

Vermont Vaccines for Children/Vaccine for Adults Program
REVISED Restitution Policy
Effective January 1, 2015

Vaccine accountability is an essential requirement of the Vermont Department of Health's Vaccines for Children (VFC) and Vaccines for Adults (VFA) programs. Assuring vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until administration. Provider practices may have inventory in excess of \$30,000. Funding for vaccine purchases requires careful stewardship. Restitution is only required when loss was directly caused by negligence on the part of the provider practice.

I. Immunization Program Policy:

As part of the VFC/VFA enrollment process, provider practices agree to comply with program requirements for vaccine ordering, storage, handling and accountability. Beginning in 2013, digital data loggers that record and store temperatures at frequent intervals were provided to every VFC/VFA practice by the Immunization Program, as recommended by CDC. This was intended to enhance temperature monitoring and provide a more accurate assessment of temperature excursions.

Since July 2011, enrollment in the VFC/VFA program has included an agreement that a practice's failure to store or handle vaccines properly, due to negligence, may result in the practice being liable for wasted doses. The practice assumes responsibility to replace wasted vaccine on a dose for dose basis. Cost per incident will be capped at \$2,500.

If restitution is required, the practice must show they have purchased replacement vaccine and resolved the problem that caused the waste, before being allowed to receive additional state-supplied vaccine.

Definitions:

Waste: Any non-viable vaccine that cannot be used. This includes expired, spoiled and unaccounted for vaccine.

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

Spoiled: Any vaccine that is stored or transported outside of approved cold chain procedures or any vaccine that has been pre-drawn and not used within an acceptable time frame. Always consult with the VDH Immunization Program immediately upon discovery of break in cold chain before determining that the vaccine is spoiled.

Actions:

Promptly call the Immunization Program when it's suspected that vaccine has been exposed to a temperature excursion. The Immunization Program will work with practice staff to understand the cause and with vaccine manufacturers to determine vaccine viability.

Restitution will only be required for an incident where ten or more doses of vaccine are wasted due to negligence as defined below.

If restitution is required, the provider will be asked to privately purchase replacement vaccine and submit documentation of an order confirmation or an invoice to the Immunization Program. Failure to replace vaccine will result in a delay of future VFC and/or VFA vaccine orders.

Situations Requiring Restitution:

- Failure to contact the Immunization Program when repeated refrigerator or freezer malfunctions result in temperature excursions and vaccine loss. The Vermont Vaccine Management Plan noted that all temperature excursions should be reported to the Immunization Program when they occur.
- Failure to notify the Immunization Program prior to the expiration of 10 doses or more of vaccine except influenza for the purpose of redistribution.
- Vaccine is received but not placed in the refrigerator or freezer resulting in vaccine loss.
- Vaccine is left out of the refrigerator or freezer and becomes non-viable

Vaccine viability depends upon actions of knowledgeable staff. Please contact the Immunization Program when there are staff assignment changes related to vaccine storage and handling duties. For questions concerning this policy, please call the Vermont Department of Health Immunization Program at (802) 863-7638 or toll free at 1-800-640-4374.