



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY, M.D.
COMMISSIONER

January 15, 2015

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TTY: 1-800-735-2989
www.dshs.state.tx.us

RE: Policy 0015-1 Routine and Emergency Vaccine Storage and Handling Plans

Dear Texas Vaccines for Children (TVFC) provider,

The Centers for Disease Control and Prevention (CDC) requires Vaccine for Children (VFC) providers to develop and implement feasible and appropriate plans for routine and emergency vaccine management. As such, the Texas Department of State Health Services (DSHS) Immunization Branch has developed Vaccine Management Plan Templates (E11-11190) as a resource available to all TVFC providers.

The Vaccine Management Plan Templates include templates for both the Routine Vaccine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan. These templates capture all information required by the CDC.

Please note, TVFC providers are not required to use these templates, but they are valuable tools available to providers should they need assistance in developing the required vaccine management plans. If the templates are not used, providers must develop routine and emergency vaccine management plans that include all of the information included in the templates provided by the TVFC Program.

TVFC providers must review and update their Routine Storage and Handling Plan and the Emergency Vaccine Storage and Handling Plan annually or more frequently if there are any changes to the plan, changes in equipment used to store TVFC vaccine or changes to staff in charge of vaccine management. 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 must be posted on or near the refrigerator or freezer containing TVFC vaccine. Providers must ensure that all employees involved with vaccine management are aware of this plan.

The TVFC Program has updated the Emergency Vaccine Storage and Handling Plan Checklist (E-11-14497) for providers to use in the event of an emergency situation. This checklist provides guidance for the emergency transport of both refrigerated and frozen vaccines.

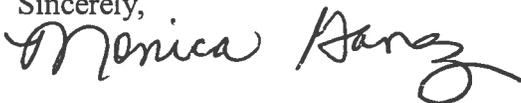
Further guidance regarding routine and emergency vaccine management and vaccine transport can be found in Chapter 3 – Vaccine Management of the TVFC Provider Manual. The TVFC Provider Manual is available online at: <http://www.dshs.state.tx.us/immunize/tvfc/ProviderResources.shtm>.

Thank you for your continued support of the TVFC Program. For any questions, please contact the appropriate DSHS Health Service Region (HSR) below.

DSHS Health Service Region Phone List

Provider PINS Beginning With	Health Service Region	Phone Number
01	HSR 1	806-783-6416
02	HSR 2	325-795-5660
03	HSR 3	817-264-4793
04 or 05 not in Hardin, Jefferson or Orange Counties	HSR 4/5N	903-533-5310
05 in Hardin, Jefferson or Orange Counties or 06 or 25	HSR 6/5S	713-767-3410
07	HSR 7	254-778-6744
08 or 00	HSR 8	210-949-2067
09	HSR 9	432-571-4132
10	HSR 10	915-834-7924
11	HSR 11	956-421-5552

Sincerely,



Monica Gamez
Director, Infectious Disease Control Unit

Vaccine Management Plan Templates

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

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Contact List

Vaccine Coordinators			
Vaccine Coordinators (Name/Title)	Telephone Number (home, cell, pager)	Alt. Telephone Number (home, cell, pager)	E-mail Address
Primary:			
Alternate (Back-up #1):			
Alternate (Back-up #2):			
Resources Contact List			
Resources	Telephone Number	E-mail Address	
Local Health Department (LHD)			
DSHS Health Service Region (HSR)			
DSHS Vaccine Call Center	1-888-777-5320	VacCallCenter@dshs.state.tx.us	
DSHS Pharmacy	512-776-7500		
Additional Resources	Company/Entity Name	Telephone Number	E-mail Address
Electric Power Company			
Refrigerator Repair			
Freezer Repair			

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

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

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

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

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

Routine Vaccine Storage and Handling Plan reviewed and updated by:

Name:	Title:
Signature:	Date of Last Review:

Procedures for Proper Storage and Handling of Vaccine

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

Temperature Monitoring

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

Vaccine Storage

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

Vaccine Storage (continued)

- It is never acceptable to store food or drinks in the same refrigerator or freezer as vaccine.
- Refrigerators and freezers storing vaccine must be plugged directly into a wall outlet with a plug guard. Multi-strip outlets must not be used.

Vaccine Shipping and Receiving Procedures

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

Vaccine Ordering Procedures

- _____ is responsible for ordering vaccine.
- All vaccine orders will be placed in EVI unless internet access is unavailable.

Vaccine Ordering Procedures (continued)

- Providers are required to enter into EVI all vaccine received, doses transferred, doses administered, expired/wasted vaccine and a physical count for all TVFC vaccines in their inventory each month regardless of whether an order is placed.
- Temperature Recording Forms (C-105) must be completed and submitted monthly to their responsible entity.
- Providers should abide by their established maximum stock levels (MSL) and tiered ordering frequency (TOF) when ordering vaccine. Providers are allowed to request quantities exceeding their MSL; however, a justification is required.
- Providers are responsible for entering accurate provider information into EVI, including shipping address, days and hours available to receive vaccine shipments, and primary and back-up contact information.

Inventory Control (e.g., Stock Rotation)

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

Vaccine Loss (Expired, Spoiled, and Wasted Vaccine)

- Providers are required to follow the procedures listed below when vaccine loss occurs:
 - _____ is responsible for completing and submitting the Vaccine Loss Reports.
 - Remove expired/spoiled vaccine from the vaccine storage unit immediately.
 - Contact your responsible entity immediately with the antigen, lot number, expiration date and reason for expiration/loss.
 - Report every dose of vaccine that is lost (wasted, spoiled or expired) to the TVFC Program on a Vaccine Loss Report electronically generated in EVI within four days of the date of the loss.
 - The completed Vaccine Loss Report must be signed by the medical provider who signed the VFC Program Provider Agreement.
- Providers should follow the procedures listed below for returning nonviable vaccine (if applicable):
 - is responsible for returning nonviable vaccine.
 - Complete the Vaccine Loss Report as indicated above and submit to the responsible entity.

Vaccine Loss (Expired, Spoiled, and Wasted Vaccine) (continued)

- Once the Vaccine Loss Report is processed, TVFC providers will receive a shipping label from McKesson.
- Providers must ensure that all and only vaccines listed on that Vaccine Loss Report are included in the box for return.
- If more than one box will be used, mark the boxes with “Box 1 of 2,” “Box 2 of 2,” etc.
- A copy of the Vaccine Loss Report should be included in each box when returning the non-viable vaccine.
- Providers must indicate on the Vaccine Loss Report the number of the box in which the vaccine is being shipped (e.g., “Box 1 of 2,” “Box 2 of 2,” etc.).
- Any wasted vaccine listed on the Vaccine Loss Report (opened multi-dose vials, dropped or broken vials/syringes) should be marked through with a single line.
- NEVER include broken vials/syringes or exposed syringe needles in the box for return.
- Providers must wait until UPS returns to their office with the next delivery to return the box with the nonviable vaccines.