WEST VIRGINIA DIVISION OF IMMUNIZATION SERVICES

Vaccine management: Storage & Handling Plan

Office/Clinic _____ VFC PIN _____

Directions:

- **The primary person in charge of vaccines should review and complete this document annually.**
- **All staff handling vaccines at this practice must adhere to the protocols described in this document and must review it annually.**
- **This document should be maintained at a location accessible to all staff handling vaccines and close to the vaccine storage unit.**

Designation of Vaccine Personnel:

Name of the primary vaccine storage coordinator _____
Name of the back-up vaccine storage coordinator _____

Both coordinators named above must be knowledgeable and able to perform the responsibilities of vaccine storage coordinator to assure vaccine stability and prevent wastage of vaccines. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office.

- The designated vaccine coordinator and backup must be responsible for reviewing vaccine storage unit temperatures to ensure they are within the recommended ranges and documenting the temperature on the temperature logs for each storage unit twice a day.
- Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training must be kept and displayed as documentation.
- Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contact for the office.

Storage and Handling Plans:

Routine vaccine storage and handling plans.

1. Inspect and document vaccine shipments.

- Ensure that vaccines are delivered during office hours
- Store vaccines at the recommended temperatures IMMEDIATELY upon arrival
- Examine the vaccines on arrival:
    1. Check package contents with packing slip.
    2. Check enclosed refrigerator & freezer temperature indicators.
    3. Check shipment date; interval between shipment date and arrival at your office should be no more than 48 hours.
- If you have any questions about whether any vaccines have been transported properly, contact:
    1. The vaccine manufacturers (privately purchased vaccine).
    2. The Division of Immunization Services (DIS) at 800-642-3634 (VFC vaccine).

2. Monitor and document vaccine storage and handling every day.

- Make sure you have certified digital data loggers (DDL) that have not expired in both the refrigerator and freezer. Keep certificates of calibration.

1. **Refrigerator** temperatures should be between **36°- 46° F (2°-8° C).**
2. **Freezer** temperature should be **between -58°F and +5°F [between -50°C and -15°C] at all times.**

- Check refrigerator and freezer temperatures **twice a day:**
  1. when the clinic opens.
  2. before the clinic closes.
- Document temperatures in both the refrigerator and freezer on a temperature log. Post the temperature logs and guidelines for storage and handling on the refrigerator. Document changes on the 2nd page of the temperature log in the comment section.
- Keep vaccines in the original box until time to use it:
  1. Exposure to light may affect the potency of vaccines.
  2. Decreases the potential for medication errors.
- Clearly label each vaccine stored VFC/CHIP or private vaccine.
- Check expiration dates monthly. Rotate vaccine stock so the oldest vaccine is used first.

Emergency plan for maintaining vaccine in the event of a power failure or mechanical difficulty.

(Use the Division of Immunization Services "Vaccine Storage & Handling Emergency Protocol Template", complete page 6 or develop your own):

- Designate personnel who have 24-hour access to location where the vaccines are stored.
- Set up a system to notify designated personnel during power outages.
- Identify steps to assure proper storage and handling of vaccines during an emergency.
- Identify an alternate power source (generator) if your clinic does not have one or alternate storage units or facilities (nearby hospital, pharmacy, other provider's office.) Identify procedures that allow access to alternate facilities.
- Keep a cooler in the office; place a copy of the Emergency Response Plan Worksheet in the cooler.
- Follow and complete the Emergency Response Plan and Worksheet.
- DO NOT automatically discard the vaccine that has been compromised.
- Mark exposed vaccine and store separately from undamaged vaccines; storing appropriately in a refrigerator/freezer.
- Call vaccine manufacturers and/or *Division of Immunization Services* at 800-642-3634 for further instructions.

COMMUNICATE YOUR VACCINE MANAGEMENT PLAN TO ALL STAFF.

Additional instructions:

- In any type of power outage:
  1. Freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternative storage location.
  2. Temperatures and duration of power outage must be monitored; vaccine should not be discarded or administered until the situation has been discussed with public health authorities.
- At a minimum, the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff that have responsibilities specified in the emergency plan.

Vaccine Storage Equipment

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. Two types of storage units are acceptable (Please indicate the type of storage unit(s) available in your practice.

- A refrigerator that has a separate freezer compartment with a separate exterior door, and separate thermostat. The CDC recommends using only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines. A separate stand-alone freezer should then be used to store frozen vaccines.
- Stand-alone refrigerator (without a freezer compartment), single-purpose refrigerators.
- Stand-alone freezer, single-purpose freezers.

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year's largest inventory;
- Have a working DDL calibrated and certified to monitor vaccines in both the refrigerator and the freezer.
- 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.)

