

# Texas Vaccines *for* Children



## **PROVIDER MANUAL**



Dear Texas Vaccines for Children (TVFC) Provider,

Thank you for choosing to be a provider in the Texas Vaccines for Children (TVFC) Program. At the heart of the TVFC Program are the healthcare providers who are dedicated to the care of the children of Texas.

The TVFC Program removes barriers to childhood immunizations by providing enrolled providers with all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) to vaccinate eligible children. Providers in the TVFC Program enable their patients to remain in his or her “medical home” which benefits both the provider and the child.

This Provider Manual is a comprehensive guide which outlines the procedures and requirements for participation in the TVFC Program. The content in this manual was developed to ensure that our patients receive the highest quality of care and service from the TVFC Program. It also contains all forms and documents needed to participate in the program. Content includes:

- Provider eligibility and enrollment
- Patient eligibility and screening
- Vaccine management
- Billing and administration
- Program evaluation
- Fraud and abuse prevention and reporting
- Documentation requirements
- Adult Safety Net (ASN) Program
- Resources and references for providers

Providers must review the handbook and ensure that staff understands all TVFC procedures and requirements. Throughout the year, the Texas Department of State Health Services (DSHS) Immunization Branch and TVFC will educate providers on new policies via official policy letters. All updates will be included in the Provider Manual posted on the TVFC webpage. For providers using printed copies, each policy letter should be placed in the back of the TVFC Provider Manual. The Provider Manual will undergo a comprehensive review annually.

The DSHS Immunization Branch thanks you for your continued support of the TVFC Program and looks forward to working with you toward our vision of a Texas free from vaccine-preventable diseases.

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# **TEXAS VACCINES FOR CHILDREN (TVFC) PROGRAM PROVIDER MANUAL**

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

**Last Updated: 10/2014**

## **I. Provider Manual Information**

The Texas Department of State Health Services (DSHS) Immunization Branch has prepared the Texas Vaccines for Children (TVFC) Program 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 document for providers. Throughout the year, the DSHS Immunization Branch and TVFC will educate providers on new policies via official policy letters. All updates will be included in the Provider Manual posted on the TVFC webpage. For providers using printed copies, each policy letter should be placed in the back of the TVFC Provider Manual. The Provider Manual will undergo a comprehensive review annually.

## **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 317 and State General Revenue funds to support TVFC and all immunization activities across Texas.

TVFC enables thousands of children to have access to immunizations. This is accomplished through a network of support within DSHS and with support from public and private entities, such as local health departments (LHD) and private physicians.

## **III. Vision and Mission of the DSHS Immunization Branch**

**Vision:** A Texas free of vaccine-preventable diseases.

**Mission:** To provide leadership to 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 Branch**

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

#### **V. Goals of the TVFC Program**

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

# **CHAPTER 1**

## **TVFC PROVIDER ELIGIBILITY AND ENROLLMENT**

**Last Updated: 10/2014**

### **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)

TVFC requires all other health care providers to enroll under the standing delegation orders of a physician, including:

- Registered Nurses (RN)
- Licensed Vocational Nurses (LVN)
- Medical Assistants (MA)
- Nurse Assistants (NA)
- Emergency Medical Technicians (EMT)

### **II. Provider Enrollment Requirements**

#### **A. Specific Terms of Agreement**

In order to participate in the TVFC Program, each provider must follow program requirements. By signing the VFC Program Provider Agreement, the office and any/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 patients at each immunization encounter.
- Administer TVFC purchased vaccine only to 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.
- Not charge an administration fee in excess of \$22.06 per vaccine dose. Providers must not charge administration fees for Medicaid or CHIP patients.
- Immunize eligible children with publicly supplied vaccine. Providers must not charge the patient for the vaccine.
- Not deny administration of a TVFC vaccine to an eligible child because of the inability of the child's parent/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 current Vaccine Information Statements (VIS) for each vaccine at the time of administration.
- Comply with DSHS requirements for vaccine management including proper storage and handling practices.
- Operate within the TVFC Program in a manner intended to avoid fraud and abuse.
- Participate in TVFC Compliance Visits, including unannounced visits, and other educational opportunities as required.
- Acknowledge that DSHS may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office/facility agrees to return any unused TVFC vaccines.

## **B. Initial Enrollment**

The VFC Program Provider Agreement Form must be completed at initial enrollment and updated annually. The Provider Agreement includes basic information about the facility and responsible provider. It also briefly outlines the provider's responsibilities. The VFC Program Provider Agreement signed by the responsible health care professional must be received and processed by DSHS 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 Provider Agreement. The listing must include the signing provider's information. Information required for the healthcare providers include:

- Provider Name
- Title
- Texas Medical License Number
- National Provider Identification (NPI)

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

The Provider Profile includes the projection and identification of clients the clinic will serve in the upcoming year. The Provider Profile Form requests information about the provider's patient population. Providers must provide accurate data from the previous 12 months. These numbers must be specific to the clinic site and not combined with other clinics' patient numbers. Data sources may include, but are not limited to, immunization registry, benchmarking, number of Medicaid Claims or other billing data, as well as client encounter data.

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.

### **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. The purpose of this visit is to ensure that the provider and office staff are educated on all TVFC requirements. The visit will include the following:

- Reviewing and confirming that the provider and staff understand and can implement all TVFC requirements.
- Confirming the provider has the proper equipment to maintain TVFC vaccine and that the staff understands how to properly store, handle, and monitor TVFC vaccine, and who to contact if problems arise.
- Verifying that the provider has completed the required training, "You Call the Shots" Module 10 - Vaccine Storage and Handling and Module 16 - Vaccines for Children.
- Placing a certified and calibrated thermometer in the unit(s) that will store TVFC vaccine.
- Checking placement of thermometers and the calibration certificates for all thermometers.
- Verifying the following:
  - The provider has identified a vaccine coordinator and at least one back-up coordinator
  - The provider has a plan for routine vaccine management
  - There are adequate water bottles in the refrigerator and ice packs in the freezer
  - The vaccine storage units have enough storage space to accommodate the provider's maximum capacity of vaccine

- Assisting the new provider with:
  - Vaccine choice options
  - Establishing maximum stock levels (MSLs)
  - Online vaccine management in the Electronic Vaccine Inventory (EVI) system
  - Setting up initial order
  - Creation of a Vaccine Storage Contingency Plan
  - Completion of the Temperature Recording Form
- Verifying that plug guards are installed.
- Verifying that the following posters are hung in the clinic:
  - “Vaccine Management: Recommendation for Handling & Storage of Selected Biologicals” Poster
  - “How to Administer Injections” Poster
  - “Guide to Contraindications” Poster
  - “Giving All the Doses” Chart
  - Refrigerator Warning Signs
  - “Do Not Unplug or Break Circuit” stickers
- Providing Recommended Immunization Schedules, Catch-up Schedules, Resource Lists, and other materials to the provider.

If any of the items above were not given to you as a new TVFC provider, please contact your responsible entity (DSHS HSR or LHD) contact person to have any missing items sent to you.

Temperatures must be logged and in range for fourteen days before the provider is authorized to store TVFC vaccine.

#### **D. Vaccine Accountability**

Vaccine accountability is a cornerstone of the TVFC Program and one of highest priorities for DSHS. TVFC providers must ensure:

- Vaccines purchased with TVFC funds are administered only to TVFC-eligible children
- Vaccine loss and waste are minimized
- The TVFC Program is protected against fraud and abuse
- TVFC and other federally- and state-purchased vaccines are ordered appropriately based on a provider’s TVFC-eligible population
- TVFC vaccine inventory is accurately reported on a monthly basis

#### **E. Provider Identification Number (PIN)**

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

that the clinic is enrolled 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 ImmTrac, the Texas Immunization Registry, user account. Information regarding ImmTrac may be found in Chapter 7- Documentation Requirements and on the ImmTrac webpage: <http://www.dshs.state.tx.us/immunize/immtrac/default.shtm>

## **F. Provider Change of Information**

It is the provider's responsibility to maintain correct demographics, days and hours available to receive vaccine shipments, and profile information in EVI. TVFC requires that when a provider changes location that the responsible entity (DSHS HSR or LHD) be contacted immediately to inform them of the change. In addition, TVFC requires that the provider update the information in EVI.

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

## **G. Annual Re-Enrollment**

The annual re-enrollment period is from January 1 through March 31. TVFC requires that the VFC Program Provider Agreement and Provider Profile Forms be updated annually. The VFC Program Provider Agreement and Provider Profile Forms 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. Vaccine shipments may be interrupted if TVFC providers do not have current enrollment information on file. Providers are required to complete the "You Call the Shots" Module 10 - Vaccine Storage and Handling and Module 16 - Vaccines for Children annual training prior to re-enrolling. Certificates of completion must be included with the re-enrollment forms.

## **H. Deputization of Clinics**

In an effort to increase the number of children who are eligible for federal entitlement vaccine and ensure state compliance with the federal VFC eligibility, Texas has implemented deputization of public health department clinics. Delegation of Authority (DOA) or deputization, allows Texas federally qualified health centers (FQHCs) and rural health centers (RHCs) to confer authority for vaccinating underinsured children. Underinsured served in FQHC/RHC or deputized sites are eligible for federal VFC vaccine according to federal guidance.

### **III. Provider Withdrawal from TVFC**

Providers wanting to withdraw from the TVFC Program must contact the responsible entity (DSHS HSR or LHD) 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 the DSHS HSR or LHD.

### **IV. Provider Termination from TVFC**

Providers may be terminated for non-compliance with TVFC requirements and/or fraud and abuse. Information regarding fraud and abuse in the TVFC Program may be found in Chapter 6 – Fraud and Abuse. Providers who have been terminated from the TVFC Program must wait one year before being allowed to re-enroll. An orientation of the TVFC guidelines, on-site education and a focused site review assessment to confirm that the problems have been resolved will occur prior to their re-enrollment into the program. The provider must have a current and valid license to administer vaccine in the state of Texas. In addition, the TVFC Program checks the OIG List of Excluded Individuals or Entities for federally-funded healthcare programs to ensure that a pending provider is eligible to participate in the TVFC Program. TVFC requires the provider to meet and perform all enrollment processes, including demonstrating that they have the proper vaccine storage and procedures in place prior to receiving vaccines.

# **CHAPTER 2**

## **TVFC PATIENT ELIGIBILITY AND SCREENING**

**Last Updated: 10/2014**

### **I. Patient Eligibility Requirements**

#### **A. 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:

- Medicaid eligible
- Enrolled in CHIP and the provider bills CHIP for the services
- Is an American Indian
- Is an Alaskan Native
- Does not have health insurance
- Is underinsured:
  - A child who has commercial (private) health insurance, but coverage does not include vaccines;
  - A child whose insurance does not cover all ACIP recommended vaccines (TVFC-eligible for non-covered vaccines only); or
  - A child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

Immigration status does not affect a client's eligibility for TVFC. Immigrants should be offered the same immunization services that other clients receive in public health clinics.

If a child younger than nineteen years of age loses access to his or her health insurance because of incarceration, the child is considered uninsured and TVFC eligible.

Children who have private insurance that covers vaccines are not eligible to receive TVFC vaccines in public health department clinics, but instead will be referred to their medical home for immunizations. A LHD that provides comprehensive healthcare services to children with private insurance may continue to serve as the medical home for their privately insured patients. However, TVFC requires that private stock vaccine be purchased to continue to vaccinate fully, privately insured children.

American Indian and Alaskan Native children with private insurance 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 that will require the least out-of-pocket expense for the parent/guardian.

Table 2-1: A Quick View of TVFC Eligibility can be used to help determine patient eligibility.

**Table 2-1: A Quick View of TVFC Eligibility**

Scenario: The child...	Insurance Status	Is the child eligible to receive federal VFC-supplied vaccine through the TVFC Program?	Is the child eligible to receive state-supplied vaccine through the TVFC Program?
Has private health insurance	Insured	No	No
Is insured and has not yet met plan's deductible	Insured	No	No
Is insured and the plan covers all ACIP recommended vaccines but excludes certain products/combination vaccines	Insured	No	No
Is insured but the plan only covers a portion of the vaccine cost and the <b>does not have Medicaid as a secondary insurance</b>	Insured	No	No
Is enrolled in Medicaid	Medicaid eligible	Yes	No
Has Medicaid as secondary insurance	Medicaid eligible	Yes	No
Has insurance and plan only covers a portion of the vaccine costs <b>and has Medicaid as secondary insurance</b>	Medicaid eligible	Yes	No
Has insurance and has not met the plan's deductible and has Medicaid as secondary insurance	Medicaid eligible	Yes	No
Cannot access health insurance due to being incarcerated	Uninsured	Yes	No
Is enrolled in separate Children's Health Insurance Program	Insured	No	Yes *
Has insurance, but coverage does not include vaccines	Underinsured	Yes (only at a FQHC, RHC or approved deputized provider)	Yes †
Has insurance, but plan does not cover all ACIP recommended vaccines	Underinsured	Yes ‡ (only at a FQHC, RHC or approved deputized provider)	Yes †‡
Has insurance, but plan caps vaccine coverage at a certain amount	Underinsured (once the coverage amount is reached)	Yes (only at a FQHC, RHC or approved deputized provider)	Yes †
Does not have health insurance	Uninsured	Yes	No
Is American Indian or Alaskan Native	Any	Yes	No

\* Provider must bill CHIP

† Texas supplies vaccines for underinsured children who are not immunized at an FQHC, RHC or deputized site

‡ Eligible only for ACIP recommended vaccines that are not covered by insurance

## **B. Children's Health Insurance Program (CHIP)**

TVFC providers who administer TVFC vaccines to CHIP children are required to bill CHIP for the vaccines administered. Because children with CHIP are not eligible for the federal VFC Program, the State must reimburse CDC for the cost of the vaccines used to immunize CHIP children. CHIP pays the provider for the administration fee and reimburses the DSHS Immunization Branch for the cost of the vaccines that were administered to CHIP children. The DSHS Immunization Branch uses these vaccine funds to replenish those doses 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/guardian of a child with Medicaid as a secondary should never be billed for a vaccine administration fee.

## **D. Nineteen-year Olds**

Individuals who are 19 years of age and previously initiated a vaccination series under the TVFC Program, but have not completed the series, may complete the series using Adult Safety Net (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 individuals that have not yet reached their 20th birthday.

## **II. Patient Eligibility Screening**

Screening for eligibility is the foundation of provider-level accountability. Screening all children for and documenting eligibility at every visit is the only way to ensure that TVFC vaccine is used only for TVFC eligible patients. As such, anything less than full compliance is not allowable. The enrolled provider will have additional follow-up actions if found deficient.

Providers must document the eligibility category of each client receiving TVFC vaccine in the patient's chart or in an electronic data file. During a child's initial visit to the provider site, the provider must document the child's eligibility category per TVFC guidelines and update the child's eligibility information during future visits. Documentation of eligibility screening must include the following elements:

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

Providers may choose to use the Patient Eligibility Screening Record (C-10) or electronically store eligibility screening information. The Patient Eligibility Screening Record provides a means of recording responses to TVFC eligibility questions. The parent, guardian, individual of record, or provider may complete this form. Verification of parent/guardian response is not required.

For providers opting to use the Patient Eligibility Screening Record (C-10), the most current version of the Patient Eligibility Screening Record (rev. 03/2014) is to be completed for all patients, including patients with a prior version on file, and updated at every immunization visit.

The eligibility information should be easily retrievable. The patient eligibility record must be maintained on file by the provider for a minimum of five years after the last date of service to the patient.

# CHAPTER 3

## VACCINE MANAGEMENT

Last Updated: 10/2014

### I. Approved Vaccines

The TVFC Program supplies the following ACIP routinely recommended vaccines/toxoids to enrolled providers. All providers participating in the TVFC Program are required to offer ALL recommended vaccines to the eligible population they serve:

- Diphtheria and Tetanus toxoids, adsorbed (DT)
- Diphtheria-Tetanus toxoids and acellular Pertussis vaccine (DTaP)
- Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, Hepatitis B, and inactivated polio vaccine (DTaP-Hep B-IPV)
- Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, inactivated polio vaccine, and *Haemophilus influenzae* type b vaccine (DTaP-IPV/Hib)
- Diphtheria-Tetanus toxoids and acellular Pertussis vaccine and inactivated polio vaccine (DTaP-IPV)
- Hepatitis A vaccine (Hep A)
- Hepatitis B vaccine (Hep B)
- *Haemophilus influenzae* type b (Hib)
- *Haemophilus influenzae* type b and Hep B (Hib-Hep B)
- Human Papillomavirus vaccine (HPV)
- Influenza vaccine
- Inactivated polio vaccine (IPV)
- Measles, Mumps, and Rubella (MMR)
- Measles, Mumps, Rubella and Varicella virus vaccine (MMRV)
- Menhibrix (HIBMENECY)
- Meningococcal Conjugate (MCV4)
- Pneumococcal Conjugate (PCV13)
- Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
- Rotavirus vaccine (RV)
- Tetanus and diphtheria toxoids, adsorbed (Td)
- Tetanus and diphtheria toxoids and acellular Pertussis vaccine (Tdap)
- Varicella

## II. Vaccine Ordering

### A. Provider Vaccine Choice

The TVFC Program supplies all ACIP recommended vaccines/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. House Bill 448 from the 81<sup>st</sup> Texas Legislature gives TVFC and Adult Safety Net (ASN) providers the opportunity to choose their preferred brands and presentations of vaccines.

The medical provider who signs the VFC Program Provider Agreement can either choose vaccine brands and presentations, or be consulted with and agree to the choices made for the clinic. The DSHS HSR or LHD will create the initial Biological Order Form (EC-68) for new TVFC providers. The initial Biological Order Form will reflect the provider choices, maximum stock levels (MSL), tiered ordering frequency (TOF), and order quantity.

Vaccine choices will remain in effect until the vaccine choice optional update is opened. Each quarter, providers will have the opportunity to choose the brand and presentation for each TVFC vaccine in EVI and can change/adjust specific vaccine brands, presentations, and percentages within each vaccine “family” (i.e. DTaP) or take no action to maintain the current selections. A representative for the provider may complete the process; however, the provider who signed the TVFC Provider Agreement must be consulted with and agree to the vaccine choices. The vaccine choices, as well as the person making changes, are captured electronically in EVI. Providers are notified prior to the opening and closing of the vaccine choice period.

Only vaccines supplied to DSHS through contracts with the CDC will be available for choice. Vaccines exceeding 115% of the lowest-priced equivalent vaccine may not be available.

In the event any vaccine chosen is not available, DSHS has the authority to replace the chosen vaccine with a comparable substitution until the chosen vaccine becomes available. Vaccine choices do not apply in the event of a disaster or public health emergency, terrorist attack, hostile military or paramilitary actions, or an extraordinary law enforcement emergency.

### B. Maximum Stock Levels (MSL)

Maximum Stock Level: A calculated peak dose inventory (per vaccine type). The standard number of doses a provider should order up to on each regularly scheduled vaccine order.

DSHS HSRs and LHDs will work with the provider to develop MSLs. MSLs are monitored, calculated, and revised in EVI. Online MSL adjustment will include a variable MSL based on season and an adjustment for upward or downward administration trends.

MSLs are calculated manually using the following process:

1. Obtain an average of the doses administered for each vaccine, excluding any month's data that could skew the result. The average can be based on any number of months as long as they are reflective of current usage.

2. Multiply the average obtained in Step 1 by 2.5 for a monthly provider, 3.5 for a bi-monthly provider, or 4.5 for a quarterly provider.

The number obtained in Step 2 is the MSL for the provider.

