CHAPTER 3: VACCINE MANAGEMENT

I. Approved Vaccines

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

- Diphtheria and Tetanus toxoids, adsorbed (DT)
- Diphtheria-Tetanus toxoids and acellular Pertussis (DTaP)
- Diphtheria-Tetanus toxoids and acellular Pertussis, Hepatitis B, and inactivated polio (DTaP-HepB-IPV)
- Diphtheria-Tetanus toxoids and acellular Pertussis, inactivated polio, and Haemophilus influenzae type b (DTaP-IPV/Hib)
- Diphtheria-Tetanus toxoids and acellular Pertussis and inactivated polio (DTaP-IPV)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Haemophilus influenzae type b (Hib)
- Human Papillomavirus (9vHPV)
- Influenza (Flu)
- Inactivated polio (IPV)
- Measles, Mumps, and Rubella (MMR)
- Measles, Mumps, Rubella, and Varicella (MMRV)
• Meningococcal groups C and Y and *Haemophilus influenzae* b (tetanus toxoid) (HIBMENCY)
• Meningococcal conjugate (MCV4)
• Meningococcal Serogroup B (MenB)
• Pneumococcal Conjugate (PCV13)
• Pneumococcal Polysaccharide 23-valent vaccine (PPSV23)
• Rotavirus (RV)
• Tetanus and diphtheria toxoids, adsorbed (Td)
• Tetanus and diphtheria toxoids and acellular Pertussis (Tdap)
• Varicella

II. Vaccine Ordering

A. Vaccine Choice

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

The provider who signs the VFC Program Provider Agreement can choose vaccine brands and presentations. The provider’s Responsible Entity (DSHS HSR or LHD) will create the initial Biological Order Form for new TVFC providers. The initial Biological
Order Form will reflect the provider’s vaccine choices, their maximum stock level (MSL), and order quantity.

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

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

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

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

**Note:** vaccine choice does not apply in the event of a disaster or public health emergency, terrorist attack, hostile military or paramilitary actions, or any other extraordinary law enforcement emergency.
B. Vaccine Inventory Plan and Maximum Stock Levels

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

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

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

See Section VIII. Reporting Requirements, for more detail of the monthly reporting requirements.

**C. Increasing and Decreasing Maximum Stock Levels**

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

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

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

**D. Short-Dated Vaccine**

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

Each TVFC provider is required to notify their Responsible Entity 90 days prior to the expiration of vaccine. If the provider is unable to administer the vaccine prior to expiration, the Responsible Entity may assist with moving the vaccine to another provider site, provided another provider is willing to accept the vaccine.

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

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

**E. Storage Capacity for Vaccine Orders**

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

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

The TVFC Program uses the EVI system for vaccine ordering. EVI allows TVFC providers to manage their vaccine inventory online. All vaccine orders will be placed in EVI unless internet access is unavailable. A TVFC provider may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

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

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

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

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

• Temperature logs (EC-105); and
• Borrowing form (EF11-14171), if applicable.

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

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

Vaccine loss is captured electronically in EVI. When a TVFC provider documents, as required, any expired, spoiled, or wasted vaccine in EVI, the system will automatically place subsequent orders on “Hold” until the nature of the loss has been determined.
All TVFC providers are able to view their order status on the “Order History” page of EVI. Status definitions are the following:

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

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

**G. Vaccine Ordering for TVFC Providers without Internet Access**

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

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

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

**H. Vaccine Ordering for Newly Enrolled TVFC Providers**

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

- Biological Order Form (EC-68-1); and
- Temperature Recording Form(s) (EC-105).
I. Ordering Influenza Vaccine

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

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

If the orders exceed the expected number of eligible children from the TVFC provider profile, providers may be contacted for an explanation. If a TVFC provider who sees TVFC-eligible children does not order influenza vaccine for the upcoming season, they must complete a separate section of the survey explaining why they are not ordering the vaccine. A TVFC provider is required to follow all ACIP recommendations, including the administration of influenza vaccine. A TVFC provider who does not order influenza vaccine will receive a follow-up phone call from their Responsible Entity or the TVFC Program.

