before at the end each business day (if the device requires this function).

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

Refrigerators and freezers that store TVFC vaccines are to be dedicated to storing vaccine only. Food or drinks in the same refrigerator or freezer as vaccines is not allowed. If other biologics must be stored in the same unit, store them below the vaccines to avoid contamination.

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

- A Temperature Recording Form (EC-105) is required to be located on or near all units that store TVFC vaccines;
- Freezer and/or refrigerator temperatures are required to be checked, recorded, and initialed twice daily;
- Minimum and Maximum temperatures must be recorded on the Temperature Recording Form once at the beginning of each business day;

A TVFC provider using data loggers must still comply with twice daily temperature and Minimum and Maximum recording requirements.

- Minimum and Maximum temperature readings must be reset from the day before at the end of each business day;
- Temperatures must be recorded manually on Temperature Recording Forms, even when using a digital data logger;
- Temperature Recording Forms must be posted on each vaccine storage unit door or nearby in a readily accessible and visible location; and
- Temperature Recording Forms must be maintained for five years and made easily available.

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

- Place vaccines in a Vaccine Quarantine Bag and label vaccines as “DO NOT USE”;
- Store vaccines in a unit where they can be kept under appropriate conditions;
- Generate a report from the data logger for manufacturer contact;
- Contact the vaccine manufacturer, to obtain documentation for the viability of the vaccine; and
- Contact the Responsible Entity to report the manufacturer’s vaccine viability determination and complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form.

B. Data Logger Requirements

As of January 1, 2018, DSHS requires a data logger for all units that contain TVFC or ASN vaccines and a back-up temperature monitoring device (that is also a data logger).

Units that store TVFC or ASN vaccines must contain a centrally located data logger with a current and valid Certificate of Calibration Testing (also known as a Report of Calibration), set at a minimum recording interval of at least every 30 minutes.

A data logger provides more accurate and comprehensive monitoring of temperature excursions to which vaccines may be exposed. Using a data logger may reduce vaccine loss by providing necessary data when the vaccine would otherwise be lost.

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

A digital data logger must have:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door;

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

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

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

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

- Fluid-filled bio-safe liquid temperature monitoring devices;
- Bi-metal stem temperature monitoring devices;
- Food temperature monitoring devices;
- Household mercury temperature monitoring devices;
- Chart recorders;
- Infrared temperature monitoring devices;
- Temperature monitoring devices that are not calibrated; and
- Thermometer (beginning in January 2018).

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

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

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

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

The data logger probe must not be:

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

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

A valid certificate of calibration matching the serial number of the data logger in use is to be posted on the refrigerator and/or freezer. The certificate is valid for two years from the date of calibration or the date of expiration, whichever occurs first. A continuous-read temperature-recording device does not replace the requirement for a certified data logger.

Certificates must contain:

- Model number;
- Serial number;
- Date of calibration; and

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

All TVFC providers must have at least one backup data logger with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day. Backup data loggers must be readily available in case a data logger in use is no longer working appropriately or calibration testing of the current equipment is required.

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

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

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

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

Figure 3-1, on the next page, presents an example of a valid certificate of calibration.

Figure 3-1: Example of a Valid Certified Data Logger Certificate

Data Logger Company

CERTIFICATE OF CALIBRATION

Certificate Information:

Certificate Number: C-13-04-95-019

Calibration Technician: S Perez

Calibration Date: 2013-04-26

Next Calibration Due: 2014-04-26

CERTIFICATE OF CALIBRATION

Device Name: RHTemp2007

Device ID: P05758

Model Description: Temperature Recorder

Condition As Received: Good

Inc. of Standards and Test: The unit has been calibrated using NIST-traceable standards. The calibration is valid for the duration of the certificate. The unit is certified to the specifications of the National Institute of Standards and Technology (NIST).

Published Specifications: The Temperature certificate is published in the specifications of the unit.

Accuracy: ±0.1°C

Range: -20 to 50°C

Resolution: 0.1°C

Channel 1 - All data points	Standard	Actual Temperature	Allowable Deviation	Corrected Value	Device Error
1	25.00	25.00	±0.1°C	25.00	0

Gain: 1

Offset: 0

Calibration And Service:

For information regarding this calibration, please contact the factory, calibration or other service for this product. The unit is certified to the specifications of the National Institute of Standards and Technology (NIST).

Issued By: _____

Approved By: _____

Date: 2013-04-26

Date: 2013-04-26

Maintaining Calibration:

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

Certificate Number: C-13-04-95-019

Date Created: 2013-04-26

Date Printed: 2013-04-26

Certificate Page: Page 1

Company Contact Information:

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

C. Vaccine Storage Requirements

Some vaccines are sensitive to light and their efficacy could be compromised if exposed to the light. All TVFC providers must safeguard the following vaccines from light: Hib, HPV, MCV4, MMR, MMRV, Rotavirus, and Varicella.

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

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

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

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

All TVFC providers also enrolled in the ASN Program must separate TVFC provided pediatric doses from ASN supplied adult doses. All TVFC providers must identify sufficient alternate

During re-enrollment, the primary and back-up vaccine coordinators must complete the mandatory 2018 TVFC Provider Policy Training module.

space to store vaccines and maintain the cold chain during any period when the refrigerator/freezer is out of service.

D. Protective Equipment

The power supply for vaccine storage units must be protected by following:

- Plug unit directly into a wall outlet;
- Plug only one unit into an outlet;
- Plug guards are required to be used on all units that store TVFC vaccines. Plug guards are effective tools in preventing the accidental unplugging of equipment;
- A “Do Not Unplug” sign is required to be posted on or near all outlets of units; and
- A “Do Not Disconnect” sign must be posted by each circuit breaker.

Do not:

- Use multi-outlet power strips;
- Use outlets with built in circuit switchers;
- Use power outlets that can be activated by a wall switch;

E. Personnel

Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle TVFC vaccine must be trained on proper storage, handling, and administration of vaccine as well as aware of and familiar with the written procedures for

emergency situations to assure continued viability of the vaccines. The site is required to designate a primary and at least one back-up vaccine coordinator to ensure that the TVFC vaccines are handled and stored properly.

The training requirements for vaccine coordinators are as follows:

- All new TVFC providers must have their primary and back-up vaccine coordinators complete the mandatory 2018 TVFC Provider Policy Training module and CDC “You Call the Shots” training modules and provide the Certificates of Completion to their Responsible Entity.
- Replacement primary and/or back-up vaccine coordinators must complete the mandatory 2018 TVFC Provider Policy Training module and CDC “You Call the Shots” training modules and provide the Certificates of Completion to their Responsible Entity.
- During re-enrollment, the primary and back-up vaccine coordinators must complete the mandatory 2018 TVFC Provider Policy Training module and upload the Certificate of Completion into the electronic re-enrollment form.

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

F. Mass Vaccination Clinic Requirements

To ensure vaccine storage and handling for mass vaccination clinics is managed properly the following storage and handling practices are required:

- All TVFC vaccine must be ordered and shipped directly to a location within the ordering provider's DSHS Health Service Region (HSR).
- The vaccine must be properly transported, not shipped, to local schools or other community sites where the mass vaccination clinics will be held.
- Only amounts of vaccines that are appropriate, based on TVFC need, should be transported to each scheduled clinic.
- Vaccine must be transported to and from the scheduled mass vaccination clinic at appropriate temperatures and must be monitored by a continuous monitoring and recording device that includes a digital display (that can be viewed outside of the storage unit) and probe in buffered material that closely resembles a vaccine.
- The vaccine being transported should be tracked in order to maintain accountability for monthly reporting in EVI. This includes:
 - Vaccine type(s) and brand names;
 - Quantity of each type;
 - NDC numbers;
 - Lot numbers; and
 - Expiration dates.