MSLs are based upon a 45-day base of vaccine to allow for potential distribution delays, plus vaccine for the number of days between orders. See table below:

<b>Tier</b>	<b>Base Days</b>		<b>Days Between Orders</b>		<b>Total Days of Vaccine</b>
<b>Monthly</b>	<b>45 (1.5 months)</b>	+	<b>30 (1 month)</b>	=	<b>75 (2.5 months)</b>
<b>Bi-Monthly</b>	<b>45 (1.5 months)</b>	+	<b>60 (2 months)</b>	=	<b>105 (3.5 months)</b>
<b>Quarterly</b>	<b>45 (1.5 months)</b>	+	<b>90 (3 months)</b>	=	<b>135 (4.5 months)</b>

### C. Tiered Ordering Frequency (TOF)

Tiered Ordering Frequency: The period of time between scheduled vaccine orders. There are three typical TOFs: monthly, bi-monthly, and quarterly.

DSHS HSRs and LHDs will determine a provider’s TOF upon enrollment along with the MSL. The TOF is based upon actual or projected annual vaccines usage and provider storage capacity. Providers will be scheduled to place vaccine orders:

- **Monthly** - Once a month if more than 6,000 doses are ordered per year
- **Bi-Monthly** - Once every other month if between 800 – 6,000 doses are ordered per year
- **Quarterly** - Every three months if between 200 - 799 doses are ordered per year

Large providers will order more frequently, while smaller providers will order less often.

### D. Storage Capacity

A provider must have adequate refrigeration/freezer space to accommodate a maximum order based on TOF and MSL, as well as largest annual inventory. A Storage Calculation Tool and instructions are available on the TVFC website under “Provider Resources” at <http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>. Providers should take into consideration that additional space may be needed.

## E. Vaccine Ordering in the Electronic Vaccine Inventory (EVI) System

EVI allows providers to manage their vaccine inventory online. All vaccine orders will be placed in EVI unless internet access is unavailable. Providers are required to enter into EVI all vaccine received, doses transferred, doses administered, expired/wasted vaccine and their physical count for all TVFC vaccines each month regardless of whether an order is placed. When a provider places an order in EVI, the system requires doses administered to be entered up to the current date and the current inventory to be dated within two days of placing an order.

All orders will be reviewed and approved by the DSHS HSR or LHD pending the provider's completion and submission of the Temperature Recording Form (C-105) and resolution of any outstanding issues. Incomplete or inaccurate online orders will be placed on "Hold" by the system pending corrections by the provider which may cause orders to be delayed.

Providers should abide by their established MSLs and TOFs when ordering vaccine. EVI uses the provider's MSLs and current inventory to determine a suggested quantity of vaccine on the "Place Order" tab. Providers are allowed to request quantities exceeding their MSL; however, a justification is required for each brand/presentation in the "Comment" section on the "Place Order" tab to validate the request.

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

Providers are responsible for entering accurate provider information into EVI, including shipping address, days and hours available to receive vaccine shipments, and primary and back-up contact information. Providers may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

Providers are able to view their order statuses on the "Order History" page of EVI:

<b>Open</b>	Indicates that the order is ready to be sent to the distributor for shipment three business days from the date the order is placed
<b>Hold</b>	Indicates that the order is inaccurate, requires submission of documents, or has other identified issues
<b>Packed</b>	Indicates that the order has been sent to the distributor
<b>Shipped</b>	Indicates that the order is in transit or a transfer has been conducted in EVI
<b>Received</b>	Indicates that the provider has received the order or transfer

## **F. Vaccine Ordering for Providers without Internet Access**

TVFC providers without access to the internet will contact their responsible entity (DSHS HSR or LHD), who will then enter the provider's order online. Providers without internet access will submit the following paper reports to the responsible entity in order to place their vaccine order:

- Monthly Biological Report (EC-33, rev. 02/12)
- Biological Order Form (EC-68, rev. 03/14)
- Temperature Recording Form (C-105, rev. 10/14)

## **G. Vaccine Ordering for Newly Enrolled Providers**

Newly enrolled providers will coordinate vaccine ordering through their responsible entity (DSHS HSR or LHD) until they are established in EVI. Newly enrolled providers will submit the following paper reports to the responsible entity in order to place their vaccine order:

- Biological Order Form (EC-68, rev. 03/14)
- Temperature Recording Form (C-105, rev. 10/14)

## **H. Ordering Influenza Vaccine**

Annual influenza vaccine orders are typically pre-booked by TVFC providers between February and March each year. The pre-book is a commitment by the provider to order doses for the upcoming season. Providers will use an online survey tool to select their vaccine choices for the upcoming season. The link to the survey is released to the TVFC providers in a memo with a brief description of the influenza vaccines available for the upcoming season.

If the orders are outside the expected number of eligible children from the provider profile, providers are contacted for an explanation. If a TVFC provider who sees TVFC-eligible children does not order flu vaccines for the upcoming season, they must complete a separate section of the survey explaining why they are not ordering flu vaccine. TVFC providers are expected to follow all ACIP recommendations, including the administration of influenza vaccine. Providers who do not order influenza vaccine will receive a follow-up phone call from the DSHS HSR or the TVFC Program.

The Immunization Branch orders a limited quantity of additional doses to account for new 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 doses to the state may also be considered for first round allocation.

Influenza vaccine will be allocated to providers as influenza vaccine is made available to Texas. The DSHS Immunization Branch typically completes all pre-booked and new provider orders first. A second influenza survey tool will be re-opened for providers that did not order during the pre-book period and for those providers who wish to add to their original order. When first

round and second round orders are entirely filled, any remaining influenza vaccines will be added to the EVI system for general ordering by all providers. If there is an additional need for influenza vaccine, the Immunization Branch will contact other providers in Texas for a possible vaccine transfer or place an additional order with the CDC.

### **III. Vaccine Distribution**

#### **A. Vaccine Distributors**

DSHS uses two vaccine distribution centers:

- McKesson Specialty, a third party distributor which ships the majority of TVFC vaccines
- Merck, the manufacturer of varicella-containing vaccines, which ships directly to providers

#### **B. Receiving Vaccine Orders**

TVFC requires providers always accept vaccine shipments. Never refuse or return vaccine shipments without specific instructions from DSHS or your DSHS HSR or LHD. Providers must ensure that the accurate shipping address and delivery hours are entered into EVI.

In order for providers to receive vaccine shipments, providers must be on site with appropriate staff available at least one day a week other than Monday, and for at least four consecutive hours that day. Providers will be held responsible for incomplete or erroneous information entered into EVI which results in vaccine loss.

Providers can expect their approved orders approximately one to three weeks after placing their online order in EVI. It is important to recognize and store vaccine shipments immediately to ensure vaccine viability. Providers are required to train all staff on what a vaccine shipment looks like. TVFC requires all providers to have a protocol to ensure the vaccine gets stored quickly and appropriately upon arrival. The following steps should be taken when a vaccine shipment arrives:

1. Check actual vaccine received against packing list to verify all vaccines have been received.
2. Verify the packing list against order placed in EVI to ensure all vaccines ordered were received.
3. Ensure adequate diluent is included for vaccines requiring reconstitution (i.e., MMR, Hib, varicella).
4. IMMEDIATELY contact the DSHS HSR or LHD if the appropriate vaccine (or diluent) is not received.

5. Place vaccine in appropriate storage immediately.
6. Make sure to check expiration dates and rotate stock to ensure short-dated vaccine is used first.
7. Each package shipped from McKesson comes with a temperature monitoring strip(s). If the monitor strip indicates, or if staff suspects, that the cold chain has been compromised, staff should immediately contact their appropriate responsible entity (HSR or LHD). Follow the procedures below for “Vaccines Received Warm or Questionable.”

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

Manufacturer and distributor pack vaccine using qualified pack-outs and containers that have been tested to maintain appropriate temperatures for a given length of time up to a maximum ambient temperature. Refrigerated vaccine is packed to maintain the cold chain for 72 hours (3 days). 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-containing products are direct-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. Providers should immediately store the varicella-containing vaccines in proper storage. If the vaccine arrives outside of the four day pack out, then the provider should immediately store the vaccine properly and contact the manufacturer. Replacement instructions will be determined on a case-by-case basis.

Merck has implemented a cooler recycling program for direct ship products. A prepaid UPS shipping label is included with each container. Once the vaccine is removed and the container is empty, the provider should seal the container and affix the prepaid UPS shipping label. Providers will have to wait until UPS returns to their office with the next delivery to return the cooler. If the provider calls UPS to schedule a pick-up, the provider will be charged a pick-up fee.

### **C. Vaccines Received Warm or Questionable**

Vaccine must always be stored properly, even if viability is questionable. If vaccine is received warm, damaged, or otherwise questionable, the provider needs to immediately contact the DSHS HSR or LHD. Questionable vaccine should be labeled “Do Not Use” and segregated in proper storage until viability can be determined.

Examples of potentially non-viable vaccines are:

- Vaccine shipment received with temperature indicator strip showing out of range
- Vaccine is warm to touch
- Vaccines are received damaged

Instructions to follow if vaccine viability is questionable upon receipt:

- Before storing the questionable vaccines in the refrigerator and/or freezer, place questionable vaccines in a bag labeled “Do Not Use” or attach a piece of paper with “Do Not Use” written in large letters. Do not write on the vaccine itself. Labeled vaccine must be stored in appropriate storage. Do not use questionable vaccine until further directions are received.
- Contact the DSHS Pharmacy or manufacturer immediately to determine the viability of the vaccine. If the provider contacts the manufacturer, the provider must receive documentation of the determination in writing. This documentation must be maintained with the provider’s TVFC records for a minimum of five years. Providers must contact their responsible entity to inform them of the determination of the viability of the vaccine. Providers should never contact the distributor unless instructed to do so by the DSHS HSR or LHD.
- Wait for the instructions for replacement, reporting loss, etc. from the DSHS HSR or LHD. DSHS HSR and LHD staff cannot make the determining factor on vaccine viability. The DSHS HSR or LHD will direct you to the appropriate contact for determination.

Note: Vaccine returns due to shipping issues are required to be returned to McKesson within 48 hours.

#### **D. Vaccines Received in Error**

TVFC providers must call their responsible entity (DSHS HSR or LHD) immediately upon receipt of vaccine(s) received in error. The provider may opt to keep the vaccine if they have storage capacity and can administer the doses. If the provider cannot absorb the vaccine into their stock, then the DSHS HSR or LHD will assist in redistributing vaccine to other TVFC providers to prevent vaccine wastage.

### **IV. Vaccine Storage and Handling**

#### **A. Refrigerator and Freezer Requirements**

- Providers are required to have appropriate equipment that can store vaccine and maintain proper conditions. Two types of storage units are acceptable for storage: a refrigerator that has a separate freezer compartment with a separate exterior door or a stand-alone, single-purpose refrigerator or freezer. CDC strongly recommends stand-alone freezers and refrigerators without freezers for vaccine storage. A frost-free or automatic defrost unit is preferred.

- Combination units, if used, must have separate thermostats for the refrigerator and freezer compartments.
- Small combination refrigerator-freezer units outfitted with a single external door and dorm-style refrigerators are never allowed for the storage of TVFC vaccine.
- High volume clinics may find separate refrigerators and freezers useful. A standard side-by-side or top-freezer unit is sufficient. Frost-free freezers are preferred. There are small, stand-alone freezers specifically manufactured to maintain very cold temperatures; these freezers are acceptable for the storage of varicella, MMRV, or MMR only.
- The refrigerator compartment is to maintain temperatures between 35°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at midrange, 40°F (5°C). The freezer compartment should maintain temperatures between -58°F and +5°F (-50°C and -15°C). An alarm system and back-up generator are recommended to help reduce vaccine loss when unexpected temperature fluctuations occur.
- Water bottles and frozen coolant packs will help maintain stable temperatures with frequent opening and closing of unit doors, in the event of a power failure, and serve as a physical barrier to placing vaccines in an area where there is greater risk for temperature excursions. Place water bottles (labeled “Not for consumption”) on the top shelf, floor, and in door racks of the refrigerator. Place frozen coolant packs along walls, back, and bottom of freezer and inside the door racks. Diluents may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water. Place items in unit doors carefully so they cannot dislodge, and prevent doors from closing or weighing them down so much that seals are not tight. Placing bottles of water in the lower bins of the refrigerator is also helpful as this space cannot be used for vaccine storage.
- 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 should be adequate water bottles in each refrigerator and adequate ice packs in each freezer to help maintain proper storage temperature during peak usage of the unit or until vaccine can be moved to another refrigerator or freezer. Gel packs are only allowed for use in the freezer.
- If a refrigerator or freezer is new or newly repaired, allow a week of refrigerator and freezer temperature readings/recordings (a minimum of two times each workday) including minimum/maximum temperatures one time each morning to make sure temperatures are within appropriate ranges before using the unit to store vaccines. Read the refrigerator and freezer instructions carefully before adjusting the temperature control settings, and then make sure temperatures do not change overnight. Some manufacturers recommend resetting the controls in the summer and winter. If so, post instructions on the refrigerator door.

**Figure 3-1: Correct Vaccine Storage**



**Correct Storage**

1. Correct placement of the thermometer probe in the refrigerator
2. Vegetable bins are empty
3. Water bottles are placed in the unit along the back wall and floor of the unit
4. Vaccines are kept in original packaging
5. Vaccines are organized and not touching walls

- Refrigerator/freezer units must be large enough to hold the year's largest inventory.
- All TVFC providers should identify sufficient alternative space to store vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service.
- Refrigerators and freezers that store TVFC vaccine are to be dedicated to storing vaccine only. Food or drinks in the same refrigerator or freezer as vaccine is not acceptable.
- A Temperature Recording Form (C-105) is required to be located on or near all units that store TVFC vaccine. Freezer/refrigerator temperatures are required to be checked, recorded and initialed twice daily.
- Refrigerators and freezers storing vaccine should be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.

## **B. Thermometer Requirements**

Refrigerators and freezers that store TVFC vaccine must contain a centrally located thermometer with a current certificate of calibration. The thermometer probe should be placed as close to the vaccine as possible. Thermometers may be supplied by the TVFC Program when funding allows; however, it is the responsibility of the provider to ensure they have a thermometer accompanied by a current certificate of calibration in each refrigerator and freezer that stores TVFC vaccine. A valid certificate of calibration matching the serial number of the thermometer in use is to be posted on the refrigerator.

Each thermometer must be covered by a Certificate of Traceability and Calibration. Figure 3-2 on the following page presents an example of a valid certificate of calibration. The traceability declaration is to confirm the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to the National Institute of Standards and Technology (NIST), or to another internationally recognized standards agency. The accompanying certificate should be retained as proof of certification. 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 thermometer.

All certificates of calibration must contain:

- Model number
- Serial number
- Date of calibration
- Measurement results that indicate unit passed the test and the documented uncertainty is within suitable limits (recommended uncertainty = +/-1°F (0.5°C))

Figure 3-2: Example of a Valid Certified Thermometer Certificate

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**CALIBRATION REPORT FOR THERMOMETER**

Report No. U173259 Page 1 of 2 SO: 123456

THE INSTRUMENT DESCRIBED BELOW WAS EXAMINED AND TESTED IN ICL'S ISO/IEC 17025 ACCREDITED CALIBRATION LABORATORY, USING NIST TRACEABLE REFERENCE STANDARDS, IN ACCORDANCE WITH ICL'S ISO/IEC 17025 CALIBRATION PROCEDURE REFERENCED BELOW. THIS CALIBRATION MEETS THE REQUIREMENTS OF ISO/IEC 17025, ANSI/NCSL Z540-1-1994, (WHICH SUPERCEDED AND REPLACED MIL-STD 45662A), AND THE ISO-9000 AND QS-9000 SERIES OF QUALITY STANDARDS.

**CUSTOMER INFORMATION**

SAMPLE CUSTOMER  
 STREET ADDRESS  
 CITY, STATE ZIP

PURCHASE ORDER NUMBER: NOT AVAILABLE

SUBMITTED BY: SAMPLE COMPANY

**DATES**

DATE REPORT ISSUED: 05-16-2011

**INSTRUMENT INFORMATION**

THERMOMETER ASTM 12F INSCRIPTION: LSW  
 MODEL: 10012F-C RANGE: -5/215F DIVISIONS: .5 °F IMMERSION: TOTAL  
 ENGINEERING UNITS: degrees Fahrenheit  
 SERIAL NUMBER: XXXX

ACCURACY TOLERANCE (maximum scale error permitted by ASTM E 11): +/- 0.25F

**RESULTS OF PHYSICAL EXAMINATION**

THIS INSTRUMENT WAS EXAMINED UNDER A POLARIZED LENS AND STRAINS IN THE GLASS, IF ANY, WERE JUDGED TO BE MINIMAL AND OF NO DETRIMENT TO THE FUNCTION OF THE INSTRUMENT.

THE CAPILLARY OF THIS THERMOMETER WAS EXAMINED UNDER MAGNIFICATION WITH RESULTS AS FOLLOWS: NO FOREIGN MATERIAL, MOISTURE, OR OTHER EVIDENCE OF CONTAMINATION WERE DISCOVERED. NO DISCERNABLE CAPILLARY IRREGULARITIES WERE NOTED.

IT WAS DETERMINED THAT THIS INSTRUMENT IS IN GOOD WORKING ORDER AND IS THEREFORE SUITABLE FOR CALIBRATION.

**CALIBRATION PROCEDURE USED:** ICL Procedure 01, which is based upon ASTM E 77, NBS Monograph 150 & NIST SP 250-23

**RESULTS OF CALIBRATION**

NOTE: The indications of this instrument cannot be adjusted or modified by ordinary means; accordingly, the readings given in the table below should be considered, in effect, to be both "As Found" and "As Left" readings.

TEST TEMP	READING	CORRECTION	ACCEPT LIMIT* (+ or -)	P/M/F	UNCERTAINTY
-4.00 °F	-4.00 °F	0.00 °F	0.246 °F	PASS	0.12 °F
15.00 °F	14.95 °F	+0.05 °F	0.246 °F	PASS	0.12 °F
32.00 °F	31.95 °F	+0.05 °F	0.246 °F	PASS	0.12 °F
50.00 °F	50.90 °F	+0.10 °F	0.246 °F	PASS	0.12 °F
60.00 °F	59.85 °F	+0.15 °F	0.246 °F	PASS	0.12 °F
75.00 °F	74.90 °F	+0.10 °F	0.246 °F	PASS	0.12 °F
100.00 °F	99.85 °F	+0.15 °F	0.246 °F	PASS	0.12 °F
125.00 °F	124.90 °F	+0.10 °F	0.246 °F	PASS	0.12 °F
150.00 °F	149.85 °F	+0.15 °F	0.246 °F	PASS	0.12 °F
175.00 °F	174.80 °F	+0.20 °F	0.246 °F	PASS	0.12 °F
200.00 °F	199.75 °F	+0.25 °F	0.246 °F	PASS	0.12 °F
210.00 °F	209.90 °F	+0.10 °F	0.246 °F	PASS	0.12 °F

\*ACCEPT LIMIT(S) The acceptance limit(s) shown above represent a statistical evaluation of the instrument's tolerance relative to the

Certified calibrated thermometers for use in any refrigerator/freezer unit with TVFC vaccine should include the following functions:

- Current temperature, as well as minimum and maximum temperatures and
- Detachable temperature probe in bio-safe glycol filled glass bottle or a similar temperature buffered probe rather than measurement by ambient air temperatures.

Refrigerators and freezers that are manufactured with built-in temperature monitoring capability are required to be accompanied by a certificate of calibration for the thermometer.

The temperature probe in the unit needs to be centrally located, and the temperature thermostat is to be capable of being adjusted by the provider as needed to maintain proper temperature.

The TVFC Program requires the use of a digital thermometer with a biosafe glycol-encased probe that measures liquid temperature. Additionally, it is recommended that the temperature monitor is placed on the outside of the unit door to allow for reading temperatures without opening the unit door.

