CHAPTER 3: VACCINE MANAGEMENT

I. Approved Vaccines

The ASN Program supplies the following Advisory Committee on Immunization Practices (ACIP) routinely recommended vaccines and toxoids to enrolled providers. All providers participating in the ASN Program are required to offer ALL recommended vaccines to the eligible populations they serve.

- Hepatitis A (Hep A) vaccine
- Hepatitis B (Hep B) vaccine
- Hepatitis A and hepatitis B (Hep A - Hep B) combination vaccine
- Human papillomavirus (HPV) vaccine
- Meningococcal conjugate (MCV4) vaccine
- Measles, mumps, and rubella (MMR) vaccine
- Pneumococcal conjugate (PCV13) vaccine
- Pneumococcal polysaccharide (PPSV23) vaccine
- Tetanus and diphtheria toxoids (Td) vaccine
- Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine
- Varicella vaccine
- Zoster vaccine

The ASN vaccine formulary is subject to change based on availability of funding. Any changes to available vaccines (adding or removing vaccines from the formulary) will be communicated to providers.
II. Vaccine Ordering

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

The provider who signs the ASN Program Provider Agreement can choose vaccine brands and presentations. The responsible entity (DSHS HSR or LHD) will create the initial Biological Order Form for new ASN providers. The initial Biological Order Form will reflect the provider choices, maximum stock levels (MSL), and order quantity.

Each quarter, ASN providers will have the opportunity to choose the brand and presentation for each ASN vaccine in the Electronic Vaccine Inventory (EVI) system and can change or adjust specific vaccine brands, presentations, and percentages within each vaccine “family” (i.e., Tdap), or take no action to maintain the current selections. A provider’s primary or secondary coordinator may complete the process, however, the provider who signed the ASN Program Provider Agreement must be consulted with and agree to the vaccine choices. The vaccine choices, as well as the person
making the changes, are captured electronically in EVI. ASN 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 ASN Program will be available for vaccine choice.

In the event that a chosen vaccine is not available, the ASN Program has the authority to replace the chosen vaccine with a comparable substitution until the chosen vaccine becomes available. Vaccine choice does not apply in the event of a disaster or public health emergency, terrorist attack, hostile military or paramilitary actions, or an extraordinary law enforcement emergency.

**B. Vaccine Inventory Plan and Maximum Stock Levels**

The vaccine inventory plan requires all enrolled providers to maintain a monthly (60 day) supply of vaccine inventory. 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 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. The 60 day supply of vaccine also allows providers 30 days of vaccine inventory when providers place their next vaccine order. All providers are placed on a monthly ordering frequency. Providers are not required to order each month, but as needed to maintain a 60 day supply of vaccine.
CHAPTER 3: VACCINE MANAGEMENT

The maximum stock level (MSL) is a calculated peak dose inventory (per vaccine type) and is the standard number of doses an ASN provider can order each month to maintain the 60 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 review and permission from their responsible entity (DSHS HSR or LHD) prior to ordering outside of their suggested quantity.

Upon initial enrollment, the responsible entity (DSHS HSR or LHD) will work with the ASN 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 (DSHS HSR or LHD) after 3 months with the ASN Program.

MSLs are recalculated twice a year based upon doses administered data. A monthly average MSL is determined from this data. Providers may not order vaccine in excess of their suggested quantity. Providers may place a second vaccine order within a given month, as long as all required reporting has been submitted, as detailed in subsection F. Vaccine Ordering in the Electronic Vaccine Inventory System, and they are not exceeding their MSL.

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 ASN eligible adults served changes, or if there are any applicable changes to the status of the facility that might impact vaccine usage. ASN providers can notify their responsible entity (DSHS HSR or LHD) 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.

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. Vaccine surplus kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of refrigerator / freezer failure. When ordering vaccines, ASN providers must keep no more than the designated MSL. Clinic staff must note vaccine expiration dates when physically counting inventory at the end of the month. Short-dated vaccine must be used first.
Each ASN provider is required to notify their responsible entity (DSHS HSR or LHD) 90 days prior to the expiration of vaccine. If the provider is unable to administer the vaccine prior to expiration, the responsible entity (DSHS HSR or LHD) may assist with re-distribution of the vaccine and move it accordingly, if accepted at another provider site.

Diluents must be managed in the same manner as vaccines; the expiration date of diluents must be checked prior to every reconstitution. ASN providers must also rotate diluent stock to use the shortest expiration date first.

If vaccines are allowed to expire, they are considered nonviable and must be placed in a vaccine quarantine bag clearly labeled “Do Not Use” and must be removed from storage units.

**E. Storage Capacity for Vaccine Orders**
An ASN provider must have adequate refrigeration and / or freezer space to accommodate a maximum order based on their MSL. An ASN provider must also take into consideration the space needed for their private stock when calculating storage capacity. Storage units must be approved and monitored according to this chapter.