- Upon arrival at the clinic site, the TVFC mass vaccination provider must ensure that 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 day of the clinic using a continuous monitoring and recording device with a digital display and probe in buffered material. Temperature form EC-105 may be used to document hourly temperatures.
- After each clinic day, the TVFC provider must perform a physical count of the remaining vaccine and assess temperatures prior to placing vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised.
- Vaccines exposed to temperature excursions, when the temperature goes above or below its required temperature, must be separated in a Vaccine Quarantine Bag and labeled “Do Not Use” until further information can be gathered from the manufacturer(s). The vaccine should be kept at appropriate temperatures until the viability determination is made.

G. Routine and Emergency Storage and Handling Plan

All TVFC providers must have plans for routine and emergency vaccine management. The TVFC Program provides templates

for the Vaccine Management Plan and the Emergency Vaccine Storage and Handling Plan Checklist. The plan and checklist templates contain comprehensive information on best practices and the most current information about the storage and handling of vaccines. A TVFC provider is not required to use these templates, but they are valuable tools available to providers should they need assistance in developing an emergency plan. If the templates are not used, the TVFC provider must develop routine and emergency vaccine management plans that include all of the information on the templates provided by the TVFC Program.

The Vaccine Management Plan and the Emergency Vaccine Storage and Handling Plan Checklist must be reviewed and updated annually. They must include the signature, name, and title of the preparer as well as the date the documents were reviewed.

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

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

- 1.2 Identify an alternative location to take the TVFC vaccine for storage. A location with a power generator or other alternate source of power such as a hospital, pharmacy, or grocery store is preferable. Ideally, this facility must be located within a reasonable distance from the TVFC provider's clinic, and can maintain the cold chain during any period when the TVFC provider's refrigerator or freezer is out of service, as well as adequate space to accommodate the largest vaccine inventory. Temperatures for storage units are required to be monitored and recorded.
- 1.3 Adequate supplies in amounts sufficient for packing and transporting the entire TVFC vaccine inventory must be available in case of an emergency.
- 1.4 Be sure to contact the emergency storage location for their approval before including them as part of the plan. List their contact person(s) and phone number(s) on the plan. An alternative back-up location must be considered in case the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.

All TVFC providers will be asked to provide a copy of their Vaccine Management Plan and Emergency Vaccine Storage and Handling Plan Checklist at TVFC Compliance Site Visits. The documents must be posted on or near the refrigerator or

freezer containing the TVFC vaccine. The TVFC provider must ensure all employees involved with vaccine management are aware of this plan.

H. Vaccine Protection in the Event of an Emergency

As noted above, every facility maintaining an inventory of state-provided vaccine is required to develop and display an Emergency Vaccine Storage and Handling Plan in the event of emergencies that could result in the loss of vaccine. Once completed, this template can serve as the required Emergency Vaccine Storage and Handling Plan.

All TVFC providers must review and update this plan annually or more frequently if there are any changes to the plan or changes in staff responsible for vaccine management, storage, and handling. The most current Emergency Vaccine Storage and Handling Plan will be reviewed during TVFC Compliance Site Visits and any Unannounced Storage and Handling Visits.

In the event of an emergency, a TVFC provider must contact their Responsible Entity immediately to inform them of the situation.

The TVFC provider will need to be prepared to provide the following information:

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

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

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

I. Cold Chain Management and Vaccine Transport

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

All TVFC providers must identify sufficient alternative space to store TVFC vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service. Providers must ensure adequate supplies for packing and transporting the entire TVFC provider's vaccine supply/inventory must be available in case of an emergency.

Avoid prolonged temperature extremes inside vehicles, by using transport containers containing the vaccines and taking the quickest route possible. Do not leave vaccines unattended in vehicles. Do not place vaccines in the trunk of a vehicle.

Pack refrigerated vaccines first. If followed, the directions below will help maintain the cold chain for up to eight hours during transport of refrigerated and frozen vaccines.

Refrigerated Vaccine Transport

Assemble Packing Supplies

CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler

with at least 2-inch walls, Styrofoam vaccine shipping container or other qualified container may be used if it can maintain the recommended temperature range (between 36°F [2°C] and 46°F [8°C]).

- Hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container is required:
 - Coolers should be large enough to hold the TVFC provider's typical supply of refrigerated vaccines;
 - Original shipping boxes from the manufacturer can be used, if available; and
 - Do NOT use soft-sided collapsible coolers.
 - Label the container with facility name and "Fragile Vaccines – Do Not Freeze" and the date and time the vaccine was removed from the permanent storage unit.
- Conditioned frozen water bottles are required:
 - Use 16.9 oz. bottles for medium/large coolers and 8 oz. bottles for small coolers;
 - Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated; and
 - DO NOT reuse coolant packs from original vaccine shipping containers, they may freeze vaccine.

- Insulating material – two of each layer is needed:
 - Insulating cushioning material – Bubble wrap, packing foam, or Styrofoam for a layer, at least 1-inch thick, above and below the vaccines. Make sure it covers the cardboard completely;
 - Corrugated cardboard – two pieces cut to fit the internal dimensions of the cooler(s) and placed between the insulating cushioning material and the conditioned water bottles; and
 - DO NOT use packing peanuts or other loose material that may shift during transport.
- Temperature monitoring device – A digital data logger with a buffered probe should be used:
 - The probe is buffered by pre-chilling it in the refrigerator for at least five hours prior to transport;
 - Data logger must have current and valid certificate of calibration testing;
 - Data logger must be accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$); and
 - The temperature monitoring device currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for remaining vaccines.

Packing for Transport

- Line the bottom of the cooler with a single layer of conditioned water bottles;
- Place a sheet of corrugated cardboard over the water bottles;
- Place at least 2" layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the cardboard;
- Stack boxes of vaccines and diluents on top of insulating material;
- When cooler is halfway full, place the buffered temperature probe in the center of the vaccines, but keep the display out of the cooler;
- Cover vaccines with another 2" layer of insulating material;
- Add the second layer of corrugated cardboard;
- Fill the remaining space in the cooler with conditioned water bottles;
- Close the lid of the cooler securely and attach the digital data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport;
- Use the Temperature Recording Form to record the time and temperature inside of the storage unit at the time the vaccines are removed;
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly; and
- As soon as the destination site is reached, check and record the vaccine temperature.

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

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

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

Frozen Vaccine Transport

Varicella and MMRV vaccines are fragile and must be frozen!

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

Assemble Packing Supplies:

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

In addition to the above packing instructions:

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

Figures 3-2 and 3-3 on the following pages, illustrate proper vaccine storage and handling for transport during emergencies when portable refrigerators and/or freezers are not available.