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

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

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

**J. Vaccine Ordering for Mass Vaccination Clinics**

Mass vaccination clinics may be set up for seasonal vaccines, such as influenza, to protect a large group of patients.
Routine transport of vaccine is not recommended due to the risk of compromising the cold chain and vaccine viability. However, because most temporary mass clinics typically require vaccine transport on the day of the clinic, these temporary clinics (e.g., school located clinic) require enhanced storage and handling practices.

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

- Showing the established vaccine needs (e.g., provider profile);
- A plan for overseeing vaccine ordering for each clinic site to ensure that proper amounts of TVFC stock are transported on each clinic day;
- The type of portable storage unit being used;
- How the cold chain will be maintained from the beginning to the end of the mass vaccination clinic; and
- Each site location should be documented on the Temperature Recording Form (EC-105).

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

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

A. Vaccine Distributors

The TVFC Program uses two vaccine distribution centers:

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

B. Receiving Vaccine Orders

The TVFC Program requires that TVFC providers always accept vaccine shipments and never refuse or return the shipments without specific instructions from the TVFC Program or from their Responsible Entity. The TVFC provider must ensure that the accurate clinic address and delivery hours are entered into EVI.

In order for TVFC providers to receive vaccine shipments, appropriate staff must be on site and available at least one day a week other than Monday and for at least four consecutive hours during the hours of 8:00 a.m. – 5:00 p.m. Each TVFC provider establishes the hours available to accept vaccine shipments when they submit their initial vaccine order in EVI. The vaccine will be shipped so that it will arrive when the provider is available to accept the order. The TVFC provider will not be able to change their available hours in EVI once an order is placed. The TVFC provider will be held responsible for incomplete or erroneous information entered into EVI which can result in vaccine loss.
The TVFC provider can expect their approved orders approximately two to three weeks after placing their online order in EVI. It is important to recognize and store vaccine shipments immediately upon receipt to ensure vaccine viability. All TVFC providers are required to train their staff on what a vaccine shipment looks like and have a vaccine management plan in place to ensure the vaccine is stored quickly and correctly upon arrival.

The following steps are required when a vaccine shipment arrives:

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

Each package shipped from McKesson comes with a temperature monitoring strip(s). If the monitor strip(s) indicates, or if staff suspects that the cold chain has been compromised, staff must immediately follow the instructions in subsection D below, “Vaccines Received Warm or Questionable”.

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

C. Manufacturer and Distributor Maintenance of the Cold Chain

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

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

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

If the vaccine arrives outside of the four-day pack-out, then the TVFC provider must immediately place the vaccine in a Vaccine Quarantine Bag provided by the TVFC Program, store the vaccine properly, notify their Responsible Entity, and contact the manufacturer.

Replacement instructions will be determined on a case-by-case basis.

Merck has implemented a cooler recycling program for direct ship products. A prepaid United Parcel Service (UPS) shipping label is included with each container. Once the vaccine is removed and the container is empty, the provider must seal the container and affix the prepaid UPS shipping label.

The TVFC provider will have to wait until UPS returns to their office with the next delivery to return the cooler. If the TVFC provider calls UPS to schedule a pick-up, the provider will be charged a pick-up fee.

**D. Vaccines Received Warm or Questionable**

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

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

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

- Separate the questionable vaccine in a Vaccine Quarantine Bag and place questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine itself.
- Contact the manufacturer immediately to determine the viability of the vaccine. If the manufacturer is unable to respond, the provider must inform their Responsible Entity.
- Contact your Responsible Entity on the same day the vaccine arrived at the TVFC provider’s office. Any calls received after the day of delivery will result in the CDC’s liability for vaccine replacement, regardless of the cause of the temperature excursion. This documentation must be maintained with the provider’s TVFC records for a minimum of five years.
- Inform the Responsible Entity of the determination of the viability of the vaccine.
- All TVFC providers must keep the vaccine quarantined and wait for the instructions for replacement, reporting loss, etc. from their Responsible Entity.
Note: Vaccine returns due to shipping issues are required to be returned to McKesson within 48 hours. Merck requires that the request for replacement be received within 15 days of the original shipment.