All TVFC enrolled providers are recommended to have at least one back-up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer) for use when a thermometer in a storage unit unexpectedly stops working or when the thermometer needs to be sent for re-calibration. Please note: beginning January 1, 2015 this will become a TVFC Program requirement.

The TVFC Program also recommends that providers utilize data loggers. A data logger provides more accurate and comprehensive monitoring of temperature excursions to which vaccines may be exposed. Data loggers, if used, must be accompanied by a current certificate of calibration. If a digital data logger is used, it must have the following capabilities:

- Detachable probe (kept in the glycol-filled bottle)
- Alarm for out-of-range temperatures
- Current temperature, as well as minimum and maximum temperatures
- Reset button
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate)

Providers must also have a room thermometer to record the room temperature when a temperature excursion occurs in a vaccine storage unit. This requirement will be effective as of January 1, 2015.

### **C. Vaccines**

- Some vaccines are sensitive to light; vaccine efficacy could be compromised if exposed to the light. Providers should safeguard the following vaccines from light: MMR, MMRV, HPV, MCV4, some Hib vaccines, rotavirus, and varicella.
- All vaccines are to be stored in the refrigerator and should never be frozen. The exceptions are varicella, MMR, and MMRV.
- All vaccines should be stored in the central area of the refrigerator/freezer shelves, not in the vegetable bins, meat drawer, or in the door. Storing vaccine in the central body of the refrigerator/freezer helps maintain vaccine at proper temperatures.

- Vaccines should be stored and/or stacked to allow cold air to circulate freely.
- TVFC vaccines must be stored separately from privately purchased vaccine. Public and private stocks should be labeled accordingly.
- TVFC supplied vaccine may be stored in a “blended manner”. Providers do not have to separate public vaccines based on funding source (e.g., VFC, 317, CHIP, and State funds).
- TVFC providers enrolled in the ASN Program must separate public pediatric doses from public adult doses.

#### **D. Protective Equipment**

- The power supply for vaccine storage units must be protected.
- Plug guards are required to be used on all refrigerators/freezers that store TVFC vaccines. Plug guards are effective tools in preventing the accidental unplugging of equipment. If a plug guard will not fit then tape the appliance cord to the wall and post on the wall nearby a sign stating “Do Not Unplug.” DSHS HSRs, LHDs, and quality assurance contractors are responsible for providing plug guards to providers.
- A “Do Not Unplug” sign is required to be posted on or near all outlets of refrigerators/freezers used for storing vaccine.
- A “Do Not Disconnect” sign must be posted by each circuit breaker.

#### **E. Personnel**

- Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle TVFC vaccine should be trained on proper storage, handling, and administration of vaccine. The facility is required to designate a primary and at least one back-up vaccine coordinator to ensure that TVFC vaccines are handled and stored properly. Both employees are required to complete the mandatory “You Call the Shots” training modules annually.
- All staff that handles TVFC vaccine is to be aware of and familiar with the written procedures for emergency situations to assure continued viability of the vaccines.
- New employees must be adequately trained regarding the proper storage and handling of vaccine prior to administering TVFC vaccine.
- The DSHS Immunization Branch has developed the Texas Vaccine Education Online to provide short online training courses on topics related to vaccines. After enrolling

online, individuals may log in and take any course free of charge. Additional information and a course listing are available at [www.vaccineeducationonline.org](http://www.vaccineeducationonline.org).

## **F. Routine and Emergency Storage and Handling Plan**

TVFC providers must have plans for routine and emergency vaccine management. The TVFC Program provides templates for the Routine Vaccine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan. Providers are 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, providers must develop routine and emergency vaccine management plans that include all of the information on the templates provided by the TVFC Program.

The Routine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan must be reviewed and updated annually. A review date is required on all plans in order to verify that they are current. All plans must include the signature, name, and title of the preparer of the documents.

TVFC providers will be asked to provide a copy of their routine and emergency vaccine storage and handling plans at VFC Compliance Visits. The plans should be posted on or near the refrigerator or freezer containing TVFC vaccine. Make sure all employees involved with vaccine management are aware of this plan.

## **G. 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.

In the event of an emergency, contact your responsible entity (DSHS HSR or LHD) to inform them of the situation. Be prepared to provide the following information:

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

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

- Identify a responsible person and a responsible back up person to enact the contingency plan. Be sure to include contact information such as home, office, and cell phone numbers for each. Contact information should be updated annually.
- Identify an alternative location to take the TVFC provided vaccine for storage. A location with a power generator or other alternate source of power such as a hospital or

grocery store is preferable. Ideally, this facility should be located within a reasonable distance from your clinic. Be sure to contact the alternate location for their approval before including them on your plan and list their contact person(s) and phone number(s) on your plan.

- Specify the steps to transport vaccine to the alternate location. Steps should include:
  1. Noting the time of the emergency situation/power outage.
  2. Noting the temperature of the refrigerator and freezer before removing any vaccine for transportation.
  3. Indicating what containers will be used and how the refrigerated vaccine should be packed for transportation (i.e., conditioned ice packs separated from the vaccine by plastic bubble wrap or crumpled paper to prevent freezing and damage).
  4. Taking inventory of the vaccine as you move it into the transport container, being careful to indicate the number of doses of each vaccine and the expiration dates.
  5. Keeping a certified and calibrated thermometer in the transport container and noting the time and temperature when you place the vaccine in the alternate storage. This reveals how long the vaccine was at less-than-ideal temperature.

## **H. Cold Chain Management and Vaccine Transport**

- TVFC 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 vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service. Enough proper supplies for packing and transporting the entire provider vaccine supply/inventory needs to be available in case of an emergency.
- Providers must complete routine and emergency vaccine storage and handling plans. These documents must be reviewed and updated annually. The Routine Vaccine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan must be posted on or near the refrigerator or freezer that contains TVFC vaccine. Staff members are required to be aware of the emergency plan and be able to follow it in case of an emergency.
- Avoid prolonged temperature extremes by using transport containers containing vaccine inside vehicles and taking the quickest route possible. Do not leave vaccine unattended in vehicles. Do not place vaccine in the trunk of a vehicle.

- Pack refrigerated vaccine first. Following the steps below will help maintain the cold chain during transport of refrigerated and frozen vaccines.

### ***Refrigerated Vaccine Transport***

#### **1. Assemble Packing Supplies**

- Cooler. 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 may be used if it can maintain the recommended temperature range (between 35°F and 46°F). 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.
  - Cold packs. Do not use dry ice. Cold packs that are frozen need to be “conditioned” by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and the packs look like they have been “sweating”. Frozen coolant packs that are not “conditioned” can freeze vaccine.
  - Thermometer. Use a certified and calibrated thermometer (preferably with a biosafe glycol encased thermometer probe). Prepare the thermometer by placing it in the refrigerator at least 2 hours before packing the vaccine.
  - Packing material. Use two 2-inch layers of bubble wrap or crumpled paper between each layer of ice packs and vaccine as well as at the top of the cooler. Not using enough bubble wrap/crumpled paper can cause the vaccine to freeze.
2. Spread a layer of conditioned cold packs (at least 2 inches) to cover the bottom of the cooler.
  3. Completely cover the conditioned cold packs with a 2-inch layer of bubble wrap/crumpled paper.
  4. Stack layers of vaccine boxes on the bubble wrap/crumpled paper. Do not let boxes of vaccine touch the cold packs.
  5. Place the thermometer/probe next to vaccines on top of the bubble wrap.
  6. Completely cover the vaccine with another 2-inch layer of bubble wrap/crumpled paper.
  7. Spread conditioned cold packs to cover the bubble wrap/crumpled paper. Make sure the cold packs do not touch the boxes of vaccine.

8. Fill the cooler to the top with bubble wrap/crumpled paper. Place the thermometer's digital display on top of the bubble wrap/crumpled paper. Include a list of the vaccines that are stored in the container. Secure the lid to the cooler.
9. Use a Temperature Recording Form (C-105) to record the temperature inside of the storage unit at the time the vaccines are removed, as well as the time. Also record the temperature of the transport container on the Temperature Recording Form. If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
10. As soon as you reach the destination site, check and record the vaccine temperature. If the vaccine is:
  - Between 35°F and 46°F, place it in the refrigerator.
  - Below 35°F or above 46°F, label the vaccine “Do Not Use,” place it in the refrigerator, and immediately contact your responsible entity.

Note: Always keep vaccine properly stored until otherwise instructed by a State pharmacist or the vaccine manufacturer.

### ***Frozen Vaccine Transport in an Emergency Situation***

Varicella-containing vaccines are fragile! The CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If these vaccines need to be relocated in an emergency situation, the following steps must be taken.

1. 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 in some places. Label the portable freezer with facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.
  - **Thermometer.** Use a certified and calibrated thermometer (preferably with a biosafe glycol encased thermometer probe). Prepare the thermometer by placing it in the portable freezer unit at least 2 hours before packing the vaccine.
  - **Cooler (if portable freezer is unavailable).** If a portable freezer is unavailable, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain the temperature between -58°F and +5°F (-50°C and -15°C). Label the container with facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.

- Coolant packs (if portable freezer is unavailable). Do not use dry ice. Coolant packs should be frozen.
  - Dry ice is not allowed to be used for transporting vaccines, even for temporary storage or emergency transport. Dry ice may subject vaccine to temperatures colder than -58°F (-50°C).
2. If a portable freezer is not available and a cooler must be used, follow the packing instructions for transporting refrigerated vaccine. Ensure that the coolant packs used in the cooler are frozen.
  3. Place a calibrated thermometer in the container used for transport as close as possible to the vaccine.
  4. Use a Temperature Recording Form (C-105) to record the temperature inside of the storage unit at the time the vaccines are removed, as well as the time. Also record the temperature of the transport container on the Temperature Recording Form.
  5. Continually monitor the vaccine temperature.
  6. Place the vaccine in the freezer immediately upon arrival at the alternate storage facility.
  7. Document the time the vaccine was removed from the transport container and temperature of the transport container and placed in the alternate storage unit.
  8. Immediately contact the manufacturer for stability data and guidance any time frozen vaccine has been exposed to a temperature above +5°F. Do not discard the vaccine without contacting the manufacturer. Viability determination will be made on case by case basis. Contact your responsible entity with the viability determination from the manufacturer.

## **V. Vaccine Transfers**

The routine re-distribution of TVFC vaccine is not allowed. The transfer of vaccine between TVFC clinic sites may only be conducted for the following reasons: overstock of vaccine, short dated vaccine, withdrawal of a provider from the TVFC Program, replenishing another clinic's inventory, or an emergency situation.

TVFC providers are required to submit a Transfer Authorization Form (EC-67) to the DSHS HSR and receive pre-approval prior to conducting vaccine transfers.

All vaccine transfers require a certified calibrated thermometer to be included in the transport container. The thermometer must have minimum and maximum temperature recording capability to ensure temperature excursions have not occurred during the vaccine transfer. The certificate of calibration for the thermometer must be included in the transfer.

To conduct a vaccine transfer, the TVFC provider, or authorized designee, who is transferring the vaccine, must do the following:

1. Ensure that the vaccine transfer is for one of the following reasons:
  - Overstock of vaccine
  - Short dated vaccine
  - Withdrawal of a provider from the TVFC Program
  - Replenishing another clinic's inventory
  - Other (emergency situations)
2. Complete and sign the TVFC Vaccine Transfer Authorization Form and agree that the vaccine will be transferred in accordance to DSHS vaccine storage and handling guidelines (to ensure the proper cold chain will be maintained throughout the transfer process). Each vaccine that is going 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, the lot number, the expiration date and the number of doses that are being transferred.
3. Fax the completed Vaccine Transfer Authorization Form to the appropriate DSHS HSR. Note: For emergency situations, providers must call the DSHS HSR prior to faxing the TVFC Vaccine Transfer Authorization Form.
4. Once the DSHS HSR approves the transfer (within 2 business days), a signed copy of the form will be faxed or emailed to both the provider requesting the transfer and the LHD (if applicable). Once the provider receives the approval fax or email from the DSHS HSR, the provider may conduct the transfer in EVI.
5. Ensure that vaccine is packaged using proper cold chain management and a certified, calibrated thermometer is enclosed with the packaged vaccine.
6. 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.
7. Include a Temperature Recording Form (C-105) to document temperatures before, during, and at the conclusion of the vaccine transfer. The 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 Vaccine Transfer Authorization Form on file for a minimum of five years.

## **VI. Vaccine Borrowing**

Vaccine Borrowing – Using publicly purchased vaccine to vaccinate non-TVFC eligible patients.

TVFC providers are expected to maintain adequate inventory of vaccine for both their TVFC eligible and privately insured clients. Vaccines supplied by the TVFC Program cannot be provided to a non-TVFC eligible client. Administering TVFC vaccines to a non-TVFC eligible patient is considered fraud. Providers must not use TVFC vaccines as a replacement system for filling the vaccine needs of a non-TVFC privately insured client.

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

1. Complete a 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.
2. Replace the vaccine immediately and account for the replacement in EVI.
3. Fax a copy of the Vaccine Borrowing Form to the appropriate DSHS HSR within 24 hours. Providers must follow HIPAA guidelines when faxing this form to the DSHS HSR.
4. The Vaccine Borrowing Form must be kept as part of the TVFC Program records for a minimum five years and be made easily available.

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

## **VII. Vaccine Loss**

### **A. Expired, Spoiled and Wasted Vaccine**

The Immunization Branch requires all unopened or unused vials and syringes of expired TVFC vaccines/toxoids/biologicals 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 Branch, DSHS HSR or LHD. Any exception to this rule will be communicated by the DSHS Immunization Branch on a case-by-case basis. Providers are to immediately notify the DSHS HSR or LHD of vaccine cold chain failure events or vaccine wastage incidents involving TVFC vaccines upon discovery of the incident.

Expired or spoiled vaccine: any nonviable vaccine in its original container (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
- Failure to store vaccine properly upon receipt

- Vaccine spoiled in transit
- Mechanical failure
- Recall

Wasted vaccine: 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 but doses not administered
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial

Wasted and expired/spoiled vaccines should be removed from the storage unit to prevent inadvertent administration. Wasted and expired/spoiled vaccine should be segregated, labeled “Do Not Use,” and stored pending return to distributor. The third party distributor, McKesson, will document Texas losses and return vaccines to the manufacturer for excise tax credit. All vaccine returns to McKesson must occur within six months.

Diluents should be managed similar to vaccines; the expiration date of diluents should be checked prior to every reconstitution. Providers should also rotate diluent stock to use the shortest expiration date first. Expired diluents do not need to be returned.

Vaccine loss must be documented on a Vaccine Loss Report electronically in EVI no later than four days past the date of the incident(s).

## **B. Short Dated Vaccine**

Placing orders according to the established MSLs and rotating vaccines so that shortest dated vaccines are used first will help to prevent losses due to expiration. Too much vaccine kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of refrigerator failure. When ordering vaccines, providers should keep no more than the designated MSL. Clinic staff should make note of vaccine expiration dates when physically counting on-hand inventory at the end the month. Vaccine with the shortest date must be used first.

Providers are required to notify the DSHS HSR or LHD 90 days prior to vaccine expiration. If the vaccine cannot be used before expiration, the DSHS HSR or LHD will assist with re-distribution of the vaccine.

## **C. 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.
- Contact your responsible entity (DSHS HSR or LHD) immediately with the following information:
  - Antigen
  - Lot number
  - Expiration date
  - Reason for expiration/loss
- If storage was compromised, provide DSHS HSR or LHD with amount of time product was out-of-range and the highest and lowest temperatures recorded.
- Document the vaccine loss on the Vaccine Loss Report electronically generated in EVI explaining the cause(s) of the loss and outlining the steps taken to ensure vaccines will be protected in the future.
- The Vaccine Loss Report should be printed and then submitted to the responsible entity, and is due within four days of the date of the loss.
- TVFC requires the completed Vaccine Loss Report to be signed or acknowledged by the medical provider who signed the VFC Program Provider Agreement. 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
  - Explanation of loss
  - 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 nonviable vaccine, if applicable. If more than one box will be used, mark the boxes with “Box 1 of 2,” “Box 2 of 2,” etc.
- Providers must ensure that all and only vaccines listed on that Vaccine Loss Report are included in the box for return. If more than one box is used to return nonviable 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.). A copy of the Vaccine Loss Report (including box number) should be included in each box when returning the non-viable vaccine.
- 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 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 nonviable 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 Branch.

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 provider should discuss the situation with the DSHS Pharmacy or manufacturer to determine 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 DSHS Pharmacy or manufacturer.

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 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 DSHS HSR or LHD 90 days in advance of the expiration date
- Refrigerator or freezer door left open
- Refusal of a vaccine shipment

Certain vaccine loss circumstances may qualify for insurance policy reimbursement depending on the type of insurance your facility has. Loss of TVFC vaccine under the following circumstances may be covered by insurance:

- Power outages due to inclement weather (e.g., flood, hurricane, freezing temperatures, tornado)
- Fire
- Robbery

## VIII. Reporting Requirements

TVFC requires providers to monitor the temperatures of all refrigerators and freezers containing TVFC vaccine and to submit reports on DSHS forms documenting vaccine inventory and usage.

All records related to the TVFC Program are required to be maintained for five years. These records include (but are not limited to):

- Monthly Biological Report (EC-33)
- Biological Order Form (EC-68)
- Temperature Recording Form (C-105)
  - Refrigerator Fahrenheit (C-105– RF )
  - Refrigerator Celsius (C-105 – RC)
  - Freezer Fahrenheit (C-105 – FF)
  - Freezer Celsius (C-105 – FC)
- Any other reports or required documents

All forms are available at the back of the Provider Manual, as well as under TVFC Forms on the TVFC webpage: <http://www.dshs.state.tx.us/immunize/tvfc/default.shtm>

### A. Reports Summary

#### *Monthly Biological Report (EC-33)*

The Monthly Biological Report is now documented in EVI as 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 providers who participate in the ASN Program are required to distinguish between their adult and pediatric vaccines and order and report adult vaccines separately from TVFC pediatric vaccines. The Combined Tally and Inventory Sheet (EC-88) is an optional form that may assist in tracking pediatric doses versus adult doses administered.

For those providers without internet access, the provider must complete the Monthly Biological Report and submit it to their responsible entity each month. The person completing the paper Monthly Biological Report should 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)*

This form is 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

should be ordered to bring the clinic up to their pre-determined MSL. For orders above the MSL, an explanation is required in the comment section.

### ***Temperature Recording Form (C-105)***

Completed Temperature Recording Forms for the previous month are to be submitted to the DSHS HSR or LHD. 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 (C-105-RF and C-105-FF) or Celsius (C-105-RC and C-105-FC) forms.

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

If an out-of-range temperature is observed, immediately contact the responsible entity (DSHS HSR or LHD) and complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form. Providers must include:

- 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 with whom you spoke)
- Results

All documentation regarding temperature deviations should be retained for review during VFC Compliance Visits and Unannounced Storage and Handling Visits. An example of the Vaccine Storage Troubleshooting Record can be found in the “Forms” section of the Provider Manual following the Temperature Recording Form.

### **B. Monthly Requirements**

On a monthly basis the following documents must be submitted to the DSHS HSR or LHD:

- Monthly Biological Report (EC-33) (only if internet access is unavailable)
- Temperature Recording Form (EC-105)
- Biological Order Form (EC-68) (only if internet access is unavailable)
- Any additional/associated forms as required by DSHS HSR or LHD

Monthly online vaccine management is required in EVI regardless of whether an order is submitted. Providers without internet access will need to continue to submit the Monthly Biological Report each month to their responsible entity (DSHS HSR or LHD).

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# **CHAPTER 4**

## **BILLING/ADMINISTRATION**

**Last Updated: 10/2014**

### **I. Billing for Vaccine**

Providers enrolled in the TVFC Program are prohibited from charging eligible patients, Medicaid, CHIP, or other entities for the cost of vaccine. The vaccine is provided at no cost to the provider to vaccinate eligible children. Charging for the cost of vaccine supplied by TVFC 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 immunizations if the provider has already accepted that child into the practice as their patient, unless directed by DSHS.

