ILLINOIS VACCINES FOR CHILDREN IMMUNIZATION PROGRAM

VACCINE LOSS AND REPLACEMENT POLICY

Current state and federal vaccine contracts stipulate that spoiled or expired vaccines cannot be returned to the manufacturer for credit or replacement. Such vaccine losses are absorbed directly by our program’s budget. Since the Illinois Department of Public Health (Department) Vaccines for Children (VFC) program is so important to the health and well-being of the people of Illinois, it is essential that all of us work together to ensure that every dose of vaccine is used to provide protection against preventable diseases. As a provider responsible for state-supplied vaccines, you and your staff should continually monitor vaccine storage and handling practices. Please notify the Department’s VFC Program if you or your staff would like to receive an educational visit regarding vaccine storage and handling.

VFC providers are required to report all wasted, expired, spoiled or lost vaccine to the Illinois VFC Program. This document serves as the Department’s VFC Program’s policy for management of incidents that result in loss of state-supplied vaccine. Dose for dose reimbursement for state-supplied vaccine will be requested if wastage was due to the provider’s failure to properly store, handle or rotate vaccine inventory.

DEFINITIONS

Wasted: Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the Department before determining that the vaccine is nonviable.

Lost: Commercial carrier (FedEx or UPS) or United State Postal Service (USPS) does not deliver the vaccine or does not deliver in a timely manner.
SITUATIONS THAT REQUIRE FINANCIAL RESTITUTION

Expired Vaccine

- Failure to rotate or attempt to transfer vaccine that results in expired vaccine.

Spoiled Vaccine

- Pre-drawn vaccine that is not used. Please note the Illinois VFC program strongly discourages the practice of pre-drawing vaccine.
- Handling and storage mishaps by provider staff.
- Vaccine that is left out of the refrigerator or freezer and becomes nonviable. Call the vaccine manufacturer first to help you determine the stability/viability of vaccine left out of the refrigerator/freezer.
- Vaccine stored in dorm style refrigerators.
- Freezing vaccine that is supposed to be refrigerated.
- Refrigerating vaccine that is supposed to be frozen.
- Refrigerator/freezer left unplugged.
- Refrigerator/freezer door left open or ajar.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the Illinois VFC program within 30 days from the date you became aware of the situation.
- Power outages in which the provider fails to follow the facility’s VACCINE STORAGE AND EMERGENCY RESPONSE PLANS.
- Vaccine that is considered spoiled due to the provider not checking, reviewing and recording refrigerator and freezer temperatures or failing to use currently certified calibrated thermometer to check temperatures twice daily.
- Vaccine that is considered spoiled because a provider did not take immediate or appropriate action on out-of-range temperatures.
- Replacement vaccine: health care providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of acceptable range) or improper administration will be responsible for replacement of the vaccine needed to re-vaccinate.
**Wasted Vaccine**

- State-provided vaccine given to children or adults who are not eligible to receive it based on the most recent VFC eligibility criteria and Illinois immunization guidelines.

- Discarding vaccine before the manufacturer’s expiration date (includes multi-dose vials discarded after 30 days).

**SITUATIONS THAT DO NOT REQUIRE VACCINE REPLACEMENT**

Below is a list of situations that are NOT considered “provider negligence.” This list is not exhaustive. In these situations, the provider is deemed not to be at fault. You may be required to produce a letter from the alarm/alert company or the power company.

- A commercial carrier or USPS does not deliver to the provider in a timely manner. Before making the determination that the vaccine is nonviable, first call the vaccine manufacturer.

- A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider.

- A provider moves vaccine to a nearby hospital due to anticipated inclement weather, the hospital experiences a power failure, and the Illinois VFC program later deems the vaccine not viable.

- Power was interrupted or discontinued due to a storm, provider is able to confirm that the facility’s VACCINE STORAGE AND EMERGENCY RESPONSE PLAN was followed and after consultation with the vaccine manufacturer and the Illinois VFC program, it is determined that vaccine is not viable.

- A vial that is accidentally dropped or broken by a provider.

- Vaccine that is drawn at the time of the visit but not administered due to parental refusal or a change in physician orders.

- Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).

- Extraordinary situations not listed above which are deemed by Illinois VFC program to be beyond the provider’s control.

- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Illinois VFC program within 30 days from the date you became aware of the situation.
PROCEDURES FOR RETURNING NONViable VACCINE TO MCKESSON SPECIALTY

• Call the vaccine manufacturer and the Illinois VFC program as soon as you suspect vaccine may not be viable.

