

## **Vaccine Restitution Policy – Agreement**

### **Introduction**

This policy outlines conditions to replace vaccine dose-for-dose that was lost due to provider negligence. Vaccines that are lost due to expiration are excluded from restitution.

### **Scope**

This policy applies to all that receive Vaccines for Children (VFC) vaccine and state-supplied vaccine.

### **Roles and responsibilities**

The Wisconsin Immunization Program staff, as directed by the program director and the Vaccines for Children coordinator are responsible for the enforcement of this policy.

### **Definitions**

For the purposes of this document, a “provider” is defined as any staff member of a provider’s office or a local health department, tribal health office, or Federally Qualified Health Center/Rural Health Clinic.

### **Policy**

Purpose: The Vaccine Restitution Policy is to ensure accountability. It outlines the necessary steps for the replacement of wasted vaccine and lost vaccine.

**Policy Statement:** Appropriate vaccine storage and handling, as well as vaccine accountability, is critical to the success of the Wisconsin Immunization Program and ultimately, to the health of all Wisconsin residents who receive vaccination. Vaccine loss is costly and can be prevented. Health care providers are responsible for maintaining vaccine viability from the time a vaccine shipment arrives until the moment the vaccine is administered.

Viability of the vaccine will be determined after information has been shared with the manufacturer and they have made a recommendation as to the viability of the product.

If a loss is due to the provider’s negligence (such as leaving vaccine out at room temperature, vaccine not being put away on arrival, etc.) the provider will be responsible for purchasing dose-for-dose replacement vaccine once it is determined that the vaccine is non-viable and the wastage was preventable.

All state-supplied vaccines (317 and VFC) that have been lost and deemed eligible for replacement must be replaced dose-for-dose. The doses replaced must be used only for eligible children using the same proportions as the original funding sources (VFC and/or 317) 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 VFC-eligible children in proportions according to the original funding source of the lost doses. If a local health department is unavailable, then another provider type may serve as recipient of the vaccine.

**Note:** Providers should contact their insurance carrier to determine if their current policy covers vaccine loss. Insurance could be used to buy replacement vaccine.

As soon as a potential vaccine loss is recognized, do the following:

1. Do not throw vaccine away. Place vaccine in working refrigerator/freezer with a calibrated digital data logger so that minimum and maximum temperatures can be monitored at least once daily. Mark clearly '**Do Not Use**' and separate from viable vaccine until a determination of viability is made.
2. Download the information from your DDL from your last in range temperature through the duration of the temperature excursion.
3. Contact the vaccine manufacturer and using your DDL download data provide the following information:
  - the last known temperature of the storage unit, and time it was recorded,
  - current temperature of the storage unit,
  - duration of storage outside of the recommended temperature range,
  - number of doses, trade name, lot numbers, and expiration date of the affected vaccines,
  - any prior temperature excursions to which this vaccine may have been subjected,
  - likely cause of the problem,
  - current room temperature,
  - request a copy of the determination report from the manufacturer

After a determination is made contact the Wisconsin Immunization Vaccines for Children Program.

1. Providers must return all non-viable vaccine to McKesson following current return guidelines.
2. Providers must submit a written report, a determination report of the incident that describes the circumstances of the loss, and the steps taken to ensure that vaccine is protected in the future. Further shipments of vaccine will not be sent to the provider until this information is received.
3. Providers must email the VFC Program at [vfc@wi.gov](mailto:vfc@wi.gov) or fax to 608-267-9493, invoices or documentation of replaced vaccine, and receipt of purchase to the Wisconsin Immunization Program within 90 business days.
4. The provider must consult with staff of the Wisconsin Immunization Program to assess storage and handling policies. The Wisconsin Immunization Program may recommend further training on storage and handling of vaccines.

If special circumstances exist, contact the VFC Program at [vfc@wi.gov](mailto:vfc@wi.gov) .

## Right to Appeal

If you believe that you should not be held responsible for the vaccine loss, you may appeal the decision in writing to Ashley Sarbacker, VFC Coordinator, via email [ashley.sarbacker@wi.gov](mailto:ashley.sarbacker@wi.gov) or fax to 608-267-9493.

Note: Noncompliance with the Vaccine Restitution Policy may be grounds for placing the provider on suspension. The Wisconsin Immunization Program will determine if probation or suspension from receiving further state-supplied vaccine is warranted after an investigation surrounding the circumstances of the vaccine loss.

Facility name	VFC PIN	Area code - Phone number
Street address		
City	State	ZIP code

I have read, and agree to adhere to the Wisconsin Immunization Program Vaccine Restitution Policy, and to the provisions of this policy.

I understand that failure to adhere to this policy may result in suspension of our clinic's participation in the Vaccines for Children Program.

The person signing below accepts responsibility of adherence to this policy, and has authority to request privately purchased vaccine on a dose-for-dose repayment of VFC vaccine in the event of a loss.

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Print name of representative authorized to sign on behalf of provider

<b>Signature</b> – Facility/Authorized Representative	Date signed
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