**F. Vaccine Ordering in the Electronic Vaccine Inventory System**
The ASN Program uses the EVI system for vaccine ordering. EVI allows ASN providers to manage their vaccine inventory online. All vaccine orders will be placed in EVI unless internet access is
unavailable. An ASN provider may be held responsible for vaccine loss that is a result of erroneous information entered into EVI.

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

- Verification of days and hours of operation (to receive vaccine) and the delivery address;
- Verification of primary and secondary point of contact information;
- Acceptance of all vaccines received;
- Acceptance of all vaccines transferred;
- Process all expired, spoiled, or wasted vaccine;
- Document all doses administered within the last calendar month;
- Conduct a physical count of all vaccines by brand, presentation, lot number, and expiration date within the last two days of placing their online order (C-33 report);
- Run a report of all doses that will expire within 90 days; if applicable, and
- Document all scheduled clinic closures (including holidays) in the comments section of the order.

Providers must also submit the following reports to their responsible entity (DSHS HSR or LHD) via fax or a scanned copy:

- Temperature logs (EC-105);
- Borrowing form (EF 11-14171), if applicable; and
- Doses about to expire report.
All of this reporting is required for all ASN vaccines each month whether an order is placed, or not.

All orders placed in EVI will be reviewed and approved by the responsible entity (DSHS HSR or LHD) pending the ASN provider’s completion and submission of the required monthly reporting and resolution of any outstanding issues. Incomplete or inaccurate orders will be placed on “Hold” pending corrections by the ASN provider which may cause orders to be delayed.

Each ASN provider must abide by their established MSLs when ordering vaccine. EVI uses the ASN 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 an ASN 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 ASN 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 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 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 ASN 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, ASN providers are instructed to immediately contact their responsible entity (DSHS HSR or LHD) for resolution. All vaccines must be appropriately stored immediately upon receipt regardless of any errors in the order.

G. Vaccine Ordering for ASN Providers without Internet Access

An ASN provider without access to the internet will contact their responsible entity (DSHS HSR or LHD), who will then enter the ASN provider’s order online. The ASN provider will submit the following
paper forms to their responsible entity (DSHS HSR or LHD) so that vaccine order can be placed:

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

The Monthly Biological Report is reviewed by their responsible entity (DSHS HSR or LHD) 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 ASN provider so the records can be corrected prior to ordering.

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

Newly enrolled ASN providers are set up for vaccine ordering in EVI during New Provider Training with their responsible entity (DSHS HSR or LHD). The order is placed by the ASN provider as part of the training. The responsible entity (DSHS HSR or LHD) collects and reviews the following paper reports prior to placing the new ASN provider’s vaccine order:

- Biological Order Form (EC-68); and
- Temperature Recording Form(s) (EC-105).

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

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., outreach clinic) require enhanced storage and handling practices. The ASN provider must develop mass vaccination protocols to ensure that outreach efforts meet all ASN requirements. The protocol must include information showing how the ASN provider has established vaccine needs (provider profile) and a plan for overseeing vaccine ordering for each clinic site to ensure that proper amounts of ASN stock are transported on each clinic day. The plan should include 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 ASN provider’s responsible entity (DSHS HSR or LHD) must review and approve their mass vaccination plan prior to initiation of the mass vaccination clinics.

Specific storage and handling requirements for mass vaccination clinics is discussed in Section V. Vaccine Storage and Handling, subsection F. Mass Vaccination Clinic Requirements.

III. Vaccine Distribution

A. Vaccine Distributors

The ASN Program uses two vaccine distribution centers:

- McKesson Specialty, a third party distributor which ships the majority of ASN vaccines; and
- Merck, the manufacturer and distributor of varicella-containing vaccines, which ships directly to providers.
B. Receiving Vaccine Orders

The ASN Program requires that ASN providers always accept vaccine shipments and never refuse or return the shipments without specific instructions from the ASN Program or from their responsible entity (DSHS HSR or LHD). The ASN provider must ensure that the accurate clinic address and delivery hours are entered into EVI.

In order for ASN providers to receive vaccine shipments, appropriate staff must be on site and available at least two days a week other than Monday and for at least four consecutive hours during the hours of 8 a.m. - 5 p.m. Each ASN 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 ASN provider will not be able to change their available hours in EVI once an order is placed. The ASN provider will be held responsible for incomplete or erroneous information entered into EVI which can result in vaccine loss.

The ASN provider can expect their approved orders approximately one to three weeks after placing their online order in EVI. It is important to store vaccine shipments immediately and appropriately upon receipt to ensure vaccine viability.

All ASN providers are required to train their staff on recognizing vaccine shipments. All ASN providers must have a vaccine management plan in place to ensure the vaccine gets stored quickly and appropriately 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 and monitor reading device;
- 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;
- Ensure adequate amount of diluent is included for those vaccines which require reconstitution (i.e., varicella, MMR, Zoster);
- Immediately contact the responsible entity (DSHS HSR or LHD) if the appropriate quantity and type of vaccine or diluent is not received;
- Call the responsible entity (DSHS HSR or LHD) immediately upon receipt of vaccines that have been received in error;
- If vaccines appear to be compromised, store appropriately and contact the responsible entity (DSHS HSR or LHD) immediately;
- Appropriately store all vaccines immediately upon receipt regardless of errors (i.e., quantity, shipping, and transport);
- Check expiration dates and rotate stock to ensure short-dated vaccines are used first; and
- Immediately approve 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. Vaccines Received Warm or Questionable.