### **II. Administration Fees**

Providers may charge an administration fee for administering vaccine to TVFC-eligible children. The maximum fee a provider may charge for administration is \$22.06 per vaccine. Vaccines are required to be administered even if the patient/guardian/parent is unable to pay the administration fee.

Providers may not send a patient/guardian/parent to collections or charge fees for the patient's inability to pay administration fees.

### **III. Medicaid and CHIP Clients**

Medicaid and CHIP patients must not be charged any fees for vaccine or for vaccine administration. Medicaid and CHIP will reimburse providers for administration fees. Providers are required to enroll in the TVFC Program to obtain vaccine at no cost to vaccinate Medicaid and CHIP patients because Medicaid and CHIP will not reimburse providers for the cost of routinely recommended childhood vaccines. TVFC providers who administer vaccines to CHIP children are required to bill CHIP for the vaccines administered.

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# **CHAPTER 5**

## **PROGRAM EVALUATION**

**Last Updated: 10/2014**

### **I. Compliance Site Visit**

#### **A. Compliance Site Visits**

Providers at public sites participating in the TVFC Program will receive a Compliance Site Visit from a DSHS HSR or LHD reviewer annually. Providers at private facilities can expect to receive a Compliance Site Visit by a DSHS quality assurance contractor at least once every other year. By signing the VFC Program Provider Agreement, the signing physician agrees to allow a DSHS or DSHS-contracted entity to conduct a Compliance Site Visit.

The purpose of the visit is to assess, support, and educate the clinic regarding TVFC policies and procedures. If areas of need are identified, the 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 to schedule a Compliance Site Visit. Providers will receive a confirmation letter, email, or fax with 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 (and a power source if a laptop is used)
- Patient records
- Current and past temperature logs or data for the last three months, or longer if issues are found
- Current and past Vaccine Borrowing Forms
- The circuit breaker
- Admitting and billing personnel to clarify eligibility screening and billing processes
- All vaccine storage units where TVFC vaccine is stored

The Compliance Site Visit is split into two types to ensure that each site is being evaluated based on the population served. These types are described below.

#### **B. “A” site (VFC Compliance Visit & AFIX Visit)**

The “A” visit is the VFC Questionnaire and an AFIX visit utilizing the Comprehensive Clinical Assessment Software Application (CoCASA). The focus of “A” visits is for childhood assessment and review of 10-50 records on children 24-35 months of age. Reviewers use all of the qualifying records (up to 50 records). A minimum of 10 records 24-35 months is required for

childhood CoCASA assessments. Providers pull 50 charts for the CoCASA cohort prior to the site visit. The reviewer randomly selects 10 records of the charts pulled to determine compliance with VFC documentation requirements. Providers will not be notified in advance of the charts to be reviewed.

An “Adolescent” Site visit is performed if there are not enough children in the 24-35 months age range to perform an “A” site visit. The adolescent site visit uses CoCASA with a minimum of 20 records (50 preferred) of adolescents in the age range of 13-18 years.

### **C. “B” site (VFC Compliance Visit only)**

The “B” visit is the VFC Questionnaire only because there are not at least 10 records in the 24-35 months or 20 records in the 13-18 years age range. A “B” site visit, using 10 records of children from birth to 18 years of age only completes the VFC Compliance Tool.

### **D. Follow-Up Activities**

Upon completion of the Compliance Site Visit, the reviewer will discuss the outcomes of the visit with the provider staff. The discussion will include a review of the site visit findings and a formal follow-up plan with a timeline that addresses any issues on non-compliance or opportunities for improvement. Providers must sign the Acknowledgement of Receipt following the visit. The Acknowledgement of Receipt is the document that attests to the fact that a Compliance Site Visit was completed, the provider received the results of the visit, and that both the reviewer and the provider understand the non-compliance issues identified and the actions necessary to address them.

The responsible entity (DSHS HSR or LHD) will conduct follow-up activities if required. The purpose of follow-up activities is to ensure that areas for improvement identified by the DSHS HSR, LHD or QA contractor, are understood at the clinic, and corrective actions have been identified and implemented.

Follow-up activities are conducted at two weeks, three months and six month intervals following the initial site visit review. Follow up activities include, but are not limited to:

- Visiting the clinic to observe corrective actions
- Calling the TVFC Coordinator at the clinic
- Sending a letter to address the deficient items identified during the site visit

The responsible entity (DSHS HSR or LHD) works with providers on noncompliance issues by providing education and guidance regarding corrective actions. If a provider exhibits habitual noncompliance and does not take corrective actions in response to education, vaccine orders may be withheld or the provider may be withdrawn from the TVFC Program.

## **E. Electronic Medical Records (EMR)**

In recent years, the use of Electronic Medical Records (EMR) has become routine and has changed the way record reviews are conducted. Providers with EMRs have the following two immunization record review options, one of which should be available at the time of the visit:

1. 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.

Note: It is not acceptable to have a staff member log-in and then turn the EMR screens over to the reviewer; the staff person is required to be present.

2. 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: TVFC or the quality assurance contractor will not pay for or reimburse providers for the copies when the provider chooses to print out immunization records from their EMR system.

## **II. Unannounced Storage and Handling Visit**

Unannounced storage and handling visits may be conducted to serve as “spot checks” for proper vaccine storage and handling. DSHS HSRs and LHDs prioritize sites for unannounced visits based on the following criteria:

- Loss of publicly purchased vaccine
- Storing vaccines incorrectly
- Improper documentation of temperature logs
- Vaccine orders not consistent with provider profile data
- Newly enrolled provider

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.

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# CHAPTER 6

## FRAUD AND ABUSE

**Last Updated: 10/2014**

As the complexity of immunizations and immunization related programs grow, TVFC Program participants may become more vulnerable to unintentionally committing acts that could be construed as fraud and/or abuse. A working understanding of what constitutes fraud and abuse is critical for all persons working in the TVFC Program. Fraud and abuse, whether intentional or not, is subject to all Federal fraud and abuse laws.

### I. Definitions

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

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 immunization 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 cost to the Medicaid program.

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

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

Termination - The 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 public resources.

### II. Examples

Fraud or abuse can occur in many ways and some types of fraud and abuse are easier to prevent or detect than others. TVFC Program providers should familiarize themselves with the examples below illustrating common practice errors that could result in fraud or abuse allegations.

- Providing TVFC vaccine to non-TVFC eligible children
- Selling or otherwise misdirecting TVFC vaccine

- Billing a patient or third party for TVFC vaccine
- Charging more than \$22.06 for administration of a TVFC vaccine to an eligible child
- Failing to meet licensure requirements for enrolled providers
- Denying TVFC-eligible children TVFC vaccine because of parents' inability to pay the administration fee
- Failing to implement provider enrollment requirements of the TVFC Program
- Failing to screen for and document TVFC eligibility at every visit
- Failing to maintain TVFC records for five years and comply with other requirements of the TVFC Program
- Failing to fully account for TVFC vaccine
- Failing to properly store and handle TVFC vaccine
- Ordering TVFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of TVFC doses
- Waste of TVFC vaccine

### **III. 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 program requirements may occur due to an unintentional lack of understanding of the TVFC Program requirements or the behavior may be intentional. If the non-compliance appears intentional and the provider has received financial benefits from the behavior, the situation would require immediate referral for investigation of suspected TVFC fraud and abuse.

### **IV. Fraud and Abuse Prevention**

TVFC will actively work 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 TVFC Compliance visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse.

### **V. Reporting Fraud and Abuse**

Suspected fraud or abuse can be reported to the DSHS Immunization Branch, DSHS HSR or LHD via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that promote potential fraudulent situations are investigated. DSHS HSRs and LHDs and other contractors must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Branch 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.

# CHAPTER 7

## DOCUMENTATION REQUIREMENTS

Last Updated: 10/2014

### 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 healthcare provider administering the vaccine
- Address of the clinic where the vaccine was administered

Immunization cards for providers (C-100) and clients (C-102 and C-104) can be ordered free of charge from the DSHS Immunization Branch (See Chapter 10 Ordering Forms and Literature). These cards are designed to capture all information required when vaccines are administered.

### II. Decision to Not Vaccinate

Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in outbreaks of disease. While the majority of parents believe in the benefits of immunization 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 calls for both knowledge and interpersonal skills on the part of the provider. Immunization providers should have an understanding of vaccines, updated recommendations, and of reliable sources to direct patients to find accurate information. Also necessary are the skills 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 discussion regarding a vaccine concern, the provider should discuss the specific concern and provide factual information. The VIS provides an outline for discussing vaccine benefits and risk. 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 child care entry, which might require unimmunized children 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.

### **III. 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 (possible side effects) that occur after the administration of U.S. licensed vaccines.

Reports are welcome from all concerned individuals: patients, parents, health-care providers, pharmacists, and vaccine manufacturers.

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

Reports of events following vaccination at clinics using TVFC vaccine should be reported directly to DSHS.

**Please mail to:**

Department of State Health Services  
Attn: VAERS/Immunization Branch  
MC-1946  
P.O. Box 149347  
Austin, TX 78714-9347

The VAERS Reporting Form (C-76) is on the TVFC web page:

<http://www.dshs.state.tx.us/immunize/tvfc/>

Reports of events following vaccination at clinics using privately purchased vaccine should be reported directly to VAERS. Adverse events may be reported online, by mail, or fax. Contact (800) VAC-RXNS or (800) 822-7967 for information or to request pre-addressed VAERS forms. More information can be obtained from the FDA web site:

[www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents).

#### **IV. ImmTrac, the Texas Immunization Registry**

ImmTrac, the Texas Immunization Registry, is operated by DSHS. Texas Law requires medical providers to report all immunizations administered to children 17 years of age and younger to ImmTrac within 30 days of administering the vaccine. Before a provider can report the immunization information to ImmTrac, providers will need to register for registry participation and access.

For information about ImmTrac or to register to be an ImmTrac user, please call the ImmTrac Customer Support Line at (800) 348-9158 or visit the ImmTrac webpage at:

<http://www.dshs.state.tx.us/immunize/immtrac/default.shtm>

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# **CHAPTER 8**

## **ADULT SAFETY NET (ASN) PROGRAM**

**Last Updated: 10/2014**

### **I. ASN Overview**

Texas has a significant number of adults who have not received recommended vaccinations. This population is at an increased risk of contracting vaccine preventable diseases. The ASN Program helps to address this important public health issue by providing publically purchased adult vaccines at no cost to enrolled medical providers to vaccinate ASN eligible clients.

### **II. Eligible Provider Types**

Provider types that may enroll in the ASN Program include public clinics that are formally recognized as one of the following:

- DSHS HSR Offices
- LHDs
- FQHC
- RHC
- HIV Clinics
- STD Clinics
- Family Planning Clinics
- Substance Abuse Clinics (Opioid Replacement Clinics)

### **III. ASN Enrollment**

To enroll in the ASN Program, providers must be enrolled in TVFC. Prospective ASN providers must complete the ASN Enrollment Form and submit the form to their responsible entity (DSHS HSR or LHD). All ASN providers must agree to comply with the policies and requirements of both the TVFC Program and the ASN Program.

### **IV. ASN Eligibility**

Adults aged nineteen years and older who have no medical insurance are eligible to receive ASN vaccine. Those with medical insurance, including Medicare, Medicaid, or any other insurance 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.

Eligibility status must be screened and documented on the Adult Eligibility Screening Record (EF11-12842) when administering any ASN vaccine. Using the Adult Eligibility Screening Record will ensure program accountability and client eligibility. This form must be retained for a minimum of five years and made available upon request from the responsible entity (DSHS HSR or the LHD).

Individuals who are 19 years of age and 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 individuals that have not yet reached their 20th birthday, after that point, the provision no longer applies.

## **V. Administration Fee**

Providers may charge ASN clients an administration fee of up to \$25.00 per dose. However, providers cannot deny the administration of vaccine if a client is unable to pay the administration fee. Providers may not send a patient to collections or charge fees for the patient's inability to pay administration fees.

## **VI. ASN Vaccine Formulary**

The current ASN vaccine formulary includes:

- Hepatitis A vaccine
- Hepatitis B vaccine
- Hepatitis A and Hepatitis B combination vaccine (Twinrix®)
- Human Papillomavirus (HPV) vaccine
- Measles/Mumps/Rubella (MMR) vaccine
- Pneumococcal Polysaccharide (PPSV23) vaccine
- Tetanus, Diphtheria, and Pertussis (Tdap) vaccine
- Tetanus and Diphtheria (Td) vaccine

ASN sites that have other adult vaccines remaining in their inventory from previous orders may continue to provide these vaccines to eligible clients until the stock is depleted.

## **VII. Vaccine Storage**

ASN providers are required to follow all TVFC storage and handling guidelines at all times. If a provider administers both ASN and TVFC vaccines, the publicly-funded adult vaccines must be stored separately from the TVFC vaccines. Also, ASN vaccines must be stored separately from privately-purchased adult vaccines.

## **VIII. Mobile Vaccination Clinics**

ASN providers may conduct off-site, mobile vaccination clinics using ASN vaccine. However, ASN eligibility needs to be determined through use of the Adult Eligibility Screening Record (EF11-12842) for all clients that receive ASN vaccine. 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 vaccines and take quick action when temperature excursions occur.

## **IX. Advertisement of ASN Vaccine by Provider**

Providers may advertise and promote the availability of ASN vaccines to eligible clients.

## **X. Reporting Doses Administered**

All ASN vaccine doses administered are to be reported as “19 and over” in EVI, under the “Doses” tab. Providers are required to accurately report all doses provided to adults. The DSHS Immunization Branch uses this information to account for adult usage and to project and maintain supply.

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# CHAPTER 9

## VACCINE INFORMATION STATEMENTS (VIS)

**Last Updated: 10/2014**

Federal law requires all immunization providers (regardless of whether they are enrolled in the TVFC Program) to provide a parent, guardian, or other responsible adult a current VIS for *each* vaccine the child is to receive, every time a vaccine is administered. Providers should ensure they are using the most current version of each VIS. Copies of VISs can be found on the Immunization Branch main page:

<http://www.dshs.state.tx.us/immunize/literature/litlist.shtm>

.

Providers should take reasonable steps to provide information in the appropriate languages in order to ensure clients with limited English proficiency are effectively informed. VISs in more than 20 additional languages can be downloaded from the Immunization Action Coalition (IAC) website at <http://www.immunize.org/vis>

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# CHAPTER 10

## ORDERING FORMS AND LITERATURE

**Last Updated: 10/2014**

DSHS offers providers various forms, literature, brochures, posters, and vaccine information statements that can be ordered free of charge directly from the DSHS Immunization Branch. Forms are available to view and download or can be ordered and shipped directly to the provider. Forms may be ordered monthly and 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 DSHS. When placing orders in writing please include the following:

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

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

**Mail to:**

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

**Fax to:** (512) 776-7288 Attn: Ordering Department

If you have questions regarding forms or the ordering process, please call **the Ordering Department** at (512) 776-6516 or toll free at (800) 252-9152.

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# CHAPTER 11

## IMMUNIZATION RESOURCES

Last Updated: 10/2014

**Texas DSHS Immunizations Homepage**

<http://immunizetexas.com>

**Texas Vaccines for Children (TVFC) Homepage**

<http://www.dshs.state.tx.us/immunize/tvfc/>

**Texas Adult Safety Net (ASN) Homepage**

<http://www.dshs.state.tx.us/asn/>

**Texas Vaccine Education Online**

<http://www.vaccineeducationonline.org>

**ImmTrac, the Texas Immunization Registry**

<http://www.dshs.state.tx.us/immunize/immtrac/default.shtm>

**CDC Immunizations Homepage**

<http://www.cdc.gov/vaccines/>

**CDC Immunization Schedules**

<http://www.cdc.gov/vaccines/schedules/index.html>

**CDC Vaccines for Children (VFC) Homepage**

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

**CDC “You Call the Shots” Training**

<http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>

**CDC Vaccine Storage and Handling Toolkit**

<http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html>

**Immunization Action Coalition**

<http://www.immunize.org>

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# **TVFC FORMS AND RESOURCES**

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## **TVFC FORMS AND REFERENCES**

- VFC Program Provider Agreement (E6-102)
- Provider Withdrawal Form (F11-11443)
- Patient Eligibility Screening Record (C-10)
- Patient Referral Form for Vaccination From Local Health Department or Public Health Clinic (EF11-13788)
- TVFC Patient Screening Decision Tree (EF11-13789)
- Biological Order Form (EC-68-1)
- Combined Tally and Physical Inventory (C-88)
- Monthly Biological Report (C-33-A)
- Temperature Recording Form (C-105)
- Vaccine Management Plan Templates (E11-11190)
- Emergency Vaccine Storage and Handling Plan Checklist (E11-14497)
- Vaccine Transfer Authorization Form (C-67)
- Vaccine Borrowing Form (EF11-14171)
- Vaccine Adverse Event Reporting System (VAERS) Form (C-76)
- Adult Safety Net Provider Enrollment Form (F11-14143) Adult
- Eligibility Screening Record (EF11-12842)

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# VFC Program Provider Agreement



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## VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT

FACILITY INFORMATION			
Facility Name:		VFC Pin#:	
Facility Address:			
City:	County:	State:	Zip:
Telephone:		Fax:	
Shipping Address (if different than facility address):			
City:	County:	State:	Zip:
MEDICAL DIRECTOR OR EQUIVALENT			
<b>Instructions:</b> <i>The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.</i>			
Last Name, First, MI:	Title:	Specialty:	
License No.:	Medicaid or NPI No.:	Employer Identification No. (optional):	
VFC VACCINE COORDINATOR			
<b>Primary Vaccine Coordinator Name:</b>			
Telephone:	Email:		
Completed annual training: <input type="radio"/> Yes <input type="radio"/> No	Type of training received:		
<b>Back-Up Vaccine Coordinator Name:</b>			
Telephone:	Email:		
Completed annual training: <input type="radio"/> Yes <input type="radio"/> No	Type of training received:		



## PROVIDER AGREEMENT

*To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:*

1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2.	<p>I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:</p> <p>A. Federally Vaccine-eligible Children (VFC eligible)</p> <ol style="list-style-type: none"> <li>1. Are an American Indian or Alaska Native;</li> <li>2. Are enrolled in Medicaid;</li> <li>3. Have no health insurance;</li> <li>4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.</li> </ol> <p>B. State Vaccine-eligible Children</p> <ol style="list-style-type: none"> <li>1. In addition, to the extent that my state designates additional categories of children as “state vaccine-eligible”, I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.</li> </ol> <p>Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are <b>not</b> eligible to receive VFC-purchased vaccine.</p>
3.	<p>For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:</p> <ol style="list-style-type: none"> <li>a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;</li> <li>b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.</li> </ol>
4.	I will maintain all records related to the VFC program for five years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6.	I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of \$22.06 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

7.	I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8.	I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9.	I will comply with the requirements for vaccine management including: <ul style="list-style-type: none"> <li>a) Ordering vaccine and maintaining appropriate vaccine inventories;</li> <li>b) Not storing vaccine in dormitory-style units at any time;</li> <li>c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Texas Department of State Health Services storage and handling recommendations and requirements;</li> <li>d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration</li> </ul>
10.	I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program: <p><b>Fraud:</b> is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.</p> <p><b>Abuse:</b> 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 immunization 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 cost to the Medicaid program.</p>
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the Texas Department of State Health Services to serve underinsured VFC-eligible children, I agree to: <ul style="list-style-type: none"> <li>a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;</li> <li>b) Vaccinate "walk-in" VFC-eligible underinsured children; and</li> <li>c) Report required usage data</li> </ul> <p>Note: "Walk-in" in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.</p>
13.	For pharmacies, urgent care, or school located vaccine clinics, I agree to: <ul style="list-style-type: none"> <li>a) Vaccinate all "walk-in" VFC-eligible children and</li> <li>b) Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.</li> </ul> <p>Note: "Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.</p>

14.	I understand this facility or the Texas Department of State Health Services may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Texas Department of State Health Services.
-----	--

<b><i>By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.</i></b>	
Medical Director or Equivalent Name (print):	
Signature:	Date:



## Vaccines for Children (VFC) Program Provider Profile Form

All health care providers participating in the Vaccines for Children (VFC) program must complete this form annually or more frequently if the number of children served changes or the status of the facility changes during the calendar year.