E. Vaccines Received in Error

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

IV. Vaccine Loss

A. Expired, Spoiled and Wasted Vaccine

The Immunization Unit requires all unopened or unused vials and syringes of expired TVFC vaccines be returned to the third-party distributor (McKesson). Vaccine manufacturers reimburse CDC for the federal excise tax portion of the cost of the vaccine. Therefore, providers should not discard any vaccine unless specifically directed by the DSHS Immunization Unit, DSHS HSR, or LHD. Any exception to this rule will be communicated by the DSHS Immunization Unit on a case-by-case basis. Providers are to immediately notify their Responsible Entity of vaccine cold chain failure events or vaccine wastage incidents involving TVFC vaccines upon discovery of the incident.
Expired or Spoiled Vaccine is any non-viable vaccine in its original container such as a vial or syringe that can be returned for excise tax credit. This includes expired vaccine or vaccine that has been spoiled as a result of the following:

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

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

- Vaccine drawn into the syringe but not administered;
- Vaccine in open vial multi-dose vial where all doses have not been administered (partial vial);
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility);
- Lost vial;
- Vaccine drawn into the syringe but refused by the patient;
- Incorrect vaccine that has been prepared for patient; and/or
- Incorrect diluent drawn for vaccine.
Wasted and expired/spoiled vaccines should be removed from the storage unit, labeled “Do Not Use,” and stored pending return to distributor. Expired diluents do not need to be returned. Lost vials are expected to be adjusted on the provider inventory.

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

B. Procedures for Vaccine Loss

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

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

- Remove expired/spoiled vaccine from the vaccine storage unit and place in a Vaccine Quarantine Bag.
- Contact your Responsible Entity immediately with the following information:
  - Antigen;
  - Lot number;
  - Expiration date; and
  - Reason for expiration/loss.
• If storage was compromised, provide the Responsible Entity with amount of time product was out-of-range and the highest and lowest temperatures recorded (this information may be gathered from the data logger download).

• Document the vaccine loss on the Vaccine Loss Report electronically generated in EVI within four days past the date of the incident of loss. Explain the cause(s) of the loss and outline the steps taken to ensure vaccines will be protected in the future.

• The Vaccine Loss Report must also be printed and signed by the same medical provider who signed the VFC Program Provider Agreement. The report must then be emailed or faxed to the Responsible Entity within four days of the date of the loss.

• The Vaccine Loss Report includes the following sections:
  • Clinic demographics;
  • Date loss was discovered;
  • Type of loss;
  • Reason for loss;
  • Corrective action taken to avoid re-occurrence;
  • List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost.

TVFC providers will receive a shipping label from McKesson for returning non-viable vaccine, if applicable. The provider must wait until UPS returns for the pickup to avoid paying a fee.
• Providers must ensure that all vaccines listed on that Vaccine Loss Report are included in the box for return (except for dropped or broken vials/syringes).

• If more than one box is used to return non-viable vaccine, providers must indicate on the Vaccine Loss Report the number of the box in which the vaccine is being shipped (e.g., “Box 1 of 2,” “Box 2 of 2,” etc.).

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

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

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

TVFC providers who have lost vaccine as a result of improper temperature storage must assess how long the vaccines were stored improperly and how many children may have received the affected vaccines. The signing clinician determines whether or not children will need to be recalled and revaccinated.
The TVFC Program will not provide the vaccine for recalled children in these circumstances. The clinic will assume all financial responsibility for the cost of vaccines for recalls. Providers must contact their Responsible Entity with the determination from the signing clinician.

C. **Negligent Vaccine Loss**

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

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

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

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

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

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

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

A. Refrigerator and Freezer Requirements

TVFC providers are required to have appropriate equipment that can store vaccine and maintain proper conditions:
• Refrigerator and freezer units must be large enough to hold the year’s largest inventory without crowding.

• Two types of refrigerator units are acceptable for storage: a stand-alone, single-purpose refrigerator or a pharmaceutical/purpose-built unit.

