



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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COMMISSIONER

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October 28, 2014

RE: Vaccine Loss Policy

Dear Texas Vaccines for Children (TVFC) Provider:

The Immunization Branch would like to reiterate the importance of provider adherence to the Branch policies regarding vaccine loss. Please make it a priority to review the Branch policies and implement these practices for managing vaccine loss.

Return of all unopened or unused vials and syringes of expired or spoiled TVFC vaccines is required. Providers cannot discard any vaccine unless specifically directed by the Department of State Health Services (DSHS) Immunization Branch, DSHS Health Service Region (HSR) or Local Health Department (LHD). Any exception to this rule will be communicated by the Immunization Branch on a case-by-case basis.

Please refer to the following definitions for guidance in determining those vaccines available for return to the distributor.

Expired or spoiled vaccine: any nonviable vaccine in its original container (vial or syringe) that can be returned for excise tax credit. This includes expired vaccine or vaccine that has been spoiled as a result of the following:

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

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

- Vaccine drawn into the syringe but not administered
- Vaccine in open vial but doses not administered
- Syringes or vials that are broken or lost

Spoiled and expired vaccine must be segregated, labeled “Do Not Use,” and stored pending return to the distributor. Upon receipt, the third party distributor, McKesson, will match the contents of the package against the included Vaccine Loss Report (VLR). Therefore it is imperative that the included contents are an accurate reflection of what is documented on the VLR. Although all vaccine returns to McKesson must occur no later than six months from of the date of the loss, it is best practice to return vaccines as soon as possible. Do not return expired diluents.

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

Important Note: Every wasted, spoiled or expired dose of vaccine must be reported to the TVFC Program on a Vaccine Loss Report electronically generated in the Electronic Vaccine Inventory system (EVI). The VLR documentation in EVI must occur within four days of the incident(s).

Providers must follow the procedures listed below when vaccine loss occurs:

- Remove expired/spoiled vaccine from the vaccine storage unit.
- Contact your responsible entity (DSHS HSR or LHD) immediately with the following information:
 - antigen
 - lot number
 - expiration date
 - reason for expiration/loss
- Document the vaccine loss on the Vaccine Loss Report electronically generated in EVI explaining the cause(s) of the loss and outlining the steps taken to ensure vaccines will be protected in the future. The Vaccine Loss Report should be printed, signed by the medical authority, and then submitted to the responsible entity within **four days of the date of the loss**. (Completed Vaccine Loss Reports must be signed or acknowledged by the medical provider who signed the TVFC Program Provider Agreement.)
- TVFC providers will receive a shipping label from McKesson for return of nonviable vaccine, if applicable.
- Providers must ensure that only vaccines listed on that Vaccine Loss Report are included in the box for return. If more than one box is used to return nonviable vaccine, providers must indicate on the Vaccine Loss Report the number of the box in which the vaccine is being shipped (e.g., “Box 1 of 2,” “Box 2 of 2”). A copy of the Vaccine Loss Report (including box number) must be included in each box.
- Any wasted vaccine listed on the Vaccine Loss Report (dropped or broken vials/syringes or open multi-dose vials) must 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 are to be included for return. Broken vials/syringes or exposed syringe needles should **NEVER** be included in the box.
- Providers will have to wait until UPS returns to their office with the next delivery to return the box with the nonviable vaccines. If the provider calls to schedule a pickup, the provider will be charged a pick up fee. McKesson will not schedule pickups on behalf of TVFC providers unless special arrangements are made by the DSHS Immunization Branch.

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

- Vaccine stored improperly
- Vaccine left out of the refrigerator or the freezer
- Refrigerator or freezer unplugged (plug guard not used)
- Vaccine transported inappropriately (appropriate cold chain was not maintained)
- Improper monitoring of temperatures in refrigerator or freezer
- Allowing vaccine to expire without notifying the DSHS HSR or LHD 90 days in advance of the expiration date
- Refrigerator or freezer door left open
- Refusal of a vaccine shipment

Certain vaccine loss circumstances may qualify for insurance policy reimbursement depending on the type of insurance your facility has. Loss of TVFC vaccine under the following circumstances may be covered by insurance. Some examples include, but are not limited to, vaccine loss as a result of:

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

Thank you for your continued support of the TVFC Program. If you have additional questions please contact your DSHS HSR or LHD.

Sincerely,

A handwritten signature in black ink, appearing to read "Monica M. Gamez", with a stylized flourish at the end.

Monica M. Gamez
Director, Infectious Disease Unit