

# Childhood Vaccine Program

Office of Immunization and Child Profile | (360) 236-2829 | [doh.wa.gov/cvp](http://doh.wa.gov/cvp) | [wachildhoodvaccines@doh.wa.gov](mailto:wachildhoodvaccines@doh.wa.gov)

## Vaccine Loss Policy

### Introduction

Proper vaccine storage, handling, and accountability are vital components to the success of the Washington State Department of Health's (DOH) Childhood Vaccine Program (CVP). This policy outlines processes and repercussions when vaccine is lost.

### Scope

This policy applies to all Washington providers that receive publicly supplied childhood vaccine.

### Definitions

- **Provider:** An individual, partnership, private organization, or public organization enrolled in the CVP.
- **Incident/Vaccine Loss:** Expired, spoiled, wasted, or lost/unaccounted for vaccine.
- **Negligence:** Failure to take reasonable action to prevent vaccine loss.

### Expectations of Providers

- Providers agree to maintain proper storage and handling practices to avoid vaccine loss.
- Providers agree to manually review vaccine storage unit temperatures during clinic hours based on program requirements.
- Provider agree to contact the vaccine manufacturer immediately if temperatures remain out of range for 30 minutes or more.
- Providers agree to report all vaccine loss using the online return function in the Washington State Immunization Information System (IIS).
- Providers agree to retain the monthly paper [Vaccine Loss Log](#) for three years and submit to [WACHildhoodVaccines@doh.wa.gov](mailto:WACHildhoodVaccines@doh.wa.gov) depending on the loss scenarios listed below.

### Vaccine Loss and Repercussions

In accordance with the Provider Agreement and Vaccine Management Plan:

- All providers will sign the Vaccine Loss Policy, acknowledging and agreeing that DOH may require the provider to complete additional training and/or purchase or update equipment to help reduce the risk for future vaccine loss. DOH's Office of Immunization and Child Profile (OICP) will work in partnership with the provider to determine if the loss was due to negligence. See the scenarios and repercussion key below.

#### Vaccine Loss Scenarios

- Provider's first incident within 365 days that's greater than \$2,500.00 but less than \$10,000.00 (A,B,C).
- Provider experiences any additional negligent incidents that are greater than \$2,500.00 within 365 days of their most recent negligent incident (A,B,C,D,E).
- Provider experiences any negligent incident greater than \$10,000.00 (A,B,C,D,E).
- Provider continues to have negligent incidents (A,B,C,D,E,F).
- Provider fails to comply with the Vaccine Loss policy (A,G).

#### Repercussion Key

- DOH may turn off provider vaccine ordering permissions until issue is resolved.
- DOH will provide an email and resources to educate the provider regarding their incident.
- DOH will require the provider to submit their Vaccine Loss Log to DOH outlining the incident and actions they plan to take to prevent future vaccine loss.
- DOH will require providers to complete additional training regarding vaccine storage and handling procedures.
- DOH may require the provider to purchase or update equipment to help reduce the risk for future incidents (i.e. digital data loggers, remote monitoring data loggers, or pharmaceutical grade storage units).
- DOH may perform an unannounced site visit to ensure the provider is following best practices.
- DOH may disenroll provider.

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**Reasons of negligence include but are not limited to the following:**

- Failure to open vaccine shipments from McKesson or Merck immediately, resulting in damaged and non-viable vaccine.
- Failure to rotate vaccine stock, resulting in preventable expired vaccine.
- Failure to alert DOH three months prior to vaccine expiration to determine vaccine transfer options.
- Not requesting prior approval from DOH to transfer vaccine and/or transferring vaccine inappropriately, thereby potentially impairing vaccine viability.
- Failure to follow an emergency response plan.
- Using publicly supplied childhood vaccine for unapproved adult populations.
- Freezing vaccine intended to be refrigerated and/or refrigerating vaccine intended to be frozen.
- Failure to maintain proper refrigeration and/or freezer temperatures.
  - ▶ Refrigerator or freezer left unplugged.
  - ▶ Electrical breaker switched off by provider staff, contractors, or any other individual.
  - ▶ Refrigerator or freezer door left open or ajar by staff, contractors, or any other individual.
  - ▶ Any power outage in which the provider fails to act according to their vaccine storage back up plan.
  - ▶ Not having correct/certified thermometers and/or incorrect placement in each vaccine refrigerator and freezer compartment.
  - ▶ Failure to read and record refrigerator and freezer temperatures, and/or failure to take immediate corrective action when temperatures are determined to be out of range.
- Vaccine left out of the storage unit for 30 minutes or more (always call the vaccine manufacturer to determine vaccine viability).
- Failure to notify DOH when provider office hours change or the provider address changes, resulting in vaccine not being delivered and consequently becoming non-viable.
- Discarding non-expired vaccine prior to stated expiration date.
- Routinely pre-drawing (pre-filling) syringes that go unused resulting in non-viable vaccine. Pre-drawing vaccines for later use, even if kept within temperature requirements so the vaccine stays viable, is not acceptable. Routinely pre-drawing syringes is not a best practice and is against state and federal vaccine requirements. Pre-drawing is acceptable if done following CDC guidelines for mass immunization clinics.
- Failure to use continuous temperature monitoring devices (data loggers) and required back-up thermometers to monitor vaccines during routine onsite storage of vaccine, during transport of vaccine, and during mass vaccination clinics.
- Any other preventable incidents made by provider.

**Acknowledgment of Receipt and Agreement to the Vaccine Loss Policy:**

Provider Name:	PIN:	Telephone:
Street Address:		
City:	State:	Zip:

I have read, and agree to adhere to the Washington State Department of Health, Office of Immunization and Child Profile's Vaccine Loss Policy, and to the provisions of this policy.

I understand that failure to adhere to this policy may result in suspension of our participation in the Washington State Childhood Vaccine Program.

I, the signatory on the Provider Agreement, accepts responsibility of adherence to this policy.

Print Name of Signatory:	
SIGNATURE of Signatory:	Date: