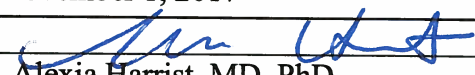


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Policy Title:	PVP: Vaccine Restitution	
Policy Number:	IMM-001	
Effective Date:	November 1, 2017	
Approval:	 Alexia Harrist, MD, PhD State Health Officer Public Health Division	10/18/17 Date

Purpose: As vaccines become more expensive and immunization programs more complex, the Public Vaccine Programs (PVP) managed by the Wyoming Department of Health (WDH) become more affected by vaccine loss and waste, which can be costly. The intention of this policy is to establish a process for the prevention of vaccine loss and for requesting restitution for these vaccines.

Scope: This policy applies to primary healthcare providers enrolled in any PVP.

Policy:

1. Definitions

- a. "Expired or spoiled vaccine" means nonviable vaccine in its original container (vial or syringe) that is able to be returned for excise tax credit. This includes expired vaccine or vaccine that has been spoiled as a result of the following:
 - i. Natural disaster/power outage;
 - ii. Refrigerator too warm or too cold;
 - iii. Failure to store properly upon receipt;
 - iv. Vaccine spoiled in transit;
 - v. Mechanical failure;
 - vi. Spoiled-other; or
 - vii. Recall.
- b. "Expiration date" means the last date on which a vaccine may be used; expired vaccine includes vaccine that is past the manufacturer's expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.
- c. "Wasted vaccine" means nonviable vaccine that is NOT able to be returned to the vaccine distribution center. This includes:
 - i. Vaccine drawn into a syringe but not administered;
 - ii. Vaccine in open vial but doses not administered; or
 - iii. Compromised vial (e.g., due to a drop causing damage to the vial integrity or sterility), broken vial.

- d. "Lost vaccine" means any vaccine that was delivered to a provider's office but cannot be located.

2. Situations That May Require Vaccine Replacement

- a. Vaccine replacement may be required in, but is not limited to, the following situations:
 - i. Pre-drawn vaccine that is not used;
 - ii. Failure to prevent vaccine expiration by:
 - 1. Rotating vaccine stock within the storage unit by expiration date to ensure staff use vaccine that will expire first prior to vaccine that will expire later, or
 - 2. Transferring vaccine to another provider to use prior to expiration;
 - iii. Failure to store vaccine at proper temperatures;
 - iv. Refrigerator or freezer was left unplugged;
 - v. Refrigerator or freezer door was left open or ajar;
 - vi. Power outages in which the provider fails to take precautions (e.g., not following an established emergency plan);
 - vii. Failure to respond to a storage unit alarm immediately upon notification;
 - viii. Failure to report out of range temperatures to the Immunization Unit immediately upon discovery; or
 - ix. Vaccine that is signed for by a staff member at the provider office upon delivery but cannot be located.

3. Oversight Personnel

- a. When vaccine waste is identified, the VFC Coordinator makes the decision to refer for restitution. This request goes through the Immunization Unit Manager to the State Health Officer.
- b. The State Health Officer makes the final determination of whether or not vaccine restitution is required.

4. Prevention

- a. When providers enroll in a PVP, they agree to comply with all of the requirements of the specific program(s) in which they enroll. The following is completed in order to assist in the prevention of vaccine waste:
 - i. Enrolled providers and their staff are required to complete the Vaccine Coordinator Training Program which includes a module on vaccine storage and handling;
 - ii. Compliance Visits take place at least every other year for every enrolled provider which specifically covers vaccine storage and handling including how to prevent waste.

5. Identification of Vaccine Waste

- a. Vaccine waste due to expiration is identified when providers submit vaccine returns in the Immunization Information System (IIS) adopted by WDH.
- b. Waste is also monitored by utilizing reports in the IIS that show vaccine waste per provider.

6. Return or Disposal of Wasted Vaccine

- a. All wasted/expired vaccine must be returned to the CDC's centralized vaccine distributor within six (6) months of the vaccine being wasted/expired.

- i. Any vaccine that is dropped/spilled/broken or a multi-dose vial that has been used at least once is not eligible for return and must be appropriately disposed of.
- b. All vaccine returns are to be submitted in the IIS. Returns are processed monthly by the Provider Support Specialist. Upon processing, the provider will receive a shipping label via email to return the wasted/expired vaccine.