Figure 3-2: Supplies for Transport of Vaccines during Emergencies

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

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

1 Gather the Supplies



Hard-sided coolers or Styrofoam™ vaccine shipping containers

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



Conditioned frozen water bottles

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



Insulating material — You will need two of each layer

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



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

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

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



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

CS248275-1 August 2015

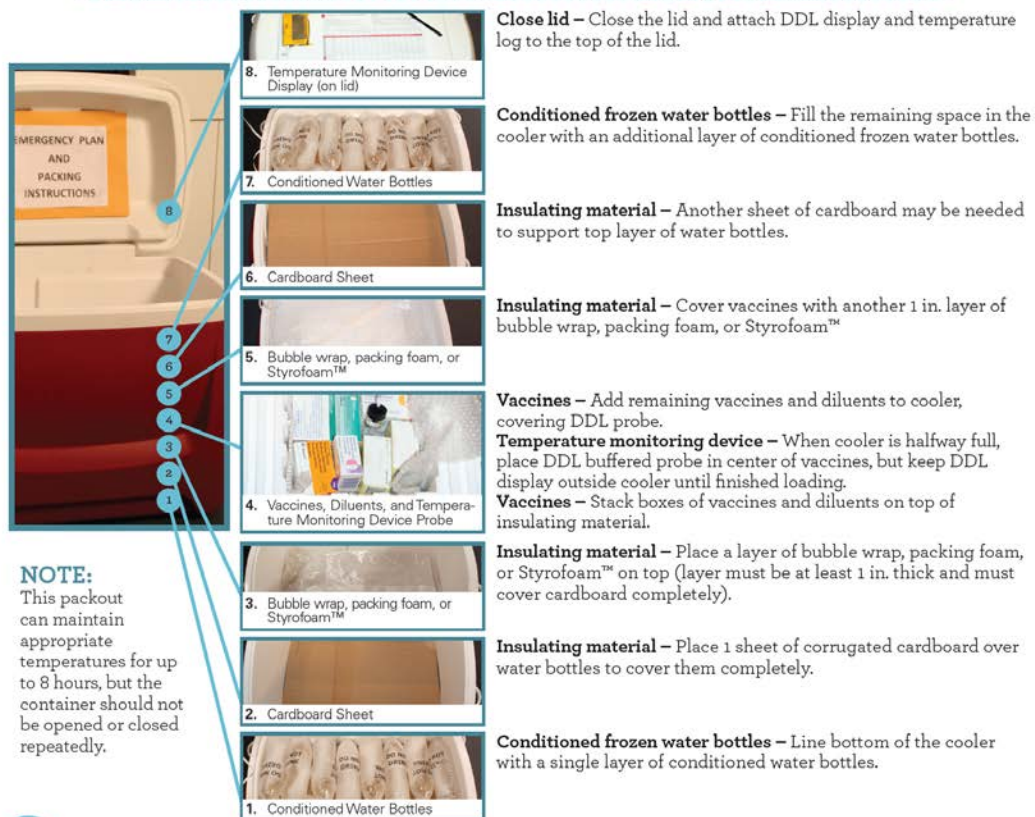
Figure 3-3: Packing of Vaccine for Transport during Emergencies

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

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



3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.

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

VI. Vaccine Transfers

The routine re-distribution of TVFC vaccine is not allowed. However, vaccine transfer can be allowed between TVFC providers when necessary to avoid vaccine loss. If a transfer must occur, TVFC providers are required to submit a TVFC Vaccine Transfer Authorization Form (EC-67) to their Responsible Entity and receive pre-approval prior to conducting vaccine transfers. The Responsible Entity or provider can then initialize a vaccine transfer as long as they have the TVFC Program PIN of where they are transferring the vaccine. The transfer information is documented and tracked in EVI.

To conduct a vaccine transfer, the TVFC provider, transferring the vaccine, must complete the following requirements:

- Ensure that the vaccine transfer is occurring for one of the following reasons:
 - Short dated vaccine;
 - Withdrawal, suspension, or termination of a TVFC provider from the TVFC Program; or
 - Other (emergency situations).
- Complete and sign the TVFC Vaccine Transfer Authorization Form and agree that the vaccine will be transferred in accordance to TVFC Vaccine Storage and Handling Guidelines to ensure the proper cold chain will be maintained throughout the transfer process. Each vaccine to be

transferred must be listed on a separate row on the Vaccine Transfer Authorization Form and include:

- The vaccine type;
 - The National Drug Code (NDC);
 - The lot number;
 - The expiration date; and
 - The number of doses that are being transferred.
- Fax the completed TVFC Vaccine Transfer Authorization Form to the Responsible Entity. For emergency situations, TVFC providers must call the Responsible Entity prior to faxing the form.
 - Once the DSHS HSR receives the form (either from the TVFC provider or LHD), they will approve or deny the transfer, if applicable, within two business days. If approved, a signed copy of the form will be faxed or emailed back to the TVFC provider requesting the transfer and the LHD (if applicable). Once the TVFC provider receives the approval fax or email, the TVFC provider may conduct the transfer in the EVI system;
 - The Responsible Entity will ensure that the vaccine is packaged using proper cold chain management as detailed in [Section IV – Vaccine Storage and Handling, subsection I – Cold Chain Management and Vaccine Transport](#), of this chapter, and a certified, calibrated data logger is enclosed with the packaged vaccine;

- Include a copy of the EVI Transfer Form in the transfer package. The EVI Transfer Form is printed after the transfer is conducted in EVI; and
- Include a Temperature Recording Form to document temperatures before, during, and upon conclusion of the vaccine transfer. The TVFC provider taking possession of the vaccine will append the Temperature Recording Form from the transfer to the monthly Temperature Recording Form.

The TVFC provider taking possession of the vaccine must keep the TVFC Vaccine Transfer Authorization Form on file for a minimum of five years and be made easily available.

VII. Vaccine Borrowing

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

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

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

Undocumented borrowing and administering of TVFC vaccines

to a non-TVFC patient is considered fraud. No provider may use TVFC vaccines as a replacement system for filling the vaccine needs of a non-TVFC privately insured patient. For example, providers may not borrow TVFC flu vaccine for privately insured patients if the TVFC flu vaccine arrived in their office prior to their privately purchased flu vaccine.

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

- Document the incident by completing the TVFC Vaccine Borrowing Form (EF11-14171). Each vaccine that was administered to a non-TVFC-eligible client must be listed on a separate row on the form. The form is available online at: <http://www.dshs.texas.gov/immunize/tvfc/publications.aspx>;
- Report the incident by faxing a copy of the TVFC Vaccine Borrowing Form to their Responsible Entity **within 24 hours**. Adherence to HIPAA guidelines is mandatory when faxing this form to the Responsible Entity. The TVFC Vaccine Borrowing Form must be kept as part of the TVFC Program records for a minimum of five years and be made easily available; and
- Replace the vaccine immediately and account for the replacement in the EVI system.

It is the responsibility of the TVFC provider to ensure that all staff members are familiar with TVFC Program requirements.

Adequate vaccine supply must be maintained in accordance with the clinic's patient population (TVFC and private patients). The TVFC vaccine and private vaccine must be kept separately and clearly labeled as such. All TVFC providers must track vaccine usage and account for all doses of TVFC vaccine.

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

VIII. Reporting Requirements

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

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

On the 5th of each month, the following documents must be completed and submitted to the Responsible Entity.

These records include (but are not limited to):

- Monthly Biological Report (C-33);
- Biological Order Form (EC-68-1);

- Temperature Recording Form (EC-105), including:
 - Refrigerator Fahrenheit (EC-105RF);
 - Refrigerator Celsius (EC-105RC);
 - Freezer Fahrenheit (EC-105FF);
 - Freezer Celsius (EC-105FC);
- Vaccine Loss Report, if applicable;
- TVFC Vaccine Borrowing Form, if applicable; and
- Any other reports or required documents.