All ASN providers are required to approve the receipt of the vaccine in EVI upon arrival of vaccine shipment to maintain correct 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 Zoster products are shipped directly from Merck 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 ASN provider must immediately store the frozen vaccine in the proper storage unit.

If the vaccine arrives outside of the four-day pack date, then the ASN provider must immediately place the vaccine in a vaccine
quarantine bag provided by the ASN Program, store the vaccine properly, contact the manufacturer, and notify their responsible entity (DSHS HSR or LHD).

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

**D. Vaccines Received Warm or Questionable**

Vaccines must always be stored properly, even if viability is questionable. If vaccines are received warm, damaged, or otherwise questionable, the ASN provider needs to immediately contact their responsible entity (DSHS HSR or LHD). Questionable vaccine must be placed in a vaccine quarantine bag provided by the ASN Program and segregated in proper storage until viability can be determined.

Examples of potentially nonviable vaccines:

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

If vaccine viability is questionable upon receipt, follow these instructions:

- Isolate questionable vaccine in a vaccine quarantine bag, provided by the ASN Program, and place the questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine box.
CHAPTER 3: VACCINE MANAGEMENT

- It is critical to contact your responsible entity (DSHS HSR or LHD) on the same day the vaccine arrived at the ASN provider’s office as documented by the carrier. Any calls received after the day of delivery will result in the denial of CDC’s liability for vaccine replacement, regardless of the cause of the temperature excursion. This documentation must be maintained with the provider’s ASN records for a minimum of five years.

- Contact the manufacturer immediately to determine the viability of the vaccine. The provider must request documentation from the manufacturer supporting vaccine viability. Documentation must be kept on file for a minimum of 5 years.

- Contact the responsible entity (DSHS HSR or LHD) to inform them of the manufacturer’s vaccine viability determination. The responsible entity will provide instructions on vaccine replacement and/or reporting loss.

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
ASN providers must call their responsible entity (DSHS HSR or LHD) immediately upon receipt of vaccines that are received in error. The ASN provider may opt to keep the vaccine if they have storage capacity and can administer the doses. If the ASN provider cannot
absorb the vaccine into their stock, then their responsible entity (DSHS HSR or LHD) may assist in redistributing the vaccine to other ASN 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 ASN vaccines / toxoids / biologicals be returned to the third-party distributor (McKesson). Vaccine manufacturers reimburse CDC for the federal excise tax portion of the cost of the vaccine. Therefore, providers should not discard any vaccine unless specifically directed by the DSHS Immunization 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 (DSHS HSR or LHD) of vaccine cold chain failure events or vaccine wastage incidents involving ASN vaccines upon discovery of the incident.

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

- Natural disaster / power outage;
- Refrigerator 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: Any nonviable vaccine that cannot be returned for excise tax credit. This includes:

• Vaccine drawn into the syringe but not administered;
• Vaccine in an open multi-dose vial but not all doses administered;
• Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), or broken vial;
• Incorrect vaccine prepared for patient; and / or
• Incorrect diluent drawn for vaccine.

Wasted and expired / spoiled vaccines should be removed from the storage unit to prevent inadvertent administration. Wasted and expired / spoiled vaccine should be segregated, labeled “Do Not Use,” and stored pending return to distributor. The third party distributor, McKesson, will document Texas losses and return vaccines to the manufacturer for excise tax credit. All vaccine returns to McKesson must occur within six months.

Lost vials (those that cannot be accounted for) are expected to be adjusted on the provider inventory.

Diluents should be managed similar to vaccines; the expiration date of diluents should be checked prior to every reconstitution. Providers should also rotate diluent stock to use the shortest
expiration date first. Expired diluents do not require a loss report form and are not returned to McKesson.

Vaccine loss must be documented on a Vaccine Loss Report electronically in EVI no later than four days past the date of the incident(s).

B. Procedures for Vaccine Loss

Every dose of vaccine that is wasted, spoiled or expired must be reported to the ASN 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 their responsible entity (DSHS HSR or LHD) immediately with the following information:
  - Antigen;
  - Lot number;
  - Expiration date; and
  - Reason for expiration / loss.
- If storage was compromised, provide DSHS HSR or LHD with amount of time product was out-of-range and the highest and lowest temperatures recorded (this information may be gathered from data logger or thermometer).
• Document the vaccine loss on the Vaccine Loss Report Form that is generated in EVI within four days of the incident(s) of loss 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 Form must be printed and signed by the medical provider who signed the ASN Program Provider Agreement and then emailed or faxed to the responsible entity (DSHS HSR or LHD).