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Provider Identification Number# \_\_\_\_\_

FACILITY INFORMATION		
Provider's Name:		
Facility Name:		
Vaccine Delivery Address:		
City:	State:	Zip:
Telephone:	Email:	
FACILITY TYPE (select facility type)		
Private Facilities	Public Facilities	
<input type="checkbox"/> Private Hospital <input type="checkbox"/> Private Practice (solo/group/HMO) <input type="checkbox"/> Private Practice (solo/groups as agent for FOHC/RHC-deputized) <input type="checkbox"/> Community Health Center <input type="checkbox"/> Pharmacy <input type="checkbox"/> Birthing Hospital <input type="checkbox"/> School-Based Clinic <input type="checkbox"/> Teen Health Center <input type="checkbox"/> Adolescent Only Provider <input type="checkbox"/> Other _____	<input type="checkbox"/> Public Health Department Clinic <input type="checkbox"/> Public Health Department Clinic as agent for FOHC/RHC-deputized <input type="checkbox"/> Public Hospital <input type="checkbox"/> FOHC/RHC (Community/Migrant/Rural) <input type="checkbox"/> Community Health Center <input type="checkbox"/> Tribal/Indian Health Services Clinic <input type="checkbox"/> Woman, Infants and Children <input type="checkbox"/> Other _____ <div style="float: right; width: 200px;"> <input type="checkbox"/> STD/HIV  <input type="checkbox"/> Family Planning  <input type="checkbox"/> Juvenile Detention Center  <input type="checkbox"/> Correctional Facility  <input type="checkbox"/> Drug Treatment Facility  <input type="checkbox"/> Migrant Health Facility  <input type="checkbox"/> Refugee Health Facility  <input type="checkbox"/> School-Based Clinic  <input type="checkbox"/> Teen Health Center  <input type="checkbox"/> Adolescent Only           </div>	
VACCINES OFFERED (select only one box)		
<input type="checkbox"/> All ACIP Recommended Vaccines  <input type="checkbox"/> Offers Select Vaccines (This option is only available for facilities designated as <u>Specialty Providers</u> by the VFC Program)		
<p>A "<u>Specialty Provider</u>" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g., OB/GYN; STD clinic; family planning) or (2) a specific age group within the general population of children ages 0-18. Local health departments and pediatricians are not considered specialty providers. The VFC Program has the authority to designate VFC providers as specialty providers. At the discretion of the VFC Program, enrolled providers such as pharmacies and mass vaccinators may offer only influenza vaccine.</p>		
<b>Select Vaccines Offered by Specialty Provider:</b>		
<input type="checkbox"/> DTaP <input type="checkbox"/> Hepatitis A <input type="checkbox"/> Hepatitis B <input type="checkbox"/> HIB <input type="checkbox"/> HPV <input type="checkbox"/> Influenza	<input type="checkbox"/> Meningococcal Conjugate <input type="checkbox"/> MMR <input type="checkbox"/> Pneumococcal Conjugate <input type="checkbox"/> Pneumococcal Polysaccharide <input type="checkbox"/> Polio <input type="checkbox"/> Rotavirus	<input type="checkbox"/> TD <input type="checkbox"/> Tdap <input type="checkbox"/> Varicella <input type="checkbox"/> Other, specify:

## PROVIDER POPULATION

Provider Population based on patients seen during the previous 12 months. *Report the number of children who received vaccinations at your facility, by age group. Only count a child once based on the status at the last immunization visit, regardless of the number of visits made. The following table documents how many children received VFC vaccine, by category, and how many received non-VFC vaccine.*

VFC Vaccine Eligibility Categories	# of children who received VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaska Native				
Underinsured in FQHC/RHC or Deputized Facility <sup>1</sup>				
<b>Total VFC:</b>				
Non-VFC Vaccine Eligibility Categories	# of children who received non-VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Insured (private pay/health insurance covers vaccines)				
Other Underinsured <sup>2</sup>				
Children's Health Insurance Program (CHIP) <sup>3</sup>				
<b>Total Non-VFC:</b>				
<b>Total Patients</b> (must equal sum of Total VFC + Total Non-VFC)				

<sup>1</sup>Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance.

In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate these underinsured children.

<sup>2</sup>Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.

<sup>3</sup>CHIP – Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.

### TYPE OF DATA USED TO DETERMINE PROVIDER POPULATION (choose all that apply)

- Benchmarking                       Doses Administered  
 Medicaid Claims                     Provider Encounter Data  
 IIS                                         Billing System  
 Other (must describe):

# Provider Withdrawal Form

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# PROVIDER WITHDRAWAL FORM

\*PIN: \_\_\_\_\_ \*Withdrawal Date: \_\_\_\_\_

Please complete this form when you no longer wish to participate in the Texas Vaccine for Children (TVFC) Program. Fax the completed form to your Regional TVFC contact. Any remaining state vaccine will be picked up within 5 days of withdrawal from the TVFC Program. Please remember that Texas Health Steps providers may not refer Texas Health Steps patients elsewhere for immunizations.

Name of Facility: \_\_\_\_\_

Provider Name: \_\_\_\_\_  
(Last Name) (First Name) (MI) (Title)

Contact Name: \_\_\_\_\_  
(Last Name) (First Name) (MI) (Title)

Address: \_\_\_\_\_  
(Street Address) (City) (Zip) (County)

Phone #: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ Fax #: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

## \*Reason for Withdrawal:

- |  |   |
|--|---|
| <input type="checkbox"/> 1. Facility is Closing            | <input type="checkbox"/> 7. No Longer Enrolled in Medicaid        |
| <input type="checkbox"/> 2. No Longer Seeing Children      | <input type="checkbox"/> 8. Relocating Out of Area<br>*New County |
| <input type="checkbox"/> 3. Too Much Paperwork             | _____   |
| <input type="checkbox"/> 4. Staffing Issues                | <b>New Address</b>  |
| <input type="checkbox"/> 5. Physician no longer practicing | _____   |
| <input type="checkbox"/> 6. Not Using TVFC Vaccine         | <input type="checkbox"/> 9. Other:                                |
|  | _____   |
|  | _____   |
|  | <input type="checkbox"/> 10. Provider Withdrawn by HSR/AO         |

## \*Required Fields

### For HSR/LHD Use Only:

Date faxed to HSR: \_\_\_/\_\_\_/\_\_\_

Date faxed to AO: \_\_\_/\_\_\_/\_\_\_

Date vaccines picked up: \_\_\_/\_\_\_/\_\_\_



# Patient Eligibility Screening Record

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## Texas Vaccines for Children Program Patient Eligibility Screening Record

A record of all children 18 years of age or younger who receive immunizations through the Texas Vaccines for Children (TVFC) Program must be kept in the health care provider's office for a minimum of five years. The record may be completed by the parent, guardian, individual of record, or by the health care provider. TVFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure eligibility status for the program. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccines under the TVFC Program.

1. Child's Name: \_\_\_\_\_  
Last Name
First Name
MI
  
2. Child's Date of Birth: \_\_\_/\_\_\_/\_\_\_\_\_
  
3. Parent/Guardian/Individual of Record: \_\_\_\_\_  
Last Name
First Name
MI
  
4. Primary Provider's Name: \_\_\_\_\_  
Last Name
First Name
MI

5. To determine if a child (0 through 18 years of age) is eligible to receive federal vaccine through the TVFC program, at each immunization encounter/visit enter the date and mark the appropriate eligibility category. *If Column A-F is marked, the child is eligible for the TVFC program. If column G is marked the child is not eligible for TVFC vaccine.*

	Eligible for VFC Vaccine				State Eligible		Not Eligible
	A	B	C	D	E	F	G
Date	Medicaid Enrolled	No Health Insurance	American Indian or Alaskan Native	*Underinsured served by FQHC, RHC or deputized provider	**Enrolled in CHIP	***Other underinsured	Has health insurance that covers vaccines
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance. In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate underinsured children.

\*\*Children enrolled in separate state Children's Health Insurance Program (CHIP). These children are considered insured and are eligible for vaccines through the TVFC program as long as the provider bills CHIP for the administration of the vaccine.

\*\*\* Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.





## Programa de Vacunas para los Niños de Texas (TVFC) Registro de determinación del derecho a la participación del paciente

En el consultorio de un proveedor de salud debe mantenerse un registro de determinación del derecho a la participación de todos los niños de 18 años de edad o menos que reciban inmunizaciones por medio del Programa TVFC. Dicho registro lo puede rellenar el padre o la madre, el tutor, el individuo cuyo nombre consta en el registro o el proveedor de salud. En cada visita de inmunización debe determinarse y documentarse el derecho a la participación en el programa TVFC para asegurarse de que la persona tenga derecho a participar en el programa. Aunque no se requiere verificar las respuestas, es necesario conservar este registro, o uno similar, por cada niño que reciba vacunas bajo el Programa TVFC.

1. Nombre del niño o niña: \_\_\_\_\_  
Apellido Primer nombre Inicial del 2.º nombre

2. Fecha de nacimiento del niño o niña: \_\_\_\_\_  
mm/dd/aaaa

3. Padre o madre, tutor o individuo cuyo nombre consta en el registro: \_\_\_\_\_  
Apellido Primer nombre Inicial del 2.º nombre

4. Nombre del proveedor o de la clínica: \_\_\_\_\_

5. Para determinar si un niño o niña (de 0 a 18 años de edad) cumple los requisitos estatales o federales para recibir las vacunas mediante el Programa TVFC, en cada inmunización o visita médica anote la fecha y marque la categoría apropiada de derecho a la participación. *Si se ha marcado una columna de la A a la F, el niño o niña tiene derecho a participar en el programa TVFC. Si se ha marcado la columna G, el niño o niña no reúne los requisitos para participar en el programa TVFC.*

	Con derecho a participar en el Programa de vacunas VFC				Con derecho a participación estatal		No cumple los requisitos para participar
	A	B	C	D	E	F	G
Fecha	Inscrito en Medicaid	No tiene seguro médico	Indio americano o nativo de Alaska	*Con seguro insuficiente, recibe atención de un FQHC, una RHC o un proveedor autorizado	**Inscrito en el CHIP	***Otras situaciones de seguro insuficiente	Tiene seguro médico que cubre las vacunas
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*\*El seguro insuficiente incluye a los niños cuyo seguro médico no incluye las vacunas o solo cubre ciertos tipos específicos de vacunas. Los niños solo tienen derecho a recibir las vacunas que no están cubiertas por un seguro. Además, para recibir las vacunas del Programa VFC, los niños con seguro insuficiente deben ser vacunados en un Centro de Salud Federalmente Calificado (FQHC) o en una Clínica de Salud Rural (RHC), o por un proveedor aprobado y autorizado. El proveedor autorizado debe tener un acuerdo por escrito con un FQHC o una RHC y con el programa de inmunización estatal, local o territorial para poder vacunar a los niños con seguro insuficiente.*

*\*\*Niños inscritos en el Programa estatal separado de Seguro Médico Infantil (CHIP). Estos niños se consideran asegurados y tienen derecho a recibir vacunas mediante el programa TVFC siempre y cuando el proveedor facture al CHIP el importe de la administración de la vacuna.*

*\*\*\* Otros niños con seguro insuficiente son aquellos cuyo seguro es insuficiente pero que además no tienen derecho a recibir vacunas federales por medio del programa VFC porque el proveedor o el centro no es un FQHC o una RHC, o no es un proveedor autorizado. Sin embargo, estos niños pueden ser atendidos si las vacunas son proporcionadas por el programa estatal para dar cobertura a aquellos niños que no tienen derecho a beneficiarse del programa VFC.*





**Patient Referral  
Form for  
Vaccination from  
Local Health  
Department or  
Public Health  
Clinic**

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**Patient Referral Form for Vaccination  
From Local Health Department or Public Health Clinic**

(Patient Name) \_\_\_\_\_

Date of Birth (\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_) \_\_\_\_\_

This patient needs one or more vaccinations but has private health insurance and is not eligible for publically purchased vaccines available through the Texas Vaccines for Children (TVFC) Program.

Effective January 1, 2012, Public Health no longer vaccinates clients who are privately insured. *Therefore, we are referring this patient to his/her medical home for the needed vaccinations.*

If the medical home is not able to provide the immunization(s), the patient should be referred to another clinic that accepts the patient's medical insurance.

Referring Public Health Clinic:

NOTE: Issuance of this Patient Referral Form for Vaccination does not extend any state mandated vaccine requirements, or allow children to enter school without appropriate immunizations.

## Referral Process

When a patient presents for services at a local health department or public health clinic, staff should first ask if the patient has health insurance.

If no: The patient is eligible for TVFC vaccine.

If yes: Is the insurance Medicaid, CHIP, or other private insurance?  
If private insurance: Explain to the patient that the clinic no longer accepts their insurance due to billing issues, and they need to receive vaccines from their medical home. Provide *Patient Referral Form for Vaccination* if helpful or necessary.

If the patient has Medicaid or CHIP: The patient is eligible for TVFC vaccine.

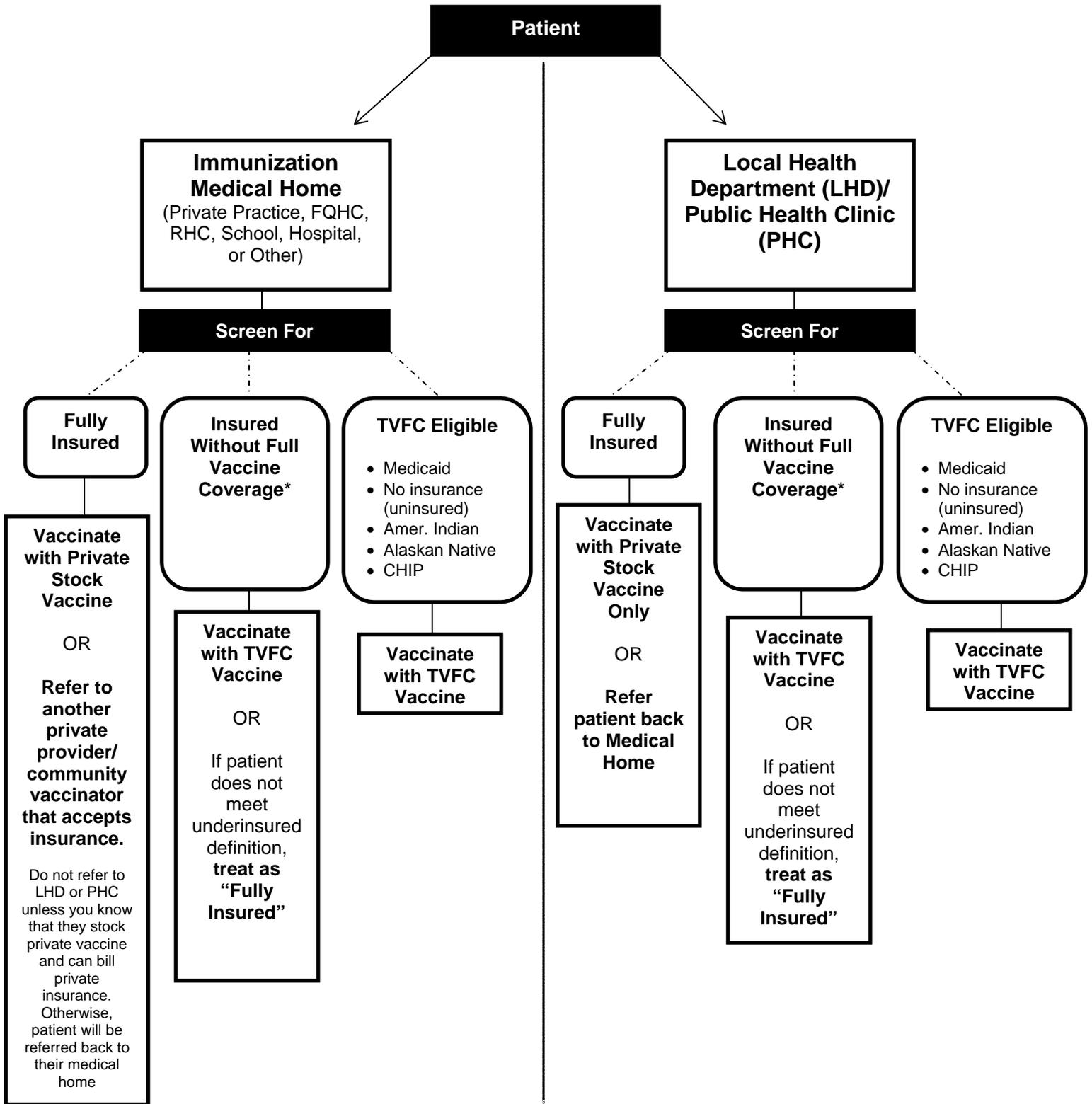
Local Referral Sites (if available):

Name	Phone number	Address
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

# TVFC Patient Screening Decision Tree

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# Texas Vaccines for Children Patient Screening Decision Tree



\* Effective January 1, 2012, the definition of “Underinsured” is: 1) commercial (private) health insurance, but coverage does not include vaccines; or 2) insurance covers only selected vaccines (TVFC-eligible for non-covered vaccines only); or 3) insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

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# Biological Order Form

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**Texas Department of State Health Services**

**INITIAL ORDER**

**PEDIATRIC Biological Order Form**

**PIN:**

<b>CLINIC DAYS/HOURS</b>	<b>OPEN</b>	<b>LUNCH</b>	Contact Person
MON	<u>CLOSE</u> to <u>CLOSED</u>	<u>CLOSED</u> to <u>CLOSED</u>	Phone - -
TUE	<u>CLOSE</u> to <u>CLOSED</u>	<u>CLOSED</u> to <u>CLOSED</u>	Fax - -
WED	<u>CLOSE</u> to <u>CLOSED</u>	<u>CLOSED</u> to <u>CLOSED</u>	Clinic Name
THUR	<u>CLOSE</u> to <u>CLOSED</u>	<u>CLOSED</u> to <u>CLOSED</u>	Address
FRI	<u>CLOSE</u> to <u>CLOSED</u>	<u>CLOSED</u> to <u>CLOSED</u>	
Holidays Closed:			

PROVIDER TIER AND ORDERING SCHEDULE

**PICK FROM LIST B1 (JAN, MAR, MAY, JUL, SEP, NOV)**

VACCINE	MAXIMUM STOCK LEVEL	% SELECTED	ORDER AMOUNT
<b>DT</b>			
DT, single-dose vial (Ped)			
<b>DTaP</b>			
DAPTACEL, single-dose vial (Ped)			
INFANRIX, single-dose vial (Ped)			
INFANRIX, PF syringe (Ped)			
<b>DTaP/HepB/IPV</b>			
PEDIARIX, PF syringe (Ped)			
<b>DTaP-IPV</b>			
KINRIX, single-dose vial (Ped)			
KINRIX, PF syringe (Ped)			
<b>DTaP/IPV/Hib</b>			
PENTACEL, single-dose vial (Ped)			
<b>Hep A</b>			
HAVRIX, single-dose vial (Ped)			
HAVRIX, PF syringe (Ped)			
VAQTA, single-dose vial (Ped)			
VAQTA, 6 pk PF syringe (must order in quantities of 6)			
<b>Hep B</b>			
ENGERIX B, single-dose vial (Ped)			
ENGERIX B, PF syringe (Ped)			
RECOMBIVAX HB, single-dose vial (Ped)			
RECOMBIVAX, 6 pk PF syringe (must order in quantities of 6)			
<b>Hep A/Hep B</b>			
TWINRIX, single-dose vial (Ped)			
TWINRIX, PF syringe (Ped)			
<b>Hep B/HIB</b>			
COMVAX, single-dose vial			