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

A. Reports Summary

Monthly Biological Report (C-33)

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

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

For those providers without internet access, they must complete the Monthly Biological Report and submit it to their Responsible Entity each month. The person completing the paper Monthly Biological Report must always sign and date the report and provide a telephone number where they can be reached. This is required in case discrepancies are identified on the report and a follow-up phone call is needed.

Biological Order Form (EC-68-1)

This form is used only for initial orders or for those providers that do not have internet access. The Biological Order Form documents the amount of vaccine the clinic will order. All vaccines must be ordered to bring the clinic up to their pre-determined Maximum Stock Level (MSL). For orders above the MSL, an explanation is required in the comment section.

Temperature Recording Form (EC-105)

A Temperature Recording Form is to be maintained on all refrigerators and freezers that store TVFC vaccine (including temporary day storage units). Providers may choose to use Fahrenheit (EC-105RF and EC-105FF) or Celsius (EC-105RC and EC-105FC) forms.

All TVFC vaccines are required to be maintained at proper storage temperatures at all times. To ensure proper temperatures are maintained, the TVFC Program requires providers to record refrigerator and/or freezer temperatures twice daily for all units that store TVFC vaccine. TVFC providers

are also required to record minimum and maximum temperatures since the last reading, at least once daily, preferably in the morning. Results of each check must be documented on the Temperature Recording Form and the form must be initialed by the staff member conducting the check. Instructions for completing the Temperature Recording Form are listed on the top of the form.

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

In case of a temperature excursion, providers must notify their Responsible Entity immediately and include the following information on the Troubleshooting Record (found on the last page of the EC-105):

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

All documentation regarding temperature deviations must be retained for review during TVFC Compliance Visits and any Unannounced Storage and Handling Visits. An example of the

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

Vaccine Storage Troubleshooting Record can be found in the Forms section of the TVFC Provider Manual following the Temperature Recording Form.

B. Monthly Requirements

On a monthly basis the following documents must be submitted to the Responsible Entity (DSHS HSR or LHD) by the 5th of each month:

- Monthly Biological Report (only if internet access is unavailable);
- Temperature Recording Form;
- Biological Order Form (only if internet access is unavailable);
- Vaccine Loss Report, if applicable;
- TVFC Vaccine Borrowing Form, if applicable; and
- Any additional and/or associated forms as required by the Responsible Entity.

Monthly vaccine management and reporting is required in EVI regardless of whether an order is submitted or not. Any TVFC provider without internet access will need to continue to submit the Monthly Biological Report each month to their Responsible Entity.

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*The maximum administration fee that a provider may charge is **\$14.85** per dose.*

CHAPTER 4: BILLING AND ADMINISTRATION

I. Billing for Vaccine

Providers who are enrolled in the Texas Vaccines for Children (TVFC) Program are prohibited from charging any TVFC-eligible child for the cost of vaccines. TVFC vaccines are provided at no cost to the provider in order to vaccinate eligible children.

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

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

II. Administration Fee

Providers are required to enroll in the TVFC Program to obtain vaccines at no cost to vaccinate TVFC-eligible children, including Medicaid and CHIP children. The TVFC provider may charge an administration fee for administering vaccine to TVFC-eligible children. The maximum administration fee that a provider may charge is **\$14.85** per dose.

For Medicaid VFC-eligible children, the provider must accept the reimbursement for immunization administration fee set by the state Medicaid agency or the contracted Medicaid health plans.

Providers are reimbursed the lesser of the billed amount or the maximum allowable fee. As stated in the CDC Vaccines for Children (VFC) Operations Guide, the state Medicaid agency may have the discretion to pay an administration fee up to the regional maximum amount.

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

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

Providers may not charge Medicaid patients for the vaccine received from the TVFC Program. Providers may charge a usual and customary fee not to exceed **\$14.85** for vaccine administration when providing immunizations to a patient eligible for the TVFC vaccines.

A provider must not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of **\$14.85** per dose. For Medicaid VFC-eligible children, the provider must accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

For more information on Medicaid reimbursement, please refer to the Texas Medicaid Provider Manual located at:

http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx.

Children (0-18 years of age) who are enrolled in CHIP are eligible to receive TVFC vaccines; however, TVFC providers must bill CHIP for the administration of a vaccine to a CHIP-enrolled child. For more information on CHIP reimbursement, please refer to the CHIP Provider Manual located at:

<http://www.texaschildrenshealthplan.org/sites/default/files/Provider%20Manual.pdf>.

Vaccines are required to be available to all TVFC-eligible children. Services cannot be denied due to the parent's or guardian's inability to pay the administration fee. A TVFC provider may not send a parent or guardian to collections. A TVFC provider may not charge penalties for the inability to pay administration fees.

For additional information on the Vaccines for Children (VFC) statutory requirements for the VFC Program regarding the vaccine administration fee, please go to the following Centers for Disease Control and Prevention (CDC) link:

<http://www.cdc.gov/vaccines/programs/vfc/providers/index.html>.

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The purpose of the compliance visit is to assess, support, and educate the site regarding TVFC policies and procedures.

CHAPTER 5: PROGRAM EVALUATION

I. Provider Site Visits

By signing the TVFC Program Provider Agreement, the signing clinician agrees to allow DSHS or DSHS quality assurance (QA) contractors to conduct site visits at least every other year at their site. Providers at DSHS Health Service Regional (HSRs) clinics and Local Health Departments (LHDs) participating in the TVFC Program will receive a scheduled site visit from a DSHS HSR reviewer annually. The DSHS HSRs are responsible for conducting annual site visits at all DSHS HSR field offices and LHDs. Providers at private facilities can expect to receive a site visit at least once every other year by a DSHS QA contractor. In some cases, site visits may be conducted by the DSHS LHDs. Newly enrolled providers should receive a site visit between 6-12 months after enrollment.

A. Compliance Site Visits

Provider Compliance Site Visits are driven by data, not dates, to ensure that providers with the most needs are seen first. The purpose of the compliance visit is to assess, support, and educate the site regarding TVFC policies and procedures, not to critique. If areas of concern are identified, the Responsible Entity (DSHS HSR or LHD) will provide a follow-up call or visit to assist the clinic with any changes or questions.

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

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

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

B. AFIX Site Visits

AFIX is a CDC quality improvement program conducted by immunization programs to support Vaccines for Children (VFC) providers throughout the United States. The goal of the AFIX program is to increase vaccination of children and adolescents with all Advisory Committee for Immunization Practices (ACIP)-

recommended vaccines by reducing missed opportunities to vaccinate and improving immunization delivery practices at the provider level.

The AFIX program consists of four components: Assessment, Feedback, Incentives, and eXchange.

- **Assessment** involves generating data reports on the vaccination coverage levels of selected health care providers and examining the effectiveness of providers' immunization delivery practices.
- **Feedback** provides an opportunity to share with each provider their Assessment results, discuss practice procedures and barriers, and collaborate to develop customized evidence-based quality improvement strategies.
- **Incentives** recognize provider accomplishments and can be powerful motivation for providers to improve vaccination coverage rates.
- **eXchange** is the regular follow-up with providers to monitor their quality improvement progress and offer support through guidance and Incentives.

AFIX serves to assist and support health care providers by identifying low immunization rates, determining opportunities for improving immunization delivery practices, and ensuring that providers are:

- Aware of and knowledgeable about their immunization rates and missed opportunities to vaccinate;
- Motivated to incorporate changes into their current practices;
- Ready to try new immunization service strategies; and
- Capable of sustaining improvements to their vaccination delivery services.

