Indiana Department of Health

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Title: Storage and Handling-Vaccine Management	**Policy #**: IDOH Immunization Division Policy 7
Effective dates: 01-Jan-25 to 31-Dec-25	**Approvals**: Dave McCormick Dave McCormick, Immunization Director January 1, 2025 Date

Policy Statement

All Vaccines for Children (VFC) providers must comply with the program requirements for vaccine management, including the storage of vaccine under proper conditions, at all times. Routine and emergency vaccine storage and handling plans should be developed and maintained to provide guidance for daily activities, such as ordering and accepting vaccine deliveries, managing inventory, and managing potentially compromised vaccines.

In addition, vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are changes to the storage and handling guidelines for a particular vaccine. The Indiana Immunization Division offers training on vaccine-specific topics for all facilities. *The vaccine management plan as well as the Immunization Division policies and procedures should be available in writing as a reference for all staff members.*

Privately purchased vaccines should be kept separate from publicly funded vaccines, and clearly marked. In addition, all vaccines from different funding sources (VFC, Adult 317, COVID-19 Bridge Access Program) should be kept separate and clearly marked.

Vaccine Ordering and Inventory Control

Vaccine coordinators should order vaccines to maintain an adequate amount to meet the

needs of the facility's patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly. Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves.

A vaccine inventory should be conducted at least monthly to ensure adequate supply to meet demand. Vaccine diluents should also be included in the inventory to ensure adequate supplies are available. Determining factors for the amount of vaccine and diluent ordered include projected demand, storage capacity and current vaccine supply. It is also important to avoid overstocking vaccine supplies which could lead to vaccine wastage or having outdated vaccine on hand. Providers can order every month, so only a four to six-week supply is needed unless a peak period is anticipated.

Vaccine Inventory Management

- Vaccine and diluent expiration dates should be closely monitored
    - Expired vaccine and diluent should never be used and should be promptly removed from the storage unit
- Rotate stock so that vaccine and diluent with the shortest expiration date are used first to avoid waste from expiration
- If the date on the label has a specific month, day, and year (mm/dd/yyyy), the vaccine can be used through the end of that day
- If the expiration date on the label is a month and year (mm/yyyy), the vaccine can be used through the end of that month
- **Opened vials of multi-dose vaccines should NOT be wasted before the manufacturer's expiration date.** Multi-dose vials of vaccines have different storage and handling requirements than multi-dose vials of medications.
    - **Multi-dose vials should not be discarded 28 or 30 days after opening.** Providers who discard open multi-dose vials after 28 or 30 days may be required to replace the wasted vaccines, according to the vaccine loss and replacement policy. Some flu vaccines should be disposed after 28 days; information will be provided each flu season.
    - A multi-dose vial is intended only for the number of doses indicated in the manufacturers insert and should not be punctured more than the indicated times
    - Use tick marks on the box to ensure only 10 doses are used
- Mark reconstituted vaccine with the date and time it is reconstituted. The expiration date or time might change once the vaccine is opened or reconstituted. This information is

provided in the manufacturer's product information.

- **Keep vaccines in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type.** This prevents exposure to light and prevents mixing of lot numbers and expiration dates. Exposure to light can reduce the potency of vaccines.

Managing Potentially Compromised Vaccines

If vaccine and/or diluent has expired or has been exposed to a temperature excursion, the Vaccine Coordinator should identify and isolate all potentially compromised vaccines and store separately in an alternate storage unit within the recommended temperature range. Label these as "DO NOT USE".

Contact the vaccine manufacturers and then the Immunization Division for appropriate actions that should be followed for all potentially compromised vaccines and diluents. Notify your regional quality assurance specialist as to whether vaccines are determined viable or nonviable.

Educate all staff on correct handling and preparation procedures to decrease the likelihood of vaccines and diluents inadvertently being compromised.