• 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; and
  • List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost.

ASN providers will receive a shipping label for returning nonviable vaccine, if applicable.

• Providers must ensure that all and only vaccines listed on that Vaccine Loss Report Form are included in the box for return. If more than one box is used to return nonviable vaccine, providers must indicate on the Vaccine Loss Report the number of the box in which the vaccine is being shipped (e.g., “Box 1 of 2”, “Box 2 of 2”, etc.).
- 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 to be 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 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 ASN providers unless special arrangements are made by the DSHS Immunization Unit.

ASN providers who have lost vaccine as a result of improper temperature storage must assess how long the vaccines were stored improperly and how many adults may have received the affected vaccines. The provider should discuss the situation with the manufacturer to determine whether or not adults will need to be recalled and revaccinated.

The ASN Program will not provide the vaccine for recalled adults in these circumstances. The clinic will assume all financial responsibility for the cost of vaccines for recalls. Providers must contact their responsible entity (DSHS HSR or LHD) with the determination from the manufacturer.
C. Negligent Vaccine Loss
ASN 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;
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility) or broken vial; or
- Incorrect vaccine prepared for patient; and / or incorrect diluent drawn for vaccine.

V. Vaccine Storage and Handling
A. Refrigerator and Freezer Requirements
ASN 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;
The CDC recommends stand-alone refrigerators without freezers for vaccine storage. 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 or zoster vaccine 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. When using a combination refrigerator and freezer unit, the CDC recommends not using the freezer section of the dual unit to store frozen vaccines. A separate stand-alone freezer unit is recommended by the CDC to store all frozen vaccines;

Dorm-style and small combination refrigerator and freezer units outfitted with a single external door are NEVER allowed for the storage of ASN vaccine;

The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature must 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; and

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 not be used in pharmaceutical / purpose-built units if the manufacturer indicates that water bottles negatively impacts the functionality of the unit.

**For the refrigerator:**

- Replace crisper bins with water bottles to help maintain consistent temperature;
- 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 weighing down the door so much that it does not seal tightly;
• Place water bottles against the walls, in the back, on the floor, and in the door racks;

• Place water bottles on the top shelf of the refrigerator to act as a barrier between the cooling vent and the vaccine;

• Do not store vaccine on the top shelf, directly under the cooling vent;

• Do not store food or beverages in the refrigerator;

• Do not store vaccines in the doors or on the floor of the refrigerator;

• Do not drink from or remove the water bottles;

• Leave 2-3 inches between all vaccine and the refrigerator walls to allow for air circulation throughout the unit;

• Arrange vaccines in rows, allowing space between rows to promote air circulation;

• 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;

• 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;

• Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature; and

• Store privately purchased vaccine on different shelves from ASN to minimize the risk of administering ASN vaccine to non-eligible patients.

• **For the freezer:**

  • Use frozen water bottles to help maintain consistent temperature;

  • Post “Do Not Unplug” signs on the freezer and by the electrical outlet;

  • Place water bottles in unit doors carefully so they cannot dislodge, and prevent the door from closing securely or weighing the door down;

  • Place water bottles against the walls, in the back, on the floor, and in the door racks;

  • Do not store food in the freezer;
• Do not store vaccines in the freezer doors;
• Leave 2 - 3 inches between all vaccines and the freezer walls;
• Arrange vaccines in rows, allowing space between rows to promote air circulation;
• Store each type of vaccine in a separate container;
• Place vaccines with the earliest expiration dates in front of those with later expiration dates;
• Attach labels to shelves and containers to clearly identify where each type of vaccine is stored;
• Store 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;
• Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature; and
• Store privately purchased vaccine on different shelves from ASN to minimize the risk of administering ASN vaccine to non-eligible patients.

Depending on the size of the unit, the amount of vaccine stored, and the time of year, “adequate” 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 (when door(s) are opened / closed frequently) of the unit or until vaccines can be moved to another refrigerator or freezer.

Prior to using a new or newly repaired unit to store vaccines, unit temperatures must be monitored and recorded twice a day for a minimum of 10 business days on the EC-105 form. In addition, minimum / maximum temperatures must be recorded one time at the beginning of each business day to ensure temperatures are within appropriate ranges. Submit the recordings to the responsible entity (DSHS HSR or LHD) 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 of each business day.

Read the refrigerator and freezer instructions carefully before adjusting the temperature control settings and then verify that the temperatures did not change overnight.

Refrigerators and freezers that store ASN 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 ASN temperature logging requirements are mandatory for all ASN providers:

- A Temperature Recording Form (EC-105) is required to be located on or near all units that store ASN vaccines. 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; and
- Temperature Recording Forms must be maintained for five years and made easily available.

If any out-of-range temperature excursion is observed, the ASN 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;
• Contact the vaccine manufacturer, to obtain documentation for the viability of the vaccine; and

• Contact the responsible entity (DSHS HSR or LHD) to report the manufacturer’s vaccine viability determination and complete the Vaccine Storage Troubleshooting Record attached to the Temperature Recording Form (on page 3).