A dormitory-style refrigerator (a small combination refrigerator-freezer unit outfitted with a single external door) is never acceptable for storage of any VFC vaccines.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the provider/clinic vaccine coordinator or the vaccine coordinator's back-up. If delegated to the back-up, the designated vaccine coordinator must monitor these activities regularly.

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine.
- Notify the VFC Program of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the VFC Program and only if the cold chain can be ensured, redistribute short dated vaccines to high-volume providers who are able to administer it before it expires.
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Store vaccine with enough space to allow for cold air circulation around the vaccine.
- Never store vaccines in the door of the storage unit.
- Never store food or drink in the storage unit.

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the provider/clinic vaccine coordinator and backup. If other staff must monitor temperatures, those persons must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Post a temperature log on the vaccine storage unit door or nearby in a readily accessible and visible location.
- Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 36° and 46° F (2° and 8°C) and the freezer temperatures are **between -58°F and +5°F [between -50°C and -15°C] always.** Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken on the 2nd page of the temperature log.
- Maintain an ongoing file of temperature logs, and store completed logs for 3 years.

Receiving Vaccine Shipments

- VFC vaccine shipments received from the distributor contain heat and freeze exposure indicators. VFC direct shipments of frozen vaccine from manufacturers are shipped in specialized boxes and do not contain heat indicators.
- Immediately upon delivery of vaccine, check the vaccine cold chain monitors, if included, and store vaccine according to manufacturers' product specifications.
- Take proper action if either the freeze or heat cold chain monitor was activated. Instructions for reading the monitors are printed on the monitor cards.
- Document heat or freeze monitor readings if indicative of out-of-range temperature exposure, and contact the VFC Program for further guidance. Document action taken based on VFC Program instructions.
- If the provider believes that a vaccine shipment is compromised, temperature monitors are out-of-range, or a heat monitor is not activated (i.e., turned on), the provider should also contact McKesson Customer Service within 2 hours of vaccine shipment delivery time at 1-877-836-7123.
- Develop policies and protocols for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations.

Vaccine Wastage

- Notify immediately the VFC Program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines after discovery of the incident. Follow the guidance of the VFC Program on how to document and report the incident.
    1. Wasted vaccine: a vaccine that cannot be used; includes expired, spoiled, drawn-up but not administered, dropped vial, broken vial, lost vial.
    2. Expiration date: the last date on which the vaccine may be used; expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution depending on the vaccine and according to manufacturer instructions.
- Implement written protocols for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain. (Return Vaccine Form).
- Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration.
- Return, as directed by the VFC Program, all wasted or expired, publicly-purchased vaccines for excise tax credit.

***Please note**: Providers should return vaccine to the centralized distributor. (Mckesson)*

Vaccine Preparation

The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention, strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** pre-draw doses before they are needed.

Vaccine Ordering and Inventory Management

- Order vaccine in accordance with actual vaccine need.
- Develop and maintain complete, accurate and separate stock records for both publicly and privately purchased vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock.

Vaccine Security and Equipment Maintenance

Post "DO NOT DISCONNECT" notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.

Provider Vaccine Management Recommendations

Providers are encouraged to implement all or some of the following vaccine management activities, as applicable to the individual practice.

Vaccine Personnel

The primary and backup vaccine coordinators should train other staff to be responsible for vaccine storage and handling requirements in case of emergency.

Vaccine Storage Practices

- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles in the refrigerator and frozen packs in the freezer.
- Keep vaccines organized.
- Open only one vial, or box, of a particular vaccine at a time to control vaccine use and allow easier inventory control.
- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.

Vaccine Security and Equipment Maintenance

- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of backup power (generator) and a security system to alert appropriate personnel in the event of a power outage.
- If applicable, test backup generators quarterly and maintain backup generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

What NOT to Return to McKesson

The following items should NEVER be returned to McKesson:

- Used syringes, with or without needles;
- Broken vials;
- Wasted products such as a syringe that was drawn up but not used;
- Any multidose vial from which some doses have been withdrawn;
- IG, HBIG, PPD;
- Diluent (expired or not expired); or Private-purchased vaccine.

The items listed above should be disposed of according to usual medical Bio-safety procedures; as ***Medical waste***

WEST VIRGINIA DIVISION OF IMMUNIZATION SERVICES

Vaccine Storage & Handling Emergency Protocol Template

Provider Name: _____ VFC PIN #: _____
Contact Name: _____ Contact phone #:_____
Alternate Contact Name: _____ Alternate Contact phone#: _____
Date Protocol Established: _____ Date Protocol Reviewed: _____

*** Vaccine should be refrigerated immediately upon receipt**

If vaccine storage temperatures are found outside the recommended guidelines for:

Refrigerator (36^0 to 46^0F / 2^0-8^0C) / Freezer (-58°F and +5°F [-50°C and -15°C]). This facility will immediately initiate the following:

1) If power outage*: contact the power company and determine anticipated length of outage. If over _____hours, vaccine will be relocated to (include the facility address, contact and phone number as well as directions on how to transport):

*****If there is no power outage, continue to #2.

2) Check all power sources**: blown fuse or breaker, unplugged, etc.