• Failure to report wasted vaccine to the Illinois VFC program may result in your facility no longer being able to receive state-supplied vaccine.

• Return all unopened vials and manufacturer’s pre-filled syringes of spoiled or expired vaccine with a completed Vaccine Waste Packing List for Return to McKesson For Excise Tax Credit and Disposal to McKesson Specialty regardless of any financial restitution status applied to the vaccine. Vaccine provided by the Illinois VFC program should never be discarded. The only exception is open vials or syringes, including multi-dose vials, from which some doses have already been withdrawn. These can no longer be sent back to McKesson. A wastage form must still be filled out and sent to the Illinois VFC program, and the open vials and syringes should then be discarded per your facility’s policy.

• Procedure for returning unopened nonviable vaccine to McKesson:
  o Complete a Vaccine Waste Packing List for Return to McKesson For Excise Tax Credit and Disposal before returning nonviable vaccine. Either faxing or e-mailing the completed form is acceptable.
  o Make two copies of the form or confirmation page, one for your records and one for McKesson.
  o Prior to shipping non-viable vaccine, fax the paper form to the Illinois VFC Program at 217-786-7506 or email to dph.vaccines@illinois.gov.
  o Providers may NOT contact McKesson to coordinate pickup of wasted/expired vaccine.
  o McKesson is no longer including pre-printed return labels with its shipments. You must contact the Illinois VFC program when you need to return nonviable vaccine.
  o McKesson will send a return label via USPS to providers. The provider may then send the labeled box of wasted/expired vaccine with the UPS driver.
  o For providers who do not have a regular UPS pickup, McKesson will contact UPS to arrange the pickup.
  o Use a container from a previous vaccine shipment to send nonviable vaccine and a copy of the completed return form to McKesson. Wasted/expired vaccine does not need to be refrigerated or frozen.
  o DO NOT ship viable vaccine to McKesson.
DO NOT ship viable or nonviable vaccine to the Illinois VFC program.

**PROCEDURES FOR VACCINE REPLACEMENT**

This updated policy applies to any vaccine received as wasted by the Illinois VFC Program on or after January 1, 2013.

- The provider will receive a notice from the Illinois VFC program requesting proof of replacement of vaccine reported as wasted to the Illinois VFC program.

- Acceptable proof is packing list or paid invoice showing type, amount, lot number and expiration date of privately purchased vaccine that will then be marked and used as VFC vaccine. OR

- If the provider is using the VFC ordering and inventory module in I-CARE, I-CARE support must be notified immediately when the purchased vaccine arrives so that the lot numbers can be entered into the I-CARE system as VFC vaccine.

- Replacement of the vaccine is due within 30 days of receiving the Illinois VFC program notice.

- If replacement is not received within 30 days, the Illinois VFC program will not supply vaccine to the negligent provider until restitution has been made.

**PROVIDER-TO-PROVIDER TRANSFER OF VACCINES**

Providers who have excess vaccine on hand that will not be used before expiration are encouraged to transfer this vaccine to other Illinois VFC providers to utilize, and thus avoid being charged for wasted vaccine. Providers should begin this process within three to six months of the vaccine expiring. **It is the provider’s responsibility to find another provider willing to accept the vaccine, and also to properly pack and ship the vaccine to that provider following standard cold-chain procedures.** While the Department’s VFC program is willing to assist when possible, it is very difficult to match odd numbers of vaccines with other provider orders and to try to arrange for shipments between providers. Providers can find contact information for other VFC providers in their area within the I-CARE Reports tab. Providers also must transfer the doses in I-CARE. Transfers of vaccine will not be deducted from the transferring provider’s stock until both the receiving facility and VFC staff have approved the transfer.

If you have any questions concerning this policy, please call the Illinois Vaccine for Children program at 217-786-7500 or by e-mail to dph.vaccines@illinois.gov.
I have read and agree to abide by the

ILLINOIS VFC IMMUNIZATION PROGRAM VACCINE LOSS AND REPLACEMENT POLICY

(Please print)

Provider Name ___________________________ PIN __________________

Address _______________________________________________________

Telephone ___________________________ Fax __________________

Physician’s Signature __________________ Date __________________

Sign and return this form to Illinois Department of Public Health, Immunization Section, VFC program

Fax to: 217-786-7506
or send a scanned electronic copy by e-mail to
Dph.vaccines@illinois.gov

Illinois Department of Public Health
Immunization Program/Vaccines for Children
2840 Via Verde St.
Springfield, IL 62703