



DEVAL L. PATRICK  
GOVERNOR

TIMOTHY P. MURRAY  
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD  
SECRETARY

JOHN AUERBACH  
COMMISSIONER

# The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

William A. Hinton State Laboratory Institute  
305 South Street, Jamaica Plain, MA 02130

Division of Epidemiology and Immunization  
617-983-6800, Fax 617-983-6924

**To:** Health Care Providers

**From:** Susan M. Lett, MD, Medical Director, Immunization Program  
Division of Epidemiology and Immunization

Robert W. Morrison, Vaccine Manager  
Division of Epidemiology and Immunization

**Date:** October 2011

**Re:** **REVISED** Vaccine Restitution Policy Effective January 1, 2012

---

MDPH is updating its Vaccine Restitution Policy for 2012. This memo is providing health care providers advanced notice that the new policy as outlined below will be implemented effective January 1, 2012.

The Vaccines For Children (VFC) program, a component of each state's medical assistance plan, is considered a Title XIX Medicaid program. Section 1928 of the Social Security Act (42 U.S.C. §1396s) provides for purchase of vaccine for administration to VFC-eligible children – "federally vaccine-eligible children" only. Federal fraud and abuse laws apply to the entire VFC program, and a specific federal protocol must be followed when problems are identified. This protocol must also be followed for problems related to state purchased vaccines.

For more information on fraud and abuse, please see the MDPH document *Guidelines for Compliance with Federal Vaccine Administration Requirements*, Section A.5 ([www.mass.gov/dph/imm](http://www.mass.gov/dph/imm) then click on Vaccine Management.)

The federal protocol described above includes procedures for collecting restitution in certain incidents of vaccine loss. The Massachusetts Department of Public Health (MDPH) implemented a vaccine restitution policy effective January 1, 2011. As of October 1, 2011 there have been 5 incidents resulting in vaccine restitution ranging from \$170 to \$27,793. Examples of vaccine loss requiring restitution have included:

- Not opening vaccine shipments on arrival
- Leaving the refrigerator or freezer door ajar
- Allowing vaccines to expire before use
- Not moving vaccine to a back up unit or facility when a refrigerator or freezer is without power or not functioning properly

## Restitution Policy

MDPH acknowledges that providers make good faith efforts to store and handle vaccines appropriately, as outlined in the Guidelines for Compliance (referenced above).

However, MDPH will require providers to provide restitution for any doses of federal or state-purchased vaccines that have been lost due to the provider's failure to properly receive, store, or use vaccines if:

- NEW a. this is the 1<sup>st</sup> incident and the total loss is over \$10,000, or
- NEW b. this is the 2<sup>nd</sup> incident (or greater) – regardless of total value, or
- c. it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine, regardless of total value.

Restitution will require the provider to privately purchase replacement doses of the vaccines that were lost. Listed below are examples of provider negligence that will require financial restitution:

- Failure to open vaccine shipments from McKesson or Merck immediately, resulting in damage to the vaccines.
- Failure to rotate vaccine stock, resulting in expired vaccine.
- Allowing vaccine to expire. Providers must contact the Vaccine Unit 2 months prior to vaccine expiration.
- Using VFC or state-provided vaccines for unapproved groups
- Freezing vaccines meant to be refrigerated.
- Refrigerating vaccines meant to be frozen.
- Refrigerator or freezer left unplugged, or electrical breaker switched off by provider staff, contractors, or any other individual.
- Refrigerator or freezer door left open or ajar by provider staff, contractors, or any other individual.
- Vaccine that is left out of the refrigeration unit and becomes non-viable (Always call the Vaccine Management Unit at 617-983-6828 to determine if vaccine can be identified as viable.)
- Any power outages in which the provider fails to act according to their vaccine storage back up plan.
- Any other handling and storage mistakes by provider staff.

The MDPH will notify the provider concerning the number of doses of each vaccine that must be replaced; vaccine must be replaced on a dose per dose basis except as noted below. Subsequent vaccine orders from the provider will not be processed by the Vaccine Management Unit until a copy of the invoice or packing list for the replacement vaccine has been received by MDPH, reviewed, and determined to be adequate.

Providers may also propose to MDPH to purchase new vaccine storage and/or monitoring equipment (i.e. refrigerator, temperature monitoring devices, alarms) in lieu of or in addition to replacement vaccine. The cost of the new equipment will be deducted from the total amount of replacement vaccine that will need to be purchased. All purchases must be preapproved by MDPH and evidence of the new purchase (i.e. invoice and/or packing slip) must be sent to the Vaccine Management Unit before the provider will be able to order more federal or state-supplied vaccine.

Please note that the MDPH will only hold providers accountable in situations of provider

negligence as outlined above and will not seek restitution for a vaccine loss that occurred due to a circumstance not in the provider's control (i.e. act of nature). Providers will be given due process to dispute cases of avoidable loss. However, MDPH retains the right to make final determinations regarding vaccine restitution.

The MDPH recommends that all health care provider offices contact their insurance companies to verify that they have adequate coverage to cover any type of vaccine loss. This coverage should be at a level adequate to cover the private market cost to fully replace the highest level of vaccine inventory that they could potentially maintain in their offices. This coverage should also be evaluated and updated on an annual basis as their vaccine formulary changes and vaccine prices go up.

Any questions on this procedure can be addressed by calling the MDPH Vaccine Unit at 617-983-6828.