<b>HIB</b>			
ACTHIB, single-dose vial (Ped)			
MENHIBRIX, single-dose vial (Ped)			
PEDVAXHIB, single-dose vial (Ped)			
<b>HPV</b>			
CERVARIX, PF syringe (Ped)			
GARDASIL, single-dose vial (Ped)			
<b>VACCINE</b>	<b>MAXIMUM STOCK LEVEL</b>	<b>% SELECTED</b>	<b>ORDER AMOUNT</b>
<b>IPV</b>			
IPOL, multi-dose vial (Ped)			
<b>MCV4</b>			
MENACTRA, single-dose vial (Ped)			
MENVEO, single-dose vial (Ped)			
<b>MMR</b>			
MMR II, single-dose vial (Ped)			
<b>PCV13</b>			
PREVNAR 13, PF syringe (Ped)			
<b>PPSV23</b>			
PNEUMOVAX 23, single-dose vial (Ped)			
<b>ROTAVIRUS</b>			
ROTARIX, oral applicator (Ped)			
ROTATEQ, oral applicator (Ped) 10 pack			
ROTATEQ, oral applicator (Ped) 25 pack (must order in quantities of 25)			
<b>Td</b>			
TENIVAC (Td), single-dose vial (Ped)			
TENIVAC (Td), PF syringe (Ped)			
<b>TDaP</b>			
ADACEL, single-dose vial (Ped)			
ADACEL, PF syringe (Ped)			
BOOSTRIX, single-dose vial (Ped)			
BOOSTRIX, PF syringe (Ped)			
<b>The following vaccine will ship separately. Allow additional time to receive:</b>			
<b>Varicella</b>			
VARIVAX, single-dose vial (Ped)			
<b>MMRV</b>			
PROQUAD, single-dose vial (Ped)			

\_\_\_\_\_  
Date of Order

\_\_\_\_\_  
Approved (Authorized Signature)

# Combined Tally and Physical Inventory

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TEXAS DEPARTMENT OF STATE HEALTH SERVICES - DAILY TALLY / INVENTORY SHEET

Inventory As of:

Completed By:

TFVC PIN:

Pediatric Tally	Brand & Presentation	Lot Number	Expiration Date	# Doses
0-18 yrs	<b>DT</b>			
	DT, SDV			
	<b>DTaP</b>			
	DAPTACEL, SDV			
	INFANRIX, SDV			
	INFANRIX, PFS			
	TRIPEDIA, SDV			
	<b>DTaP-Hep B-IPV</b>			
	PEDIARIX, PFS			
	<b>DTaP-IPV</b>			
	KINRIX, SDV			
	KINRIX, PFS			
	<b>DTaP-IPV/HIB</b>			
	PENTACEL, SDV			
	<b>Hep A</b>			
	HAVRIX, SDV			
	HAVRIX, PFS			
	VAQTA, SDV			
	<b>Hep B</b>			
	ENGERIX-B SDV			
	ENGERIX-B, PFS			

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES - DAILY TALLY / INVENTORY SHEET**

**Inventory As of:**

**TFVC PIN:**

<b>Pediatric Tally</b>	<b>Brand &amp; Presentation</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b># Doses</b>
0-18 yrs	<b>Hep B ctd.</b>			
	RECOMBIVAX HB, SDV			
	<b>Hep A-Hep B</b>			
	TWINRIX, SDV			
	TWINRIX, PFS			
	<b>Hep B-HIB</b>			
	COMVAX, SDV			
	<b>HIB</b>			
	ACTHIB, SDV			
	HIBERIX, SDV			
	PEDVAXHIB, SDV			
	<b>HPV</b>			
	CERVARIX, SDV			
	CERVARIX, PFS			
	GARDASIL, SDV			
	<b>IPV</b>			
	IPOL			
	<b>MCV4</b>			
	MENACTRA, SDV			
	MENVEO, SDV			
	<b>MMR</b>			
	MMR, SDV			

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES - DAILY TALLY / INVENTORY SHEET**

**Inventory As of:**

**TFVC PIN:**

<b>Pediatric Tally</b>	<b>Brand &amp; Presentation</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b># Doses</b>
0-18 yrs	<b>MMRV</b>			
	PROQUAD, SDV			
	<b>PCV</b>			
	PREVNAR 13, PFS			
	<b>PPSV23</b>			
	PNEUMOVAX 23, SDV			
	<b>ROTAVIRUS</b>			
	ROTARIX			
	ROTATEQ			
	<b>Td</b>			
	DECAVAC, SDV			
	DECAVAC, PFS			
	MASS BIOLOGICS, SDV			
	TENIVAC, SDV			
	TENIVAC, PFS			
	<b>TDaP</b>			
	ADACEL, SDV			
	ADACEL, PFS			
	BOOSTRIX, SDV			
	BOOSTRIX, PFS			
	<b>VARICELLA</b>			
	VARIVAX, SDV			



**TEXAS DEPARTMENT OF STATE HEALTH SERVICES - DAILY TALLY / INVENTORY SHEET**

**Inventory As of:**

**Completed By:**

**TFVC PIN:**

<b>Adult Tally</b>	<b>Brand &amp; Presentation</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b># Doses</b>
19+ yrs	<b>Hep A</b>			
	Adult HAVRIX, SDV			
	Adult HAVRIX, PFS			
	<b>Hep B</b>			
	ENGERIX-B, SDV			
	ENGERIX-B, PFS			
	RECOMBIVAX HB, SDV			
	<b>Hep A/Hep B</b>			
	TWINRIX, SDV			
	TWINRIX, PFS			
	<b>HPV</b>			
	CERVARIX, SDV			
	CERVARIX, PFS			
	GARDASIL, SDV			
	<b>MCV4</b>			
	MENACTRA, SDV			
	MENVEO, SDV			
	<b>MMR</b>			
	MMR, SDV			



**TEXAS DEPARTMENT OF STATE HEALTH SERVICES - DAILY TALLY / INVENTORY SHEET**

**Inventory As of:**

**TFVC PIN:**

<b>Adult Tally</b>	<b>Brand &amp; Presentation</b>	<b>Lot Number</b>	<b>Expiration Date</b>	<b># Doses</b>
	<b>PPSV23</b>			
	PNEUMOVAX 23, SDV			
	PNEUMOVAX 23, MDV			
	<b>Td</b>			
	DECAVAC, PFS			
	TENIVAC, PFS			
	TENIVAC, SDV			
	AKORN, SDV			
	MASS BIOLOGICS, SDV			
19+ yrs	<b>TDaP</b>			
	ADACEL, SDV			
	ADACEL, PFS			
	BOOSTRIX, SDV			
	BOOSTRIX, PFS			
	<b>VARICELLA</b>			
	VARIVAX, SDV			
	<b>ZOSTER</b>			
	ZOSTAVAX, SDV			



TEXAS DEPARTMENT OF STATE HEALTH SERVICES - DAILY TALLY / INVENTORY SHEET

Inventory As of:

Completed By:

TFVC PIN:

Pediatric Tally	Brand & Presentation	Lot Number	Expiration Date	# Doses
0-18 yrs	<b>INFLUENZA</b>			
	FLUZONE .25mL PFS			
	FLUZONE .5mL SDV			
	FLUZONE .5mL PFS			
	FLUZONE MDV			
	FLUMIST			
	FLUVIRIN .5mL PFS			
	FLUVIRIN MDV			
	AFLURIA .5mL PFS			
	FLUARIX, .5mL PFS			
19 years + For <b>HSRs ONLY</b>				
	FLUZONE MDV			

# Monthly Biological Report

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**Texas DSHS Monthly Biological Report (C-33)**

Month: \_\_\_\_\_ Year: 20\_\_\_\_ PIN \_\_\_\_\_

Agency: \_\_\_\_\_

Street Address: \_\_\_\_\_

Name of person completing report: \_\_\_\_\_

City: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone number: (\_\_\_\_\_) \_\_\_\_\_

Vaccine	A. Doses on Hand at Beginning of Month	B. Doses Received during Month	C. Doses Transferred into Inventory from Another Provider	D. Total Inventory A+B+C=	E. Doses Administered During Month <i>Subtract from Inventory</i>			F. Exp/ruined Doses Returned to Distributor	G. Doses Transferred out to Other Providers	H. Doses on Hand at End of Month	I. Net Doses Lost or Gained. Enter + or -
	<i>Beginning Inventory</i>	<i>Add to Inventory</i>	<i>Add to Inventory</i>	<i>Subtotal</i>	a. birth - 18 years	b. 19 years +	a + b = Total	<i>Subtract from Inventory</i>	<i>Subtract from Inventory</i>	<i>Physical Count</i>	
DT											
DTaP											
DTaP-HepB-IPV (Pediatrix)											
DTaP-IPV-Hib (Pentacel)											
DTaP-IPV (Kinrix)											
Hep A ped/adolescent											
Hep B ped/adolescent											
Hib											
Hib (Hiberix-booster only)											
HPV											
Influenza .25ml											
Influenza .5ml											
Influenza intranasal											
IPV											
MCV4											
MMR											
PCV7/PCV13											
Rotavirus RV5 (RotaTeq)											
Rotavirus RV1 (Rotarix)											

**Texas DSHS Monthly Biological Report (C-33)**

Month: \_\_\_\_\_ Year: 20\_\_\_\_ PIN \_\_\_\_\_

Vaccine	A. Doses on Hand at Beginning of Month	B. Doses Received during Month	C. Doses Transferred into Inventory from Another Provider	D. Total Inventory A+B+C=	E. Doses Administered During Month <i>Subtract from Inventory</i>			F. Exp/ruined Doses Returned to Distributor	G. Doses Transferred out to Other Providers	H. Doses on Hand at End of Month	I. Net Doses Lost or Gained. Enter + or -
	<i>Beginning Inventory</i>	<i>Add to Inventory</i>	<i>Add to Inventory</i>	<i>Subtotal</i>	a. Birth - 18 years	b. 19 years +	a + b = Total	<i>Subtract from Inventory</i>	<i>Subtract from Inventory</i>	<i>Physical Count</i>	
Td											
Tdap											
Varicella											
Hep A Adult*											
Hep B Adult *											
Hep A-Hep B (Twinrix)*											
PPSV23*											
Zoster *											

\* available only to practices enrolled in Adult Vaccine Program (FQHC & Title V Family Planning Clinics)

This is to certify that this report is a true accounting of the above biologicals received from the Texas Department of State Health Services that were administered during the reported time period. No one was refused immunizations for failure to pay an administrative fee or failure to make a donation to the

Explanation of expired/ruined doses(F) and gain/lost (I).

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Date

Signature of local health authority or person responsible for vaccine administration.

**Instructions**

This report should be completed each month by every organization that receives state-supplied vaccine. Retain a copy for three years. Submit to your local or regional health department each month. Please do not included doses purchased with private funds.

Column A: Starting inventory. Must match column H from previous month's C-33 report

Column B: Enter total doses of each vaccine received as shown on Biological order form C-68. Add these to the starting inventory.

Column C: State-supplied vaccine transferred from other providers. Do not include wasted or expired vaccine. Add to inventory.

Column D: Subtotal. Add column A + B + C.

Column E: Enter doses administered during month by birth though 18 years and 19 years and older in the appropriate column.

Column F: Expired or ruined doses returned to the distributor. Please give an explanation of all returned vaccines in the space above. Subtract from inventory.

Column G: Doses transferred out of your inventory to other providers. Do not include expired, ruined or wasted vaccine in this count. Subtract from inventory.

Column H: This is the physical count of each dose of the biological. This is the ending inventory for this month and will be the starting inventory for next month.

Column I: Net Doses = D - (E + F + G + H). Enter net doses lost or gained. If ending inventory (E + F + G + H) is larger than D, you have a gain (+). If it is less than D, you have a loss (-). Please explain all losses and gains in space above.

# Temperature Recording Forms

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# Temperature Recording Form for Refrigerator – Fahrenheit

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																														
Exact Time	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Min/Max Temp (since previous reading)	/		/		/		/		/		/		/		/		/		/		/		/		/		/		/	
<b>Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																														
<b>TEMPERATURES</b>	46°F																													
	45°F																													
	44°F																													
	43°F																													
	42°F																													
	41°F																													
	Aim for 40-F	40°F																												
	39°F																													
38°F																														
37°F																														
36°F																														
35°F																														
<b>Danger! Temperatures below 35°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																														
<b>ACTION</b>	Write any out-of-range temps (above 46°F or below 35°F) here:																													
	Room Temperature																													

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.





# Temperature Recording Form for Refrigerator – Fahrenheit

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_ Page 2 of 3

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Min/Max Temp (since previous reading)																
<b>Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																
<b>TEMPERATURES</b>	46°F															
	45°F															
	44°F															
	43°F															
	42°F															
	41°F															
<b>ACCEPTABLE</b>	40°F															
	39°F															
	38°F															
	37°F															
	36°F															
	35°F															
<b>Danger! Temperatures below 35°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																
<b>ACTION</b>	Write any out-of-range temps (above 46°F or below 35°F) here:															
	Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.



# Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
<b>Description of Event</b> <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> <li>• General description (i.e., what happened?)</li> <li>• Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5° F [-50° to -15°C] for freezer)</li> <li>• Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)</li> <li>• At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>• Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>• Include any other information you feel might be relevant to understanding the event.</li> </ul>					
<b>Action Taken</b> <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> <li>• When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)</li> <li>• Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li>• IMPORTANT: What did you do to prevent a similar problem from occurring in the future?</li> </ul>					
<b>Results</b> <ul style="list-style-type: none"> <li>• What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul>					

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# Temperature Recording Form for Freezer –Fahrenheit

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		
Staff Initials																															
Exact Time	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	
Min/Max Temp (since previous reading)																															
<b>Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																															
<b>ACCEPTABLE TEMPERATURES</b>	5°F																														
	4°F																														
	3°F																														
	2°F																														
	1°F																														
	0°F																														
	-1°F																														
	-2°F																														
	-3°F																														
	-4°F																														
-58°F to -5°F																															
<b>ACTION</b>	Write any out-of-range temps (above 5°F or below -58°F) here:																														
	Room Temperature																														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.



# Temperature Recording Form for Freezer –Fahrenheit

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_ Page 2 of 3

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Min/Max Temp (since previous reading)																
<b>Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																
<b>ACCEPTABLE TEMPERATURES</b>	5°F															
	4°F															
	3°F															
	2°F															
	1°F															
	0°F															
	-1°F															
	-2°F															
	-3°F															
	-4°F															
-58°F to -5°F																
<b>ACTION</b>	Write any out-of-range temps (above 5°F or below -58°F) here:															
	Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

# Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
<b>Description of Event</b> <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> <li>• General description (i.e., what happened?)</li> <li>• Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5° F [-50° to -15°C] for freezer)</li> <li>• Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)</li> <li>• At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>• Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>• Include any other information you feel might be relevant to understanding the event.</li> </ul>					
<b>Action Taken</b> <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> <li>• When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)</li> <li>• Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li>• IMPORTANT: What did you do to prevent a similar problem from occurring in the future?</li> </ul>					
<b>Results</b> <ul style="list-style-type: none"> <li>• What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul>					

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# Temperature Recording Form for Refrigerator –Celsius

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																	
Exact Time	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	
Min/Max Temp (since previous reading)		/		/		/		/		/		/		/		/	
<b>Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																	
<b>TEMPERATURES</b>	8°C																
	7°C																
	6°C																
	5°C																
<b>ACCEPTABLE</b>	4°C																
	3°C																
	2°C																
<b>Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																	
<b>ACTION</b>	Write any out-of-range temps (above 8°C or below 2°C) here:																
	Room Temperature																



If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.



# Temperature Recording Form for Refrigerator –Celsius

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_ Page 2 of 3

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Min/Max Temp (since previous reading)																
<b>Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																
TEMPERATURES	8°C															
	7°C															
	6°C															
	5°C															
ACCEPTABLE	4°C															
	3°C															
	2°C															
<b>Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																
ACTION	Write any out-of-range temps (above 8°C or below 2°C) here:															
	Room Temperature															



If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

# Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
<b>Description of Event</b> <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> <li>• General description (i.e., what happened?)</li> <li>• Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5° F [-50° to -15°C] for freezer)</li> <li>• Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)</li> <li>• At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>• Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>• Include any other information you feel might be relevant to understanding the event.</li> </ul>					
<b>Action Taken</b> <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> <li>• When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it “do not use” until after you can discuss with your state/local health department and/or the manufacturer[s].)</li> <li>• Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li>• IMPORTANT: What did you do to prevent a similar problem from occurring in the future?</li> </ul>					
<b>Results</b> <ul style="list-style-type: none"> <li>• What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul>					

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# Temperature Recording Form for Freezer –Celsius

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																														
Exact Time	am	pm																												
Min/Max Temp (since previous reading)	/		/		/		/		/		/		/		/		/		/		/		/		/		/			

**Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!**

<b>ACCEPTABLE TEMPERATURES</b>	-15°C																													
	-16°C																													
	-17°C																													
	-18°C																													
	-19°C																													
	-20°C																													
	-21°C																													
	-22°C																													
-50°C to -23°C																														
<b>ACTION</b>	Write any out-of-range temps (above -15°C or below -50°C) here:																													
	Room Temperature																													

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.



# Temperature Recording Form for Freezer –Celsius

Month/Year \_\_\_\_\_ VFCPIN \_\_\_\_\_ Page 2 of 3

Facility Name \_\_\_\_\_

TVFC Coordinator \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 5 years.

### Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible.  
Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31		
Staff Initials																			
Exact Time	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	
Min/Max Temp (since previous reading)		/		/		/		/		/		/		/		/		/	
<b>Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>																			
<b>ACCEPTABLE TEMPERATURES</b>	-15°C																		
	-16°C																		
	-17°C																		
	-18°C																		
	-19°C																		
	-20°C																		
	-21°C																		
	-22°C																		
	-50°C to -23°C																		
<b>ACTION</b>	Write any out-of-range temps (above -15°C or below -50°C) here:																		
	Room Temperature																		

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

# Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
<b>Description of Event</b> <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> <li>• General description (i.e., what happened?)</li> <li>• Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5° F [-50° to -15°C] for freezer)</li> <li>• Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)</li> <li>• At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>• Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>• Include any other information you feel might be relevant to understanding the event.</li> </ul>					
<b>Action Taken</b> <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> <li>• When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)</li> <li>• Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li>• IMPORTANT: What did you do to prevent a similar problem from occurring in the future?</li> </ul>					
<b>Results</b> <ul style="list-style-type: none"> <li>• What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul>					

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# Vaccine Management Plan Templates

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# Vaccine Management Plan Templates

- Vaccine Coordinators and Resources Equipment
- Emergency Vaccine Storage and Handling Plan
- Routine Vaccine Storage and Handling Plan

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## Contact List

<b>Vaccine Coordinators</b>			
<b>Vaccine Coordinators (Name/Title)</b>	<b>Telephone Number (home, cell, pager)</b>	<b>Alt. Telephone Number (home, cell, pager)</b>	<b>E-mail Address</b>
Primary:			
Alternate (Back-up #1):			
Alternate (Back-up #2):			
<b>Resources Contact List</b>			
<b>Resources</b>	<b>Contact Person Name/Title</b>	<b>Telephone Number</b>	<b>E-mail Address</b>
Local Health Department (LHD)			
DSHS Health Service Region (HSR)			
DSHS Vaccine Call Center			
DSHS Pharmacy			
<b>Additional Resources</b>	<b>Company/Entity Name</b>	<b>Telephone Number</b>	<b>E-mail Address</b>
Electric Power Company			
Refrigerator Repair			
Freezer Repair			

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## Texas Vaccines for Children (TVFC) Program Routine Vaccine Storage and Handling Plan

**Instructions for TVFC providers:** All TVFC providers are responsible for the proper routine management of their vaccine inventory. Once completed, this template can serve as the required Routine Vaccine Storage and Handling Plan.