B. Data Logger and Thermometer Requirements
Refrigerators and freezers that store ASN vaccines must contain a centrally located data logger or thermometer with a current certificate of calibration.

The ASN Program and the CDC recommend the use of a continuous monitoring and recording digital 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. Data loggers, if used, must be accompanied by a current certificate of calibration. An ASN provider using data loggers must still comply with recording daily temperatures twice a day along with Minimum and Maximum temperatures, as stated above. 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.
If a digital data logger is used, it must have the following capabilities:

- Alarm for out-of-range temperatures;
- Current temperature, as well as minimum and maximum temperatures;
- Reset button;
- Low battery indicator;
- Accuracy of +/-1°F (+/-0.5°C);
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full);
- User-programmable logging interval (or reading rate); and
- Detachable probe (kept in the glycol-filled bottle).

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 ASN 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; and
• Temperature monitoring devices that are not calibrated.

These devices can have significant limitations, can be difficult to read and most 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 or thermometer probe must be placed as close to the vaccine as possible. Data-logger or thermometer 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 or thermometer 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 ASN Program are required to have in each refrigerator and/or freezer that stores ASN vaccine, a calibrated data logger or thermometer accompanied with a valid and up-to-date certificate issued either by an International Laboratory Accreditation Cooperation (ILAC) laboratory or, if not ILAC accredited, the certificate must contain measurement results and a statement indicating that it meets International Organization for Standardization / International Electronic Commission (ISO/IEC) 17025 standards. A valid certificate of calibration matching the serial number of the data logger or thermometer 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 until the date of expiration, whichever occurs first. A continuous-read temperature-recording device does not replace the requirement for a certified data logger or thermometer.

All 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 ASN providers must have at least one backup data logger or thermometer with a valid and current certificate of calibration readily
available to ensure that temperature assessment and recordings can be performed twice a day (see example Figure 3-1). Backup thermometers must be readily available in case a thermometer in use is no longer working appropriately or calibration testing of the current equipment is required.

The CDC recommends that the backup data logger or thermometer 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 or thermometer should have a different calibration retesting date. If both thermometers have the same calibration date, they will need to be sent out for re-calibration at the same time. By having different calibration dates there will always be one thermometer 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 ASN provider as needed to maintain proper temperature.

In addition, ASN 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.
See Figure 3-1: Example of a Valid Certified Thermometer Certificate.

Figure 3-1: Example of a Valid Certified Thermometer Certificate
CHAPTER 3: VACCINE MANAGEMENT

C. Vaccine Storage Requirements

Some vaccines are sensitive to light and their efficacy could be compromised if exposed to light. All ASN providers must safeguard the following vaccines from light: MMR, HPV, MCV4, varicella, and Zoster.

All vaccines, with the exception of varicella and Zoster, are to be stored in the refrigerator and must never be frozen. Varicella and Zoster must be stored in the freezer in a continuously frozen state <5°F (-15°C).

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, on the floor, or on the top shelf. 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 ASN vaccines must be stored separately from privately purchased vaccines and must be labeled accordingly.

All ASN providers who are also enrolled in the TVFC Program must separate TVFC provided pediatric doses from ASN supplied adult doses.

All ASN providers must identify sufficient alternate space to store vaccines and maintain the cold chain during any period in the event when the refrigerator/freezer is out of service.
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D. Protective Equipment for Units
The power supply for vaccine storage units must be protected by the following:

- Plug unit directly into a wall outlet, do NOT use multi-outlet power strips;
- Do NOT use outlets with built in circuit switches;
- Do NOT use power outlets that can be activated by a wall switch;
- Plug only one unit into an outlet;
- Plug guards are required to be used on all refrigerators and freezers that store ASN 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 refrigerators and freezers used for storing vaccine; and
- A “Do Not Disconnect” sign must be posted by each circuit breaker.

E. Personnel
Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle ASN vaccine must be trained on proper storage, handling, and administration of vaccine. The facility is required to designate a primary and at least one secondary ASN vaccine coordinator to ensure that the ASN vaccines are handled and stored properly. Both ASN vaccine coordinators are required to complete the mandatory CDC “You Call the Shots” training modules.
annually and provide the Certificates of Completion to their responsible entity (DSHS HSR or LHD) during the re-enrollment period.

All staff who handle ASN vaccine must be aware of, and familiar with the written procedures for emergency situations to assure continued viability of the vaccines.

New employees must be adequately trained regarding the proper storage and handling of vaccines prior to administering the ASN vaccines. Replacement primary or secondary vaccine coordinators must complete the mandatory CDC “You Call the Shots” training modules and provide the Certificates of Completion to their responsible entity (DSHS HSR or LHD).

