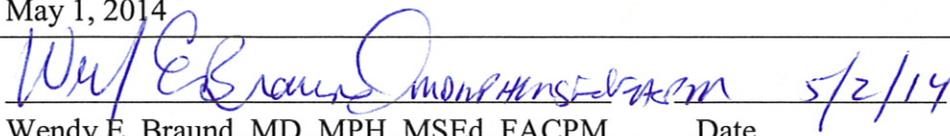


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Governor Matthew H. Mead

Policy Title:	Vaccine Replacement Policy
Effective Date:	January 1, 2012
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Approval:	 Wendy E. Braund, MD, MPH, MSEd, FACPM Date

Introduction

The Vaccines for Children (VFC) and Wyoming Vaccinates Important People (WyVIP) Programs are important to the health and well-being of Wyoming children. It is essential to ensure that vaccine is not wasted, expired, spoiled, or lost and every dose is used to protect Wyoming residents against vaccine-preventable diseases. Vaccine loss is both costly and preventable.

VFC/WyVIP providers are responsible for maintaining appropriate temperatures and vaccine quality from the time a shipment arrives until the vaccine is administered. The Immunization Unit offers free education regarding vaccine storage and handling practices at any time to VFC/WyVIP providers to ensure that their staff understand the importance of effective vaccine storage and handling processes. VFC/WyVIP providers are required to report all wasted, expired, spoiled, or lost vaccine to the Immunization Unit immediately.

This document serves as the Immunization Unit'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 loss was caused due to a provider's negligence or failure to respond, providers will be required to replace the publicly-supplied vaccine. Alternative and/or additional actions may be taken at the discretion of the Immunization Unit, with input from the State Health Officer and/or Director of the Wyoming Department of Health or his/her designee.

Definitions of Vaccine Loss Terms

Wasted vaccine: Nonviable vaccine that is NOT able to be returned to vaccine distribution center. See the *VFC/WyVIP Program Quick Reference Guide: Vaccine Returns* for specific guidelines on what cannot be returned to the vaccine distribution center. This includes:

- Vaccine drawn into the syringe but not administered
- Open vial of expired or spoiled vaccine
- Compromised vial (e.g., due to being dropped, causing damage to the integrity and sterility), broken vial, or lost vial

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

Spoiled vaccine: Vaccine in its original container that is nonviable due to exposure to out of range temperatures for a period of time.

- Determination of vaccine viability should be made in conjunction with the Immunization Unit.

Lost vaccine: Any vaccine that was delivered to a provider's office but cannot be located.

Note: The Immunization Unit has the capability of tracking all vaccine shipments from the vaccine distribution facility to a provider's office.

Vaccine Replacement Policies and Procedures

Vaccine replacement will be required in situations where it is determined by the State Health Officer that the vaccine loss was due to provider negligence. This negligence may be due to improper inventory management, including failure to rotate stock, improper storage and handling, or failure to respond to out of range temperatures. Providers must re-vaccinate due to the administration of nonviable vaccine as a result of failure to keep the vaccine viable. If the nonviable vaccine was due to provider negligence, this re-vaccination must occur with private stock vaccine

Failure to report vaccine loss to the Immunization Unit upon discovery may result in suspension from the VFC/WyVIP Program. If it has been determined that vaccine loss could have been prevented, the Immunization Unit will formally notify the VFC/WyVIP provider and include the steps that must be taken in order to replace the publicly-supplied vaccines. Vaccine replacement should occur on a schedule determined by the Immunization Unit and should not exceed a period of 90 days.

In instances where publicly-supplied vaccines may have been compromised, providers must "quarantine" the vaccines in question by marking them "Do Not Use" and continue to store them at proper temperatures until viability can be determined in conjunction with the Immunization Unit. **Note: Providers are responsible for conducting stability or viability investigations for privately-purchased vaccines.**

Once a provider has received formal notification of vaccine replacement, the replacement may take place through either of the following methods:

- A vaccine transfer from private stock to public stock.
 - Requires vaccine reconciliation and entry into the Wyoming Immunization Registry (WyIR) with vaccine indicated for public use.
 - Immunization Unit review and approval the temperatures of any storage unit used to store private vaccine to ensure viability prior to replacement.
- The purchase of vaccine with private funds.
 - Requires submission of vaccine purchase order and packing slip, as well as a report of vaccine lot numbers to the Immunization Unit.
 - Entry of the replacement vaccine in the WyIR.

Both methods require that the vaccine be physically labeled as public stock and stored with other VFC/WyVIP vaccines. The Immunization Unit must be notified when vaccine replacement has taken place so that the replacement can be confirmed.

Situations That May Require Vaccine Replacement

Vaccine replacement may be required in, but is not limited to, the following situations.

Wasted Vaccine

- Pre-drawn vaccine that is not used.

Expired Vaccine

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

Spoiled Vaccine

- Failure to store vaccine at proper temperatures.
- Refrigerator or freezer was left unplugged.
- Refrigerator or freezer door was left open or ajar.
- Power outages in which the provider fails to take precautions (e.g., not following an established emergency plan).
- Failure to respond to a storage unit alarm within a reasonable amount of time.
- Failure to report out of range temperatures to the Immunization Unit immediately upon discovery.

Lost Vaccine

- Vaccine that is signed by a staff member at the provider office but cannot be located.

Appeals Process

If a VFC/WyVIP provider disagrees with the determination of provider negligence, the provider may submit a written appeal within ten (10) business days of formal notification of vaccine replacement.

Replacement appeals must be signed by the primary practitioner or designee. 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 during the appeal review period.

Procedures for Returning Nonviable Vaccine

VFC/WyVIP providers must return all unopened vials and manufacturer's pre-filled syringes of non-viable vaccine to the vaccine distribution center regardless of any financial restitution status applied to the vaccine. Vaccine provided through the VFC/WyVIP Program should never be discarded unless they do not qualify for return (See *Quick Reference Guide: Non-Returnable Vaccine Loss*).

VFC/WyVIP providers should follow the procedures outlined by the Immunization Unit to report vaccines that qualify for return to the vaccine distribution center. All vaccine loss must be appropriately reconciled out of the WyIR.

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