SECTION 4 - VACCINE MANAGEMENT AND ACCOUNTABILITY

Training Your Personnel

Each provider must designate a primary and a back-up vaccine contact person responsible for all aspects of vaccine management. Both contact persons must be fully trained in routine and emergency procedures related to vaccine ordering, receiving, storage and handling, transferring/transporting vaccines and inventory management.

All office staff (i.e., receptionists, mail handlers, nurses, medical assistants) who accept vaccine shipments or administer vaccines must be trained on vaccine management procedures. Providers are responsible for appropriately training staff on recommended vaccine storage and handling of vaccines, as well as maintaining the vaccine cold chain.

The primary and backup vaccine contact persons are responsible for:

- Ensuring that the Vaccines for Children Program Provider Handbook and related immunization materials are current and accessible to all staff.

- Ordering, receiving and storing vaccine shipments in accordance with recommended procedures.

- Monitoring vaccine expiration dates, rotating vaccine inventory with the shortest expiration date in front, notifying the DOH regarding any short dated vaccines and removing expired vaccines from the viable vaccines storage units.

- Notifying the DOH immediately regarding any vaccine storage and handling problems.

- Proper online ordering instructions or for those providers without internet access completing and submitting the Pennsylvania Department of Health Supplied Vaccine Order, Inventory & Accountability Form.

- Identifying and separating VFC vaccines from privately purchased vaccines.

- Responding to storage temperatures outside the manufacturer's recommended range and completing and submitting the "Vaccine Incident Report and Worksheet" (Section 6 – Forms) within five days of the incident.

- Recording refrigerator/freezer temperatures twice daily (A.M. and P.M.) on a department supplied temperature log with your PIN number preprinted on it. See Section 6 – Forms for additional blank forms, if needed, and retain the temperature logs for three years.

- Recording on the temperature log actions taken for out-of-range temperatures.

- For temperatures that remain out of range for more than 30 minutes, complete a Vaccine Incident Report and Vaccine Worksheet and submit to DOH within five days of the incident.

- Developing and maintaining a maintenance schedule for storage and handling equipment used to house DOH provided vaccines.

- Submitting a copy of the Vaccine Return and Accountability Form to request return label.

- Transporting vaccine to other locations using procedures pre-approved by DOH to maintain the vaccine cold chain (located in Section 6).

- Training all staff on the proper protocols for receiving vaccine shipments in the absence of the primary and back-up vaccine contact persons.

The Vaccine Management Plan and Designated Responsible Staff form, located in section 6 of this handbook is required by the CDC to be updated annually for participation in the VFC Program . It provides direction for vaccine management which includes designating staff responsible for ensuring that proper vaccine receiving, ordering, inventory control, storage and handling procedures are in place. It must contain current information and must be reviewed and updated annually. It must be available for review upon request of the VFC Program staff.

Maintaining Temperatures and the Cold Chain

- Maintain proper temperature for vaccine storage (Conversion Chart, Section 6).
    - **Refrigerator: 35° to 46° Fahrenheit / 2° to 8° Celsius Average 40° Fahrenheit (5° Celsius)**
    - **Freezer: - 58° to 5° Fahrenheit /-50° to -15° Celsius**
- Ensure working thermometers are used inside both refrigerators and freezers. NIST certified thermometers, calibrated per manufacturer's recommendations are required for vaccine storage. Thermometers should be placed in the center of each compartment.
- Manually check and document temperatures twice a day on the temperature log regardless of whether a continuous reading or alarmed units are in use. Daily documentation should include the time when temperatures were checked and initials of staff checking the temperatures.
- If vaccine temperatures are out of recommended ranges for less than 30 minutes during temperature logging, take immediate action to correct the problem and document the action taken on the temperature log or attach an explanation of action taken.
- If vaccine temperatures are out of recommended ranges for more than 30 minutes the vaccine manufacturers must be called. Complete and submit the Vaccine Incident Report and Worksheet (section 6) within 5 days of incident.
- Indicate on your log or attach an explanation for times the office may be closed for vacations and assure a back up vaccine monitoring plan is in place to cover during these times

Setting Up Your Refrigerator

- Obtain one week of in-range temperatures before using the unit.

