

## Section Two: Standards and Policies

*Policy:* All agencies offering and utilizing TVFC vaccine must abide by the guidelines outlined in this Section.

*Purpose:* To provide instruction and to ensure consistency and adherence regarding TVFC activities and standards.

### I. Provider Eligibility

#### A. Organization Participation

These organizations are eligible for state and federally funded vaccines:

1. Public hospitals, medical school clinics, and hospitals that will vaccinate children according to Chapter 43, Health and Safety Code (Senate Bill 266, 73<sup>rd</sup> Texas Legislature).
2. Texas state agencies.
3. Public and private schools, colleges, universities, and private hospitals.
4. Federally funded community health centers, migrant health centers, rural health initiatives clinics, urban Indian health programs, housing programs, homeless programs, and other federally qualified health centers.
5. Health Service Regions (HSRs) and Local Health Departments (LHDs).

These organizations **ARE NOT** routinely eligible for state and federally funded vaccines:

1. No federal organization that receives funds for their own immunization programs, such as the Immigration and Naturalization Service, Veterans Administration, and military organizations.
2. Health maintenance organizations and preferred provider organizations. (Individual providers who participate in these organizations may enroll in the TVFC.)

## **B. Provider Participation**

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

1. Physician (Medical Doctor (MD) or Doctor of Osteopathy (DO))
2. Nurse Practitioner (NP)
3. Certified Nurse Midwife (CNM)
4. Physician Assistant (PA)

All other health care providers must enroll under the standing delegation orders of a physician including:

1. Pharmacists (RPH)
2. Nurses (Registered Nurses (RN) or Licensed Vocational Nurses (LVN))
3. Medical Assistants (MA)
4. Nurse Assistants (NA)
5. Emergency Medical Technicians (EMT)

Medicaid and Children's Health Insurance Plan (CHIP) providers must enroll in the TVFC or use their private stock vaccines. They may not refer children to LHDs or other entities for routinely recommended vaccinations. A TVFC Provider Enrollment Form is included in the Medicaid provider enrollment packet.

**NOTE: Medicaid and CHIP programs do not reimburse providers for the cost of routinely recommended childhood vaccines but do reimburse an administration fee.**

## **C. Provider Enrollment**

1. The TVFC Provider Enrollment Form must be completed at initial enrollment and updated annually. A signed enrollment by the Medical Director of the HSRs or LHDs/districts, private physicians (MD or DO), NP, PA, or CNM must be in DSHS- Austin Office (AO) prior to receiving state and federally funded vaccines. Generally, the individual who signs the TVFC Provider Enrollment Form will be the physician who signs the standing delegation orders for the clinic or the physician-in-chief.

- a) The Provider Enrollment Form must be updated when the provider who signed the original form is no longer associated with the clinic.
  - b) Each clinic site that maintains a TVFC vaccine inventory must be enrolled as a separate TVFC clinic site. Group practices may elect to enroll as one entity, or each physician may enroll separately.
  - c) The LHD will forward initial enrollments to the HSR. The HSR must fax or mail all initial enrollments to AO to obtain a Provider Identification Number (PIN). AO staff will notify regional staff of the new PIN via email or phone. The PIN will be the clinic's identification number for the duration that the clinic is enrolled in the TVFC. All subsequent enrollment forms and vaccine orders must have the PIN written on all forms. Any form without this PIN will not be processed and will be returned to the sender.
2. The Provider Enrollment, Provider Profile, and Provider List Addendum Forms must be completed at initial enrollment and updated annually.
- a) HSRs have two options when obtaining public annual re-enrollments:
    - i. The Provider Enrollment, Provider Profile, and Provider List Addendum Forms may be completed during the annual TVFC On-site Quality Assurance Visit or Contract Monitoring Visit and submitted to AO.
    - ii. The Provider Enrollment, Provider Profile, and Provider List Addendum Forms may be completed for all public providers at one time and then submitted to AO.
  - b) The quality assurance contractor will obtain the Provider Enrollment, Provider Profile, and Provider List Addendum Forms for private providers during the annual TVFC On-site Quality Assurance Visit and will post the enrollment forms on the TVFC website; hard copies will also be submitted to the AO. If the quality assurance contractor cannot obtain all required information for the re-enrollment, the incomplete paperwork will then be sent to the AO. The AO will forward to the HSR to obtain all required information.
  - c) The patient numbers requested on the Provider Profile form must be specific to the clinic site where the child will be vaccinated and not combined with other clinics' patient numbers. The numbers must be based on real data, e.g. registry data, billing data.
  - d) The Provider List section of the Provider Profile Form and the Provider List Addendum must list the provider who signs the Provider Enrollment Form. All licensed and/or certified individuals within the practice who will be administering TVFC supplied vaccines must be listed on this form. This includes MD, DO, NP, CNM, RPH, PA, RN, LVN, EMT, MA, and NA.

3. Vaccine may not be supplied to TVFC providers who do not have current enrollment information on file. Providers will be granted a 90-day grace period from the date the enrollment expires to allow a site visit to be conducted and the enrollment paperwork completed. Failure to obtain the required paperwork will result in vaccine shipment delays or removal of provider from program.

*See Appendix B for the Provider Enrollment, Provider Profile and List, Provider List Addendum.*

#### **D. Provider Exclusion**

AO staff will verify all doctors listed on the provider list section of the enrollment/re-enrollment forms against the Medicaid Provider Exclusion List before assigning a PIN. The Medicaid Exclusion List is a database used to verify if a MD or DO is eligible to participate in the Medicaid program. Any provider who has been excluded from participation in Medicaid will be denied enrollment into the TVFC. The form can be signed and resubmitted by another MD, DO, NP, PA, or CNM in the clinic. However, the excluded physician will not be eligible to receive or administer TVFC vaccine and cannot be listed on the provider list. Once a provider has been reinstated, they may enroll in the TVFC.

#### **E. Provider Withdrawal**

If a provider withdraws from the TVFC, a Provider Withdrawal Form must be completed and submitted to AO within one business day after the date of withdrawal. Provider Withdrawal Forms completed by the LHD shall be forwarded to the HSR. The HSR will forward the form to the AO. When providers withdraw from the TVFC, viable and non-viable vaccines must be removed from the provider's clinic site within five business days by the HSR or LHD. Viable vaccine should be redistributed to other enrolled clinics. Non-viable vaccine should be returned to the third party distributor along with the HSRs non-viable stock. If a vaccine loss occurred, a Vaccine Loss Report Form (EC-69) should be generated by the LHD or HSR and forwarded to the AO.

*See Appendix O for the Provider Withdrawal Form*

**Note: Picking up viable and non-viable vaccine from a withdrawn provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).**

## **F. Provider Fraud & Abuse Reporting**

HSRs and LHDs and other contractors must report all cases of alleged or suspected fraud according to the procedures outlined in the DSHS Policy AA-5042. DSHS employees and contractors shall immediately report all allegations of fraud and other unlawful activities to the Office of Inspector General (OIG) as directed by OIG procedures. These procedures are located at [https://oig.hhsc.state.tx.us/Fraud\\_Report\\_Home.aspx](https://oig.hhsc.state.tx.us/Fraud_Report_Home.aspx). This site contains forms and instructions for either on-line or paper reporting. Vaccine Services is currently working with the CDC and OIG to improve the process for prevention, identification, investigation and resolution of suspected cases of fraud and abuse.

It is important that TVFC providers understand that the TVFC is subject to all federal fraud and abuse laws, and that unintentional abuse or error is nevertheless unacceptable. The following definitions and examples are provided so that DSHS staff can better identify and intervene in activities that could be defined as fraud or abuse.

### **Fraud**

Fraud is defined as an intentional deception or misrepresentation made 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**

Abuse is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices, and that 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.