The ASN 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 ASN vaccines must be ordered and shipped directly to a location within the ordering provider’s DSHS HSR.
CHAPTER 3: VACCINE MANAGEMENT

- The vaccine must be 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 ASN need, should be transported to each scheduled clinic.
- Record of the vaccine being transported should be tracked in order to maintain accountability for monthly reporting in EVI. This includes:
  - Vaccine type(s);
  - Quantity of each type;
  - NDC numbers;
  - Lot numbers; and
  - Expiration dates.
- 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 with a digital display and probe in buffered material. Temperatures during transport must be documented.
- Temperature form (EC-105) may be used to document hourly temperatures.
- Upon arrival at the mass vaccination clinic site, the ASN mass vaccination provider must ensure that the vaccine is stored properly 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.

- After each clinic day, the ASN mass vaccination provider must perform a physical count of the remaining vaccine and assess data 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 must be segregated in a vaccine quarantine bag and labeled “Do Not Use” until further information can be gathered from the manufacturer(s) on the viability of the vaccine. The vaccine should be kept at appropriate temperatures until the viability determination is made.

G. Routine and Emergency Storage and Handling Plans

All ASN providers must have plans for both routine and emergency vaccine management. The ASN Program provides templates for these plans within the Vaccine Management Plan. An ASN 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 ASN provider must develop routine and emergency vaccine management plans that include all of the information on the templates provided by the ASN Program.

The Routine Vaccine Storage and Handling Plan and Emergency Vaccine Storage and Handling Plan must be reviewed and updated annually by the ASN provider. 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 two responsible people to carry out the 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 ASN 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 ASN provider’s clinic, and can maintain the cold chain during any period when the ASN provider’s refrigerator or freezer is out of service.

3. Adequate supplies in amounts sufficient for packing and transporting the entire ASN vaccine inventory needs to 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 and list their contact person(s) and phone number(s) on the plan. A back-up location must be considered in case the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.
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All ASN providers will be asked to provide a copy of their Routine Vaccine Storage and Handling Plan and Emergency Vaccine Storage and Handling Plan at ASN Compliance Site Visits. The documents must be posted on or near the refrigerator or freezer containing the ASN vaccine. The ASN 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 for use in the event of emergencies that could result in the loss of vaccine.

All ASN 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 ASN Compliance Site Visits and Unannounced Storage and Handling Visits.

In the event of an emergency, an ASN provider must contact their responsible entity (DSHS HSR or LHD) immediately to inform them of the situation.

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

- The temperature of the vaccine;
- The amount of vaccine;
CHAPTER 3: VACCINE MANAGEMENT

- Expiration dates of the vaccine; and
- How long the vaccine was exposed to inappropriate temperatures.

The ASN provider will need to specify the following steps when transporting vaccine to the alternate location:

- Note the time of the emergency situation / power outage;
- Note 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 (i.e., 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, if applicable;
- 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 that the Emergency Vaccine Storage and Handling Plan is available for documenting this process.
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I. Cold Chain Management and Vaccine Transport

The ASN 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 ASN providers must identify sufficient alternative space to store ASN vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service. Adequate supplies for packing and transporting the entire ASN provider’s vaccine supply / inventory needs to 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 in an Emergency Situation_

**Assemble Packing Supplies**

CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls, Styrofoam vaccine shipping containers, or other qualified container may be used if it can maintain the recommended temperature range (between 36°F and 46°F). Label the container
with facility name and “Fragile Vaccines – Do Not Freeze” and the date and time the vaccine was removed from the permanent storage unit.

- Hard-sided coolers, Styrofoam vaccine shipping container, or other qualified container are required:
  - Coolers should be large enough to hold the ASN provider’s locations typical supply of refrigerated vaccines;
  - Original shipping boxes from the manufacturer can be used, if available; but
  - Do NOT use soft-sided collapsible coolers.
- Conditioned frozen water bottles are required:
  - Use 16.9 oz. bottles for medium / large coolers or 8 oz. bottles for small coolers;
  - DO NOT reuse coolant packs from original vaccine shipping containers, they may freeze vaccine; instead
  - Condition the frozen water bottles 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 surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated.
- Insulating material – Two of each layer is needed:
  - 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;
• 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; but

• Do NOT use packing peanuts or other lose material that may shift during transport.

• Temperature monitoring device – A digital data logger or calibrated, certified thermometer with a buffered probe should be used:
  • Data logger or thermometer must have a current and valid certificate of calibration;
  • Data logger or thermometer must be accurate within ±1°F (±0.5°C); and
  • If the probe can be separated from the back-up thermometer, it may be stored in the unit and kept “primed” and ready to use in case of emergency transport; or
  • The probe can be buffered by pre-chilling it in the refrigerator for at least five hours prior to transport.

**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 an inch of insulating material (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 temperature display outside the cooler;
• Add the remaining vaccine and diluents;
• Cover vaccines with another layer of insulating material;
• Add the second layer of corrugated cardboard; and
• Fill the remaining space in the cooler with conditioned water bottles.