- Ensure that refrigerator doors close properly and that the unit is level and in good working order. Notify the designated vaccine contact person immediately if problems occur.

- Never store vaccines in the door, crisper bins, on the bottom of the storage unit, near the outlet valve or in closed containers.

- Conduct monthly inventories and order according to Economic Order Quantity (EOQ) instructions.

- Advise maintenance and cleaning personnel not to unplug storage units. Post "Do Not Unplug" stickers near the outlet.

Temperature Logs

Temperature logs are required by every provider. Temperatures are to be checked twice daily and recorded on the department- supplied temperature log with your PIN preprinted on it. Temperature logs are to be retained at the provider site for three years and available upon request for review by PA VFC staff.

Key points to remember when completing your monthly temperature log:

- Log time and place initials of the person checking the temperatures. The CDC requires close attention and accountability for proper vaccine storage and handling. If your office is going to be closed for a period of time other than holidays or weekends, the vaccine should be moved to your alternate delivery site where the vaccines can be monitored. If this cannot or has not been done, the manufacturers must be contacted to ascertain the vaccine viability during those periods when temperatures were not taken. If the manufacturer says the vaccine is ok during this period or if the doctor feels the vaccine is safe to use and is accepting responsibility for the use of this vaccine, then these comments must be documented on the temperature log or sent to the VFC program in writing. If it is determined that the vaccine must be wasted, then an Incident Report & Worksheet, found in Section 6 of this handbook, must be completed and sent to the VFC program.

- If a temperature is out of range for less than 30 minutes, note any adjustments done by site staff in the margin of the temperature log form.

- For temperatures that remain out of range for more than 30 minutes, must notify the vaccine manufacturer immediately and complete a Vaccine Incident Report and Worksheet and submit to DOH within five days of the incident.

Instructions for Completing a Temperature Log

1. *Month/Year* **-** Please indicate the month and year that the data was entered. On non-business days, such as Sundays, indicate that the office was closed.

2. *PIN Number* **-** Please indicate your provider identifier number. An identifier number is assigned by the PA VFC Program and used on temperature logs, vaccine orders, phone inquiries and all VFC interactions.

3. *Day of Month* - the numeric day of the month that the temperature was recorded from the refrigerator(s) and freezer(s) where vaccines are stored. Begin completing the temperature log the first day of the month.

4. *Time* -Please indicate the time the temperature was checked and recorded. Temperatures from refrigerator(s) and freezer(s) where vaccines are stored should be checked and recorded once in the a.m. and once in the p.m.

5. *Staff Initials*- Note that the initials of the staff person that checked and recorded temperature(s) must be provided.

6. *Record Temperature* **-**Please place an "x" in the box that indicates the refrigerator(s) and/or freezer(s) current temperature.

Documented temperatures must be continuously within the following acceptable ranges:

- Acceptable refrigerator compartment temperature range:
  35° to 46° Fahrenheit /2° to 8° Celsius
  Average 40° Fahrenheit / 5° Celsius

- Acceptable freezer compartment temperature range:
  - 58° to 5° Fahrenheit / -50° to -15° Celsius

If recorded temperatures are not within acceptable ranges and placed in the gray areas indicated by “Too Warm” or “Too Cold” on the temperature log:

1. Complete the Incident Report and Worksheet located in Section 6 of your VFC Provider Handbook.

2. Document corrective action taken on the temperature log and recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable ranges. If there is not enough space on the temperature log to document corrective action taken, please write action taken on a separate sheet of paper and attach to temperature log. Retain for three years.

3. Call the PA Immunization Program at (888) 646-6864 for questions or assistance.

Ordering Vaccine

Before ordering vaccine, you must take an inventory of what you currently have. Taking inventory at least once a month will help you decide how much vaccine to order in the future.

- Order online through PASIIS. Those providers without internet access may fax the order form.