TVFC providers must review and update the plan **annually** or more frequently if there are any changes to the plan, changes in equipment used to store TVFC vaccine or changes to staff in charge of vaccine management, storage and handling. The most current Routine Vaccine Storage and Handling Plan will be reviewed during TVFC Compliance Site Visits and Unannounced Storage and Handling Visits.

**A copy of this plan, along with the Emergency Vaccine Storage and Handling Plan must be posted on or near any refrigerator or freezer used to store TVFC vaccine.**

Practice Name:	Clinic Address:
TVFC PIN#:	E-mail Address:
Telephone Number: (    )    -	Fax Number: (    )    -
Name of Managing Physician of Equivalent:	TVFC Contact:
Primary Vaccine Coordinator:	Back-up Vaccine Coordinator(s):
Person Responsible for Receiving Vaccine Shipments:	Person Responsible for Vaccine Inventory & Ordering:
Person Responsible for Rotating Vaccine Inventory:	Person Responsible for Completing Vaccine Loss Reports:

### **Routine Vaccine Storage and Handling Plan reviewed and updated by:**

Name:	Title:
Signature:	Date of Last Review:

## Procedures for Proper Storage and Handling of Vaccine

For guidance, refer to Chapter 3 of the TVFC Provider Manual.

### Temperature Monitoring

- \_\_\_\_\_ is responsible for monitoring and recording temperatures of all vaccine storage units.
- A Temperature Recording Form (C-105) must be posted on or near all units that store TVFC vaccine.
- Freezer/refrigerator temperatures must be checked twice daily.
- Providers are required to record min/max temperatures at least once daily, preferably in the morning.
- Results of each temperature check must be documented on the Temperature Recording Form (C-105). The time and the initials of the staff member monitoring/recording must be documented on the form.
- If an out-of-range temperature is observed, immediately contact your responsible entity (DSHS HSR or LHD) and complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form.

### Vaccine Storage

- Providers are required to have appropriate equipment that can store vaccine and maintain proper conditions.
- Refrigerator/freezer units must be large enough to hold the year's largest inventory without crowding.
- Two types of storage units are acceptable for storage: a refrigerator that has a separate freezer compartment with a separate exterior door and separate thermostat controls for the refrigerator and freezer compartments or stand-alone, single-purpose refrigerators and freezers.
- Small combination refrigerator-freezer units outfitted with a single external door and dorm-style refrigerators are never allowed for the storage of TVFC vaccine.
- The refrigerator compartment must maintain temperatures between 35°F and 46°F (2°C and 8°C) for vaccine viability
- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C).
- Place water bottles (labeled "Not for consumption") on the top shelf by the cold air vent, floor, and in door racks of the refrigerator.
- Place frozen coolant packs along walls, back, and bottom of freezer and inside the door racks.
- Diluents that do not contain antigen may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water.
- It is never acceptable to store food or drinks in the same refrigerator or freezer as vaccine.
- Refrigerators and freezers storing vaccine must be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.

## **Vaccine Shipping and Receiving Procedures**

- \_\_\_\_\_ is responsible for receiving vaccine orders.
- Providers must always accept vaccine shipments. Never refuse or return vaccine shipments without specific instructions from DSHS or your responsible entity.
- Providers must ensure that the accurate shipping address and delivery hours are entered into the Electronic Vaccine Inventory (EVI) system.
- TVFC requires all providers to have a protocol to ensure the vaccine is stored immediately and appropriately upon arrival. The following steps should be taken when a vaccine shipment arrives:
  1. Check the vaccine received against packing list to verify all vaccines have been received.
  2. Verify the packing list against order placed in EVI to ensure all vaccines ordered were received.
  3. Ensure adequate diluent is included for vaccines requiring reconstitution.
  4. IMMEDIATELY contact your responsible entity if vaccine (or diluent) ordered is not received.
  5. Place vaccine in appropriate storage immediately.
  6. Make sure to rotate stock to ensure short-dated vaccine is used first.
- If the temperature monitoring strip indicates, or if staff suspects, that the cold chain has been compromised, staff should immediately:
  - Label questionable vaccine “Do Not Use” and segregate in proper storage until viability can be determined. Do not write on the vaccine itself.
  - Contact the DSHS Pharmacy or manufacturer immediately to determine the viability of the vaccine.
  - Contact responsible entity to inform them of the determination of the viability of the vaccine.
- TVFC providers must call their responsible entity immediately upon receipt of vaccine(s) received in error.

## **Vaccine Ordering Procedures**

- All vaccine orders will be placed in EVI unless internet access is unavailable.
- Providers are required to enter into EVI all vaccine received, doses transferred, doses administered, expired/wasted vaccine and a physical count for all TVFC vaccines in their inventory each month regardless of whether an order is placed.
- Temperature Recording Forms (C-105) must be completed and submitted monthly.

- Providers should abide by their established maximum stock levels (MSL) and tiered ordering frequency (TOF) when ordering vaccine. Providers are allowed to request quantities exceeding their MSL; however, a justification is required.
- Providers are responsible for entering accurate provider information into EVI, including shipping address, days and hours available to receive vaccine shipments, and primary and back-up contact information.
- \_\_\_\_\_ is responsible for ordering vaccine.

### **Inventory Control (e.g., Stock Rotation)**

- \_\_\_\_\_ is responsible for controlling TVFC inventory.
- Vaccine with the shortest date must be used first.
- Providers are required to notify their responsible entity 90 days prior to the vaccine expiration date.
- \_\_\_\_\_ is responsible for reporting vaccine received, doses administered, vaccine transferred, vaccine loss, and physical count in EVI each month.

### **Vaccine Loss (Expired, Spoiled, and Wasted Vaccine)**

- Providers are to follow the procedures listed below when vaccine loss occurs:
  - Remove expired/spoiled vaccine from the vaccine storage unit.
  - Contact your responsible entity immediately with the antigen, lot number, expiration date and reason for expiration/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 within four days of the date of the loss.
  - The completed Vaccine Loss Report must be signed by the medical provider who signed the VFC Program Provider Agreement.
  - \_\_\_\_\_ is responsible for completing and submitting the Vaccine Loss Reports.
- Providers should follow the procedures listed below for returning nonviable vaccine (if applicable):
  - TVFC providers will receive a shipping label from McKesson.
  - Providers must ensure that all and only vaccines listed on that Vaccine Loss Report are included in the box for return.
  - If more than one box will be used, mark the boxes with “Box 1 of 2,” “Box 2 of 2,” etc.
  - A copy of the Vaccine Loss Report should be included in each box when returning the 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 (opened multi-dose vials, dropped or broken vials/syringes) should be marked through with a single line.

- Broken vials/syringes 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 nonviable vaccines.
- \_\_\_\_\_ is responsible for returning nonviable vaccine.

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## Texas Vaccines for Children (TVFC) Program Emergency Vaccine Storage and Handling Plan

**Instructions for TVFC providers:** All TVFC providers are responsible for the proper management of their vaccine inventory in the event of an emergency. Once completed, this template can serve as the required Emergency Vaccine Storage and Handling Plan.

TVFC providers must review and update the 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 Unannounced Storage and Handling Visits.

**A copy of this plan, along with the Routine Vaccine Storage and Handling Plan must be posted on or near any refrigerator or freezer used to store TVFC vaccine.**

Practice Name:	Clinic Address:
TVFC PIN#:	E-mail Address:
Telephone Number: (    )    -	Fax Number: (    )    -
Name of Managing Physician of Equivalent:	TVFC Contact:
Primary Vaccine Coordinator:	Back-up Vaccine Coordinator(s):

### Location vaccines will be transferred to in case of emergency:

Location Name:	Contact Person at Receiving Location:
Address:	Telephone Number:
Is there a generator? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date of Agreement:

### Emergency Vaccine Storage and Handling Plan reviewed and updated by:

Name:	Title:
Signature:	Date of Last Review:

## Procedures for Proper Emergency Storage and Handling of Vaccine

- Identify a responsible person and a responsible back-up person to enact the Emergency Vaccine Storage and Handling Plan. Be sure to include contact information such as home, office, and cell phone numbers for each.

The person responsible for enacting the Emergency Vaccine Storage and Handling Plan is: \_\_\_\_\_. The back-up person is: \_\_\_\_\_.

- Identify an emergency storage location to take the TVFC provided vaccine for storage. The emergency storage location must have appropriate vaccine storage equipment that maintains temperatures within the accepted ranges, that has adequate space to accommodate your largest vaccine inventory without crowding and must also be able to monitor/record storage unit temperatures per CDC guidelines. A location with a power generator or other alternate source of power such as a hospital, pharmacy or grocery store is preferable. (Note the emergency location on the first page of the Emergency Vaccine Storage and Handling Plan.)
- Be sure to contact the emergency storage location for their approval before including them on your plan and list their contact person(s) and phone number(s) on your plan. You might consider locating a back-up location in case your primary location is unavailable or unable to store your vaccine inventory for any reason.
- Specify the steps to transport vaccine to the alternate location. Steps should include:
  1. Noting the time of the emergency situation/power outage.
  2. Noting the temperature of the refrigerator and freezer before removing any vaccine for transportation.
  3. Indicating what containers will be used and how the refrigerated vaccine should be packed for transportation (i.e., conditioned ice packs separated from refrigerated vaccine by plastic bubble wrap or crumpled paper to prevent freezing and damage; frozen vaccine placed directly on ice packs to maintain frozen temperature if a portable freezer is not used).
  4. Taking an inventory of the vaccine as you move it 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 (EC-67).
  5. Keeping a certified and calibrated thermometer in the transport container next to the vaccines and noting the time and temperature when you place the vaccine in the alternate storage. This information reveals how long the vaccine was at less-than-ideal temperature and may be needed in the event a determination of viability is required once the vaccines are returned to your facility.

The Emergency Vaccine Storage and Handling Plan Checklist (E11-14497) is available for documenting this process in the event of an emergency.

For detailed guidance regarding proper cold chain management during vaccine transport, refer to: Chapter 3 of the Provider Manual, Section IV. Vaccine Storage and Handling, Subsection H. Cold Chain Management and Vaccine Transport.

In the table below, please provide where to obtain the items required for emergency transport of vaccine and the appropriate contact information.

<b>Where to obtain:</b>	<b>Phone number:</b>
Portable Refrigerator: (Optional)	(     )     -
Portable Freezer: (Optional)	(     )     -
Cooler:	(     )     -
Cold Packs:	(     )     -
	(     )     -
	(     )     -

In the event of a city-wide evacuation, contact your responsible entity for evacuation plan.



# Emergency Vaccine Storage and Handling Plan Checklist

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## Emergency Vaccine Storage and Handling Plan Checklist

<b>Contact with responsible entity made prior to transport by:</b>	
Date:        /        /	Time:        :        AM <input type="checkbox"/> PM <input type="checkbox"/>
<b>Person Transporting Vaccine:</b>	
<b>Transport of refrigerated vaccine</b>	
<input type="checkbox"/>	<p>Assemble packing supplies.</p> <p>Container used to transport refrigerated vaccines:</p> <p style="padding-left: 40px;"><input type="checkbox"/> Portable refrigerator        <input type="checkbox"/> Cooler</p> <p>Other supplies:</p> <p style="padding-left: 40px;"><input type="checkbox"/> Conditioned cold packs*        <input type="checkbox"/> Certified and calibrated thermometer</p> <p style="padding-left: 40px;"><input type="checkbox"/> Packing material</p> <p><small>* To “condition” cold packs, remove them from the freezer and leave them at room temperature for 1 to 2 hours until edges have defrosted and packs look like they have been “sweating.” Frozen coolant packs that are not “conditioned” can freeze vaccines.</small></p>
<input type="checkbox"/>	Spread a layer of conditioned cold packs (at least 2 inches) at the bottom of the cooler. Cover the conditioned cold packs with a 2-inch layer of bubble wrap/crumpled paper.
<input type="checkbox"/>	Stack vaccine boxes on the bubble wrap/crumpled paper. Vaccines must not touch the cold packs in the cooler.
<input type="checkbox"/>	Place the thermometer/probe next to vaccines on top of the bubble wrap.
<input type="checkbox"/>	Cover vaccine with 2-inch layer of bubble wrap/crumpled paper. Spread conditioned cold packs to cover the bubble wrap/crumpled paper.
<input type="checkbox"/>	Fill the cooler to the top with bubble wrap/crumpled paper.
<input type="checkbox"/>	Place the thermometer’s digital display on top of the bubble wrap/crumpled paper.
<input type="checkbox"/>	Include a list of the vaccines that are stored in the container. Use a Vaccine Transfer Authorization Form (EC-67).
<input type="checkbox"/>	<p>Record temperatures on a Temperature Recording Form (C-105) prior to transport.</p> <p style="padding-left: 40px;">Temperature of storage unit at the time the vaccines are removed: _____</p> <p style="padding-left: 40px;">Time vaccines were removed from storage unit: _____</p> <p style="padding-left: 40px;">Temperature of the transport container when vaccines were placed inside: _____</p>
<input type="checkbox"/>	<p>Record temperatures on a Temperature Recording Form (C-105) upon arrival at the emergency storage location.</p> <p style="padding-left: 40px;">Temperature of transport container at the time the vaccines are removed: _____</p> <p style="padding-left: 40px;">Time vaccines were removed from transport container: _____</p> <p style="padding-left: 40px;">Temperature of the storage unit at the time vaccines were placed inside: _____</p>

## Emergency Vaccine Storage and Handling Plan Checklist

<b>Contact with responsible entity made prior to transport by:</b>	
Date:        /        /	Time:        :        AM <input type="checkbox"/> PM <input type="checkbox"/>
<b>Person Transporting Vaccine:</b>	
<b>Transport of frozen vaccine</b>	
<input type="checkbox"/>	<p>Assemble packing supplies.</p> <p>Container used to transport frozen vaccines:</p> <p style="text-align: center;"> <input type="checkbox"/> Portable freezer                      <input type="checkbox"/> Cooler                      <input type="checkbox"/> VaxiPac         </p> <p>Other supplies:</p> <p style="text-align: center;"> <input type="checkbox"/> Frozen cold packs                      <input type="checkbox"/> Certified and calibrated thermometer  <input type="checkbox"/> Packing material                      <input type="checkbox"/> VaxiPac PXC coolant packs         </p>
<b>If cooler is used:</b>	
<input type="checkbox"/>	Spread a layer of frozen cold packs (at least 2 inches) at the bottom of the cooler. Cover the frozen cold packs with a 2-inch layer of bubble wrap/crumpled paper.
<input type="checkbox"/>	Stack vaccine boxes on the bubble wrap/crumpled paper. Vaccines must not touch the cold packs.
<input type="checkbox"/>	Place the thermometer/probe next to vaccines on top of the bubble wrap.
<input type="checkbox"/>	Cover vaccine with 2-inch layer of bubble wrap/crumpled paper. Spread frozen cold packs to cover the bubble wrap/crumpled paper.
<input type="checkbox"/>	Fill the cooler to the top with bubble wrap/crumpled paper.
<input type="checkbox"/>	Place the thermometer's digital display on top of the bubble wrap/crumpled paper.
<b>If VaxiPac is used:</b>	
<input type="checkbox"/>	Pack vaccine in accordance with manufacturer instructions.
<input type="checkbox"/>	Include thermometer probe with vaccines. The digital display will remain on the outside of the VaxiPac.
<b>For all transport of frozen vaccine:</b>	
<input type="checkbox"/>	Include a list of the vaccines that are stored in the container. Use a Vaccine Transfer Authorization Form (EC-67).
<input type="checkbox"/>	Record temperatures on a Temperature Recording Form (C-105) prior to transport. Temperature of storage unit at the time the vaccines are removed: _____ Time vaccines were removed from the storage unit: _____ Temperature of the transport unit at the time vaccines were placed inside: _____
<input type="checkbox"/>	Record temperatures on a Temperature Recording Form (C-105) upon arrival at the emergency storage location. Temperature of transport container at the time the vaccines are removed: _____ Time vaccines were removed from transport container: _____ Temperature of the storage unit at the time vaccines were placed inside: _____

# Vaccine Transfer Authorization Form

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## Texas Vaccines for Children (TVFC) Program Vaccine Transfer Authorization Form

**Guidance:**

Texas Vaccines for Children (TVFC) providers are expected to maintain an adequate inventory of vaccine. Vaccine transfers are limited to: overstock of vaccine, short dated vaccine, withdrawal of a provider from the TVFC Program, replenishing another clinic's inventory, or other (i.e. emergency disaster or equipment failure). When a vaccine transfer occurs, the proper cold chain must be maintained. When a provider needs to conduct a transfer of vaccine from one clinic to another, permission must be granted from the designated DSHS Health Service Region (HSR) prior to the vaccine transfer.

**Directions for use of this form:**

The TVFC providers must complete the Vaccine Transfer Authorization Form (EC-67) for each vaccine transfer. Each vaccine that is going to be transferred must be listed on a separate row. Transfer requests must be signed by the DSHS HSR and returned to the clinic before a transfer can be conducted. The Vaccine Transfer Authorization Forms must be kept on file for a minimum of five years as required by the TVFC Program and made easily accessible.

Vaccine Transferring From:	Vaccine Transferring To:	Reason for Transferring Request: (Check the appropriate reason)
PIN/Customer ID:	PIN/Customer ID:	1. Overstock of Vaccine <input type="checkbox"/> 2. Short Dated Vaccine <input type="checkbox"/> 3. Withdrawal from the TVFC Program <input type="checkbox"/> 4. Replenishing another clinic's inventory <input type="checkbox"/> 5. Other <input type="checkbox"/> _____  <small>In an emergency, please contact the DSHS HRS by phone prior to faxing the Vaccine Transfer Authorization Form.</small>
Facility Name:	Facility Name:	
Address:	Address:	
City/State/Zip:	City/State/Zip:	
Phone:	Phone:	
Fax:	Fax:	
Contact:	Contact:	
Email:	Email:	

Vaccine Type:	National Drug Code (NDC):	Lot Number:	Expiration:	Dose Quantity:

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose transfers reported on this form has been accurately reported and conducted in conformance with VFC provisions for such transfers and further certify that all VFC transfers will maintain the proper cold chain as outlined in the TVFC Provider Manual.

Provider Name: \_\_\_\_\_ Provider Signature<sup>1</sup>: \_\_\_\_\_ Date: \_\_\_\_\_

DSHS HSR Representative Name: \_\_\_\_\_ DSHS HSR Signature: \_\_\_\_\_ Date: \_\_\_\_\_

<sup>1</sup> Provider or designee with authorization to act on behalf of the organization





# Vaccine Borrowing Form

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## Texas Vaccines for Children (TVFC) Program Vaccine Borrowing Form

**Guidance:**

Texas Vaccines for Children (TVFC) providers are expected to maintain an adequate inventory of vaccine for both their TVFC eligible and privately insured clients. Vaccines supplied by the TVFC Program cannot be provided to a non-TVFC eligible client. Borrowing TVFC vaccines for non-TVFC eligible clients is not allowed. If a TVFC dose(s) is accidentally administered to a non-TVFC eligible client, the provider must complete the TVFC Vaccine Borrowing Form and replace the vaccine immediately. TVFC vaccines should not be used as a replacement system for filling the vaccine needs of a non-TVFC privately insured client.

