

# 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

**ICL CALIBRATION LABORATORIES, INC.**

ISO/IEC 17025 and ANSI/NCSL Z540-1 accredited  
 The specialists in ASTM and laboratory thermometers & hydrometers  
 Members: ASTM API NCSL ASQ NCWM

1501 Decker Avenue Suite 118 Stuart, FL 34994 USA  
 Tel: 772 286 7710 1-800-713-6647  
 Fax: 772 286 6737 E-mail: sales@iclab.com  
 Internet: www.iclabs.com

Setting new standards in calibration excellence!

**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	174.85 °F	+0.15 °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).