- Vaccine should be ordered based on your EOQ schedule.

- Vaccine should arrive within 30 days after ordering. Shipments are delivered through McKesson Specialty Distribution Center Tuesday through Friday via express carrier. Varicella and MMR-V- (if available) are shipped directly from the manufacturer.

- Always tell your front-office staff or supply personnel when a vaccine delivery is expected and ask them to notify the appropriate staff when it is received.

- If you have problems or need help ordering vaccine, call the VFC toll-free line 888-646-6864.

Receiving Your Vaccines

Most vaccine orders submitted to the DOH are processed and shipped within five to 10 business days. However, providers should allow 30 days for delivery and should maintain a 30-day inventory to allow for processing delays. **If your office closes unexpectedly and a vaccine shipment is expected, you must contact the DOH regarding the shipping status of the vaccine order. If the vaccine order is in the shipping process (on the delivery truck), it is the responsibility of the provider to ensure that arrangements have been made for staff to be available to receive and properly store the vaccines. Alternate delivery site instructions are clearly posted.** PA-SIIS staff will notify online participating providers when to expect their shipment.

When the vaccine shipment is received:

- Upon delivery, open the box immediately and inspect the contents for any potential damage that may have occurred during shipment. **If** the shipment cannot be opened and inspected immediately, place the entire contents into a plastic bag and place the bag into proper storage (i.e., refrigerator or freezer).

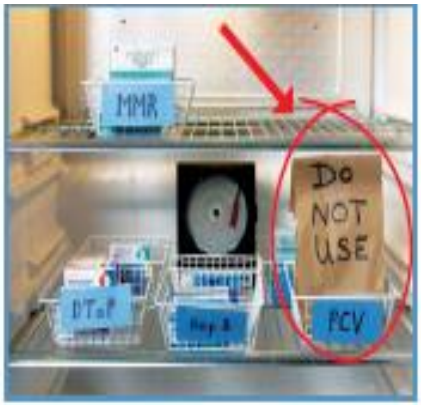
McKesson shipping package

Varicella shipping package

- Allow sufficient time to properly unpack the vaccine, review the shipping invoice and inspect the shipment.

- Evaluate the condition of the vaccines and ensure the vaccines are cool to the touch. If the color is odd, the package is damaged or the vaccine seems warm, designate as “DO NOT USE” and properly store the

vaccine until a determination has been made on the viability of the vaccine. **<u>Do not leave the vaccine out and assume it is not viable.</u>** It may still be viable and simply differ from your previous experience with vaccine. Contact the vaccine manufacturer for further instructions. Complete a Vaccine Incident Report and Worksheet form and Vaccine Return form, if necessary, found in section 6 of the PA VFC provider handbook. Fax forms to the PA VFC program (717)-214-7223.



WHAT'S WHERE IN THE VARICELLA/PROQUAD/ZOSTER SHIPMENTS

MERCK'S DIRECT SHIP SHIPPING CARTON

1) **DILUENT** is packaged in the **LID** of the upper compartment of the shipping container.

2) **VACCINE** is in the **LOWER COMPARTMENT** of the shipping container.

NOTE: IMPORTANT INFORMATION REGARDING CHANGE IN SHIPPING PACKAGING FOR VARIVAX (VARICELLA) VACCINE AT THE END OF THIS SECTION.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately mark the vaccine and diluent as "DO NOT USE" and store them under the proper conditions. Contact the DOH for further instructions.

- Check the contents of the shipment against the shipping invoice.

- Compare quantities, lot numbers and expiration dates carefully. Immediately advise the DOH the same day or next business day regarding any discrepancies between the contents and the shipping invoice. PA-SIIS participating providers should also compare the quantity, lot numbers and expiration dates with the data in the PA-SIIS.

- Check the temperature indicator (CFreezemarker) enclosed in the shipment to determine if the vaccines were exposed to temperatures outside of the proper range for storage and handling and immediately notify McKesson Specialty Customer Care directly at 877-TEMP123 (877-836-7123).

- If the bulb is clear and colorless, as shown here, store the vaccines as instructed and begin use.