### **Examples of Fraud and Abuse**

Fraud and abuse can occur in many ways, and some types of fraud and abuse are easier to prevent or detect than others. TVFC staff and contractors should familiarize themselves with the examples below that illustrate common practice errors that could result in fraud or abuse allegations. Prevention education is critical. In order to prevent unintentional fraud or abuse situations, providers should be educated at every opportunity (including site visits, trainings, and phone calls)

regarding appropriate use of TVFC vaccines, and warned that federal fraud and abuse laws apply to the TVFC.

Some examples of potential fraud and abuse that TVFC staff might encounter include:

#### Fraud

- Selling or otherwise misdirecting TVFC vaccine;
- Billing a patient or third party for TVFC vaccine;
- Failing to meet licensure requirements for enrolled providers;

#### Fraud or Abuse

- Providing TVFC vaccine to non-TVFC-eligible children;
- Charging more than \$14.85 for administration of a TVFC vaccine to a vaccine-eligible child;
- Failing to screen patients for TVFC eligibility;
- Failing to fully account for TVFC vaccine;
- Failing to properly store and handle TVFC vaccine;
- Wastage of TVFC vaccine.

#### Abuse

- Failing to complete a Provider Enrollment or Re-enrollment Agreement;
- Not providing TVFC-eligible children TVFC vaccine because of parents' inability to pay for the administration fee;
- Not implementing provider enrollment requirements of the TVFC;
- Failing to maintain TVFC records and comply with other requirements of the TVFC;
- Ordering TVFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of TVFC doses.

## **II. Patient Eligibility**

### **A. Requirements for Patient Eligibility Screening**

1. The Patient Eligibility Screening Form may be used to document the category of eligibility. Although this form is not required, providers must document the eligibility category of each client receiving TVFC vaccine. Providers may document eligibility in the patient's chart or in an electronic data file; however, the information should be easily retrievable. Federal law requires that the provider maintain the screening record for three years.
2. The Patient Eligibility Screening Form is a one-time form until the child's category of eligibility changes. When eligibility changes happen, a new form must be completed.
3. No clinic or provider is waived from conducting patient eligibility screening - it is a federal requirement. The screening is a self-declaration by the parent or guardian. Providers are not required to verify that the self-declaration is accurate.
4. Any child who meets any one of the eligibility criteria listed below, and who is 18 years of age or younger, qualifies for TVFC vaccine:
  - a) Enrolled in Medicaid, or
  - b) Does not have health insurance, or
  - c) Is an American Indian, or
  - d) Is an Alaskan Native, or
  - e) Underinsured (has health insurance that does not pay for vaccines, has a co-pay or deductible the family cannot meet, or has insurance that provides limited wellness or prevention coverage), or
  - f) Enrolled in CHIP
  - g) Is a patient who is served by any type of public health clinic and does not meet any of the above criteria
5. Immigration status does not affect a client's eligibility for the TVFC. Immigrants should be offered the same immunization services that other customers receive in public health clinics.

### **B. Two-Tiered Vaccines**

Due to certain funding limitations, some vaccines may not be available to underinsured children except when they present at a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). These vaccines may be referred to as two-tiered. AO will notify all TVFC providers via official memorandum when funding limitations exist and vaccines are two-tiered.

All two-tiered vaccines designated by AO may be administered in all TVFC-enrolled clinic sites to children in Categories a, b, c, d, f, and g only (see above). This vaccine can only be administered to children in Category e (underinsured) when they present for services in a FQHC or RHC. Provider offices that do not have one of these designations should assist qualified patients with the appropriate referral. As a public service, HSRs, LHDs, and enrolled clinics should provide this referral to the nearest FQHC/RHC that is providing immunization services to underinsured children, regardless of the distance. All public and private TVFC-enrolled provider sites must follow this guideline.

*See Appendix C for the Patient Eligibility Screening Form*

### **III. Vaccine Management**

Throughout 2009, public sites may be implementing the Pharmacy Inventory Control System (PICS) to electronically receive, track, transfer, and maintain vaccine inventory that is purchased through the TVFC. Sections B and C below will separate PICS and non-PICS responsibilities.

#### **A. Vaccine Distribution**

Texas Department of State Health Services (DSHS) uses three vaccine distribution centers: McKesson, a third party distributor (ships the majority of TVFC vaccines); the DSHS Pharmacy Branch; and Merck, the manufacturer of varicella and MMRV, ships directly to providers.

#### **B. Vaccine Ordering**

##### **1. Non-PICS Users**

All TVFC provider sites submit vaccine orders to their LHD or HSR. The LHD or HSR reviews the order to ensure that all information is included on the form, and that providers are ordering within the established MSL agreed upon with the LHD or HSR. The LHD or HSR submits the order to AO.

All clinics must provide the following information each month in order to receive vaccine:

- a) The Monthly Biological Report Form (EC-33),
- b) The Temperature Recording Form (EC-105),
- c) Complete the Biological Order Form (EC-68) when appropriate

Providers must order using their established MSL. For vaccine orders outside a provider's MSL, an explanation should be added to the comment section on the EC-68. Incomplete or inaccurate forms should be returned to the provider.

##### **HSR/LHD Procedures**

When a vaccine order and/or report is received from a provider, the LHD or HSR will perform a quality assurance check to include the following:

- a) Verify the address, shipping hours, and shipping days on the EC-68 are correct.
- b) Verify that the amount ordered equals the MSL or has a valid reason for being above or below the MSL.

- c) Verify the PIN is correct.
- d) Verify that an authorized person listed on the TVFC Provider Enrollment Form signed the EC-68.
- e) Review the EC-33 to ensure that the beginning inventory matches last month's ending inventory and that calculations are correct. Check column I, net lost or gained, to ensure that it does not exceed 5 doses of any one vaccine. Report any corrections to the originating clinic so they can adjust their records.
- f) Resolve discrepancies with clinic involved.
- g) Review the EC-105 to determine if refrigeration problems exist in the clinic.
- h) Submit EC-33 and EC-68 forms to AO as they are received and processed (do not hold forms for large batches).

**NOTE: To assist LHD/HSR with QA on EC-68s and EC-33s, a checklist has been developed and is located in Appendix M.**

In extenuating circumstances an urgently needed order (UNO) may be submitted. A valid reason must be noted in the comment section of the EC-68 for the UNO to be processed. HSRs/LHDs should verify that providers are ordering up to the max stock levels on all vaccines. HSRs/LHDs should also verify that a current Temperature Recording Log is on file and temperatures are within range.

## 2. PICS Users

Replenishment of vaccines will occur on a monthly basis. All recording of usage and reconciliation activities must be completed to initiate the replenishment order. The initiation of automatic replenishment involves five steps:

- a) Complete usage recording on a daily, weekly or monthly basis. It is recommended that a site record usage on a daily basis; however, it must be completed by the week of replenishment. Each site will have vaccine replenishment amounts determined by min/max stock levels. Each vaccine will have a min/max stock level determined by historical usage patterns. Recording of usage deducts product from site's inventory and ensures successful automatic replenishment. Usage recording also provides the information necessary to generate reports such as the Monthly Biological Report (EC-33).
- b) Verify that the physical inventory is in line with the electronic inventory. If adjustments are required: PICS allows the site to record doses that have been expended for reasons other than patient usage, including expired, spoiled, wasted, or gained

vaccines. If you record a loss in PICS, follow the TVFC guidelines for the submission of the Vaccine Loss Report (EC-69).

- c) PICS enables the Site Administrator to modify specific demographic information to minimize risk of vaccine loss due to incorrect information. Important information includes the site's **Contact Person, Days/Hours of Operation, Phone Number, Fax Number, Mailing Address, and Shipping Address**. A site may be billed for any vaccine loss due to incorrect site demographic information.
- d) Each site must conduct an electronic reconciliation process in PICS. This must be completed no more than 4 days prior to the replenishment deadline. If missed, the site must contact the appropriate Approval Authority immediately.
- e) Site **MUST** click the 'Submit' button for the replenishment process to be complete.