If YES**:** make corrections if possible (implement use of do not unplug sign, replace fuse) and refer to *Vaccine Incident Management Guidance* at bottom of page.

**If power is ON, continue to #3.

3) Check data loggers DDLs*** for accuracy or damage:

If DDLs are not accurate or damaged, replace them and monitor for correct temperatures, then document actions on temperature log.

***If DDLs are accurate, continue to #4.

4) Remove vaccine and place in appropriate storage (Refer to relocation in #1 above), then adjust thermostat****** in refrigerator / freezer and recheck every 30 minutes until temperatures return to correct range. If successful, refer to *Vaccine Incident Management Guidance* at bottom of page.

****If unable to adjust temperature, continue to #5.

5) Emergency Contact person _____ at _____ to _____
Request service / repairs and refer to *Vaccine Incident Management Guidance* below. Or CALL 1-800-642-3634.

Vaccine Incident Management Guidance

In circumstances wherein vaccine may be compromised either by becoming too warm or too cold:

1) Check temperature log for time and date of previous reading.
2) Perform hands-on inventory of questionable vaccine.
3) Contact each vaccine manufacturer to determine viability. Refer to *VFC Vaccine Incident Management Directives* for phone numbers. (Note: Be prepared to provide lot numbers/expiration dates of affected vaccine and provide temperature log information.) 4) Contact the WV Division of Immunization Services at 1-800-642-3634.
5) Complete Return Vaccine Form (RVF) in accordance with individual manufacturers' guidance/response and fax to Division of Immunization Services at 1-304-957-7591.
6) Document time and findings, corrective actions taken, communications and final outcomes.

Vaccine Handling Guidelines

1) Vaccines should be ordered monthly by the 5th day of the month.
2) Keep no more than two months of vaccine on hand at any time, keep shortest dated vaccines in front and rotate stock on a monthly basis.
3) Report any wasted or expired vaccine to the VFC program. Any vaccines that will be expiring within 3 months that will not be used should also be reported to the VFC program.
4) Protect all light sensitive vaccines including Varicella, HPV, MMR, MMRV, Rotavirus, ActHib, Hiberix, Menactra, Menveo Bexsero and inactivated Flu vaccine.
5) Stack vaccines so that air can circulate around them, do not place vaccines in the door or the crisper, do not store food or drink in refrigerator, place water bottles in refrigerator and ice packs in freezer to stabilize temperature.
6) Always maintain the cold chain with vaccines even when moving or transporting.

For additional Storage & Handling information refer to the VFC manual.

WEST VIRGINIA DIVISION OF IMMUNIZATION SERVICES TRANSPORTING VACCINE

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 16.9 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 interior 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 +/-1°F (+/-0.5°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 many remaining vaccines.

Varicella, Proquad and Zostavax should be transported only in a portable freezer:

Varicella Containing Vaccines - Special Instructions for Transport

CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If varicella-containing vaccines must be transported, 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 in some places. If varicella containing vaccines must be transported and a portable freezer unit is not available complete the following actions: Varicella-containing vaccines may be transported at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution.

1. Place a calibrated thermometer in the container used for transport as close as possible to the vaccine.
2. Record:
   a. the time the vaccine was removed from the storage unit and placed in the container
   b. temperature during transport
   c. document the time and temperature at the beginning and end of transport
3. According to the vaccine manufacturer, **immediately** upon arrival at the alternate storage facility:
   a. place **the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C).** Any freezer that has a separate sealed freezer door and reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of Varicella containing vaccines.
   b. document the time the vaccine was removed from the container and placed in the alternate storage unit.

c. note that this is considered a temperature excursion, so **contact the manufacturer at 1-800-637-2590 for further guidance.**

4. Do not discard vaccine without contacting the manufacturer and/or the immunization program for guidance. Use of dry ice is not recommended, even for temporary storage or emergency transport. Dry ice may subject varicella containing vaccine to temperatures colder than -58°F (-50°C)

Update Vaccine Related Documents annually (or as staff changes)

At a minimum, the entire plan must be reviewed and updated annually or as necessary or when there is a change in any staff that has responsibilities specified in this plan.

Last reviewed on _____ by _____
Date Name

Last reviewed on _____ by _____
Date Name

Last reviewed on _____ by _____
Date Name

Last reviewed on _____ by _____
Date Name