- If the bulb is violet in color, as shown below, store the vaccines as instructed and call 877-TEMP123 (877-836-7123) or your state/local immunization program right away for further instruction before using.

Coldmark Freeze Indicator decision table:

Bulb Color	Vaccine type	
	MMR, ActHIB, LAIV	All other vaccine
Clear and colorless	Ready for use	
Violet	Ready for use	Call 877-836-7123 or your state/local immunization program right away.

NOTE: If there is any question about the vaccine, place a thermometer in the shipment container, properly store the vaccine and check the temperature after 30 minutes. Any vaccine in question should be marked "DO NOT USE" and placed in the required storage conditions until viability is determined.

- Re-check the shipping carton and packing materials to ensure that all vaccines have been removed from the carton.

- Properly distinguish DOH-provided vaccines from privately-purchased vaccines by using color labels (i.e., blue for DOH vaccines, green for private, dollar sign for private, etc.) or storing in a separate storage unit.

Storing Vaccines Properly

Proper storage and handling of vaccine is important not only for the shelf life and effectiveness of a vaccine, but for the safety of the person receiving the vaccine as well. Vaccines must be properly stored in combination refrigerator/freezer units with separate doors or stand-alone units to ensure maximum potency and safety. Each unit must have a National Institute of Standards and Technology (NIST)-certified calibrated thermometer. Dormitory-style refrigerators are **NOT** acceptable for vaccine storage. Any site using a dormitory style storage unit for DOH supplied vaccines will be suspended immediately from ordering vaccines.

SUITABLE STORAGE UNITS

Freezerless

Dual-zone *

Under-the-Counter

Full-sized

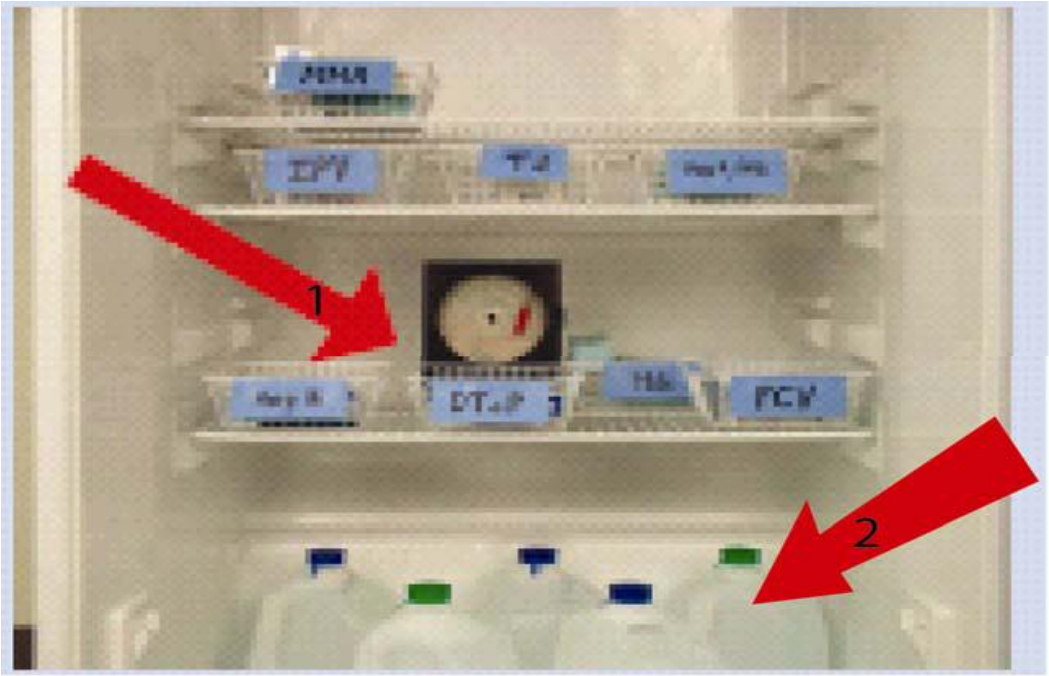
*** Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment**