Recording Temperature during Transport

• Close the lid of the cooler securely and attach the digital data logger or thermometer display and a temperature log to the top of the lid;
• Use the Temperature Recording Form to record the time, as well as the temperature inside of the storage unit at the time the vaccines are removed;
• Record the temperature of the transport container on the Temperature Recording Form. If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly; and
• As soon as the destination site is reached, check and record the vaccine temperature.
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If the vaccine is:

- Between 36˚F and 46˚F, place it in the refrigerator;
- Below 36˚F or above 46˚F, place the vaccine in a quarantine bag, place it in the refrigerator and immediately contact the vaccine manufacturer to determine viability; and
- Contact the responsible entity (DSHS HSR or LHD) immediately with the manufacturer’s viability determination.

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

Frozen Vaccine Transport in an Emergency Situation

Frozen vaccines are fragile! The CDC and the vaccine manufacturer do not recommend transporting frozen vaccines. 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.
- **Thermometer** – Use a certified, calibrated thermometer, or digital data logger with a current and valid certificate of
calibration. If the probe can be separated from the back-up thermometer, it may be stored in the unit and kept “primed” and ready to use in case of emergency transport. Otherwise, prepare the thermometer or 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 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, follow the packing instructions for transporting refrigerated vaccine, and in addition:

- Ensure that the water bottles used in the cooler are frozen;
- Place a calibrated data logger or thermometer in the container used for transport as close as possible to the vaccine;
• Use a Temperature Recording Form to record the time, as well as the 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;
• Continually monitor the vaccine temperature;
• 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 manufacturer for viability data and guidance when frozen vaccine has been exposed to a temperature above +5°F. Do not discard the vaccine without contacting the manufacturer. Store the vaccine appropriately until determination of viability; and
• Viability determination will be made on a case-by-case basis. Contact the responsible entity (DSHS HSR or LHD) with the viability determination from the manufacturer.
On the following pages, Figures 3-2 and 3-3, 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 manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

**Conditioned frozen water bottles**
- Use 150 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 inner 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 (±0.3°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 measure temperatures 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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Figure 3-3: Packing of Vaccine for Transport during Emergencies

2. **Pack for Transport**

- **Conditioning frozen water bottles**
  - Put frozen water bottles in a 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

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

To conduct a vaccine transfer, the ASN provider, or authorized designee, who is transferring the vaccine, must do the following:

- Ensure that the vaccine transfer is for one of the following required reasons:
  - Short dated vaccine;
  - Withdrawal, suspension or termination of ASN provider from the ASN Program; or
  - Other (emergency situations).

- Complete and sign the Vaccine Transfer Authorization Form and agree that the vaccine will be transported in accordance to ASN Vaccine Storage and Handling Guidelines to ensure the proper cold chain will be maintained throughout the transfer process.
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Each vaccine to be transferred must be listed on a separate line 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 Vaccine Transfer Authorization Form to their DSHS HSR and await for approval before moving the vaccine.

**Note:** For after hour emergency situations, ASN providers must call their DSHS HSR of the situation as soon as reasonably expected. A Vaccine Transfer Authorization Form is still required to be submitted but since it was an emergency situation, it may occur after the vaccine has been moved.

- Once the DSHS HSR approves the transfer (within two business days), a signed copy of the form will be faxed or emailed to the ASN provider requesting the transfer and the LHD (if applicable). Once the ASN provider receives the approval fax or email from the DSHS HSR, the ASN provider may conduct the transfer in EVI;
- Ensure that the vaccine is packaged using proper cold chain management, as detailed in Section V. Vaccine Storage and Handling, subsection I. Cold Chain Management and Vaccine Transport, and a certified, calibrated data logger or thermometer 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 ASN provider taking possession of the vaccine will attach the Temperature Recording Form from the transfer to their monthly Temperature Recording Form, ensuring the form states it is from the transferred vaccine.

The ASN provider taking possession of the vaccine must keep the Vaccine Transfer Authorization Form on file for a minimum of five years and it must be easily accessible.

VII. Vaccine Borrowing

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

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

All ASN providers are expected to maintain an adequate inventory of vaccine for both their ASN-eligible and insured patients. Vaccines supplied by the ASN Program cannot be provided to a non-ASN-eligible patient. Undocumented borrowing and administering of ASN
vaccines to a non-ASN patient is considered fraud. All ASN providers must not use ASN vaccines as a replacement system for filling the vaccine needs of a non-ASN insured patient.

If an ASN vaccine is accidently administered to a non-ASN-eligible client, the ASN provider must:

- Complete the Vaccine Borrowing Form (EF11-14171). Each vaccine that was administered to a non-ASN-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](http://www.dshs.texas.gov/immunize/tvfc/publications.aspx);

- Replace the vaccine immediately and account for the replacement in EVI; and

- Fax a copy of the Vaccine Borrowing Form to their responsible entity (DSHS HSR or LHD) within 24 hours of borrowing. Adherence to HIPAA guidelines is mandatory when faxing this form to the responsible entity.