### **C. MSL and Tiered Ordering Frequency (TOF): Calculating and Updating**

MSL: 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.

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

#### **MSL**

LHDs and HSRs are expected to develop MSL for every new TVFC provider. MSL and/or TOF should be re-calculated every six months, or more often if necessary to ensure that vaccine orders are consistent with current usage. Providers should always be consulted when adjusting tiers or significantly increasing vaccine order amounts to ensure that adequate storage is available and that the provider is willing to take on any added liability of maintaining a larger inventory.

MSL revisions typically begin by updating the doses administered data to the most current 12 months in the calculation spreadsheet. However in some cases the most current 12 months may not reflect current or usual usage patterns, and fewer months may need to be used to calculate the MSL. Examples of this include:

- o new vaccines -- uptake and usage changes very quickly and may need to be re-evaluated every 2 to 3 months;
- o clinic loses or gains providers -- uptake could be significantly increased or decreased, and doses administered information from months prior to the change should not be considered in the MSL calculation.

- provider has a special clinic for one vaccine such as Hepatitis A during an outbreak -- usage for that month is much higher than a normal month's usage, and should not be used in calculating the MSL;
- provider was not practicing for a period of time and usage declines significantly -- do not include that month's usage data in the MSL calculation; and
- provider was unable to give a vaccine due to a shortage or some other factor -- that month's data should not be used in the MSL calculation.

MSLs are calculated using the following process:

1. Obtain an average of the doses administered data 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 or predicted future usage (typically 12 months).
2. Multiply the average obtained in step one by 2.5 for a monthly provider, 3.5 for a bi-monthly provider or 4.5 for a quarterly provider.
3. The number obtained in step 2 is the MSL for the provider.

Recommendations on MSL and TOF should be submitted to the appropriate health service region for approval and submission to the AO.

MSL is based upon a 45-day base of vaccine, 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>+</b>	<b>30 (1 month)</b>	<b>=</b>	<b>75 (2.5 months)</b>
<b>Bi-Monthly</b>	<b>45 (1.5 months)</b>	<b>+</b>	<b>60 (2 months)</b>	<b>=</b>	<b>105 (3.5 months)</b>
<b>Quarterly</b>	<b>45 (1.5 months)</b>	<b>+</b>	<b>90 (3 months)</b>	<b>=</b>	<b>135 (4.5 months)</b>

## **TOF**

HSR/LHD should 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 orders:

- Once a month (monthly)
- Once every other month (Bi-Monthly)
- Every three months (Quarterly)

Large providers will order more frequently, while smaller providers will order less often. The chart below is a gauge of how to categorize a provider's TOF based on vaccine usage.

Order less than 500 doses/year	Order vaccines every 3 months (Quarterly)
Order 500-1999 doses/year	Order vaccines every 2 months (Bi-monthly)
Order more than 2000 doses/year	Order vaccines every month (Monthly)

In addition to usage, a provider must have enough refrigeration/freezer space to accommodate a maximum order based on TOF and MSL. A guide to help determine TOF based on storage space is below.

Storage Capacity	Frequency
2-4 Cubic feet of storage in refrigerator	MONTHLY OR BI-MONTHLY (<250)
6-14 Cubic feet of storage in refrigerator	MONTHLY OR BI-MONTHLY (depends on annual orders)
15+ Cubic feet of storage in refrigerator	MONTHLY, BI-MONTHLY OR QUARTERLY (depends on annual orders)

## D. Receiving Vaccine

### 1. Non-PICS Users

#### **Provider Procedures:**

It is important to recognize and store vaccine shipments immediately to ensure vaccine viability. The following steps should be taken when a vaccine shipment arrives:

- a) Check actual vaccine received against packing list to verify all vaccines have been received.
- b) Put vaccine into appropriate storage immediately. Make sure to check expiration dates and rotate stock so short-dated vaccine can be used first.
- c) Make sure diluent that accompanies MMR and varicella matches amount of vaccine received.
- d) Each order generates a faxed confirmation that shows the vaccines that have been ordered. Checking the packing list against the faxed confirmation will verify that all vaccines ordered by DSHS were received.
- e) If a provider does not receive the appropriate vaccine, he/she will contact the LHD or HSR immediately.

- f) Providers should expect their orders approximately three weeks from the time of submission of paperwork.
- g) Vaccine is packed to maintain the cold chain for 72 hours (3 days).
- h) Vaccine will be shipped using high quality cardboard boxes with Styrofoam inserts.
- i) 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.
- j) Each package comes with a temperature monitor(s). If monitors indicate, or if staff suspects that the cold chain has not been maintained, staff must place vaccines in the refrigerator and immediately contact their appropriate approval authority—LHD or HSR.

**LHD/HSR Procedures:**

In the event a provider receives vaccines they did not order the LHD or HSR will:

- a) Check with assigned TVFC Consultant for the reason behind the error
- b) Request that the provider absorb the received vaccine into their stock
- c) If the provider does not want to keep the vaccine, LHD/HSR will arrange for the redistribution within the HSR
- d) If the vaccine cannot be placed within the HSR, the HSR will contact their TVFC Consultant for assistance with placement.

**Note: Picking up and redistributing vaccine from a provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).**

2. PICS Users

Vaccines must be received into PICS before usage can be recorded. The initiation of receiving vaccine involves:

- a) Upon receipt, the site must compare the information in PICS with the actual vaccine information to include: vaccine type, lot number, expiration date, and amount received.
- b) When the site accepts the receipt of the vaccine, the products are added to the doses on hand.

**E. Vaccine Received Warm or Questionable**

**NOTE: Providers should always accept vaccine shipments. Never refuse or return vaccine shipments without instructions from AO. If**

there are questions about improperly handled vaccine while in transit, providers will call the LHD or HSR immediately.

Examples of potentially non-viable vaccines are:

1. Vaccine shipment is received with the temperature indicator strip showing out of range.
2. No ice packs or dry ice (Varicella) are present.
3. The vaccine is **warm** to touch.
4. Vaccines are received damaged.

**Provider Procedures:**

If vaccine is suspected of being non-viable at receipt, providers should:

1. Place a thermometer in the shipping container with the vaccines before removing them from the container. Document the temperature.
2. **Before** storing the questionable vaccines in the refrigerator and/or freezer, label the outside of the container, **Do Not Use** until further directions are received from the LHD/HSR. Instruct staff not to write on the vaccine itself. Large lettering on paper attached to the container is recommended.
3. After steps above are complete place the vaccine in appropriate storage.
4. Contact appropriate approval authority (LHD or HSR) immediately. Providers should never contact the distributor or manufacturer directly unless directed to do so by AO.
5. Await information from their LHD or HSR on a procedure for replacement, reporting loss, etc. The LHD or HSR may recommend contacting the DSHS Pharmacist at (512) 458-7500, or Merck for varicella and/or zoster for determination of vaccine viability.

**LHD/HSR Procedures:**

If vaccine is non-viable at receipt, LHDs and HSRs should:

1. Instruct the provider to place a thermometer in the shipping container if the vaccines haven't already been removed from the shipping container. Document the temperature.
2. Isolate the questionable vaccine in a bag, box, or shipping container.

