



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Infectious Disease and Laboratory Sciences
305 South Street, Jamaica Plain, MA 02130

MAURA T. HEALEY
Governor

KIMBERLEY DRISCOLL
Lieutenant Governor

Immunization Division

Tel: (617) 983-6800

Fax: (617) 983-6840

www.mass.gov/dph/imm

KATHLEEN E. WALSH
Secretary

ROBERT GOLDSTEIN, MD, PhD
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

To: Vaccine Providers

From: Pejman Talebian, MA, MPH, Director
Immunization Division
Rattana Bip, Vaccine Manager
Immunization Division

Date: January 2025

Re: Vaccine Restitution Policy

This memo summarizes Vaccine Program's current Vaccine Restitution Policy.

The Vaccine Program consists of three sub-programs: universal state pediatric vaccine program, federal vaccines for children (VFC) program, and the limited adult vaccine program. All sites enrolled in the Vaccine Program (including Specialty providers, Respiratory Vaccine-Only providers, or Adult-Only providers) must consider all doses received via the Vaccine Program as state-supplied vaccine.

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 Vaccine Program, and a specific federal protocol must be followed when problems are identified. This protocol must also be followed for problems related to state-supplied vaccines.

For more information on fraud and abuse, please see the MDPH document [Guidelines for Compliance with State Vaccine Program Requirements](#), Section A-6.

The federal protocol described above includes procedures for collecting restitution in certain incidents of vaccine loss. The Vaccine Program implemented a vaccine restitution policy effective January 1, 2011. Examples of the most common 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 Section A-7 of 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:

- a. this is the 1st incident and the total loss is over \$25,000, or
- b. this is the 2nd incident in less than a 12-month period and the total loss is over \$5,000, or
- c. this is the 3rd incident (or greater) in less than a 12-month period regardless of the total value, or
- d. it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine, regardless of total value, or
- e. it is due to a failure to store refrigerated vaccine in a refrigerator or failure to store frozen vaccine in a freezer 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, Merck or Pfizer immediately, resulting in damage to the vaccines.
- Failure to rotate vaccine stock, resulting in expired vaccine.
- Allowing vaccine to expire. Providers must transfer soon to expire vaccine to another practice 2-3 months prior to vaccine expiration. If unable to locate a practice, contact the Vaccine Program for assistance at 617-983-6828.
- Using state-supplied vaccines for unapproved groups including non-eligible adult patients 19 years and older.
- 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 at your site, resulting in damaged vaccines.
- Refrigerator or freezer door left open or ajar by provider staff, contractors, or any other individual at your site, resulting in damaged vaccines.
- Vaccine that is left out of the storage units and becomes non-viable (always contact the vaccine manufacturer to determine if vaccine can be identified as viable).
- Any power outages in which the provider fails to act according to provider's vaccine standard operating procedures.
- Ordering state-supplied vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of state-supplied vaccines.
- Wastage of state-supplied vaccine, including a pattern of pre-drawing vaccines resulting in the loss of unused doses.
- A refrigerator malfunction in a non-pharmaceutical grade unit that is being used to store vaccines for a pediatric practice resulting in damaged vaccines.
- Storing state-supplied vaccines in a household combination or dormitory style unit.
- Failure to notify the Vaccine Program of any temperature excursion in storage units containing state-supplied vaccine.

- Failure to complete the associated Temperature Excursion Reporting Form for any out-of-range temperatures in storage units containing state-supplied vaccine.
- Any other handling and storage mistakes by provider staff.

The Vaccine Program requires all pediatric practices (any site that administers at least some vaccine to those <19 years of age, excluding sites that only administer flu vaccine) to have pharmaceutical grade refrigerators for all vaccine storage units in their facility.

Although there is no specific description of a pharmaceutical grade refrigerator, some of the characteristics include:

- Internal overhead fans to disperse cold air throughout the unit, eliminating cold pockets of air
- Adjustable wire shelves to allow better air flow
- No storage bins, or shelves on door
- Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 Celsius degrees or 3 Fahrenheit degrees)
- Electronic digital thermostat
- Micro Processor

The Vaccine Program 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 with privately purchased vaccine. Subsequent vaccine orders from the provider will not be processed by the Vaccine Program until a copy of the vaccine replacement form is received and processed. The Vaccine Program may request copies of the invoice for the privately purchased replacement vaccines if lot numbers match state-supplied vaccine doses in inventory

The Vaccine Program 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, the Vaccine Program retains the right to make final determinations regarding vaccine restitution.

The Vaccine Program 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 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 Vaccine Program at 617-983-6828.