Vaccine storage units must:

- Be able to maintain required vaccine storage temperatures year-round (refrigerator: 35°F to 46°F /2°C to 8°C and freezer: -58°F to 5°F/-50°C to -15°C).
- Be large enough to hold the year's largest inventory.
- Be defrosted on a routine basis if freezer unit is not self-defrosting.
- Be cleaned every month to discourage bacterial and fungal growth.
- Be placed in a well-ventilated room with sufficient space (at least 4 inches) around the sides and top for air circulation.
- Have a NIST-certified calibrated thermometer placed in the middle of each storage compartment. **NOTE**: There is a list of thermometer manufacturers in Section 7.

PROPER THERMOMETER PLACEMENT

Fluid-filled bio-safe liquid in freezer | **Minimum/maximum thermometer in freezer**



1. **Chart recorder in refrigerator**
2. **Add bottles of water**

- Be dedicated to the storage of vaccines. Food and beverages **MUST NOT** be stored in a vaccine storage unit, because this practice results in frequent opening of the door and destabilization of the temperature.

If possible, other medications and other biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines if the other products spill and reduces the likelihood of medication errors.

Never store food or beverages inside the vaccine refrigerator or freezer.

- Have a safety-lock plug or “DO NOT UNPLUG” sign at the unit.
- Have a “DO NOT DISCONNECT” sign at the breaker box.

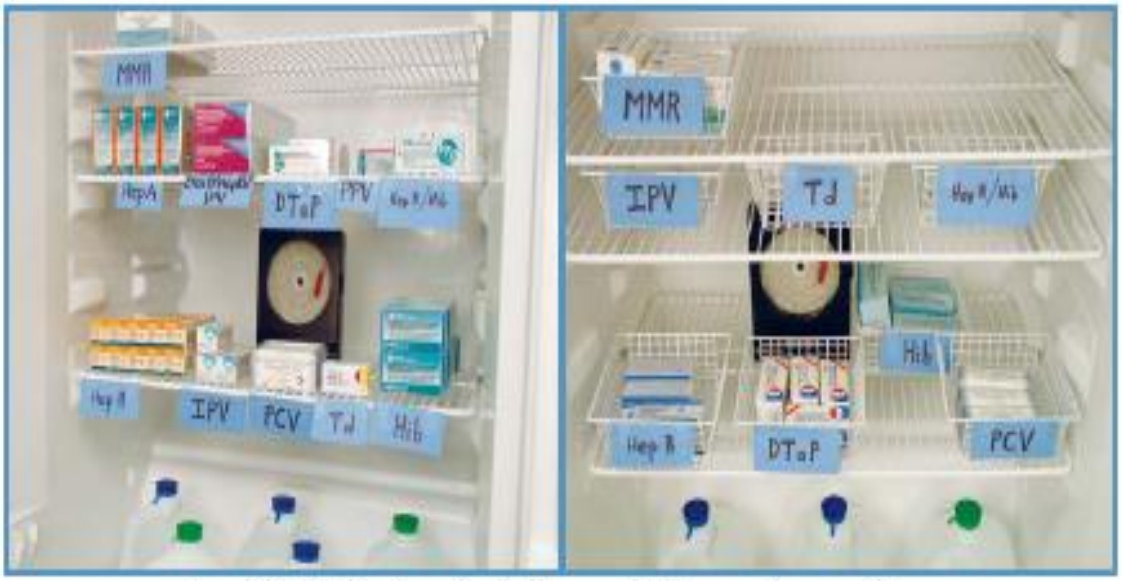
Safety-lock plug

Use outlet covers. Post warning signs and labels.

Do not use power outlets with built-in circuit switches and outlets that can be activated by a wall switch.

Vaccines must be:

- Stored in their own specifically labeled section of the unit.



Attach labels directly to the shelves on which the vaccines are sitting and label the trays or containers according to the vaccines they contain.

