Rhode Island State-Supplied Vaccine (SSV) Program
Vaccine Replacement Policy

The Vaccine Replacement Policy was developed in accordance with Rhode Island's SSV Program to replace wasted or spoiled vaccine due to negligence and/or failure to properly store and handle vaccine inventory.

Definitions

Wasted: Any vaccine that cannot be used. This includes expired, spoiled, lost, or excess vaccine.

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

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Contact your Immunization Representative (IR) to determine if a vaccine is viable.

Lost: Any vaccine ordered but not delivered (or not delivered in a timely manner) by the shipping company resulting in lost and/or spoiled vaccine.

Excess: Vaccine that was ordered but unable to be administered or transferred prior to the expiration date.

Negligence: Failure on the part of the practice, either intentionally or unintentionally, to properly supervise the storage and handling of state-supplied vaccines.

Situations Requiring Vaccine Replacement

The following are examples of negligence that may require vaccine replacement. *This list is not exhaustive:*

- Failure to rotate or transfer vaccine that results in expired vaccine;
- Use of a dorm-style refrigerator to store vaccine;
- Drawing up vaccine prior to patient screening;
- Handling and storage mistakes by provider staff;
- Vaccine that is left out of the refrigeration unit and becomes non-viable;
- Freezing vaccine meant to be refrigerated or refrigerating vaccine meant to be frozen;
- Refrigerator left unplugged or electrical breaker switched off;
- Refrigerator door left open or ajar by provider staff, contractors, or guests;
- Refrigerator/freezer equipment problems where proof of repair or replacement is not

provided to the Immunization Program within 30 days of the date the problem is identified;

- Any power outages in which the provider fails to act according to the practice's ***Vaccine Storage Emergency Preparedness Plan;***
- Situations in which providers must re-vaccinate due to failure to keep vaccine viable (temperatures out of acceptable range) or improper administration. Provider will be responsible for the cost of vaccine for re-vaccination as well; and
- Ordering habits resulting in excess that lead to expired vaccine (e.g. maintaining a greater than 90-day supply of vaccines).

Situations Not Requiring Vaccine Replacement

The following examples are situations considered to be out of a provider's control, and generally do not require vaccine replacement. This list is not exhaustive. Providers must always contact their IR for a determination regarding the viability of suspect vaccine.

- Package is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit;
- A provider moves vaccine to a location with a secure power source due to anticipated inclement weather, but power is lost at that location;
- Partially-used, multi-dose vials that could not be transferred before expiration;
- Expired vaccine that the provider attempted to redistribute 120 days or more prior to expiration but was unsuccessful;
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Program within 30 days from the date you become aware of the situation; and
- Extraordinary situations not listed above which are deemed by the Immunization Program to be beyond the provider's control.

When reporting wastage of any kind, providers should provide documentation that demonstrates staff's use of the practice's ***Vaccine Storage Emergency Preparedness Pla*n**.

Annual Wastage Allowance

Practices have a 5% allowance toward wasted vaccine. The allowance is based on the total cost of vaccines wasted compared to the total cost of vaccines ordered in the previous 12-month period.

- Once a practice reaches the 5% allowance, it needs to go 12 consecutive months without incident before another 5% allowance will be given.
    - Example – A vaccine delivery is left out containing vaccine worth $15,000. The practice has ordered $100,000 worth of inventory in the past 12 months; therefore, the practice is required to replace $10,000 worth of vaccines ($5,000 waived for allowance). Any additional events in the next 12 months require 100% replacement, since the 5% allowance was met after the first incident.

Vaccine Replacement

- Each incident will be reviewed on a case-by-case basis.
- If the practice is found to be at fault, the practice will receive a notice from their IR reflecting the

current replacement process.

- Proof of replacement (manufacturer or distributor invoice) for the vaccine wasted must be submitted to RIDOH 30 days from the date of the notice.
- Failure to meet the required replacement protocols will result in vaccine delays or forfeiture of future program enrollment.

Returning Vaccine

- Prior to returning any vaccine, contact your IR for viability status as soon as you suspect vaccine may have spoiled. Complete the ***Temperature Excursion Response Worksheet***.
- Properly store the vaccine until you receive confirmation from your IR that the vaccine is no longer viable.
- If the vaccine is deemed non-viable, you will need to enter the Return/Waste into the Ocean State Management of State-Supplied Immunizations System (OSMOSSIS).
- RIDOH will forward the return information to CDC the first week of each month. CDC's distributor will then send a return label to the practice so it can return the vaccine.

Appeal Process

If your practice experiences a wastage situation which is defined as provider negligence, and you believe there are circumstances which prove it is not negligence, you may appeal ***after*** you receive the notice of replacement.

This appeal must be in writing and can be submitted by mail or email, on your practice letterhead or on a ***Vaccine Replacement Appeal Form*** (next page). If you choose not to use the *Vaccine Replacement Appeal Form*, you must include the same information required on the form. Be sure to include *all* information you would like considered (e.g. repair invoices) in your appeal. The practice's lead physician/medical director must sign the appeal.

Mail to: Rhode Island Department of Health
Immunization Program
Attention: Vaccine Manager
3 Capitol Hill – Room 302
Providence, RI 02908

Email to: Denise.Cappelli@health.ri.gov
Subject Line: (SSV Pin) Vaccine Replacement Appeal

Your office will receive written notification on the outcome of your appeal within 30 days of RIDOH's receipt of the initial appeal.

If you have any questions concerning this policy, please email the Chief for the Office of Immunization at Tricia.Washburn@health.ri.gov.

Vaccine Replacement Appeal Form

Email to:
Denise.Cappelli@health.ri.gov

Facility Name: _____
Address: _____
Contact: _____
SSV PIN: _____

Notice of Replacement Number: _____

The vaccine in question was returned to CDC on: _____
(Attach a copy of OSMOSSIS generated packing slip for any returns)

We believe we should not be held financially responsible for the replacement of vaccine and request reconsideration for the following reason(s). Below is a detailed explanation of the circumstances surrounding the events with all substantiating attachments. (Attach additional sheet of paper if necessary.

Signature: _____ Date: _____

Printed Name of Medical Director/Lead Physician: _____

License number of Medical Director/Lead Physician: _____

RIDOH Use Only:
Final decision rendered on: _____ By: _____

☐ Responsible ☐ Not Responsible Date Notified: _____