3. **Before** storing the questionable vaccines in the refrigerator and/or freezer, label the outside of the container, **Do Not Use** until further directions are received from the LHD/HSR. Instruct staff not to write on the vaccine itself. Large lettering on paper attached to the container is recommended.
4. Obtain the pertinent information from the clinical staff to contact pharmacy or Merck. If vaccine is MERCK vaccine, instruct the staff to immediately contact MERCK for further instructions and provide a call back number for staff to report vaccine determination. If no call is received within 2 hours, contact staff for follow up.
5. Contact the DSHS pharmacy with information received from provider, or have provider call the pharmacy directly at (512) 458-7500.
6. After receiving directions from the pharmacist, contact the provider to discuss vaccine viability.
7. If the vaccines are deemed viable, return them to the inventory with other vaccines and discard the **Do Not Use** sign. Remind staff to correctly rotate this inventory into existing stock.
8. If vaccine is not viable, it should be immediately removed from the refrigerator or freezer and labeled **Do Not Use**.
9. Assist the provider with completion of vaccine loss report (C-69). Notify AO of loss immediately.
10. Assist the provider with obtaining replacement stock, if appropriate, and the method to return ruined vaccines (See H. Procedures for Vaccine Loss and Returning Vaccine below).
11. Document the name and titles of all personnel, including DSHS Pharmacist, and any unusual circumstance, and submit to TVFC consultant along with C-69.

**AO Procedures:**

1. If necessary, log the problem on the issue log and notify the PPOC via email identifying the number on the issue log.
2. Assist HSR with any needs

**NOTE: Vaccine returns must occur within 48 hours to McKesson.**

## **F. Vaccines Received in Error**

If vaccine is received and was not ordered, the TVFC provider should call the LHD or HSR immediately. The HSR should contact the AO once notified by the LHD or provider that vaccine was received in error. The AO will research the problem and then notify the HSR with further information.

1. If vaccine was shipped in error to a provider, the LHD/HSR should contact the AO. McKesson will be notified by AO staff and may arrange to have the vaccine picked-up. The vaccine may also be redistributed to other providers (see 2.b. below).
2. If the provider ordered the vaccine in error, the provider has two options:
  - a) Vaccine can be shipped back to the third party distributor at a cost to the provider.
  - b) Vaccine can be redistributed to other providers in the region who can use the vaccine. TVFC providers should contact the LHD or HSR for assistance.

**Note: Picking up and redistributing vaccine from a provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).**

## **G. Expired Vaccine**

The Immunization Branch requires that all unopened or unused vials of expired vaccines/toxoids/biologicals be returned to the third-party distributor. Vaccine manufacturers reimburse Texas for the federal excise tax portion of the cost of the vaccine, and in some cases, for the total cost of the vaccine. Therefore, providers should not discard vaccines unless specifically directed by HSR/LHD or AO. Expired vaccines should be kept together and labeled for return to distributor. Any exception to this rule will be announced by the AO on a case-by-case basis. For return process, see H below.

**NOTE: Providers should notify the LHD or HSR 90 days prior to vaccine expiration if the vaccine cannot be used before expiration. The LHD or HSR is responsible for assisting with redistribution of the vaccine.**

## H. Procedures for Vaccine Loss and Returning Vaccine

### 1. Provider Procedures:

If a provider has a vaccine loss of 5 doses or more (expired or ruined) the following procedures should be followed:

- a) Separate expired or ruined vaccine from other viable vaccines.
- b) Contact your appropriate approval authority (LHD or HSR) immediately with the following information:
  - Antigen, lot number, expiration date
  - Reason for expiration/loss –

**Note: If storage was compromised, provide LHD or HSR with amount of time product was out-of-range and highest temperature recorded.**

- c) Submit the Vaccine Loss Report Form (EC-69) explaining the cause(s) of the vaccine loss and outlining the steps taken to ensure vaccines will be protected in the future. This report is due to the HSR within 4 business days of the loss. The report may be faxed or mailed, and includes the following sections:
  - Clinic demographics
  - Date loss was discovered
  - Type of loss
  - Reason for loss
  - Explanation of loss
  - Corrective action taken to avoid re-occurrence
  - List of vaccines by antigen, manufacturer, lot number, expiration date, and doses lost

**Note: Form must be signed by a provider enrolled in TVFC.**

- d) HSR or LHD may inform the provider to contact the DSHS Pharmacy to determine if the vaccines in question can still be used. The DSHS Pharmacy may instruct the provider to contact the vaccine manufacturer to request an opinion on whether the vaccine can be used.
- e) The TVFC provider that has lost vaccine must assess how long the vaccines have been stored improperly and how many children have received the vaccines. After discussing this with the DSHS Pharmacy and manufacturers, the clinic site must determine whether or not children will need to be recalled. The TVFC 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.

- f) TVFC providers should report vaccine losses on column F of the EC-33 at the end of the month. This will ensure that the vaccine inventory balances. Losses totaling less than 5 doses should be listed on column F of the EC-33 with an explanation in the comments section for the loss.

TVFC providers may be billed for vaccine losses due to negligence. (See K. Storage and Handling #5 for definition of negligence.)

## 2. HSR and LHD Procedures:

- a) HSR/LHD will assist provider in contacting DSHS Pharmacy Branch or Merck (varicella, zoster) and in completing EC-69. EC-69 should be requested when the EC-33 indicates a loss of 5 doses or more of any one vaccine.
- b) HSR will review EC-69 for completeness and forward to AO for processing.
- c) The HSR/LHD that serves the provider must notify DSHS, Immunization Branch, VSG within 8 working hours of notification from the provider. The QA contractor may also contact the LHD or HSR. The HSR will confer with the AO consultant about the TVFC provider's loss and the details of that loss, including the number of doses of vaccine lost and the vaccine loss history of the TVFC provider.
- d) HSR/LHD must re-contact TVFC providers within 5 business days for follow-up, to retrieve vaccines, and ensure the problem that created the loss has been corrected.
- e) HSR should approve additional orders only after safe storage for vaccines has been confirmed.
- f) HSR/LHD will advise the provider on how to return vaccines using the McKesson packing boxes, and ensuring that a copy of the C-69 paperwork is correct and included with the physical vaccines.

### Instruct providers to:

- Enclose non-viable vaccine in the empty storage container;
- Enclose a copy of the fully completed EC-69 inside the container;
- If more than one box is used, mark the boxes with box 1 of 2, etc.;
- Reverse the box flaps exposing the postage paid return label and tape with clear shipping tape;
- The provider can either wait until they receive a vaccine shipment to give the container to the courier for return to McKesson, or if UPS is not the provider's regular shipper, UPS can be called to provide a pick-up free of charge;
- Providers should not be charged a pick-up fee for this service;
- Contact your consultant if UPS requests payment for box pick-up.

### 3. AO Procedures:

AO will review all EC-69s for completeness and consideration for billing provider for loss.

- Based on the information supplied by the TVFC provider and LHD/HSR, the Immunization Branch will determine whether the vaccine was lost due to negligence or an unpreventable occurrence (natural disaster, area power outages, etc.). A review of the provider's loss for the past 24 months may also be reviewed at this time to determine if the provider will be notified in writing or billed for the loss. (TVFC providers may be financially responsible for the cost of TVFC vaccine lost due to negligence.)
- A vaccine loss that was due to negligence may be billed regardless of prior history of preventable vaccine loss. (See K. Storage and Handling #5 for definition of negligence.) TVFC providers having three or more preventable vaccine losses within the prior 24-month period of time may be billed for the vaccine loss, regardless of the loss amount. TVFC providers who are newly enrolled (less than 24 months) with two or more preventable vaccine losses may be billed for the vaccine.
- A vaccine loss that was due to negligence may result in a warning letter that outlines the type of loss and the amount of the loss, but does not include a bill for the loss.
- Once it is determined that the TVFC provider will be responsible for reimbursing DSHS for the vaccine loss, DSHS Immunization Branch will bill the TVFC provider in writing. Copies of the billing letter will be provided to the appropriate HSR.

**Note: The Immunizations Branch Manager will review losses that are \$2,000 or more to determine if the provider will be billed for the lost vaccines.**

### 4. Third Party Distributor Procedures:

Third party distributor will document Texas losses and return vaccines to the manufacturer for excise tax credit.

