

# UNIVERSAL CHILDHOOD VACCINE DISTRIBUTION PROGRAM (UCVDP) FINANCIAL RESTITUTION POLICY REVISED DECEMBER 2007

This policy was developed in accordance with Session Law 1998-212, Section 12.52 (d) which states: “The division shall require as part of agreements with immunization program providers that the provider pay the cost of vaccine provided to replace vaccine provided under the program that has been wasted by the provider due to the provider’s failure to properly store, handle, or rotate vaccine inventory.”

## **Definitions:**

- Wasted:** Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.
- 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. **Always** consult with the Immunization Branch before determining that the vaccine is non-viable.
- Lost:** Shipping company does not deliver the vaccine or does not deliver in a timely manner.

## **Situations That Require Financial Restitution**

Below is a list of situations that are considered “provider negligence” and may require financial restitution. This list is not exhaustive. Failure to adhere to the current “UCVDP Minimum Required Vaccine Ordering, Handling, and Storage Procedures” document will likely result in a restitution situation. Situations that occur which are not listed here will be considered on an individual basis by Immunization Branch staff.

- ◆ Failure to rotate or transfer vaccine that results in expired vaccine (notify the Immunization Branch four months prior to expiration)
- ◆ Drawing up vaccine prior to patient screening. Please note the Immunization Branch strongly discourages the practice of pre-drawing vaccine.
- ◆ Handling and storage mistakes by provider staff
- ◆ Vaccine that is left out of the refrigeration unit and becomes non-viable. Call the Immunization Branch first to help you determine the stability/viability of vaccine left out of the refrigerator/freezer
- ◆ Freezing vaccine meant to be refrigerated
- ◆ 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 equipment replacement is not provided to the Immunization Branch within 30 days from the date you become aware of the situation
- ◆ Any power outages in which provider fails to act according to the posted Disaster Recovery Plan

- ◆ Replacement Vaccine - Health care providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of acceptable range) or improper administration will be responsible for the current cost of the vaccine needed to re-vaccinate

### **Situations That Do Not Require Financial Restitution**

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. Never make your own determination to the viability of vaccine. Call the Immunization Branch first. You may be required to produce a letter from the alarm/alert company or the power company.

- ◆ Package is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit
- ◆ 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 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
- ◆ A vial that is accidentally dropped or broken by provider
- ◆ Vaccine that is drawn after screening for contraindications and parental education, but not administered, due to parental refusal or a change in the physician orders
- ◆ Expired vaccine that is not due to provider negligence
- ◆ Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Branch within 30 days from the date you become aware of the situation
- ◆ Extraordinary situations not listed above which are deemed by the Immunization Branch to be beyond the provider’s control (when reporting wastage of any kind, providers should provide documentation that demonstrates staff’s use of the clinic Disaster Recovery Plan)

### **Procedures for Financial Restitution**

This updated policy applies to any vaccine received as wasted by the Immunization Branch on or after **April 1, 2000**.

- ◆ The provider will receive an invoice for vaccine reported as wasted to the Immunization Branch from the Department of Health and Human Services (DHHS), Controller’s Office.
- ◆ The invoice will reflect the Center for Disease Control and Prevention (CDC) cost of the vaccine, minus the excise tax. In accordance with DHHS Cash Management Plan, reimbursement for the cost of vaccine wasted shall be due **30 days** from the date of the invoice.
- ◆ General Statute 147-86.23 requires interest be charged at the rate established pursuant to General Statute 105-241.1 on past due accounts. A late penalty of 10 percent may be charged on past due accounts.

### **Procedures and Policy for Returning Vaccine to the Immunization Branch**

- ◆ **Never** send viable vaccine anywhere without prior approval from the receiving organization, because the cold chain may be broken and the vaccine will be considered spoiled.
- ◆ Call the Immunization Branch as soon as you suspect vaccine may be spoiled and prior to returning **ANY** vaccine.

- ◆ Return all open and unopened vials and manufacturer's pre-filled syringes of spoiled or expired vaccine with a completed Wasted/to the Immunization Branch, regardless of any financial restitution status applied to the vaccine. Never return needles to the Immunization Branch.

**Procedures and Policy for an Appeal Process**

The Financial Restitution Policy allows for an appeal process. If your office/agency 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 invoice. A format for appeal is attached.

This appeal must be in writing and can be submitted by mail or fax on your letterhead or on a Financial Restitution Appeal Form. If you choose not to use the Financial Restitution Appeal Form, you must include the same information as that contained on the form.

Fax to: (919) 870-4824  
Attention: Vaccine Manager

Mail to: DHHS/DPH/Immunization Branch  
Attention: Vaccine Manager  
1917 Mail Service Center  
Raleigh, NC 27699-1917

- ◆ Each appeal will be considered on a case by case basis.
- ◆ Your office will receive written notification regarding the outcome of your appeal within 10 days of receipt.
- ◆ Your appeal must be signed by your lead physician (if you are a private practice/facility) or your local health director (if you are a local health department).

If you have any questions concerning this policy, please call the Vaccine Manager at (919) 707-5553 for assistance.

Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