• The CDC recommends stand-alone freezers specifically manufactured to maintain very cold temperatures. These freezers are acceptable for the storage of Varicella, MMRV, or MMR vaccines only. A frost-free unit with an automatic defrost cycle is preferred.

• Combination units, if used, must have separate thermostats for the refrigerator and freezer compartments. The CDC recommends not using both the freezer and refrigerator section of a dual unit. Each unit should serve as either a freezer or a refrigerator.

• Dorm-style and small combination refrigerator and freezer units with a single external door are never allowed for the storage of TVFC vaccine.

• The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at midrange, 40°F (4°C).

• The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C) for vaccine viability.

• An alarm system and back-up generator are recommended to help reduce vaccine loss when unexpected temperature fluctuations occur.

• Refrigerators and freezers storing vaccines must be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.
Each refrigerator or freezer must contain a sufficient number of water bottles to help maintain proper storage temperature during peak usage of the unit. Peak usage is considered when there is frequent opening and closing of unit doors or a power failure. Water bottles serve as a physical barrier to prevent placing vaccines in areas where there is greater risk for temperature excursions.

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

Depending on the size of the unit, the amount of vaccine stored, and the time of year, “sufficient” may differ from one clinic to the other. However, there must be adequate water bottles in each refrigerator and adequate frozen water bottles in each freezer to help maintain proper storage temperature during peak usage of the unit or until vaccines can be moved to another refrigerator or freezer.

**For the refrigerator:**

- Make sure the refrigerator door is closed completely;
- Replace crisper bins with water bottles to help maintain consistent temperature (unless used for other medical equipment or supplies);
- Label water bottles “Do Not Drink”;
- Post “Do Not Unplug” signs on the refrigerator and by the electrical outlet;
• Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly;
• Place water bottles on the top shelf of the refrigerator;
• Do not use the top shelf for vaccine storage;
• Do not put food or beverages in the refrigerator;
• Do not put vaccines in the doors or floor of the refrigerator;
• Do not drink from or remove the water bottles;
• Leave 2-3 inches between all vaccine and the refrigerator walls;
• Store each type of vaccine or diluent in a separate container;
• Place vaccines with the earliest expiration dates in front of those with later expiration dates;
• Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents should never be frozen;
• Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored. If diluent is stored separately from the corresponding vaccine, label the container where it is stored;
• Store vaccines and diluents with similar packaging or names (e.g., DTaP and Tdap or Hib and HepB) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors;
• Make sure to label the formulation “pediatric” or “adult,” if applicable;
• Always store vaccines in their original packaging with lids closed until ready for administration;
• Never store loose vials or manufacturer-filled syringes outside of their packaging; and
• Do not pack a storage unit too tightly. This can restrict air circulation and impact temperature;
• Vaccines should be centrally stored within the unit;
• Store privately purchased vaccine on different shelves from TVFC to minimize the risk of administering TVFC vaccine to non-eligible patients. TVFC vaccines should be clearly marked to differentiate them from privately purchased vaccines.

For the freezer:

• Make sure the freezer door is closed completely;
• Use frozen water bottles to help maintain consistent temperature;
• Place water bottles against the walls, in the back, on the floor, and in the door racks;
• Place water bottles in unit doors carefully so they cannot dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly;
• Post “Do Not Unplug” signs on the freezer and by the electrical outlet;
• Do not put food in the freezer;
• Leave 2-3 inches between all vaccines and the freezer walls;
• Do not store vaccines in the freezer doors;
• Avoid storing vaccines in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents or shelves on the door;
• Store each type of vaccine in a separate container;
• Vaccines should be centrally stored within the unit;
• Place vaccines with the earliest expiration dates in front of those with later expiration dates;
• Attach labels to shelves and containers to clearly identify each type of vaccine;
• Store vaccines with similar packaging or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors;
• Store privately purchased vaccine in a clearly marked container separate from TVFC vaccine to ensure TVFC vaccine is not inadvertently administered to a non-eligible patient;
• Make sure to label the formulation “pediatric” or “adult,” if applicable;
• Always store vaccines in their original packaging with lids closed until ready for administration;
• Never store loose vials or manufacturer-filled syringes outside of their packaging;
• Diluents should never be frozen; and
• Arrange vaccines in rows; do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.
Prior to using a new or newly repaired unit to store vaccines, allow 10 business days of refrigerator or freezer temperature readings/recordings (a minimum of two times each workday) on an EC-105 form. Also record the required minimum/maximum temperatures one time at the beginning of each business day to ensure temperatures are within appropriate ranges. Submit the recordings to the Responsible Entity for review and approval, before placing vaccine in the storage unit. Minimum and Maximum temperature readings must be reset from the day before at the end each business day (if the device requires this function).