II. Common Site Visit Structures

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

A. Combined TVFC Compliance and Initial AFIX Site Visit

This visit includes the VFC Questionnaire and an AFIX visit utilizing the Comprehensive Clinical Assessment Software Application (CoCASA). A core component of this visit is the assessment and review of 10-50 immunization records on children 24-35 months of age. The reviewers pull qualifying records randomly (up to 50 records).

An adolescent assessment is performed if there are not enough charts for children in the 24-35 months age group to perform an “A” site visit. The adolescent site visit is conducted with a

minimum of 20 immunization records (50 preferred) of adolescents in the age group of 13-18 years. The reviewer randomly selects records from the provider's charts.

B. TVFC Compliance Site Visit Only

This visit occurs if there are not enough records to conduct an immunization assessment (i.e., less than 10 records in the age group of 24-35 months and less than 20 records in the age group of 13-18 years).

C. Initial AFIX Site Visit Only

This visit occurs if the Responsible Entity wishes to focus exclusively on AFIX activities during the site visit.

D. AFIX Follow-up Site Visit Only

This visit consists only of a re-assessment of immunization records. All providers who receive an Initial AFIX visit will also receive an AFIX Follow-Up visit 3-6 months later.

E. Unannounced Storage and Handling Visit

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

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

- Vaccine loss;
- Improper storage of vaccine;
- Improper documentation of temperature logs;
- Orders inconsistent with provider profile data;
- Newly enrolled provider; and
- Determination of the provider's compliance with corrective actions.

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

III. Follow-Up Activities

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

The vaccine coordinator must sign the Acknowledgement of Receipt following the visit. The Acknowledgement of Receipt is the document that attests to the fact that a site visit was completed, the provider received the results of the visit, and that both the reviewer and the vaccine coordinator understand all non-compliance issues identified and the actions necessary to address them.

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

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

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

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

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

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

It is not acceptable to have a staff member login and then turn the EMR screens over to the reviewer; the staff person is required to be present.

IV. Electronic Medical Records (EMRs)

Providers with Electronic Medical Records (EMRs) have the following immunization record review options, one of which must be available at the time of the visit:

- A dedicated staff member who can log-in to the EMR and sit with the field reviewer throughout the record review process to pull up EMR immunization and eligibility records; or
- Print outs from the EMR of the immunization records and documentation of the child's eligibility. The immunization records need to include all immunization history including records from other providers.

Note: It is not acceptable to have a staff member login and then turn the EMR screens over to the reviewer; the staff person is required to be present. The TVFC Program or the DSHS QA contractor will not pay for, or reimburse providers for the copies, when the provider chooses to print out immunization records from their EMR system.

V. Annual TVFC Provider Feedback Survey

In addition, the TVFC Program will conduct an annual TVFC Provider Feedback Survey to help identify areas of the TVFC Program that are working well and those that need improvement. The survey will be electronically sent to all providers and the final results will be collected and submitted to

program staff for review. Questions in the survey will address provider satisfaction with the current vaccine ordering and shipping practices, TVFC policies and procedures, reporting requirements, customer service provided by TVFC state, regional, and local staff as well as the communication methods of the TVFC Program. The survey will also ask TVFC providers about their use of the Texas Immunization Registry (ImmTrac2) as part of their daily practice.

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CHAPTER 6: FRAUD AND ABUSE

I. Fraud and Abuse

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

II. Definitions

A working understanding of what constitutes fraud and abuse is critical for all persons working in the TVFC Program. Following are definitions of terms related to fraud and abuse.

Fraud - An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in an unauthorized benefit to himself or another person. It includes any act that constitutes fraud under applicable federal or state laws.

Abuse - Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid Program (and/or including actions that result in an unnecessary cost to the TVFC Program, a health insurance company, or a patient) or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care. It

also includes recipient practices that result in unnecessary costs to the Medicaid Program.

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

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

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

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

III. Examples

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

- Provide TVFC vaccine to non-TVFC-eligible children;
- Sell or otherwise misdirect TVFC vaccine;

- Bill a patient or third party for TVFC vaccine (other than administration fees);
- Charge more than \$14.85 per dose for administration of a TVFC vaccine to an eligible child;
- Failure to meet licensure requirements for enrolled providers;
- Deny TVFC-eligible children TVFC vaccine because of the inability to pay the administration fee;
- Send a parent or guardian to collections or charge additional fees for non-payment of the administration fee;
- Failure to implement provider enrollment requirements of the TVFC Program;
- Failure to screen for and document TVFC eligibility at every visit;
- Failure to maintain TVFC records for five years;
- Failure to fully account for TVFC vaccine;
- Failure to properly store and handle TVFC vaccine;
- Order TVFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of TVFC doses; and
- Loss of TVFC vaccine due to negligent waste.

IV. Failure to Comply with TVFC Requirements

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

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

V. Fraud and Abuse Prevention

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

VI. Reporting Fraud and Abuse

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

The Responsible Entity and DSHS quality assurance (QA) contractors must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Unit in any form that merit further investigation will be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office. The state Medicaid agency will conduct preliminary investigations and, as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme at 42 CFR section 455.15 and 42 CFR section 455.23.

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CHAPTER 7: DOCUMENTATION REQUIREMENTS

I. Vaccine Record Keeping Requirements

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

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

Immunization cards are designed to capture all information required when vaccines are administered. Immunization cards for providers (C-100) and clients (C-102) can be ordered free of charge from the DSHS Immunization Unit (See [Chapter 10: Ordering Forms and Literature](#)).

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

The TVFC Program suggests the following recommendations regarding record keeping:

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

Copies of all TVFC documents must be maintained for five years and made available on request by the TVFC Program, the Responsible Entity (DSHS HSR or LHD), or DSHS QA contractor.

II. The Texas Immunization Registry (ImmTrac2)

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

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

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

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

TVFC providers must register as an authorized organization with ImmTrac2 by completing an online form. For information about

ImmTrac2 or to register, call the ImmTrac2 Customer Support Line at (800) 348-9158 or visit the ImmTrac2 webpage at: <http://www.dshs.texas.gov/immunize/immtrac/default.shtm>.

III. Addressing Vaccine Hesitancy

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

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

When a parent or patient initiates the discussion regarding a vaccine concern, the provider should discuss the specific concern and provide factual information. The Vaccine Information Statement (VIS) provides an outline for discussing vaccine benefits and risks. Providers can reinforce key points

regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about state laws pertaining to school or childcare entry, which might require unimmunized children to stay home from school during outbreaks. Documentation of these discussions in the patient's record might reduce any potential liability if a vaccine-preventable disease occurs in the unimmunized patient.

IV. Vaccine Adverse Events

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

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

- Patients;
- Parents;
- Health care providers;
- Pharmacists; and
- Vaccine manufacturers.

Use the VAERS Reporting Website to report adverse events. All information requested on VAERS should be completed. It is very important to record the vaccine manufacturer, lot number, and injection site on VAERS. VAERS also requests the types of vaccine received, the timing of vaccination, and onset of the adverse event, a description of the event, current illness, and medication, past history of adverse events following vaccination, and demographic information about the recipient (e.g., age, gender, etc.).

CHAPTER 8: ADULT SAFETY NET PROGRAM

I. Adult Safety Net (ASN) Overview

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

ASN ensures that uninsured Texas adults have access to immunizations. This is accomplished through a network of support provided by the Department of State Health Services (DSHS) and with assistance from DSHS Health Service Regions (DSHS HSRs) and contracted Local Health Departments (LHDs). These organizations function as Responsible Entities to ensure compliance with state and federal standards and the effectiveness of vaccine distribution. As a provider, you will

contact your **Responsible Entity (DSHS HSR or LHD)** for more information and for the details about required vaccine reporting.