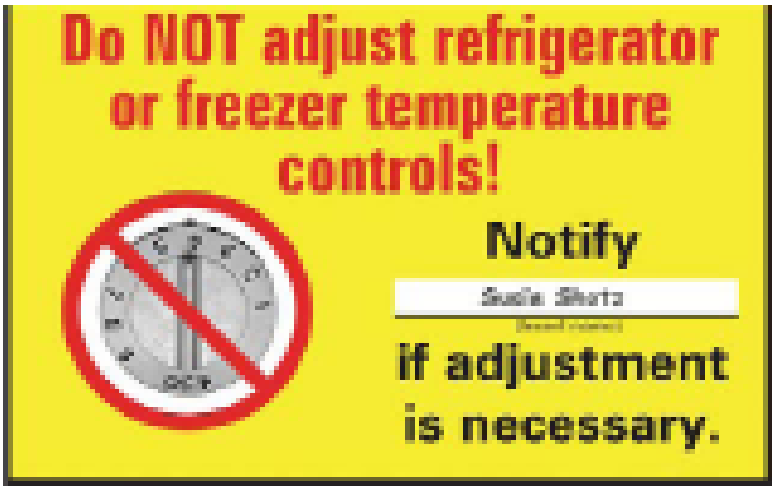
- Stored away from cold air vents and coils.
- Stored with space between to allow circulation.
- Stored with the shortest expiration date in front.
- Stored in different locations in the unit to avoid errors if packaging is similar.

Vaccine Accountability

The DOH must account for all vaccines. This accountability is achieved through:

- Limiting access to authorized personnel only.
- Tracking doses administered (in SIIS or manually).
- Reporting expired/wasted vaccines.

- Rotating inventory according to expiration date.
- Adhering to the manufacturer's recommended storage and handling.
- Administering vaccine properly (injection site, recommended schedule, etc).
- Limiting thermostat adjustments to the primary and back-up vaccine contact persons.



A warning sign must be posted on the storage unit.

- Monitoring and recording temperatures twice daily (a.m. and p.m.).
- Arranging transfer of excessive vaccine inventory.
- Transferring short-dated vaccines.

Please note the current transport policy for both frozen and refrigerated vaccine is located in Section 6. The following attachments should be reviewed

- Transporting Vaccines
- Transporting Frozen Vaccines by Necessity
- Vaccine Hourly Monitoring Report

Place in insulated containers. **Use refrigerated or frozen cold packs.**

When transporting/transferring vaccines in ordinary vehicles, use the passenger compartment – NOT the trunk.

Over-ordering, failure to rotate inventory, and failure to properly receive, store or transfer vaccines could result in loss of vaccines. In addition, vaccine stored "out of range" of the recommended temperature is much more costly if there needs to be patient recall because the vaccine was not viable.

Maintaining Your Inventory

The CDC **strongly discourages the transport of varicella-containing vaccines**. All varicella containing vaccines are fragile. If these vaccines must be transported, the manufacturer must be contacted to ascertain whether or not the vaccine is acceptable for use.

Occasionally, clinics have more vaccine than they can use before it expires. In these situations, transferring vaccine to another clinic to use is a good option. PLEASE NOTE: The transferring site is responsible for ensuring the vaccine is properly shipped or transferred and will be held responsible until the vaccine is appropriately and safely accepted by the receiving facility.

- Store and rotate vaccines according to expiration dates. Use vaccines with the shortest expiration dates first.

- Identify any vaccines that will **expire** within **90 days.** Contact your immunization nurse consultant for assistance.

- If vaccines are within 90 days of expiration and cannot be used, they may be transferred to a participating Vaccines for Children provider. Contact your QA Immunization Nurse Consultant to properly coordinate such transfers.

- The QA Immunization Nursing Consultant can assist you in finding a clinic to take the short-dated vaccine.

