

**Policies and Procedures for Vaccine Wastage
Wyoming Department of Health,
Public Health Division, Community and Public Health, Immunization Section**

November 2011

This policy applies to any wasted vaccine reported to the Immunization Section on or after January 1, 2012.

Introduction

Current state and federal vaccine contracts stipulate that wasted or expired vaccines cannot be returned to the manufacturer for credit or replacement. Such vaccine losses are absorbed directly by the Immunization Section's budget. Because the Vaccines for Children (VFC) and Wyoming Vaccinates Important People (WyVIP) programs are so important to the health and well-being of Wyoming children, it is essential to ensure that every dose of vaccine is not wasted and is used to protect Wyoming residents against vaccine-preventable diseases.

VFC/WyVIP providers must continually monitor vaccine storage and handling practices (also known as "cold chain") to ensure that vaccines are stored safely and prevent vaccine wastage. The Immunization Section offers free education regarding vaccine storage and handling practices at any time to VFC/WyVIP providers to ensure that providers and their staff members understand the significance of effective vaccine storage and handling processes.

All VFC/WyVIP providers are required to report all wasted, expired, spoiled, or lost vaccine to the Immunization Section upon discovery of "cold chain" issues.

This document serves as the Immunization Section's policy for management of incidents that result in the loss of federal- or state-supplied vaccine. In instances where it was determined that vaccine wastage was caused due to a provider's failure to properly store, handle, transfer, or rotate vaccine inventory, providers will be required to purchase private stock vaccine to replace publicly-supplied vaccine that was wasted. Alternative actions may be required at the discretion of the Immunization Section, with input from the State Health Officer and/or Director of the Wyoming Department of Health.

Definitions

- **Wasted vaccine:** Any vaccine that cannot be used. This includes expired, spoiled, and lost vaccines.
- **Expired vaccine:** Any vaccine with an expiration date that has passed.
- **Spoiled vaccine:** Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Providers should always consult with a clinical staff member of the Immunization Section so that it can be determined whether publicly-provided vaccine is unstable or non-viable.

- **Lost vaccine:** Any vaccine that was delivered to a provider's office but cannot be located within the office. Note: The Immunization Section has the capability of tracking all vaccine shipments from McKesson Specialty to provider's offices.

Vaccine Replacement Policies and Procedures

Vaccine replacement will be required in situations where a VFC/WyVIP provider is determined to be negligent or at fault for wasted vaccine due to improper storage, handling, or rotation of vaccine inventory. Providers will also need to replace their vaccine if they must re-vaccinate due to negligence as a result of a failure to keep vaccine viable (i.e. temperatures out of acceptable range) or improper administration.

- Failure to report wasted vaccine to the Immunization Section upon discovery may result in suspension from the VFC/WyVIP program.
- If it has been determined by the Immunization Section that vaccine wastage could have been prevented, the Immunization Section will formally notify the VFC/WyVIP provider and include what steps must be taken in order to replace the publicly-provided vaccines that were wasted.

Once a provider has been notified about the need to replace wasted vaccines, the provider must take the following steps:

- The VFC/WyVIP provider must order replacement vaccines with private funds.
- The Immunization Section must be notified when the privately-purchased vaccine arrives and a copy of the shipping log must be sent to the Immunization Section.
- A copy of the purchase order or invoice for any replacement vaccines must be submitted to the Immunization Section.
- The replacement vaccine will be labeled as VFC/WyVIP stock and administered to eligible VFC/WyVIP population.

Situations That May Require Vaccine Replacement

Expired Vaccine

- Failure to rotate or transfer vaccine that results in expired vaccine amounting to greater than 10 doses of any one vaccine in a 30 day period

In instances where publicly-provided vaccines may have been compromised, providers must "quarantine" the vaccines in question by placing the vaccines in a paper bag and marking it "do not use" until an investigation has been conducted by a clinical staff member of the Immunization Section. Quarantined vaccines must be stored appropriately during the investigation. **Note: Providers are responsible for conducting stability or viability investigations for privately-purchased vaccines.**

Conditions that may lead to spoiled vaccine

- Pre-drawn vaccine that is not used. Note: the Immunization Section strongly discourages the practice of pre-drawing vaccines.