Receiving and Unpacking Vaccine Shipments

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be informed of who to notify when a vaccine delivery has arrived. Educate all facility staff about proper vaccine storage.

- This is extremely important for receptionists or other front desk staff since they are often the first to know that vaccines have been delivered

Orders should also be received in the Vaccine Ordering Management System (VOMS) as soon as the shipment arrives to ensure proper inventory management. **Providers should not manually enter inventory in VOMS when receiving an order.** Failure to follow procedures for receiving vaccine orders may result in providers having large discrepancies in vaccine inventory and may result in a hold on future ordering. Lot information will be uploaded to VOMS by 10 a.m. EST. If that information is not available after that time, please contact IDOH.

NEVER refuse a vaccine shipment of publicly funded vaccine. If there is a problem with the shipment, place the vaccine in the appropriate storage unit and contact the Immunization Division immediately.

Vaccine shipments should be inspected on arrival, and the vaccines should be stored at proper temperatures, IMMEDIATELY.

- The shipping container and its contents should be examined for any evidence of damage during transport
- Both heat and cold temperature monitors/indicators should be checked upon delivery. Follow instructions on the monitors for reading and reporting.
    - If a monitor indicates possible adverse temperature excursion during shipping, the monitor reading should be documented for future reference and reported to the Immunization Division **within two hours of receipt of the shipment**
    - Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors
- Determine the length of time the vaccine was in transit by looking at the packing list
    - If the interval between shipment from the distributor and arrival of the product at the facility was more than 48 hours, this could mean the vaccine has been exposed to excessive heat or cold that might alter its integrity
- The contents should be cross checked with the packing slip to be sure they match
- Diluents should be stored according to the manufacturers' instructions. Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the packages of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This reduces confusion and helps to ensure that you use only the specific diluent provided by the manufacturer for each type of lyophilized (freeze-dried) vaccine.
- Immediately store at the appropriate temperatures

If there are any discrepancies with the packing slip or concerns about the vaccine shipment, the vaccines should be stored in proper conditions, but segregated and marked "DO NOT USE" until the integrity of the vaccines is determined. Any discrepancies or concerns should be reported to the Indiana Immunization Division at 800-701-0704 within two hours of receipt of shipment.

Receiving Direct Ship Vaccines

All varicella-containing vaccine containing varicella are shipped separately from other vaccines and are shipped directly from the manufacturer, Merck. The vaccine shipping containers are

packed according to Merck guidelines that take into account the maximum temperature the container will be exposed to, the time in transit, and the need to keep the vaccine at the appropriate temperature during shipping.

- Varicella-containing vaccine should be stored at proper temperatures IMMEDIATELY upon arrival
    - To maintain potency the vaccine must be stored frozen between -58°F and +5°F (-50°C to -15°C)
    - The manufacturer recommends that the vaccine NOT be stored on dry ice. Use of dry ice may subject the product to temperatures colder than -58°F (-50°C).
- Varicella-containing vaccine shipments should be inspected on arrival
    - The shipping container and its contents should be examined for any evidence of damage during transport
    - Determine the length of time the vaccine was in transit by looking at the packing list
    - Adequate refrigerant (frozen gel packs) is included to maintain proper temperatures for three days from the shipment date located on the packing slip. If the container is received after this time, contact Merck Order Management Center immediately for replacement instructions at 800-637-2579. The Immunization Division should also be contacted in this event.
- Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors
- Invoice and packing slips are separate from product
- Diluent is conveniently located in the top compartment of the shipping box underneath the cardboard cap. Store the diluent upon arrival in a refrigerator (2°C to 8°C/36°F to 46°F) or at room temperature (20°C to 25°C/68°F to 77°F).

Legal Authorities and References

Centers for Disease Control and Prevention (CDC). (2018) Vaccine Storage and Handling Toolkit, Revised January 2023. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Centers for Disease Control and Prevention. (13th Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised May 2021. Available at: http://www.cdc.gov/vaccines/pubs/pinkbook/index.html