#### I. **Approved Vaccines**

The vaccines/toxoids covered under this policy are:

1. Diphtheria and Tetanus toxoids, adsorbed (DT)
2. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine (DTaP)
3. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, Hepatitis B, and Inactivated Polio vaccine (DTaP-HepB-IPV)

4. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine, Inactivated Polio vaccine, and *Haemophilus influenzae* type b vaccine (DTaP-IPV/Hib)
5. Diphtheria-Tetanus toxoids and acellular Pertussis vaccine and Inactivated Polio vaccine (DTaP-IPV)
6. Flumist (LAIV)
7. Hepatitis A vaccine (HepA)
8. Hepatitis B vaccine (HepB)
9. *Haemophilus influenzae* type b (Hib)
10. Hepatitis B and *Haemophilus influenzae* type b (HepB-Hib)
11. Human Papillomavirus (HPV) vaccine
12. Influenza vaccine
13. Inactivated Polio vaccine (IPV)
14. Measles, Mumps, and Rubella (MMR)
15. Measles, Mumps, Rubella and Varicella virus vaccine (MMRV) – when available
16. Meningococcal Conjugate (MCV4)
17. Meningococcal Polysaccharide vaccine\*
18. Pneumococcal Conjugate (PCV7)
19. Pneumococcal Polysaccharide 23-valent vaccine (for high-risk patients)\*
20. Rabies\*
21. Rotavirus vaccine
22. Tetanus and Diphtheria toxoids, adsorbed (Td for adult use)
23. Tetanus and Diphtheria toxoids and acellular Pertussis vaccine (Tdap)
24. Varicella
25. Zoster
26. Immune Globulin (IG)\*

\*Some of the vaccines listed above are not for routine use. Due to funding limitations, all vaccines may not be available to vaccinate children.

\*See Appendix A, *Additional Vaccine Ordering Instructions*.

## J. Adult Safety Net Program and Adult Hepatitis B Initiative

### Adult Safety-net Program:

The adult Vaccine Safety-net was developed to ensure that adults who ordinarily seek services through local health departments or Health Service Regions would have access to recommended adult vaccines. The Adult Safety-net is not mandated by the Texas legislature and funding comes out the same budget as emergency vaccines and biologicals. In order not to strain this budget, the public agencies using state adult safety-net vaccines are meant to be 'providers of last resort.' Patients with insurance to cover the cost of vaccines are not eligible for safety net

vaccine. Insured patients should be referred to a physician or agency that purchases vaccine and bills the appropriate insurance.

LHDs may choose to immunize insured patients, but must use locally purchased vaccines, and not state purchased safety-net vaccine. Additionally, special immunization clinics should not be held for adults using safety-net vaccines (with the exception of HSR flu clinics), and advertising should not be used to promote the adult safety-net program.

The adult safety-net vaccines are available only through LHD and HSR clinics, as well as agencies contracted by a LHD to provide vaccines. Safety-net vaccines may be provided to uninsured and under-insured patients only, and eligibility must be documented and stored for three years. Eligibility is a self declaration by the patient and need not be verified by health department staff. Private providers are not authorized to provide vaccine to adults 19 years of age or older, with one exception: any person who was TVFC-eligible and started a series before his/her 19<sup>th</sup> birthday may finish the series with TVFC vaccine.

All adult vaccine doses administered should be reported on the Monthly Biological Report (C-33) under the "19+" Doses Administered column. It is important to accurately report all doses provided to adults. The Immunization Branch uses this information to account for adult usage, and to project and maintain supply.

The following chart outlines each of the adult vaccines to be made available through public health clinics with its respective eligibility criteria.

Vaccine	DSHS Health Service Regions	Local Health Departments*	TYC State Schools	Other Providers
Hepatitis A	A	A	A	L
Hepatitis B	B	B	A	L
Human Papillomavirus (HPV)	C	C	C	L
Influenza	D	E	D	X
MMR	F	F	A	L
MCV4 19-55 years only	G	G	A	X
Pneumococcal Polysaccharide (PPV23)	H	H	A	X
Td/Tdap	I	I	A	L
Varicella (chickenpox)	J	J	A	L
Zoster 60 years and older	K	K	X	X

\*Agencies contracted by Local Health Departments to provide vaccines may immunize adults under the same guidelines as the Local Health Department.

- a. All uninsured and underinsured adults.
- b. All uninsured and underinsured adults.

**Exception:** Refugee Health Programs (RHP) receive separate funding for hepatitis B vaccine, and therefore clients of RHPs who live in an area covered by a RHP are excluded.

- c. All uninsured and underinsured women between the ages of 19-26.

Note: Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, women who are sexually active should still be vaccinated. Sexually active women who have not been infected with any of the HPV vaccine types

receive the full benefit of the vaccination. Vaccination is less beneficial for women who have already been infected with one or more of the four HPV vaccine types. Vaccination is not recommended during pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy.

- d. Persons at highest risk of complications from influenza disease as defined by the ACIP. Excluding those at residential or occupational risk of exposure where the organization, proprietor, or employer is required to offer the vaccine by law.
- e. Vaccine purchased with LHD funds can be used at the discretion of the LHD.
- f. All uninsured and underinsured adults who met the following criteria:
  - Persons born during or after 1957 should receive at least one dose of MMR unless they have documentation of at least one dose, a history of measles based on health-care provider diagnosis, or laboratory evidence of immunity. Women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity should also receive one dose of MMR.
  - A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or in an outbreak setting; 2) have been previously vaccinated with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963-1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.
- g. Uninsured and underinsured adults 19-55 yrs who are risk. The following groups are considered at risk:
  - Medical indications: adults with anatomic or functional asplenia or terminal complement component deficiencies. Revaccination after 5 years might be indicated for adults previously vaccinated with MPSV4 who remain at high risk for infection.
  - Other: first-year college students living in dormitories
  - Uninsured and underinsured persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- h. Uninsured and underinsured adults who are at risk. The following groups are considered at risk:
  - All adults 65 years of age or older, including one-time revaccination of those who have not received vaccine within 5 years and were less than 65 years of age at the time of primary

vaccination. All persons over 65 who have unknown vaccination status should receive one dose of vaccine.

- Adults 19-64 who are at risk per ACIP recommendations, which includes the following:
  - Chronic disorders of the pulmonary system (excluding asthma)
  - Cardiovascular diseases
  - Diabetes mellitus
  - Chronic liver diseases, including liver disease as a result of alcohol abuse (e.g., cirrhosis)
  - Chronic renal failure or nephritic syndrome
  - Functional or anatomic asplenia (e.g., sickle cell disease or splenectomy) [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]
  - Immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection [vaccinate as close to diagnosis as possible when CD4 cell counts are highest], leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, or organ or bone marrow transplantation)
  - Chemotherapy with alkylating agents, antimetabolites, or high-dose, long-term corticosteroids
  - Cochlear implants
- *Others included:* Alaskan Natives and certain American Indian populations.

- i. All uninsured or underinsured adults.  
Please note that Tdap is only licensed for adults 19-64, and Td is indicated for adults 65 and older. Adacel® is the only Tdap vaccine licensed for adults. Another Tdap vaccine, Boostrix®, is not approved for adult use.
- j. Uninsured or underinsured adults born after 1980\* who are without evidence of immunity to Varicella should have received two doses of Varicella vaccine. Those who have received only one dose should receive the second dose.

\*For health-care workers, pregnant women, and those born outside the U.S. before 1980 should not be considered evidence of immunity.

Do not vaccinate women who are pregnant or might become pregnant within 4 weeks of receiving the vaccine. Varicella vaccine is to be administered post-partum only.

Exception: Refugee Health Programs (RHP) receive separate funding for Varicella vaccine, and therefore clients of RHPs who live in an area covered by a RHP are excluded.