- Handling, storage, and shipping mishaps by provider staff (e.g. not refrigerating vaccine upon receipt of shipment or not properly shipping transferred vaccine).
- Vaccine that is not stored in a refrigerator or freezer and becomes unstable or non-viable.
- Freezing vaccine that is supposed to be refrigerated.
- Refrigerating vaccine that is supposed to be frozen.
- Refrigerator or freezer was left unplugged.
- Refrigerator or freezer door was left open or ajar.
- Refrigerator or freezer equipment problems where proof of repair or equipment replacement was not provided to the Immunization Section within 30 days of the date the provider became aware of the situation.
- Power outages in which the provider fails to take precautions (e.g. not following an established emergency plan).
- Vaccine that is considered spoiled due to the provider not checking and/or reviewing refrigerator and freezer temperatures twice a day.
- Vaccine that is considered spoiled, because a provider did not take immediate or appropriate action for out-of-range temperatures.

Situations that would 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.

- A commercial carrier or USPS does not deliver to the provider in a timely manner.
- 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 may be required to produce a letter from the alarm/alert company or the power company.
- A provider moves vaccine to a back-up location due to anticipated inclement weather, the back-up location experiences a power failure, and the Immunization Section determines that the vaccine not viable.
- Power was interrupted or discontinued due to inclement weather, and after consultation with the Immunization Section, 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 over ordering or provider negligence (including seasonal influenza vaccine).
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Section within 30 days from the date the provider became aware of the situation.
- Extraordinary situations not listed above which are deemed by the Immunization Section to be beyond the provider’s control.

Appeals Process

If a VFC/WyVIP provider disagrees with the determination of provider negligence, the provider may appeal the determination within 10 business days of notification of the necessary action required.

Provider appeals must be signed by a primary practitioner (if the provider is a private practice/facility) or County Health Officer (if the provider is a Public Health Nursing office). Providers who appeal the determination will receive written notification regarding the outcome of the appeal within 10 days of receipt of the appeal request. Each appeal will be considered on an individual basis by the State Health Officer.

Procedures and Policy for Returning Vaccine to McKesson Specialty

In instances where vaccines have been compromised during shipment from the McKesson Specialty vaccine distribution facility, the following procedures should be followed:

- VFC/WyVIP providers should call the Immunization Section as soon as it is suspected that vaccine may be unstable or non-viable when it is received by the provider's office. VFC/WyVIP providers will not be financially accountable for any compromised vaccine that arrives directly from McKesson if they contact the Immunization Section within two hours of delivery.
- VFC/WyVIP providers must return all unopened vials and manufacturer's pre-filled syringes of non-viable vaccine with a completed "Non-Viable Vaccine Return and Wastage Form" to McKesson regardless of any financial restitution status applied to the vaccine. Vaccine provided through the VFC/WyVIP program should never be discarded. All non-viable vaccine must be returned to McKesson Specialty.
- VFC/WyVIP providers should adhere to the following procedures for returning non-viable vaccine to McKesson:
 - Complete a "Non-Viable Vaccine Return and Wastage Form" before returning non-viable vaccine.
 - Make two copies of the form -- one for the provider's records and one for McKesson.
 - Prior to returning non-viable vaccine to McKesson, fax the form to the Immunization Section at 307-777-3615.
 - Ship non-viable vaccine and a copy of the completed return form to McKesson in a shipping container received from a previous vaccine shipment from McKesson.
 - Non-viable vaccine should be shipped via UPS, using a return label provided by the Immunization Section.
 - Providers must not ship viable vaccine to McKesson.
 - Providers must not ship viable or non-viable vaccine received from McKesson to the Immunization Section.
- The Immunization Section is responsible for cold chain investigation and final viability determination on publicly-provided vaccines based upon guidance from vaccine manufacturers.

If you have any questions concerning this policy, please call the Immunization Section at 307-777-7952.