7. Facts Gathering/Investigation

- a. Enrolled providers are required to report any instance in which a publicly-supplied vaccine is exposed to improper temperatures to the Immunization Unit immediately upon discovery.
 - i. Provider staff will be responsible for submitting temperature data from the calibrated data logger thermometer used to monitor temperatures of publicly-supplied vaccine to a Compliance Specialist for review to determine:
 - 1. The amount of time that the vaccine was exposed to improper temperatures, and
 - 2. The highest or lowest temperature the vaccine was exposed to.
 - a. All providers enrolled in a PVP are required to use data logger thermometers to monitor vaccine stock.
 - ii. If a Compliance Specialist determines that a Vaccine Cold Chain Investigation is required, it is the responsibility of the provider or the provider's staff to complete all necessary actions including contacting the vaccine manufacturer(s) to determine viability of the vaccine exposed to inappropriate temperatures.
 - iii. If the vaccine is deemed no longer viable by the vaccine manufacturer and it is determined by a Compliance Specialist that the incident occurred due to provider negligence, the incident will be referred to the VFC Coordinator for vaccine replacement.

8. Determination

- a. Vaccine restitution will be required in situations where it is determined by the Immunization Unit, with the approval of the State Health Officer that the vaccine waste or loss was due to provider negligence.
 - i. This negligence may be due to improper inventory management, including failure to rotate stock resulting in expired vaccine, improper storage and handling, failure to respond to out of range temperatures immediately upon discovery, or other situations in which it is determined that the waste could have been prevented.
 - ii. Replacement of wasted vaccines will be decided on a case-by-case basis and will take into consideration compliance with vaccine storage and handling best practices, past incidents of vaccine waste, and the overall waste ratio for the facility.

9. Provider Responsibility

- a. Privately purchase the number of doses of the vaccine no later than ninety (90) days of notification to replace the publicly-supplied vaccine wasted due to negligence.

- i. Submit the vaccine purchase invoice and upon arrival, the packing slip to the Wyoming Department of Health Immunization Unit VFC Coordinator.
- b. Work with Immunization Unit staff to appropriately document the replacement vaccines in the IIS.
- c. Physically label the replacement vaccine as public stock, store with other publicly-supplied vaccines, and administer only to eligible patients.
- d. All publicly-supplied vaccines which have been wasted and deemed eligible for replacement must be replaced dose-for-dose. The doses replaced must be used only for eligible patients using the same eligibility criteria as the original funding sources of the lost doses. If a provider is unable to use the replaced doses, the doses may be shipped directly to a local health department for administration to eligible patients using the same eligibility criteria of the original funding source of the lost doses. If a local health department is unavailable, then another provider type may serve as the recipient of the vaccines.
- e. In the situation where uninsured vaccine cannot be replaced within the ninety (90) day timeframe, the provider must communicate this to the Immunization Unit to negotiate a plan for replacing the doses of vaccine including an acceptable timeline for the final replacement of the vaccine. No more than six (6) months will be allowed for replacement.

10. Monitoring the Use of Replacement Doses

- a. The VFC Coordinator will verify that the replaced doses have been entered into the IIS as public stock and administered only to eligible patients using an electronic form that captures the following information:
 - i. Date of loss;
 - ii. Vaccine type;
 - iii. Lot number;
 - iv. NDC;
 - v. Fund type (317, VFC, or State);
 - vi. Number of doses lost;
 - vii. Date vaccine replaced;
 - viii. Date replaced vaccine administered to eligible child; and
 - ix. WyIR patient identifier/Eligibility status.

11. Appeals Process

- a. If a provider disagrees with the determination of provider negligence, the provider may submit a written appeal to the State Health Officer within ten (10) business days of receiving formal notification of vaccine replacement.
- b. Replacement appeals must be signed by the Responsible Physician listed on the PVP Provider Agreement. Upon receipt of the appeal, the Immunization Unit will convene a review committee to review the appeal, the circumstances of the vaccine loss, and any other relevant information. Providers who appeal the determination will receive written notification regarding the outcome of the appeal within thirty (30) calendar days of receipt of the appeal request. Vaccine replacement activities will be on hold and the provider may remain in a Public Vaccine Program during the appeal review period as long as there is no further risk to vaccine viability.

Contacts:

Immunization Unit Main Line 307-777-7952
Immunization Unit Manager 307-777-6001
WyIR Coordinator 307-777-5773

Forms:

PVP Provider Agreement
Vaccine Coordinator Checklist

References:

Wyo. Stat. Ann. § 21-4-309
WDH Immunization Program Administrative Rules and Regulations
WY PVP Policies and Procedures