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

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

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

- A Temperature Recording Form (EC-105) is required to be located on or near all units that store TVFC vaccines;
A TVFC provider using data loggers must still comply with twice daily temperature and Minimum and Maximum recording requirements.

- Freezer and/or refrigerator temperatures are required to be checked, recorded, and initialed twice daily;
- Minimum and Maximum temperatures must be recorded on the Temperature Recording Form once at the beginning of each business day;
- Minimum and Maximum temperature readings must be reset from the day before at the end of each business day;
- Temperatures must be recorded manually on Temperature Recording Forms, even if using a digital data logger;
- Temperature Recording Forms must be posted on each vaccine storage unit door or nearby in a readily accessible and visible location; and
- Temperature Recording Forms must be maintained for five years and made easily available.

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

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

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

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

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

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

A digital data logger must have:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door;
- Functionality that does not require a password to access the temperature display;
- Alarm for out-of-range temperatures;
- A display that shows the current temperature, as well as minimum and maximum temperatures;
- Low battery indicator;
• Accuracy of +/-1°F (+/-0.5°C);
• Detachable probe in buffered material;
• Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full); and
• User programmable logging interval (or reading rate) recommended at a maximum time interval of every 30 minutes.

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

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

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

• Fluid-filled bio-safe liquid temperature monitoring devices;
• Bi-metal stem temperature monitoring devices;
• Food temperature monitoring devices;
• Household mercury temperature monitoring devices;
• Chart recorders;
• Infrared temperature monitoring devices;
• Temperature monitoring devices that are not calibrated; and
• Thermometer (beginning in January 2018).
These devices can have significant limitations, can be difficult to read, and generally only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected.

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

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

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

The data logger or thermometer probes must **not** be:

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

Providers enrolled in the TVFC Program are required to have a calibrated data logger in each unit that stores TVFC vaccine that is either International Laboratory Accreditation Cooperation (ILAC) laboratory accredited or has a valid and up-to-date certificate issued by an ILAC laboratory.
A valid certificate of calibration matching the serial number of the data logger in use is to be posted on the refrigerator and/or freezer. The certificate is valid for two years from the date of calibration or the date of expiration, whichever occurs first. A continuous-read temperature-recording device does not replace the requirement for a certified data logger.

Certificates must contain:

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

All TVFC providers must have at least one backup data logger with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day. Backup data loggers must be readily available in case a thermometer or data logger in use is no longer working appropriately or calibration testing of the current equipment is required.
The CDC recommends that the backup data logger be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

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

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

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

Figure 3-1, on the next page, presents an example of a valid certificate of calibration.
Figure 3-1: Example of a Valid Certified Thermometer Certificate
C. Vaccine Storage Requirements

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

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

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

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

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

All TVFC providers also enrolled in the ASN Program must separate TVFC provided pediatric doses from ASN supplied adult doses. All TVFC providers must identify sufficient alternate space to store vaccines and maintain the cold chain during any period when the refrigerator/freezer is out of service.
D. **Protective Equipment**

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

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

**Do not:**

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

E. **Personnel**

Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle TVFC vaccine must be trained on proper storage, handling, and administration of vaccine as well as aware of and familiar with the written procedures for emergency situations to assure continued viability of the vaccines. The site is required to designate a primary and at least one back-up vaccine coordinator to ensure that the TVFC vaccines are handled and stored properly.