The Vaccine Borrowing Form must be kept as part of the ASN Program records for a minimum of five years and be made easily available.

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

Continued non-compliance with ASN policies and procedures may be considered fraud and abuse. The ASN provider may be referred to the Office of Inspector General (OIG).

VIII. Reporting Requirements

The ASN Program requires ASN providers to monitor the temperatures of all refrigerators and freezers containing ASN vaccines and to submit reports to their responsible entity (DSHS HSR or LHD) utilizing ASN Program forms documenting vaccine inventory and usage.

All records related to the ASN Program are required to be maintained for five years and made easily accessible. These records include (but are not limited to):

- Monthly Biological Report (C-33) in EVI;
- Biological Order Form (EC-68-2) in EVI;
- Temperature Recording Form (EC-105); including
  - Refrigerator Fahrenheit (EC-105-RF);
  - Refrigerator Celsius (EC-105-RC);
  - Freezer Fahrenheit (EC-105-FF); and
  - Freezer Celsius (EC-105-FC).
- Any other reports or required documents.
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All forms are included in the ASN Provider Manual in the Forms section, as well as under Forms & Publications on the TVFC webpage at http://www.dshs.texas.gov/immunize/tvfc/publications.aspx.

A. Reports Summary

*Monthly Biological Report (C-33)*

The Monthly Biological Report is in EVI listing vaccine received, doses administered, vaccine transferred, vaccine loss, and physical count. The Tally and Physical Count report in EVI is used to help document vaccine management activities during the month.

ASN providers who participate in the TVFC Program are required to distinguish between their adult and pediatric vaccines and order and report ASN vaccines separately from pediatric vaccines.

For those providers with internet access, they must complete the Monthly Biological Report in EVI and submit it to their responsible entity (DSHS HSR or LHD) each month. Providers without internet access are required to complete a paper version of the Monthly Biological Report. The person completing the paper report must always sign and date the report and provide a telephone number where they can be reached. This is required in the event discrepancies are identified on the report and a follow-up phone call is needed.

*Biological Order Form (EC-68-2)*

This form is available from your responsible entity (DSHS HSR or LHD) and is used for initial orders or for 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 MSL. For orders above the MSL, an explanation is required in the comment section.

**Temperature Recording Form (EC-105)**

Completed Temperature Recording Forms for the previous month are to be submitted to the responsible entity (DSHS HSR or LHD). A Temperature Recording Form is to be maintained on all refrigerators and freezers that store ASN vaccine (including temporary day storage units). Providers may choose to use Fahrenheit (EC-105-RF and EC-105-FF) or Celsius (EC-105-RC and EC-105-FC) forms.

All ASN vaccines are required to be maintained at proper storage temperatures at all times. To ensure proper temperatures are maintained, the ASN Program requires providers to record refrigerator and / or freezer temperatures twice daily for all units that store ASN vaccine. The ASN 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 along with the time of the check, and the form must be initialed by the staff member conducting the check. All temperature excursions must be reported to the responsible entity (DSHS HSR or LHD) immediately and documented on the Troubleshooting Record (page 3 of the Temperature Recording Form). Instructions for completing the Temperature Recording Form are listed on the top of the form.
Providers must include the following information on the Troubleshooting Record:

- 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 (DSHS HSR or LHD) and the individual spoken to;
- Instructions or procedures given by the vaccine manufacturers, including case numbers and individuals spoken to; and
- The results.

All documentation regarding temperature excursions must be retained for review during the ASN Compliance Visits and Unannounced Storage and Handling Visits. An example of the Vaccine Storage Troubleshooting Record can be found in the Forms section of the ASN Provider Manual as page 3 of 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 (in EVI unless internet access is unavailable);
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- Temperature Recording Form;
- Biological Order Form (in EVI unless internet access is unavailable); and
- Any additional and/or associated forms as required by the responsible entity (DSHS HSR or LHD).

Monthly online vaccine management is required in EVI regardless of whether an order is submitted or not. ASN providers without internet access must submit the Monthly Biological Report each month to their responsible entity (DSHS HSR or LHD).

IX. Mobile Vaccination Clinics

An ASN provider may conduct off-site, mobile vaccination clinics using ASN vaccines. However, the ASN eligibility still needs to be determined through the use of the Adult Eligibility Screening Record for all patients that receive the ASN vaccines at each visit. Additionally, required vaccine storage and handling guidelines must be followed at all times and the vaccine must be returned to the original approved vaccine storage unit at the end of each day. Vaccines are extremely sensitive to temperature excursions. Any exposure to out-of-range temperatures could make the vaccine nonviable. For this reason, it is important to regularly monitor the temperature of the vaccines and take quick action when temperature excursions occur. Please refer to Chapter 3: Vaccine Management for specific information regarding the transporting of vaccines for Mass Vaccination Clinics and handling temperature excursions.
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X. Advertisement of ASN Vaccine by Provider

All ASN providers may advertise and promote the availability of ASN vaccines to eligible patients.