II. Provider Types

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

- DSHS Health Service Region (HSR) Offices;
- Local Health Departments (LHDs);
- Federally Qualified Health Centers (FQHCs); and
- Rural Health Clinics (RHCs).

III. ASN Enrollment

The first step in becoming an ASN Provider is completing the TVFC/ASN Program Provider Agreement forms. If you need assistance, you can call your Responsible Entity, Department of State Health Services Health Service Region (DSHS HSR) or Local Health Department (LHD). ASN providers that are a Federally Qualified Health Center (FQHC) or a Rural Health Center (RHC) should also submit a copy of the Centers for Medicare & Medicaid Services (CMS) letter.

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

The agreements include basic information about the facility and responsible provider. It also outlines the provider's responsibilities. The signed provider agreements must be received and processed by the ASN Program prior to the clinic receiving state-funded vaccines.

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

IV. ASN Patient Eligibility

A. Eligibility Criteria

Only adults aged 19 years and older who are uninsured are eligible to receive ASN vaccines. Those with medical insurance, including Medicare or Medicaid are not eligible to receive ASN vaccines. In addition, those who are underinsured (have insurance that does not cover immunizations) are not eligible to receive ASN vaccines.

Adults who have private insurance that covers vaccines are not eligible to receive ASN vaccines from ASN enrolled providers, but instead will be referred to their medical home for immunizations. An LHD that provides comprehensive healthcare services to adults with private insurance may continue to serve as the medical home for their privately insured patients. However, ASN requires that private stock vaccine be purchased to vaccinate privately insured adults.

B. Nineteen year Olds

Patients who are 19 years of age and who previously initiated a vaccination series under the TVFC Program, but have not completed the series, may complete the series using ASN vaccines regardless of their current health insurance status. The vaccine must be administered by an ASN provider at a DSHS HSR or LHD clinic. This provision only applies to patients that have not yet reached their 20th birthday.

C. Patient Eligibility Screening Record

Screening for patient eligibility is the foundation of provider-level accountability. Screening all adults at every immunization encounter and documenting eligibility screening at every visit is the only way to ensure that ASN vaccine is used only for ASN-eligible adults. As such, full compliance on screening for eligibility is required. In the event improper screening results in the administration of ASN vaccine to a non-ASN-eligible adult, providers are responsible for replacing the improperly used ASN vaccine with private stock.

Providers are required to document the eligibility of each adult receiving ASN vaccine at every visit. During a patient's initial visit to the provider site, the provider must document the patient's eligibility category per the ASN Program guidelines and update the patient's eligibility information during each future visit.

Providers may use the Adult Eligibility Screening Record (EF11-12842) or electronically store patient demographic information. Eligibility screening must be completed/updated for all adults at every visit, even including adults with a previous record on file. A patient's eligibility must be documented at every visit prior to vaccine administration. The patient or provider may complete the Adult Eligibility Screening Record.

Documentation of eligibility screening must include the following elements:

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

Adult Eligibility Screening Records must be kept on file with the patient's record, by all providers, for a minimum of five years after the last date of service to the patient and must be easily retrievable.

It is also acceptable for providers to utilize electronic medical records (EMR) system to capture and save the information from the Adult Eligibility Screening Record as long as the EMR captures all the required eligibility elements.

V. ASN Vaccine Formulary

The ASN Program supplies the following Advisory Committee on Immunization Practices (ACIP) recommended vaccines and toxoids to enrolled providers:

- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Hepatitis A and Hepatitis B (Hep A-Hep B) combination
- Human Papillomavirus (9vHPV)
- Measles, Mumps, and Rubella (MMR)
- Meningococcal conjugate (MCV4)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23)
- Tetanus and Diphtheria toxoids (Td)
- Tetanus and Diphtheria toxoids and acellular Pertussis (Tdap)
- Varicella
- Zoster

VI. Provider Enrollment Requirements

A. Specific Terms of Agreement

In order to participate in the ASN Program, each provider must agree to follow all program requirements. By signing the Vaccines for Children (VFC) Program Provider Agreement and

the Adult Safety Net (ASN) Program Provider Agreement, the office and all practitioners associated with the medical office agree to the following:

- Submit a provider profile representing populations served by the facility annually;
- Screen for and document ASN eligibility of all adults at each immunization encounter;
- Administer ASN vaccine to all adults 19 years of age or older who meet the established eligibility criteria;
- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP);
- Maintain all records related to the ASN Program for at least five years and upon request, make these records available for review;
- Immunize eligible adults with publicly supplied vaccine at no charge to the patient for the vaccine;
- Not charge an administration fee in excess of \$25.00 per vaccine dose;
- Not deny administration of a ASN vaccine to an eligible adult because of the inability of the patient to pay the administration fee;
- Not send a patient to collections or charge additional fees for non-payment of a ASN administration fee;

- Provide a copy of the most current Vaccine Information Statements (VIS) for each vaccine at the time of administration;
- Comply with the ASN Program requirements for vaccine management, including ordering and proper storage and handling practices;
- Operate within the ASN Program in a manner intended to avoid fraud and abuse;
- Participate in ASN site visits, including unannounced visits and other educational opportunities, as required;
- Acknowledge that the DSHS Immunization Unit may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office and/or facility agrees to return all ASN vaccines; and
- If a provider voluntarily withdraws from ASN at any time, the office/facility agrees to return any unused vaccine within 5 days of withdrawal. Prior to withdrawal, the provider must complete a provider withdrawal form and submit the form to the DSHS HSR or LHD.

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

administering the vaccine, must sign the provider agreement. There must be a written agreement attached to the Program Provider Agreement detailing the responsibilities of each party involved.

B. Initial Enrollment

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

C. ASN Enrollment Visit

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

D. ASN Site Set-up

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

E. Vaccine Accountability

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

All ASN providers must ensure:

- ASN vaccines are administered only to eligible adults;
- Vaccine loss and waste are minimized and documented;
- Fraud and abuse does not occur;
- ASN vaccine inventory is accurately reported monthly; and
- Patients are screened at all immunization encounters for ASN eligibility.

F. Provider Identification Number

A Provider Identification Number (PIN) will be assigned to the provider upon initial enrollment into the TVFC Program. ASN sites will use their TVFC PIN number for participation in ASN.

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

G. Provider Change of Information

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

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

H. Annual Re-Enrollment

ASN Re-Enrollment is completed electronically and is now completed using the same re-enrollment form as TVFC re-enrollment. Historically, providers were required to enroll in TVFC and ASN using two separate forms. Those forms have been combined for your convenience.

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

VII. Vaccine Ordering

A. Vaccine Choice

The ASN Program supplies ACIP recommended vaccines and toxoids to enrolled providers. Providers participating in the ASN

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

Program are required to offer all available ACIP recommended vaccines to their eligible populations. House Bill 448 from the 81st Texas Legislature gives ASN providers the opportunity to choose their preferred brands and presentations of vaccines from the available formularies.

The provider who signs the ASN Program Provider Agreement can choose vaccine brands and presentations. For new ASN providers, the Responsible Entity (DSHS HSR or LHD) will create the initial vaccine order using the Adult Biological Order Form (EC-68-2). The Adult Biological Order Form will reflect the provider's vaccine choices, their maximum stock level (MSL), and order quantity.