During re-enrollment, the primary and back-up vaccine coordinators must complete the mandatory 2018 TVFC Provider Policy Training module.
The training requirements for vaccine coordinators are as follows:

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

The TVFC Program has developed the Texas Vaccine Education Online (VEO) modules 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.

F. Mass Vaccination Clinic Requirements

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

- All TVFC vaccine must be ordered and shipped directly to a location within the ordering provider’s DSHS Health Service Region (HSR).
• The vaccine must be properly transported, not shipped, to local schools or other community sites where the mass vaccination clinics will be held.

• Only amounts of vaccines that are appropriate, based on TVFC need, should be transported to each scheduled clinic.

• Vaccine must be transported to and from the scheduled mass vaccination clinic at appropriate temperatures and must be monitored by a continuous monitoring and recording device that includes a digital display (that can be viewed outside of the storage unit) and probe in buffered material.

• The vaccine being transported should be tracked in order to maintain accountability for monthly reporting in EVI. This includes:
  • Vaccine type(s) and brand names;
  • Quantity of each type;
  • NDC numbers;
  • Lot numbers; and
  • Expiration dates.

• Upon arrival at the clinic site, the TVFC mass vaccination provider must ensure that the vaccine is stored to maintain the appropriate temperature throughout the clinic day.

• Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the day of the clinic using a continuous monitoring and recording device with a digital display and probe in buffered material. Temperature form EC-105 may be used to document hourly temperatures.
• After each clinic day, the TVFC provider must perform a physical count of the remaining vaccine and assess temperatures prior to placing vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised.

• Vaccines exposed to temperature excursions, when the temperature goes above or below its required temperature, must be separated in a Vaccine Quarantine Bag and labeled “Do Not Use” until further information can be gathered from the manufacturer(s). The vaccine should be kept at appropriate temperatures until the viability determination is made.

G. Routine and Emergency Storage and Handling Plan

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

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

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

2. Identify an alternative location to take the TVFC vaccine for storage. A location with a power generator or other alternate source of power such as a hospital, pharmacy, or grocery store is preferable. Ideally, this facility must be located within a reasonable distance from the TVFC provider’s clinic, and can maintain the cold chain during any period when the TVFC provider’s refrigerator or freezer is out of service, as well as adequate space to accommodate the largest vaccine inventory. Temperatures for storage units are required to be monitored and recorded.

3. Adequate supplies in amounts sufficient for packing and transporting the entire TVFC vaccine inventory must be available in case of an emergency.

4. Be sure to contact the emergency storage location for their approval before including them as part of the plan. List their contact person(s) and phone number(s) on the plan. An alternative back-up location must be considered in case the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.

All TVFC providers will be asked to provide a copy of their Vaccine Management Plan and Emergency Vaccine Storage and Handling Plan Checklist at TVFC Compliance
Site Visits. The documents must be posted on or near the refrigerator or freezer containing the TVFC vaccine. The TVFC provider must ensure all employees involved with vaccine management are aware of this plan.

**H. Vaccine Protection in the Event of an Emergency**

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

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

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

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

- The temperature of the vaccine;
- The amount of vaccine;
- Expiration dates of the vaccine; and
- How long the vaccine was exposed to inappropriate temperatures.
The TVFC provider will need to specify the following steps when transporting vaccine to the alternate location:

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

I. Cold Chain Management and Vaccine Transport

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

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

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

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

**Refrigerated Vaccine Transport**

**Assemble Packing Supplies**

CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, use a hard-sided insulated cooler with at least 2-inch walls, Styrofoam vaccine shipping containers or other qualified container may be used if it can maintain the recommended temperature range (between 36°F [2°C] and 46°F [8°C]).

- Hard-sided coolers, Styrofoam vaccine shipping container, or other qualified container are required:
  - Coolers should be large enough to hold the TVFC provider’s typical supply of refrigerated vaccines;
  - Original shipping boxes from the manufacturer can be used, if available; and
  - Do NOT use soft-sided collapsible coolers.
• Label the container with facility name and “Fragile Vaccines – Do Not Freeze” and the date and time the vaccine was removed from the permanent storage unit.