- k. Uninsured or underinsured adults 60 years of age and older whether or not they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for their condition. Contraindications and precautions for use of zoster vaccine are available at: <http://www.fda.gov/cber/label/zostavaxLB.pdf>
- l. Any person who was TVFC-eligible **AND** started the series **BEFORE** their 19<sup>th</sup> birthday.
- X. Not eligible for state-supplied vaccine for adults at this site. Other providers may purchase their own vaccine inventory to vaccinate adults at the client's expense.

### **Adult Hepatitis B Initiative**

In fiscal year 2008, the CDC provided DSHS with limited grant funds to implement a hepatitis B vaccine program for at-risk, uninsured, and underinsured adults. Funding is available again this year. Agencies eligible to participate in this initiative include: FQHCs, Family Planning Clinics (FPC), STD and HIV clinics, LHDs, and HSRs.

Two vaccines/toxoids are available under this initiative (1) Recombivax®, an Adult Hepatitis B vaccine manufactured by Merck and (2) Twinrix®, an adult hepatitis A/hepatitis B combination vaccine manufactured by GlaxoSmithKline.

To be eligible for the adult hepatitis B initiative, providers must be enrolled in the TVFC. Additionally, providers must complete and submit a Vendor Profile Form (see Appendix) to their LHD or HSR prior to receiving the adult hepatitis B vaccines. Providers may also use the Vendor Daily Tally sheet, which is an optional form that can assist with tracking doses administered.

All adult hepatitis B vaccine doses administered using state-provided vaccine should be reported on the Monthly Biological Report (EC-33) under the "19+" Doses Administered column. It is **important** to accurately report all doses provided to adults. The Immunization Branch uses this information to account for adult usage, and to project and maintain supply.

Adults eligible for hepatitis B vaccine include those who are uninsured or underinsured, and have some risk factor for contracting hepatitis B. Underinsured is defined as any adult who: (1) has insurance that does not cover the cost of vaccines, (2) has a co-pay or deductible the person

cannot meet, or (3) has insurance that provides limited or capped vaccine coverage.

Adults at-risk for Hepatitis B Virus (HBV) include those who meet one of the following conditions:

Persons at risk for infection by sexual exposure

- Sex partners of hepatitis B surface antigen (HBsAg)-positive persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sex with men

Persons at risk for infection by percutaneous or mucosal exposure to blood

- Current or recent injection-drug users
- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally disabled persons
- Health-care and public safety workers with reasonably anticipated risk for exposure to blood or blood contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients

Others

- International travelers to regions with high or intermediate levels (HBsAg prevalence of >2%) of endemic HBV infection (see Recommendations of the Advisory Committee on Immunization Practices Part II: Immunization of Adults for complete details: <http://www.cdc.gov/mmwr/PDF/rr/rr5516.pdf>)
- Persons with chronic liver disease
- Persons with HIV infection

**K. Storage and Handling**

1. TVFC requires that all HSR, LHD, and private providers have written procedures for vaccine storage and handling. A vaccine management protocol should be easily accessible to all clinic staff in the event of a power outage. Clearly written procedures help prevent vaccine losses (see Section L. Emergency Vaccine Storage Contingency Plan).

## 2. Proper Equipment for Storage:

- a) Providers are required to have certified, calibrated thermometers in all refrigerators and freezers used for vaccine storage. Providers should retain their accompanying certificate as proof of certification. The certification must not be more than one year past the due date. Additionally, an alarm system and back-up generator are appropriate for larger clinics.

**Note: Use of continuous recording devices, temperature alarm systems, and other equipment will not replace the need to have a certified thermometer in each refrigeration/freezer unit.**

Thermometers that have a re-certification date that is more than one year past due must either be replaced with a new certified thermometer, or recertified at the provider's expense.

Certified calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency, such as the National Institute of Standards and Technology (NIST) or a laboratory recognized by NIST. Calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process. They are then given a certificate indicating successful completion of this process, which is provided with the instrument when purchased or re-certified. Thermometers must be certified by NIST or ASTM. No refrigerator or freezer unit should ever be without a certified thermometer, even during the re-certification period.

- b) The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. Temperature should be set at midrange, about 40° F (5°C).
- c) The freezer compartment should maintain temperatures at or below 5°F (-15°C).
- d) High volume clinics may find separate refrigerators and freezers useful. A standard "kitchen" side-by-side or top-freezer unit is sufficient. Frost-free freezers are preferred.
- e) Refrigerators with a freezer unit inside (that does not have a separate outside door) are not allowed for the storage of TVFC vaccine, whether or not varicella is stored. However, these units may be used to store a clinic's single-day supply of refrigerated-only vaccines; these refrigerated vaccines should be returned to the main refrigerator at the end of the day, and must be monitored during the day. Refrigerators with a freezer unit inside (that does not have a separate outside door) should NEVER be used to store varicella or MMRV vaccine. There are small sized freezers that are

manufactured specifically to maintain very cold temperatures. These freezer units are acceptable for the storage of varicella or MMRV.

- f) Refrigerator/freezer units must be large enough to hold the year's largest inventory.
- g) MMR vaccine may be stored either frozen or refrigerated. MMR is sensitive to light and vaccine efficacy could be compromised if left out in the light.
- h) All vaccines except Varicella and MMRV are to be stored in the refrigerator and should never be frozen.
- i) Diluent may be stored in the door of the refrigerator and can provide extra insulation much like bottles of water.
- j) If the refrigerator is new or newly repaired, allow at least 24 hours for temperature adjustment. Read the 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 about this on the refrigerator door.
- k) Plug guards should be used on all refrigerators that are used for storing TVFC vaccines. (The only exceptions would be if the refrigerator is equipped with a temperature sensitive alarm, or the plug guard does not accommodate the plug.) Plug guards are effective tools in preventing the accidental unplugging of equipment. HSRs, LHDs, and the quality assurance contractor are responsible for providing plug guards to providers.
- l) A written Vaccine Storage Contingency Plan that includes at least: name and phone number of emergency contact, plan of how to move vaccine to ensure cold chain, and address of location where vaccines will be temporarily stored should also be posted on or near the refrigerator.
- m) All TVFC providers should identify sufficient alternative space to store vaccines and maintain the "cold chain" during any period when the refrigerator is out of service.
- n) It is important that vaccines be kept at the proper temperatures at all times. Opening the door frequently interrupts the cold chain and can result in cumulative loss of vaccine potency over time.
- o) Storing food or drinks in the same refrigerator as vaccine is not acceptable.
- p) "Do Not Unplug" sign must be posted on all outlets or all refrigerator units used to store vaccine.
- q) "Do Not Unplug" sign must be posted by each circuit breaker.

**The following guidelines are required of TVFC providers:**

- a) Check and record internal refrigerator and freezer temperatures on the Temperature Recording Form (EC-105) twice daily. If

temperatures fall outside the acceptable range, take immediate action to ensure vaccine viability.

- b) Store extra ice packs and/or gel packs along the walls, back, and door of the freezer compartment. This helps keep a steady temperature during the automatic defrosting cycles and provides additional reserves of cold in the event of a power failure. Air must circulate around the vaccines freely.
- c) Store large water bottles and/or diluent (as many as the refrigerator will accommodate) against the inside walls and door of the refrigerator. This helps maintain a stable temperature, and provide extra reserves of cold in the event of a power failure. Air must circulate around the vaccines freely.

**Note: It is suggested to write “not for consumption” on the water bottles.**

- d) All vaccine should be stored on 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. Temperatures are more stable in the body of the refrigerator/freezer.
- e) Stack vaccines with enough room for cold air to circulate freely around vaccine.
- f) Notify the LHD or HSR 90 days prior to vaccine expiration, if the vaccine cannot be used before expiration. The LHD or HSR will assist with redistribution of the vaccine.