Expired and Wasted Vaccines

Unopened vials of all expired/wasted vaccines, including influenza vaccine, must be returned to McKesson Specialty Distribution within six months after the expiration date. Diluent is not a vaccine and does not need to be returned. Providers do not need to return the empty boxes to McKesson Specialty Distribution and may keep or dispose of the boxes. When nonviable product needs to be returned to McKesson Specialty Distribution, the provider should complete and fax the "Vaccine Return Form" to (717) 214-7223 attention: Vaccine Management and a UPS label will be sent to your facility; allow 7 to 10 business days to receive the UPS label from McKesson. A copy of the completed Vaccine Return Form must be included with the returned vaccines. The Vaccine Return and Accountability Form is found in Section 6 of this handbook.

The VFC program staff will contact McKesson and ask them to send a return label to the provider via the U.S. Postal Service. If the provider has a regularly scheduled UPS pick up at their facility, they may hand the labeled box of wasted/expired vaccine to the UPS driver. If no scheduled stops with UPS, contact the VFC program staff to coordinate the pick-up service.

If vaccines are wasted as a result of a power outage, failure to properly store, temperatures out of range, etc., the Vaccine Incident Report and Worksheet form (Section 6 – Forms) must be completed and forwarded to the DOH by fax or email within five days following the incident. Failure to complete these forms will result in immediate suspension of vaccine ordering.

Vaccine Borrowing

Two-directional borrowing between VFC and private-stock vaccine must be documented on the VFC Vaccine Borrowing Report (Section 6). The VFC Vaccine Borrowing Report must be completed and kept at the provider site for review by the QA Immunization Nursing Consultant during VFC site visits. Borrowing should only occur when there is a lack of appropriate stock vaccine (VFC or provider purchased) due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider or new staff who calculated ordering time incorrectly. The reason cannot be provider-planned borrowing from either the private stock or the VFC stock. VFC providers who are suspended from ordering vaccine may not borrow vaccine to compensate vaccine inventory.

Vaccine Adverse Event Reporting System (VAERS)

The National Vaccine Injury Compensation Program (VICP) is a federal “no-fault” system designed to compensate individuals or families of individuals who have been injured by childhood vaccines administered by private or public providers. VAERS, operated by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), must be notified of any vaccine-related adverse event by completing a VAERS reporting form (Section 6 – Forms). Reporting an adverse advent to VAERS does not initiate a claim for compensations; a petition must be filed with VICP to start a claim for compensation.

IMPORTANT INFORMATION REGARDING CHANGE IN SHIPPING PACKAGING FOR VARIVAX® (Varicella Virus Vaccine Live) and ZOSTAVAX® (Zoster Vaccine Live)

Merck has replaced the use of dry ice with frozen gel packs in the shipping packages for VARIVAX and ZOSTAVAX.

The receiver must immediately open the container and store the vaccine in a freezer.

VARIVAX and ZOSTAVAX are packed with frozen gel packs in the shipping container. Upon delivery, the gel packs should feel cold and may be pliable to the touch. The quantity of gel packs placed in the container is based on carefully determined guidelines. These Merck guidelines take into account the maximum temperature to which the container will be exposed, the time in transit, and the need to keep the vaccine at the appropriate temperature during shipping. The product shipped with the gel packs may not be as cold as product previously shipped with dry ice.

An adequate number of gel packs were placed in this shipping container to maintain proper temperatures for THREE (3) DAYS from the shipment date located on the packing list.

If the container is received after the time period described above, contact the Merck Order Management Center immediately for replacement instructions at **1-800-MERCK-RX (1-800-637-2579).** Such requests for replacement must be received by Merck within 15 days of the original shipment.

• The vaccine is located in the lower compartment – **Store the vaccine in the FREEZER immediately.** Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains a temperature between –58°F and +5°F (–50°C to –15°C) is acceptable.

• Merck does not recommend reuse of our shipping materials, including gel packs and shipping containers, to further transport vaccine products as improper re-packaging and transportation could impact the stability of the vaccine.

• The gel packs contain water-based non-toxic gel. Please dispose of these packs with regular trash.

Store the diluent (located in the top compartment underneath the cardboard cap) in a refrigerator [36°F to 46°F (2°C to 8°C)] or at room temperature [68°F to 77°F (20°C to 25°C)].