• Conditioned frozen water bottles are required:
  • Use 16.9 oz. bottles for medium/large coolers and 8 oz. bottles for small coolers;
  • Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated; and
  • DO NOT reuse coolant packs from original vaccine shipping containers, they may freeze vaccine.

• Insulating material – two of each layer is needed:
  • Insulating cushioning material – Bubble wrap, packing foam, or Styrofoam for a layer, at least 1-inch thick, above and below the vaccines. Make sure it covers the cardboard completely;
  • Corrugated cardboard – two pieces cut to fit the internal dimensions of the cooler(s) and placed between the insulating cushioning material and the conditioned water bottles; and
  • DO NOT use packing peanuts or other lose material that may shift during transport.

• Temperature monitoring device – A digital data logger with a buffered probe should be used:
• The probe is buffered by pre-chilling it in the refrigerator for at least five hours prior to transport;
• Data logger must have current and valid certificate of calibration testing;
• Data logger must be accurate within +/- 1°F (+/- 0.5°C); and
• The temperature monitoring device currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for remaining vaccines.

Packing for Transport

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

• If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly; and

• As soon as the destination site is reached, check and record the vaccine temperature.

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

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

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

Frozen Vaccine Transport

Varicella and MMRV vaccines are fragile and must be frozen!

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

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

- **Temperature Monitoring Device** – Use a certified and calibrated digital data logger with a current and valid certificate of calibration testing. Prepare the data logger by placing it in a freezer unit at least two 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, Styrofoam vaccine shipping container, or other qualified container may be used if temperatures between -58°F and +5°F (-50°C and -15°C) can be maintained. Label the container with the facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.

- **Frozen water bottles (if portable freezer is unavailable)** – Water bottles must 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).
If a portable freezer is not available and a cooler must be used, use the following packing instructions:

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

In addition to the above packing instructions:

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

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

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

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

1. Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers
- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturer if available.
- Do NOT use soft-sided collapsible coolers.

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

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

Temperature monitoring device — Digital data logger (DDL) with buffered probe. Accuracy of ±0.5°F (±0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to monitor temperature for any remaining vaccines.

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

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

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Centers for Disease Control and Prevention

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Visit www.cdc.gov/vaccines/SandH
for more information, or your state health department.
Figure 3-3: Packing of Vaccine for Transport during Emergencies

2. Pack for Transport

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

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

3. Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.
VI. Vaccine Transfers

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

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

- Ensure that the vaccine transfer is occurring for one of the following reasons:
  - Short dated vaccine;
  - Withdrawal, suspension or termination of a TVFC provider from the TVFC Program; or
  - Other (emergency situations).
- Complete and sign the TVFC Vaccine Transfer Authorization Form and agree that the vaccine will be transferred in accordance to TVFC Vaccine Storage and Handling Guidelines to ensure the proper cold chain will be maintained throughout the transfer process. Each vaccine to be transferred must be listed on a separate row on the Vaccine Transfer Authorization Form and include:
  - The vaccine type;
  - The National Drug Code (NDC);
• The lot number;
• The expiration date; and
• The number of doses that are being transferred.
• Fax the completed TVFC Vaccine Transfer Authorization Form to the Responsible Entity. For emergency situations, TVFC providers must call the Responsible Entity prior to faxing the form.
• Once the DSHS HSR receives the form (either from the TVFC provider or LHD), they will approve or deny the transfer, if applicable, within two business days. If approved, a signed copy of the form will be faxed or emailed back to the TVFC provider requesting the transfer and the LHD (if applicable). Once the TVFC provider receives the approval fax or email, the TVFC provider may conduct the transfer in the EVI system;
• The Responsible Entity will ensure that the vaccine is packaged using proper cold chain management as detailed in Section IV – Vaccine Storage and Handling, subsection I – Cold Chain Management and Vaccine Transport, of this chapter, and a certified, calibrated data logger is enclosed with the packaged vaccine;
• Include a copy of the EVI Transfer Form in the transfer package. The EVI Transfer Form is printed after the transfer is conducted in EVI; and
• Include a Temperature Recording Form to document temperatures before, during, and upon conclusion of the vaccine transfer. The TVFC provider taking possession of the vaccine will append the Temperature Recording Form from the transfer to the monthly Temperature Recording Form.
The TVFC provider taking possession of the vaccine must keep the TVFC Vaccine Transfer Authorization Form on file for a minimum of five years and easily available.

