TO: All Users of State Supplied Vaccine

FROM: Mick Bolduc-Vaccines For Children (VFC) Coordinator

DATE: May 12, 2011

SUBJECT: Update to the Vaccine Restitution Policy

The primary purpose of this communication is to inform you of changes made to the Immunization Program’s Vaccine Restitution Policy.

**Vaccine Restitution Policy**

The Vaccines For Children (VFC) Program provides nearly $4 billion dollars’ worth of free vaccines to providers nationwide. In Connecticut our annual vaccine budget is approximately $40 million dollars including nine million in state funds. The cost of state supplied vaccines continues to increase so it is imperative that vaccine wastage be kept to a minimum. Most incidents of wastage occur from vaccines that are allowed to expire. Providers are reminded of the need to rotate stock and transfer out short dated vaccine to another provider office at least 4 months before expiration. If an office is having trouble transferring short dated vaccine, please contact the Immunization Program for help with the process. As you know in January 2011 the Immunization Program implemented a one strike policy for vaccine wastage. With the price of vaccines skyrocketing, the one strike policy has been revised to incorporate a ceiling on how much vaccine wastage the state immunization program will cover.

Effective May 1, 2011 practices who receive state supplied vaccine will be allowed a “one strike” credit towards vaccine wastage up to a limit of $1300. On the first instance of vaccine wastage the Immunization Program will absorb the cost of vaccine replacement up to $1300; any vaccine wastage totaling over $1300 will result in the provider being responsible for replacing the vaccine on a dose for dose basis at their own cost. Any subsequent occurrences will require that the provider replace all wasted doses at their own cost.

The one strike credit does not apply to providers who have already reported vaccine wastage since January 1, 2010. A subsequent loss of vaccine reported by those practices will need to be replaced on a dose for dose basis at their own cost. Providers will not be allowed to order additional doses of vaccine until they submit to the Immunization Program an invoice showing that they have replaced all wasted doses.

As always, if you have any questions, please feel free to contact the Immunization Program at (860) 509-7929.
Connecticut Vaccines For Children Program
Financial Restitution Policy
Effective May 1, 2011

The Financial Restitution Policy was developed in accordance with Connecticut’s Vaccines for Children (VFC) Program for the purpose of replacing vaccine wasted or spoiled due to negligence and/or failure to properly store, handle, or rotate vaccine inventory. The policy has been updated to address the increased costs of replacing wasted, expired or spoiled vaccines provided through the VFC Program.

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 / reconstituted and not used within acceptable time frames. Always consult with the State Immunization Program before determining if a vaccine is non-viable.

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

Situations Requiring Financial Restitution

The following situations are examples of negligence that may require financial restitution. This list is not exhaustive:

- Failure to rotate or transfer vaccine that results in expired vaccine
- Drawing up vaccine prior to patient screening
- Handling and storage mistakes by provider staff
- Vaccine left out of the refrigeration unit that becomes non-viable
- 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 Program within 30 days from the date the problem is identified
- Any power outages in which the provider fails to act according to the practice’s Back Up Protocol For Vaccine Recovery Plan
- Situations in which health care providers must re-vaccinate due to previous administration of non-viable vaccine (i.e. spoiled or expired) or improper administration. Provider will be responsible for the cost of vaccine for re-vaccination.
- Ordering habits resulting in overstock that lead to expiration of vaccines
- Delivery of vaccine during the provider’s stated business hours but the office is closed resulting in the loss of vaccine product
Examples of Situations Not Requiring Financial Restitution

The following examples are situations considered to be out of the providers’ control, and generally do not require financial restitution. This list is not exhaustive. Providers should always contact the State Immunization Program for a determination regarding the viability of suspect vaccine.

- Vaccine that is damaged, improperly stored during transit, or not delivered to the provider in a timely manner
- A company contracted to alert a provider when a refrigerator malfunctions fails to 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
- Expired vaccine that the provider attempted to redistribute 4 months 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
- 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 document the staff’s use of the practice’s Back Up Protocol For Vaccine Recovery Plan)

Wastage Allowance

All practices will be allowed a “one strike” credit towards vaccine wastage up to a limit of $1300. On the first instance of vaccine wastage the Immunization Program will absorb the cost of vaccine replacement up to $1300; any vaccine wastage totaling over $1300 will result in the provider being responsible for replacing the vaccine on a dose for dose basis at their own cost. Any subsequent occurrences will require that the provider replace all wasted doses again at their own cost. Providers will not be allowed to order additional doses of vaccine until they submit to the Immunization Program an invoice showing that they have replaced all wasted doses.

Procedure for Financial Restitution

This policy applies to any vaccine reported to the Immunization Program as wasted on or after May 1, 2011. Providers who already have reported vaccine wastage since January 1, 2010 and experience a subsequent loss of vaccine will need to replace vaccine on a dose for dose basis at their own cost since they have already used up their one strike credit.

- Each incident reported will be reviewed on a case-by-case basis by the Immunization Program to determine whether restitution will be required or if extenuating circumstances prevail.
• The provider will be required to submit an invoice to the Immunization Program showing they have privately purchased the vaccine reported as wasted.
• Failure to replace any wasted vaccine will result in a delay or forfeiture of future program enrollment for the practice.

**Procedure for Returning Vaccine**

• Call the State Immunization Program as soon as you suspect vaccine may be spoiled to determine viability status.
• Complete and fax a copy of the **Vaccine Return Form** to the Immunization Program. The Immunization Program will request a mailing label be sent from McKesson to the provider for return of the wasted vaccine.
• Once the mailing label is received the provider will return all unopened vials & pre-filled syringes of wasted vaccine to McKesson along with a copy of the **Vaccine Return Form**