*See Appendix F for the Temperature Recording Form (EC-105).*

### 3. Personnel

- a) Vaccine viability depends on the knowledge and habits of the clinic staff. One person should be trained and designated “in-charge” to ensure that temperatures are checked and vaccines are handled and stored properly. Each clinic must have a designated back-up person(s). However, all staff must be trained regarding proper storage and handling of vaccines.
- b) There must be written procedures for emergency situations to assure continued viability of the vaccines.
- c) All individuals responsible for vaccines should be knowledgeable about the required storage temperatures and handling conditions for the various vaccines. It does no good to record the temperature of the refrigerator daily if the person recording the temperature is not aware that a temperature above 48°F is too high. New employees must be trained properly and immediately.

#### 4. End-of-Month Inventory

At the end of each month, physically count the inventory on hand. Pay close attention to the expiration dates of the vaccines. Use shortest-dated vaccine first. Clinics should contact their HSR or LHD if vaccine cannot be used 90 days before expiration. It is the responsibility of the LHD or HSR to pick-up and transfer short-dated vaccines to another clinic where the vaccines may be used. Too much vaccine kept in inventory increases the risk of vaccines reaching expiration dates, and increases the amount of loss in the event of refrigerator failure. When ordering vaccines, providers should keep no more than the designated maximum on hand. (See B. Vaccine Ordering)

**Note: Picking up and redistributing vaccine from a provider is the responsibility of the facility directly overseeing the site (either the LHD or HSR).**

#### 5. Vaccine Loss Due to Negligence

Vaccine negligence may include but is not limited to the following:

- a) Vaccine stored improperly (i.e. refrigerating a vaccine that should be stored in the freezer, or freezing a vaccine that should be refrigerated).
- b) Vaccine left un-refrigerated or out of the freezer.
- c) Refrigerator or freezer unplugged (no plug guard used).
- d) Transporting vaccine inappropriately (appropriate cold chain not maintained).
- e) Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage.
- f) Improper monitoring of temperatures in freezer or refrigerator.
- g) Allowing vaccine to expire without notifying the HSR or LHD in advance (90 days) that the vaccine could not be used.
- h) Refrigerator/Freezer door left open.
- i) Refusal of vaccine shipment

TVFC providers may be required to reimburse the state for vaccine losses occurring from any of the above conditions. DSHS will require payment by check or money order for the cost of the vaccine minus the federal excise tax (if the vaccine was returned to the DSHS Pharmacy Branch or third party contractor). The check or money order must be payable to the DSHS and must list the Immunization Branch's budget number, H3000, on the payment to ensure proper credit to the provider's account. (See G. Procedures for Vaccine Loss and Returning Vaccine)

## 6. Vaccine Borrowing

TVFC providers should not borrow TVFC vaccine to give to non-TVFC eligible children. In the event a provider inadvertently makes this mistake, the CDC requires that a *VFC Vaccine Borrowing Report* be completed and submitted. This report tracks the name of the child, the vaccines borrowed, the reason, and the replacement date.

*See Appendix N for VFC Vaccine Borrowing Report*

## L. Emergency Vaccine Storage Contingency Plan

Every facility maintaining an inventory of state-provided vaccine is required to develop and display a contingency plan in the event of emergencies such as a power failure that could result in the loss of vaccine. The following items must be addressed in this contingency plan:

1. Identify a person to be responsible to enact the contingency plan and a knowledgeable alternate should the primary person not be available. Be sure to include contact information such as phone numbers (home and office).
2. Identify a location to take the state-provided vaccine for storage, preferably a location with a power generator or other alternate source of power such as a hospital or grocery store. 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.
3. Specify the steps to be taken to transport the vaccine to the alternate location being sure to include:
  - a) Note the time of the emergency situation/power outage.
  - b) Note the temperature of the refrigerator and freezer before removing any vaccine for transportation.
  - c) Indicate what containers will be used and how the vaccine should be packed for transportation (i.e. ice packs separated from the vaccine by plastic bubble wrap, or paper to prevent freezing and damage to the vaccine packaging).
  - d) Inventory the vaccine as you remove it to the transport container being careful to indicate the number of doses of each antigen and the expiration dates.
  - e) Keep a thermometer in the transport container and note the temperature when you place the vaccine in the alternate storage

and the time. This tells us how long the vaccine was at a less-than-ideal temperature.

- f) Varicella (chickenpox) vaccine *MUST* be stored on dry ice for transportation! It takes 10 pounds of dry ice to transport 100 doses of varicella. If dry ice is not available and cannot be obtained, transport the varicella as quickly as possible with ice packs.
4. Contact HSR or LHD to inform them of the emergency or call the DSHS Pharmacy at (512) 458-7500. Be prepared to give them the information concerning the temperature of the vaccine, the amount of vaccine, expiration dates, and how long the vaccine was exposed to inappropriate temperatures. For varicella or MMRV, contact Merck at (800) 672-6372 for instructions on the viability of the vaccine.

Keep in mind that you will be asked to provide a copy of this document at site reviews, so be sure to keep the plan posted on, or near the refrigerator containing state-provided vaccine. Make sure all employees involved with vaccine handling or use are aware of this plan.

A Vaccine Contingency Plan template is located in Appendix M of this manual. This template is not a required form, but is a tool that is available to providers should they need assistance in developing an emergency plan.

## **M. Box Recycling**

Empty shipment containers will be returned free of charge to McKesson. Postage paid labeling for UPS is included to facilitate container return. Each time a provider receives a vaccine shipment, the empty containers from the previous shipment can be given to the courier for return to McKesson. Providers simply reverse the box flaps exposing the postage paid return label and tape with clear shipping tape. Gel packs and temperature monitors do not need to be returned. If UPS is not the provider's regular shipper, UPS can be called to provide a pick-up free of charge. Providers should not be charged a pick-up fee for this service. Providers should contact the LHD or HSR if UPS requests payment for box pick-up.

**Note: Each site should maintain enough packing containers and supplies to transport entire inventory in the event of an emergency.**

## **IV. Administration Fees**

### **Requirements for Charging Fees**

1. Providers enrolled in the TVFC 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 the TVFC constitutes fraudulent behavior. Fraud in the TVFC will be handled the same as Medicaid fraud.
2. Medicaid and CHIP patients may not be charged any out-of-pocket fees either for vaccines or for administration of the vaccines. Both Medicaid and CHIP reimburse providers for an administration fee. Medicaid and CHIP do not reimburse providers for the cost of routinely recommended childhood vaccines. Providers must enroll in the TVFC if they want to obtain free vaccine to use for these children.
3. Providers may charge a reasonable administration fee (not to exceed \$14.85 for immunization-only services) to TVFC-eligible children excluding Medicaid and CHIP, but vaccines should be administered even if the patient/parent/guardian is unable to pay the administration fee. Providers may not deny services due to a client's inability to pay the administration fee.

Providers may not refer a TVFC-eligible child to another health care provider for immunizations if the provider has accepted that child into the practice as their patient.

4. When providers sign the Provider Enrollment Form, they agree to follow the DSHS guidelines for fees when administering vaccines. The Provider Enrollment Form contains the following statements regarding fees:
  - a) This office/facility will not charge for vaccines supplied by DSHS and administered to a child who is eligible for the TVFC.
  - b) This office/facility may charge a vaccine administration fee. This office/facility will not impose a charge for the administration of the vaccine in any amount higher than the maximum fee established by DSHS. Medicaid patients cannot be charged for the vaccine, administration of vaccine, or an office visit associated with Medicaid services.
  - c) This office/facility will not deny administration of a TVFC vaccine to a child because of the inability of the child's parent or guardian/individual of record to pay an administrative fee.

## **DSHS Clinic Administration Fee Guidelines**

DSHS has established these guidelines for administering a vaccine (injection, intranasal, or oral) to non-CHIP and non-Medicaid patients.