Each quarter, ASN providers will have the opportunity to choose the brand and presentation for each ASN vaccine in the Electronic Vaccine Inventory (EVI) system. They can change or adjust specific vaccine brands, presentations, and percentages within each vaccine "family" (i.e., Tdap), or take no action to maintain the current selections. Providers are encouraged to review all choice selections on a quarterly basis.

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

vaccine choice period. Only vaccines supplied by DSHS to the ASN Program will be available for vaccine choice.

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

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

B. Vaccine Inventory Plan and Maximum Stock Levels

The vaccine inventory plan requires all enrolled providers to maintain a **75-day supply** of vaccine inventory. All Providers should place vaccine orders monthly. All components of vaccine inventory management and MSLs are the same for TVFC and ASN.

For more information, please see the [CHAPTER 3: VACCINE MANAGEMENT > II: Vaccine Ordering > B. Vaccine Inventory Plan and Maximum Stock Levels](#) section of this manual.

C. Increasing and Decreasing Maximum Stock Levels

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

D. Short-Dated Vaccine

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

E. Storage Capacity for Vaccine Orders

An ASN provider must have adequate refrigeration and/or freezer space to accommodate a maximum order based on their MSL. An ASN provider must also take into consideration the space needed for their private stock when calculating storage capacity.

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

The ASN Program uses the EVI system for vaccine ordering. EVI allows ASN providers to manage their vaccine inventory online. All vaccine orders will be placed in EVI unless internet

access is unavailable. An ASN provider may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

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

G. Vaccine Ordering for ASN Providers without Internet Access

An ASN provider without access to the internet will contact their Responsible Entity, who will then enter the ASN provider's order online. The ASN provider will submit the following paper forms to their Responsible Entity so that vaccine order can be placed:

- Monthly Biological Report (C-33);
- Adult Biological Order Form (EC-68-2); and
- Temperature Recording Form(s) (EC-105).

The Monthly Biological Report is reviewed by their Responsible Entity to ensure that the beginning inventory matches the last month's ending inventory. Calculations must be correct and the net loss or gain must not exceed five doses of any one vaccine. Any corrections needed are reported to the ASN provider so the records can be corrected prior to ordering.

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

H. Vaccine Ordering for Newly Enrolled ASN Providers

Newly enrolled ASN providers are set up for vaccine ordering in EVI during New Provider Training with their Responsible Entity. The order is placed by the ASN provider as part of the training. The Responsible Entity collects and reviews the following paper reports prior to placing the new ASN provider's vaccine order:

- Adult Biological Order Form (EC-68-2); and
- Temperature Recording Form(s) (EC-105).

VIII. Vaccine Storage

All ASN providers are required to follow the TVFC Program storage and handling guidelines at all times. ASN providers also enrolled in the TVFC Program must separate TVFC provided pediatric doses from ASN supplied adult doses.

IX: Vaccine Management

It is critical that ASN providers familiarize themselves with expectations for vaccine management within the TVFC Program.

The policies governing vaccine management are the same in TVFC and ASN. Please ensure that you read the [CHAPTER 3: VACCINE MANAGEMENT](#) section of this manual in its entirety.

The maximum administration fee that an ASN provider may charge is \$25.00 per dose.

X. Vaccine Transfers

The routine re-distribution of ASN vaccine is not allowed. However, vaccine transfer can be allowed between ASN providers when necessary to avoid vaccine loss. If a transfer must occur, ASN providers are required to submit a TVFC Vaccine Transfer Authorization Form (EC-67) to their Responsible Entity and receive pre-approval prior to conducting vaccine transfers. The Responsible Entity or provider can then initialize a vaccine transfer as long as they have the ASN Program PIN of where they are transferring the vaccine. The transfer information is documented and tracked in EVI.

The policies governing vaccine transfers are the same in TVFC and ASN. Please ensure that you read the [CHAPTER 3: VACCINE MANAGEMENT > VI: Vaccine Transfers](#) section of this manual in its entirety.

XI: ASN Billing and Administration

A. Billing for ASN Vaccine

Providers who are enrolled in the Adult Safety Net (ASN) Program are prohibited from charging any ASN-eligible adult for the cost of vaccines. ASN vaccines are provided at no cost to the provider in order to vaccinate eligible adults. Charging for the cost of vaccines supplied by the ASN Program constitutes fraudulent behavior.

B. ASN Administration Fee

ASN providers may charge an administration fee for administering ASN vaccine to ASN-eligible adults. The maximum administration fee that an ASN provider may charge is **\$25.00** per dose. Services cannot be denied due to the patient's inability to pay the administration fee. An ASN provider may not send a patient to collections or charge penalties for the inability to pay administration fees

XII: ASN Site Visits**A. Adult Immunization Standards**

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

The Standards for Adult Immunization Practice are outlined below:

Assess

Providers should assess immunization status for all patients at every clinical encounter. To accomplish this, providers should implement policies to ensure that patients are regularly

All vaccines administered to adults should be documented.

ASN providers are highly encouraged to participate in ImmTrac2, the Texas Immunization Registry.

screened for immunizations and that they are reminded about the vaccines that they need.

Recommend

Providers should strongly recommend vaccines that patients need. Providers should stay up-to-date on information pertaining to adult vaccines to best inform their patients.

Providers should be able to explain the reasons why the patient should receive the vaccine, as well as address questions and concerns that the patient might have. A strong recommendation for a vaccine from a trusted healthcare provider can make the difference for whether or not a patient chooses to receive the vaccine.

Administer

If the patient opts to receive the vaccine, providers should administer the needed vaccine. Providers should offer the vaccines they have in stock. If there are vaccines that the patient needs that are not in stock or available through the ASN Program, providers should refer patients to a provider in the area that offers the needed vaccine.

Document

All vaccines administered to adults should be documented. Providers should include immunizations in the patient's medical records. ASN providers are highly encouraged to participate in ImmTrac2, the Texas Immunization Registry.

The ASN Program captures the aggregate number of doses administered through provider reports in the Electronic Vaccine Inventory (EVI). For more information regarding documentation requirements, see [Chapter 7: Documentation Requirements](#).

For more information regarding the Standards for Adult Immunization Practice, visit:

<http://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html>.

In January 2017, the Standards for Adult Immunization Practices were incorporated into the ASN site visits. The Texas Department of State Health Services (DSHS) Immunization Unit contracts with a Quality Assurance (QA) contractor to conduct ASN site visits. DSHS Health Service Region (DSHS HSR) staff also conduct some ASN site visits.

ASN Site Visits are driven by data, not dates, to ensure that providers with the most needs are seen first. The purpose of the compliance visit is to assess, support, and educate the site regarding ASN policies and procedures, not to critique. If areas of concern are identified, the Responsible Entity (DSHS HSR or LHD) will provide a follow-up call or visit to assist the clinic with any changes or questions.

B. Types of Adult Site Visits

ASN Site Visits are split into different types to ensure that each site is being evaluated based on the eligible populations served. These types are described below.

Combined ASN Compliance and Initial Records Assessment Site Visit

This visit combines the ASN policy review and storage and handling review with an assessment of the clinic's adherence to the Adult Immunization Standards and an initial records assessment. The reviewers pull qualifying records randomly (up to 50 records).

ASN Compliance Visit Only

This visit focuses primarily on an ASN policy review and a storage and handling review.

ASN Records Assessment Follow-up Visit Only

This visit consists only of a re-assessment of adult immunization records. All providers who receive an ASN Initial Records Assessment visit will also receive an ASN Assessment Follow-up Visit 3-6 months later.