VII. Vaccine Borrowing

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

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

All TVFC providers are expected to maintain an adequate inventory of vaccine for both their TVFC-eligible and privately insured patients. Vaccines supplied by the TVFC Program cannot be provided to a non-TVFC-eligible patient. Undocumented borrowing and administering of TVFC vaccines to a non-TVFC patient is considered fraud. No provider may use TVFC vaccines as a replacement system for filling the vaccine needs of a non-TVFC privately insured patient. For example, providers may not borrow TVFC flu vaccine for privately insured patients if the TVFC flu vaccine arrived in their office prior to their privately purchased flu vaccine.

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

- Document the incident by completing the TVFC Vaccine Borrowing Form (EF11-14171). Each vaccine that was administered to a non-TVFC-eligible client must be
listed on a separate row on the form. The form is available online at:
http://www.dshs.texas.gov/immunize/tvfc/publications.aspx;

• Report the incident by faxing a copy of the TVFC Vaccine Borrowing Form to their Responsible Entity within 24 hours. Adherence to HIPAA guidelines is mandatory when faxing this form to the Responsible Entity. The TVFC Vaccine Borrowing Form must be kept as part of the TVFC Program records for a minimum of five years and be made easily available; and

• Replace the vaccine immediately and account for the replacement in the EVI system.

It is the responsibility of the TVFC provider to ensure that all staff members are familiar with TVFC Program requirements. Adequate vaccine supply must be maintained in accordance with the clinic’s patient population (TVFC and private patients). The TVFC vaccine and private vaccine must be kept separately and clearly labeled as such. All TVFC providers must track vaccine usage and account for all doses of TVFC vaccine.

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

VIII. Reporting Requirements

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

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

A. Reports Summary

*Monthly Biological Report (C-33)*

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

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

For those providers without internet access, they must complete the Monthly Biological Report and submit it to their Responsible Entity each month. The person completing the paper Monthly Biological Report must always sign and date the report and provide a telephone number where they can be reached. This is required in case discrepancies are identified on the report and a follow-up phone call is needed.
Biological Order Form (EC-68-1)

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

Temperature Recording Form (EC-105)

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

All TVFC vaccines are required to be maintained at proper storage temperatures at all times. To ensure proper temperatures are maintained, the TVFC Program requires providers to record refrigerator and/or freezer temperatures twice daily for all units that store TVFC vaccine. The TVFC providers are also required to record minimum and maximum temperatures since the last reading, at least once daily, preferably in the morning. Results of each check must be documented on the Temperature Recording Form and the form must be initialed by the staff member conducting the check. Instructions for completing the Temperature Recording Form are listed on the top of the form.

Completed Temperature Recording Forms for the previous month are to be submitted to the Responsible Entity.
In case of a temperature excursion, providers must notify their Responsible Entity immediately and include the following information on the Troubleshooting Record (found on the last page of the EC-105):

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

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

B. Monthly Requirements

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

- Monthly Biological Report (C-33);
- Biological Order Form (EC-68-1);
• Temperature Recording Form (EC-105), including:
  • Refrigerator Fahrenheit (EC-105RF);
  • Refrigerator Celsius (EC-105RC);
  • Freezer Fahrenheit (EC-105FF); or
  • Freezer Celsius (EC-105FC);
• Vaccine Loss Report, if applicable;
• TVFC Vaccine Borrowing Form, if applicable; and
• Any additional and/or associated forms as required by the Responsible Entity.

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

All forms are included in the TVFC Provider Manual in the Forms section, as well as under TVFC Forms & Publications on the TVFC webpage:

http://www.dshs.texas.gov/immunize/tvfc.