- a) The fees will be charged according to the Federal Poverty Income Guidelines scale.
  - i. Immunization only visit for a child is \$14.85 per vaccine.
  - ii. Immunization only fees for a child may not exceed \$14.85 per vaccine even if the Poverty Income Scale is higher.
- b) A person's ability to pay the entire amount of a fee will be considered and public health services will not be denied because of a person's inability to pay.
- c) The current Federal Poverty Income Guidelines scale is available upon request from the DSHS, Disease Prevention and Intervention Section, Immunization Branch, MC-1946, P.O. BOX 149347, Austin, Texas 78714-9347, (512) 458-7284 or (800) 252-9152. It is also available online at the Immunization Branch web site:  
<http://online.dshs.state.tx.us/policy/program/povertyguidelines.pdf>

*See Appendix B for Provider Enrollment Form*

## V. Immunization Documentation

### 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:

- a) Vaccine given
- b) Vaccination date (month, day, year)
- c) Vaccine lot number
- d) Name of vaccine manufacturer
- e) Signature and title of the health care provider administering the vaccine
- f) Organization name and address of the clinic location (where the records are kept)
- g) Date of Vaccine Information Statement issued to patient, parent, or guardian

Immunization Cards for providers (C-100), and clients (C-102) are located in the *TVFC Tool Kit in Section 4*, and can be ordered from the DSHS Immunization Branch. These cards are designed to capture the required information listed above.

The TVFC also makes the following recommendations regarding record keeping:

- a) *Designate an immunization nurse to answer immunization questions for staff/parents.*
- b) *File immunization records in an accessible location within the chart, keeping the immunization record and TVFC Patient Eligibility forms together.*
- c) *Place records at the front of each child's chart and make immunizations a priority.*
- d) *Encourage parents to bring their children's immunization records with them, allowing complete documentation of immunization histories given elsewhere in patient records.*
- e) *If a child presents with no immunization record, obtain the history through the statewide tracking registry ImmTrac, or call previous providers to obtain the history.*
- f) *If a child presents with no immunization record and the history cannot be obtained, age-appropriately vaccinate during that visit to avoid a missed opportunity.*
- g) *Empower all staff to become "Immunization Advocates," and assess every child's immunization status at every encounter.*

- h) Simultaneously administer all needed vaccines, unless there is a true contraindication.*
- i) Implement a reminder/recall system to remind parents when immunizations are due and to recall patients whose immunizations are past due.*
- j) Identify clients that have not been seen within a twelve month time period and record the acronym MOGE (moved or gone elsewhere) in the chart. Proper documentation of MOGE is defined as one of the following:
  - i. Parent/Guardian/provider letter stating that they are going to a new practice.*
  - ii. Mailed reminder/recall card/letter returned without a local forwarding address.*
  - iii. Provider statement advising that they will no longer see the patient.*
  - iv. Request for medical record transfer.*
  - v. No visit to the clinic within the last twelve months.*
  - vi. Verbal notification from parent/guardian stating child is being seen by another provider.**

The provider should give a personal immunization record to each vaccine recipient showing the date (month, day, year) when each vaccine/toxoid was administered.

## **VI. Consent**

*TVFC requires providers to (1) obtain written consent for administration of a vaccine, and (2) provide information on the risks and benefits associated with each vaccine. These requirements are based on Texas and Federal laws listed below.*

### **A. Consent**

#### Definitions

Consent to Vaccinate- Approval or acceptance of a vaccine being administered to a minor or to self.

Delegation of Consent- Written authorization given by a parent, legal guardian or managing conservator of a child authorizing another adult to consent to vaccinate.

#### **Texas Laws**

1. Texas Family Code, Chapter 151 and 153 identifies who can consent for medical treatment.
2. Texas Family Code, Chapter 32 § 32.002 defines what information must be included in a Consent Form and that consent must be in writing.
3. Texas Family Code, Chapter 32 § 32.102 states a person authorized to consent to immunization of a child has the responsibility to ensure that the consent, if given, is an informed consent.
4. Delegation of Consent is defined in the Texas Administrative Code, Title 25 § 97.91 and may be required in addition to a consent form.

### **B. Vaccine Information Statements (VIS)**

In addition to State Laws that address vaccinations there are also federal requirements that apply.

1. The 1986 National Childhood Vaccine Injury Act (NCVIA) 42 U.S.C. § 300aa-25 requires that all immunization providers (regardless of whether they are enrolled in the TVFC) give each parent/guardian or other responsible adult presenting with a child needing vaccinations a current VIS to keep for each vaccine the child is to receive, every time a vaccine is administered.

2. Providers must take reasonable steps to provide information in the appropriate languages in order to ensure that a client with limited English proficiency is effectively informed. The VIS can be downloaded in more than 20 additional languages from the Immunization Action Coalition website: [www.immunize.org/vis/](http://www.immunize.org/vis/)

## VII. Public Education

### Recommendations for Public Education

1. Mass communication is generally divided into print, radio, and television. Each offers different opportunities to present the TVFC to the public and health care providers.
2. Determine the mass media outlets that are available to you locally. Know the submission requirements and deadlines of each outlet.
  - a) Print – Consider weekly, biweekly, or monthly community papers, advertising papers that include some editorial space, and local magazines. Look for specialized publications for American Indians, Alaskan Natives, and other groups, that may be TVFC-eligible. Include pictures whenever possible.
  - b) Radio can be used to reach those who may be eligible for TVFC benefits. Spanish and other foreign language radio stations are effective communication channels for the non-English speaking public.
  - c) Television – Cable TV gives you access to a much larger audience when combined with viewers reached via the four primary broadcast networks; ABC, CBS, FOX, and NBC. Local community channels and bulletin boards on cable channels usually broadcast public service messages at no charge.
3. Specialized communications are strategically placed articles and spot messages, which may be included in non-traditional settings. For example:
  - a) Publications – Review all publications from your immunization program and incorporate TVFC messages whenever possible.
  - b) If your agency publishes a newsletter, include articles on the TVFC.
  - c) Include TVFC pictures, pamphlets, text, and graphic panels in your health exhibits.
  - d) Submit a TVFC notice to community church bulletins, mailings in utility bills, and club or subdivision newsletters.
  - e) Distribute TVFC posters and flyers to child-care centers, health clinics, churches, community groups, prenatal or childbirth classes, or in a gift bag distributed by Welcome Wagon, conventions, or hospitals (ob-gyn/peds).

## **VIII: Provider Recruitment**

### **Requirements for Provider Recruitment**

DSHS, HSRs, and LHDs will conduct recruitment activities to enroll new providers into the TVFC. Because the TVFC is routinely improving business processes and service to providers and because reasons for not enrolling can change over time, HSRs and LHDs should recruit eligible providers annually. At a minimum recruitment should include:

1. HSR/LHD will utilize the Texas Medical Board (TMB) physician listing, and other provider lists as provided by AO.
  - a) The TVFC spiral brochure, stock number 11-11118, promoting the TVFC will be mailed to each physician. The sender should include a business card. The return address should be the senders address to help keep track of recruitment efforts.
  - b) Provider enrollment forms will also be included in the mailing.
  - c) Include a local contact name as an immunization resource for the physician/provider.
2. The TMB, and other provided lists contain non-enrolled providers by county. The HSR/LHD should prioritize the geographic areas and populations that may be under-represented and take steps to reach providers most likely to serve TVFC-eligible children within pockets of need.
3. Contact providers annually who have previously declined to enroll.
4. If providers decline enrollment into the TVFC, document the reason(s) for the refusal and determine whether a follow-up recruitment effort with new information might favorably change the outcome.
5. HSRs and LHDs should follow the format provided by TVFC in reporting recruitment activity.
6. LHDs who are contractors of the Immunization Branch must document recruitment activity on the tri-annual report submitted to the AO.

If resources permit, additional recruitment activities may provide a better chance of enrolling new providers; these include provider phone calls and/or recruitment visits.