**Directions for use of this form:**

The TVFC provider must complete the Vaccine Borrowing Form (EF11-14171) for each dose that was borrowed and administered to a non-TVFC eligible child. Each vaccine that was administered to a non-TVFC eligible client must be listed on a separate row on the Vaccine Borrowing Form. Once the provider replaces the borrowed dose and completes the Vaccine Borrowing Form, a copy must be faxed immediately to the appropriate DSHS Health Service Region (HSR). Please follow HIPAA guidelines when faxing this form to the HSR. The Vaccine Borrowing Form must be kept as part of the TVFC Program records for a minimum five years and be made easily available.

Vaccine Type	Vaccine Lot Number	Patient Name/Patient Identifier	Patient's DOB	Date Vaccine Was Borrowed	Reason Borrowing Occurred	Date Vaccine Was Replaced

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form."

Provider PIN: \_\_\_\_\_

Provider Name: \_\_\_\_\_

Provider Signature<sup>1</sup>: \_\_\_\_\_

Date: \_\_\_\_\_

<sup>1</sup> Provider or designee with authorization to act on behalf of the organization





# Vaccine Adverse Event Reporting System (VAERS)

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POSTAGE WILL BE PAID BY ADDRESSEE



NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES



VAERS
C/O DEPARTMENT OF STATE HEALTH SERVICES
IMMUNIZATION BRANCH
MC1946
PO BOX 149347
AUSTIN TX 78714-9909



“Fold in thirds, tape & mail --- DO NOT STAPLE FORM”

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
• Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
• Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
• These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
• Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
and 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
Item 13: List ONLY those vaccines given on the day listed in Item 10.
Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/ or neurologic disorders) for the patient.
Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
Item 26: This space is for manufacturers' use only.



# **Adult Safety Net Provider Enrollment Form**

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**TEXAS DSHS ADULT SAFETY NET (ASN) PROGRAM- PROVIDER ENROLLMENT FORM**

PROVIDER PROFILE FOR PIN: \_\_\_\_\_

**VACCINE STORAGE UNITS**

Indicate your **Refrigerator** storage units below:

Type

- |   |          |       |
|---|----------|-------|
| <input type="checkbox"/> Small/Single Exterior Door | Total    |       |
| <input type="checkbox"/> Stand-Alone Refrigerator   | Number   |       |
| <input type="checkbox"/> Combination                | of Units | _____ |
| <input type="checkbox"/> Commercial/Pharmacy Grade  |          |       |

Indicate your **Freezer** storage units below:

Type

- |   |          |       |
|---|----------|-------|
| <input type="checkbox"/> Small/Single Exterior Door | Total    |       |
| <input type="checkbox"/> Stand-Alone Freezer        | Number   |       |
| <input type="checkbox"/> Combination                | of Units | _____ |
| <input type="checkbox"/> Commercial/Pharmacy Grade  |          |       |

Type

- |   |          |       |
|---|----------|-------|
| <input type="checkbox"/> Small/Single Exterior Door | Total    |       |
| <input type="checkbox"/> Stand-Alone Refrigerator   | Number   |       |
| <input type="checkbox"/> Combination                | of Units | _____ |
| <input type="checkbox"/> Commercial/Pharmacy Grade  |          |       |

Type

- |   |          |       |
|---|----------|-------|
| <input type="checkbox"/> Small/Single Exterior Door | Total    |       |
| <input type="checkbox"/> Stand-Alone Freezer        | Number   |       |
| <input type="checkbox"/> Combination                | of Units | _____ |
| <input type="checkbox"/> Commercial/Pharmacy Grade  |          |       |

Dormitory style units are not acceptable for vaccine storage at any time.

**PATIENT PROFILE**

Please enter the number of adults who received vaccinations at your clinic in the past 12 month period ending: \_\_\_\_\_

**Number of adults, age 19 and older, with no health insurance (uninsured):** \_\_\_\_\_

**TYPE OF DATA USED TO DETERMINE PROFILE**

( select all that apply )

- |  |   |                                   |
|--|---|-----------------------------------|
| <input type="checkbox"/> Benchmarking            | <input type="checkbox"/> Doses Administered     | <input type="checkbox"/> Registry |
| <input type="checkbox"/> Provider Encounter Data | <input type="checkbox"/> Other (specify): _____ |                                   |

**PROVIDER LIST**

Please list all providers practicing at this facility authorized to write prescriptions or who possess a medical license.

Last Name	First Name	Middle Initial	Title (M.D., D.O., N.P., R.Ph., P.A., C.N.M.)	National Provider Identification	Medical License Number	Specialty (Family Medicine, Pediatrics, etc.)

**TEXAS DSHS ADULT SAFETY NET (ASN) PROGRAM- PROVIDER ENROLLMENT FORM**  
**PROVIDER ENROLLMENT AGREEMENT FOR PIN: \_\_\_\_\_**

**In order to participate in the Texas Adult Safety Net Program and receive state-supplied vaccines provided to me at no cost, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, health department, community/migrant/rural health clinic, FQHC, or other organization, agree to the following:**

1. This office/facility will screen patients for adult vaccine eligibility at all immunization encounters and administer state-purchased vaccine only to adults 19 years of age or older who do not have any health insurance.
2. This office/facility will maintain all records related to the Adult Program for at least five years. If requested, this office/facility will make such records available to the Texas Department of State Health Services (DSHS), the local health department/authority, or the U.S. Department of Health and Human Services.
3. This office/facility will comply with the appropriate vaccination schedule, dosage, and contraindications, as established by the Advisory Committee on Immunization Practices, unless (a) in making a medical judgment in accordance with accepted medical practice, this office/ facility deems such compliance to be medically inappropriate, or (b) the particular requirement is not in compliance with Texas law, including laws relating to religious and medical exemptions.
4. This office/facility will provide the most current Vaccine Information Statements (VIS) to the responsible adult each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Signatures are required for informed consent. (The Texas Addendum portion of the VIS may be used to document informed consent.)
5. This office/facility will not charge for vaccines supplied by DSHS and administered to an uninsured adult.
6. This office/facility may charge a vaccine administration fee to eligible patients not to exceed \$25.00 per dose.
7. This office/facility will not deny administration of a state-supplied vaccine to an uninsured adult because of inability to pay an administration fee. Unpaid administration fees will be waived and not submitted for collection actions.
8. This office/facility will comply with the State's requirements for ordering vaccine and other requirements as described by DSHS, and operate within the Adult Program in a manner intended to avoid fraud and abuse.
9. This office/facility or the State may terminate this agreement at any time for failure to comply with these requirements. If the agreement is terminated for any reason this office/facility agrees to properly return any unused vaccine.
10. This office/facility will allow DSHS (or its contractors) to conduct on-site visits as required by DSHS regulations.
11. This office/facility will comply with the requirements for vaccine management in accordance with the Certification of Capacity to Store and Manage Vaccines, and the manufacturer's specifications. State-supplied vaccines will only be stored at the facility stipulated in this agreement, and will not be transferred to another provider without approval of DSHS. I may be required to purchase a new refrigerator or freezer unit if equipment at my practice is deemed inappropriate for vaccine storage or not able to maintain appropriate temperatures.
12. I will identify a vaccine coordinator and a back-up coordinator in my practice who is authorized to order vaccines on my behalf. I will inform the Adult Program within 24 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf. I certify that my identification is represented correctly on this provider enrollment form.
13. This office will require the vaccine coordinator and back-up coordinator to complete all required federal and state trainings annually. Certificates of course completion will be submitted to our responsible entity (HSR or LHD). This office will keep a copy of all certificates along with documentation of all other educational trainings and will make them available for review during DSHS site visits.

**To receive state-supplied vaccines, you must confirm acknowledgement of this agreement.**

Provider-in-charge: \_\_\_\_\_  
 (Print) First Name Last Name MI Title (M.D., D.O., N.P., R.Ph., P.A. or C.N.M.†)

Provider-in-charge: \_\_\_\_\_  
 (Signature) Date

† A licensed Medical Doctor, Doctor of Osteopathy, Nurse Practitioner, Registered Pharmacist, Physician Assistant or a Certified Nurse Midwife must sign the Enrollment Form.

# TEXAS DSHS ADULT SAFETY NET (ASN) PROGRAM- PROVIDER ENROLLMENT FORM

PROVIDER CERTIFICATION OF CAPACITY FOR PIN: \_\_\_\_\_

**In order to participate in the Adult Safety Net Program and receive state-supplied vaccines provided to me at no cost, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, health department, community/migrant/rural health clinic, FQHC, or other organization, agree to the following:**

1. **Comply with Vaccine Storage Equipment Requirements**  
Providers must have appropriate equipment that can store vaccine and maintain proper conditions. Equipment must comply with DSHS vaccine storage equipment requirements. Dormitory refrigerators are not allowed for vaccine storage, under any circumstance. Vaccine storage units must be dedicated to the storage of vaccines. Food and beverages must not be stored in a vaccine storage unit.
2. **Designate a Vaccine Coordinator**  
Designate one fully trained staff member to be the primary vaccine coordinator and at least one back-up person able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. The signing physician is responsible for ensuring compliance with annual training requirements for the vaccine coordinator, back-up and other clinic staff handling and storing vaccines. Documentation of training must be maintained for the clinic. The Adult Program shall be contacted immediately to report a change in the primary vaccine coordinator or back-up coordinator.
3. **Follow Established Vaccine Storage Guidelines**  
Refrigerator and freezer units will be set up properly. Vaccine shall be stored in its original packaging and positioned 2-3 inches away from walls, floor, and with space for air circulation. State-supplied vaccine and private vaccine will be kept separate and clearly labeled. Within each supply, vaccines will be grouped by type and clearly labeled in designated spaces for each vaccine type. Vaccine will not be stored in the doors, drawers or bins. Thermometers or their probes will be placed in the center of both the refrigerator and freezer. Signs to prevent interruption of power to the vaccine storage units ("Do Not Unplug" warning signs) will be posted on the electrical outlets, and circuit breakers. The wall outlets will be protected by a plug guard to avoid accidental disconnection. No food or drinks will be stored in the units. Water bottles shall be placed in the refrigerator and ice packs in the freezer to stabilize the temperatures.
4. **Use Certified, Calibrated Thermometers**  
Each storage unit must have a National Institute of Standards and Technology (NIST) certified and calibrated thermometer centrally located within each unit. Each device is to be covered by a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Thermometer calibration must be tested annually by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory. Providers are responsible for maintaining Certificates of Traceability and Calibration Testing (also known as Report of Calibration) and must have them available for review. Thermometers deemed no longer accurate within, +/-1°F (+/- .5°C) upon calibration shall be replaced. DSHS recommends the thermometer be digital and have a biosafe glycol-encased probe.
5. **Store Vaccines at Recommended Temperatures**  
Vaccines will be maintained at all times within the recommended ranges. Vaccines stored in the freezer (MMR, MMRV, and Varicella) will be maintained at 5°F (-15°C) or below [aim for 0°F (-20°C) or lower to keep temperatures from getting too warm]. All other vaccines will be stored in a refrigerator maintained at a temperature above 35°F (2°C) and below 46°F (8°C) [aim for 40°F (5°) to keep temperatures from getting too warm or cold].
6. **Monitor and Record Refrigerator and Freezer Temperatures Twice a Day**  
The vaccine coordinator shall monitor and record the temperatures in the refrigerator and freezer twice each day. If other staff will be assigned to monitor the temperatures, they must be trained on the use of the thermometer and how to respond to and document out of range temperatures. The current temperature will be recorded on the DSHS provided temperature logs. The logs will be posted on the vaccine storage unit door or in a nearby, readily accessible location and maintained for review for 5 years. Temperatures must be taken and recorded twice each day, at the beginning and end of the day, even if a continuously recording/graphing thermometer or data logger is in use. If the temperature is identified as out of range, immediate action must be taken to prevent spoilage of the vaccine and to correct improper vaccine storage condition. This action must be documented on the temperature log and the Adult Program must be contacted immediately.

TEXAS DSHS ADULT SAFETY NET (ASN) PROGRAM- PROVIDER ENROLLMENT FORM

PROVIDER CERTIFICATION OF CAPACITY FOR PIN: \_\_\_\_\_

- 7. **Clearly Identify State-Supplied Vaccine from Privately Purchased Vaccine**  
State-supplied vaccine and privately purchased vaccine will be kept separate and clearly labeled to allow easy identification and prevent use on ineligible patients. Vaccines will be labeled either state or private for clear identification and ideally, kept on different shelves to minimize potential for confusion. Accurate and separate stock records (purchase invoices) of both state and private supplied vaccines must be maintained and be available for review upon request.
- 8. **Maintain and Rotate Stock**  
Inventory management shall be conducted by the practice’s vaccine coordinator or designee at least once a month and before ordering vaccine. State-supplied vaccine stock must be maintained in accordance with actual vaccine need. Vaccine stock will be rotated to place the vaccine with the shortest expiration date for use first. The Adult Program will be notified of any vaccine that will expire within the next 90 days. Vaccine will be maintained in its original packaging until it is used. Spoiled and expired vaccine will be removed from the vaccine storage unit immediately to prevent inadvertent use. A report of all expired or spoiled state- supplied vaccines will be submitted to the Adult Program prior to submitting a new vaccine request. Affected vaccines will be returned to the program’s vaccine distributor for excise tax credit within 6 months of expiration/spoilage.
- 9. **Monitor Vaccine Storage Unit Capacity to Store Vaccines - especially during flu season**  
The vaccine coordinator shall continuously monitor the capacity of the vaccine storage units to ensure adequate space for inventory, especially during flu season. Additional vaccine storage units must be purchased if the size of the current unit cannot accommodate the inventory in a manner consistent with DSHS requirements.
- 10. **Immediate Notification of the Adult Program for Storage and Handling Incidents or Vaccine Shipment Issues**  
If the refrigerator or freezer units experience out of range temperatures, immediate action will be taken to prevent spoilage of the vaccine. This includes extended power outages and vaccine storage unit malfunctions. Depending on the situation, this may necessitate transporting the vaccines as outlined in the emergency plan. Vaccines exposed to out of range temperatures will be marked “Do Not Use” until direction is received from the Adult Program. Contact the Adult Program immediately when out of range temperatures are identified. Shipment issues will be reported to the Adult Program within 2 hours of receiving the shipment.
- 11. **Order and Account for all State-supplied Vaccines in Accordance with Practice’s Patient Profile and DSHS Guidelines**  
Vaccines will be ordered in accordance with practice-based patient profile data, assigned Tiered Ordering Frequency (TOF), vaccine usage, and inventory on hand at the time of order placement. Practice will order all vaccines at one time. An accurate report of each state-supplied vaccine dose administered within each ordering period will be maintained. A summary of vaccine administration and on-hand inventory will be submitted with each vaccine request. All state-supplied vaccine doses will be accounted for.
- 12. **Receive and Unpack Vaccine Shipments Immediately Upon Arrival**  
Vaccine shipments will not be rejected. All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention. When new shipments arrive, vaccines should be unpacked immediately. Immediately upon receipt, vaccine shipments will be inspected to verify the shipping dates are within delivery range and that the vaccines included in the shipment match those listed on the invoice. Any shipment discrepancies or issues must be reported to the Adult Program within 2 hours of shipment delivery. Any change in the practice availability to receive vaccine shipments will be immediately reported to the Adult Program. Practice will assume responsibility for all state-supplied vaccine shipped to the site.

**To receive state-supplied vaccines, you must confirm acknowledgement of this agreement.**

Provider-in-charge: \_\_\_\_\_  
 (Print) First Name Last Name MI Title (M.D., D.O., N.P., R.Ph., P.A. or C.N.M.†)

Provider-in-charge: \_\_\_\_\_  
 (Signature) Date

† A licensed Medical Doctor, Doctor of Osteopathy, Nurse Practitioner, Registered Pharmacist, Physician Assistant or a Certified Nurse Midwife must sign the Enrollment Form.





# Adult Eligibility Screening Record

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**Department of State Health Services (DSHS)  
 Immunization Branch  
 Adult Safety Net (ASN) Program**

Clinic Use Only ASN Eligible	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ Screener's Initials	

**ADULT ELIGIBILITY SCREENING RECORD**

**PURPOSE:** To determine and record eligibility for the DSHS Adult Safety Net Program. A record of the eligibility status of adults receiving vaccine supplied by DSHS must be maintained either in hard copy by the clinic providing the service or in an electronic system such as TWICES. Hard copies must be maintained for **five (5) years**. ASN eligibility screening and documentation of eligibility status must take place at each immunization visit to ensure eligibility status for the program.

Date of Screening: \_\_\_\_\_  
(mm/dd/yy)

Name: \_\_\_\_\_  
(Last) (First) (Middle initial)

Date of Birth: \_\_\_\_\_  
(mm/dd/yy)

**Eligibility Criteria:**

- I declare that I qualify for vaccines through the Texas Vaccines for Children - Adult Safety Net Program because I do not have health insurance.
- I am 19 years of age and I have been referred to the public health department clinic to finish a vaccine series that I began when I was 18 years of age or younger and eligible under the Texas Vaccines for Children (TVFC) Program.

Referring Provider: \_\_\_\_\_

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(mm/dd/yy)

**NOTE: Knowingly falsifying information on this document constitutes fraud. By signing this form, I hereby attest that the above information is true and correct. I declare that the person named above is an authorized person and is eligible to receive ASN vaccines.**

With few exceptions, you have the right to request and to be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, and 559.004)





**Departamento Estatal de Servicios  
de Salud de Texas (DSHS)  
Rama de Inmunización del Programa  
de Protección Para Adultos (ASN)**

SÓLO PARA USO CLÍNICO: Clinic Use Only ASN Eligible	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ Screener's Initials	

**REGISTRO DE DETERMINACIÓN DEL DERECHO  
A LA PARTICIPACIÓN DE LOS ADULTOS**

PROPÓSITO: determinar y registrar el derecho a la participación en el Programa de Protección Para Adultos del DSHS. Se debe guardar un registro del estado del derecho a la participación de los adultos que reciban vacunas suministradas por el DSHS ya sea en copia impresa o en un sistema electrónico como TWICES. Las copias impresas deben guardarse por cinco (5) años. En cada visita de inmunización debe determinarse y documentarse el derecho a la participación en el programa ASN para asegurarse de que la persona pueda participar en el programa.

Fecha de la determinación: \_\_\_\_\_  
(mm/dd/aa)

Nombre: \_\_\_\_\_  
(Apellido) (Primer nombre) (Inicial del 2.º nombre)

Fecha de nacimiento: \_\_\_\_\_  
(mm/dd/aa)

**Criterios de participación:**

- Declaro que reúno los requisitos de vacunación del Programa de Vacunas Para Niños - Protección para Adultos de Texas porque no tengo seguro médico.
- Tengo 19 años de edad y me han referido a la clínica del departamento de salud pública para terminar una serie de vacunas que inicié cuando tenía 18 años de edad o menos y elegible bajo el programa Vacunas Para Niños de Texas (TVFC).

Proveedor que hizo la derivación: \_\_\_\_\_

Firma del paciente: \_\_\_\_\_ Fecha: \_\_\_\_\_  
(mm/dd/aa)

**NOTA: Falsificar información en este documento a sabiendas constituye un fraude. Al firmar este formulario, por este medio doy fe que la información es verdadera y correcta. Yo declaro que la persona nombrada arriba es una persona autorizada y reúne los requisitos para recibir vacunas del ASN.**

Con ciertas excepciones, tiene derecho a pedir y a ser informado sobre la información que el estado de Texas reúne sobre usted. Tiene derecho a recibir y examinar la información al pedirla. También tiene derecho a pedir a la agencia que corrija cualquier información que se determine es incorrecta. Consulte <http://www.dshs.state.tx.us> para obtener más información sobre la Notificación de privacidad. (Referencia: Código gubernamental, sección 552.021, 552.023 y 559.004)