Storage and Handling Visit (Can be Announced or Unannounced)

Storage and handling visits may be conducted to serve as "spot checks" for proper vaccine storage and handling. The provider's Responsible Entity will prioritize sites for storage and handling visits based on the following criteria:

- Vaccine loss;
- Improper storage of vaccine;
- Improper documentation of temperature logs;
- Orders inconsistent with provider profile data;
- Newly enrolled provider; and
- Determination of the provider's compliance with corrective actions.

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

C. Site Visit Scheduling and Clinic Access

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

During an ASN Site Visit, the reviewer will need access to the following:

- A space to work;
- A power source (Internet connectivity is recommended);
- Access to patient records;
- Any temperature logs or data for the last three months, or longer if deficiencies are found;

- Any Vaccine Borrowing Forms (EF11-14171) for the previous 12 months;
- The circuit breaker;
- Admitting and billing personnel to clarify eligibility screening and billing processes; and
- All vaccine storage units where ASN vaccine is stored.

D. Components of the ASN Site Visit

During the ASN site visit, the QA contractor or DSHS HSR reviewer and a member of your staff (who is knowledgeable about the ASN Program in your clinic) will work together to:

- Review the standards for adult immunization practices;
- Review patient immunization records and document doses of HPV, Td/Tdap, Flu, PCV13/PPSV23, and Zoster that have been administered by you or others;
- Review required elements of patient immunization records (lot number, manufacturer, title and signature of person who administered the vaccine, date of the vaccine information statement (VIS), date VIS was given to patient for review, date vaccine was given, and the clinic name and address);
- Review ASN Program requirements (administration fee, temperature recording, eligibility collection, etc.); and

- Review vaccine management requirements for the ASN Program (temperature recording forms, water bottles, proper vaccine placement, valid calibrated data logger, etc.).

The reviewer will provide a summary of areas of strength and areas for improvement. They will also provide resources/recommendations for improving practices.

E. Electronic Medical Record (EMR) Review

In recent years, the use of EMRs has become routine and has changed the way record reviews are conducted. If you use an EMR system, your staff must either:

- 1) provide a dedicated staff member who can log-in to the EMR and sit with the reviewer throughout the record review process to pull up EMR immunization and eligibility records; or
- 2) provide print-outs from the EMR of the immunization records and documentation of the adult's eligibility.

Your staff cannot login and then turn the EMR over to the reviewer – they must be present if records have not been printed.

As a reminder, by signing the ASN Provider Agreement, you agree to participate in ASN site visits, Unannounced Storage and Handling Visits (usually conducted by HSR staff), and other educational opportunities associated with ASN Program requirements.

XIII. Mobile Vaccination Clinics

An ASN provider may conduct off-site, mobile vaccination clinics using ASN vaccines. However, ASN eligibility still needs to be determined through the use of the Adult Eligibility Screening Record (EF11-12842) for all patients that receive ASN vaccines at each visit. Additionally, required vaccine storage and handling guidelines must be followed at all times and the vaccine must be returned to the original approved vaccine storage unit at the end of each day. Vaccines are extremely sensitive to temperature excursions. Any exposure to out-of-range temperatures could make the vaccine non-viable. For this reason, it is important to regularly monitor the temperature of the vaccines and take quick action when temperature excursions occur. Please refer to [Chapter 3, Vaccine Management](#), for specific information regarding the transporting of vaccines for Mass Vaccination Clinics and handling temperature excursions.

XIV. Reporting Doses Administered

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

XV. Fraud and Abuse

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

A. Definitions

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

B. Examples

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

providers should familiarize themselves with the examples below, as they illustrate common practice errors that could result in fraud or abuse allegations. **This list provides examples only, and should not be considered an exhaustive list of situations that would constitute fraud or abuse.**

- Provide ASN vaccine to non-ASN-eligible adults;
- Sell or otherwise misdirect ASN vaccine;
- Bill a patient or third party for ASN vaccine (other than administration fees);
- Charge more than \$25.00 per dose for administration of a ASN vaccine to an eligible adult;
- Failure to meet licensure requirements for enrolled providers;
- Deny ASN-eligible adults ASN vaccine because of the inability to pay the administration fee;
- Send a patient to collections or charge additional fees for non-payment of the administration fee;
- Failure to implement provider enrollment requirements of the ASN Program;
- Failure to screen for and document ASN eligibility at every visit;
- Failure to maintain ASN records for five years;
- Failure to fully account for ASN vaccine;
- Failure to properly store and handle ASN vaccine;

- Order ASN vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of ASN doses; and
- Loss of ASN vaccine due to negligent waste.

C. Failure to Comply with ASN Requirements

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

D. Fraud and Abuse Prevention

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

E. Reporting Fraud and Abuse

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

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

CHAPTER 9: VACCINE INFORMATION STATEMENT (VIS)

All immunization providers (regardless of whether they are enrolled in the TVFC Program) are required by the National Vaccine Childhood Injury Act (NCVIA-42 U.S.C. § 300ss-26) to provide a patient, parent, guardian, or other responsible adult a current Vaccine Information Statement (VIS). The appropriate VIS must be given prior to the vaccination, and must be given prior to each dose of a multi-dose series.

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

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

- A permanent, laminated, office copy of each VIS, which must be read prior to vaccination.
- A computer monitor or video display where the VIS can be reviewed.

- As a downloadable document that can be accessed via a smartphone or other electronic device by the client, parent, guardian, or other responsible adult to a smartphone or other electronic device.

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

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

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

CHAPTER 10: ORDERING FORMS AND LITERATURE

The DSHS Immunization Unit offers various forms, literature, brochures, posters, and Vaccine Information Statements (VIS) free of charge. Forms are available to view, download, or ship directly to the provider. Providers should allow 10 business days for delivery. A complete list of forms and materials available for order is online at:

<https://secure.immunizetexasorderform.com/default.asp>.

If internet access is unavailable, providers may send their literature request directly to the DSHS Immunization Unit via fax or mail.

When placing orders in writing please include the following:

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

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

Mail to:

Immunization Unit

Department of State Health Services

Mail Code-1946

P.O. Box 149347

Austin, Texas 78714-9347

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

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

CHAPTER 11: IMMUNIZATION RESOURCES

- Adult Safety Net (ASN) Website
<http://www.dshs.texas.gov/immunize/ASN/>
- CDC Immunizations Website
<http://www.cdc.gov/vaccines/>
- CDC Immunization Schedules
<http://www.cdc.gov/vaccines/schedules/index.html>
- CDC Vaccines for Children (VFC) Website
<http://www.cdc.gov/vaccines/programs/vfc/index.html>
- CDC Vaccine Storage and Handling Toolkit
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/>
- CDC “You Call the Shots” Training
<https://www.cdc.gov/vaccines/ed/youcalltheshots.html>
- ImmTrac2, the Texas Immunization Registry
<http://www.dshs.texas.gov/immunize/immtrac/default.shtml>
- Immunization Action Coalition
<http://www.immunize.org/>
- Standards for Adult Immunization Practice
<https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/>

- Texas DSHS Immunizations Website
<http://immunizetexas.com/>
- Texas Vaccines for Children (TVFC) Website
<http://www.dshs.texas.gov/immunize/tvfc/>
- Texas Vaccine Education Online
<http://www.vaccineeducationonline.org/>

TVFC Program Contact Information

Immunization Unit Central Office: **1-800-252-9152**

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



Texas Department of State Health Services
Immunization Unit

Stock No. 11-13602
Rev. 11/2017