

New York State Vaccine Program Vaccine Restitution Policy

Purpose

New York State (NYS) provides vaccine worth approximately \$79 million to Vaccines for Children (VFC) providers in New York State (outside of New York City) each year at no cost to providers. As the cost of vaccines continues to increase, vaccine wastage must be kept to a minimum. This policy outlines scenarios that could require a provider to make financial restitution as a result of vaccine wastage. Provider offices that follow all appropriate storage and handling, excursion reporting and vaccine ordering requirements described by the NYS VFC Program will be far less likely to have vaccine wastage that results in restitution.

Policy

According to the NYS VFC Annual Healthcare Provider Agreement, providers agree "...to replace vaccine purchased with federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis."

Definitions

Wasted: Any vaccine that cannot be used. This includes expired and non-viable vaccines, vaccine that is pre-drawn or reconstituted and not used within acceptable time frames, and vaccine unaccounted for after delivery.

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

Non-viable: Any vaccine dose or doses that for whatever reason (expired, damaged, or improperly stored and handled) is deemed inappropriate for administration to a patient.

Situations Requiring Financial Restitution

The following situations are examples of negligence that may require financial restitution if vaccine is wasted, expired or non-viable. This list is not exhaustive.

- Failure to rotate or transfer vaccine close to expiration that results in expired vaccine.
- Drawing up vaccine prior to patient screening which is subsequently not administered.
- Storage and handling mistakes by provider staff resulting in non-viable vaccine.
- Vaccine left out of the refrigeration or freezer 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 others at a provider office and time-temperature limits are exceeded such that vaccine is determined to be non-viable.

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- Refrigerator/freezer equipment is not consistent with the NYS VFC Program requirements and has a temperature excursion resulting in vaccine loss.
- Refrigerator/freezer equipment is consistent with the NYS VFC Program requirements but has a temperature excursion that results in vaccine loss when equipment failure and that loss is not reported within 1 business day.
- Any power outages in which the provider fails to act according to the practice's Vaccine Emergency Plan.
- Ordering habits resulting in overstock that lead to expiration of vaccines. Overstock is defined as having more than two months of vaccine supply on hand for any vaccine at the time of vaccine expiration.
- Delivery of vaccine during the provider's stated business hours but the office is closed, resulting in non-viable vaccine.
- Loss of vaccine viability due to failure to maintain a certified calibrated thermometer as defined in the NYS VFC Provider Manual.

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 NYS VFC Program for a determination regarding the viability of suspect vaccine.

- Vaccine that is damaged or improperly stored during transit to the provider, or is not delivered by the distributor to the provider in a timely manner resulting in a break of the cold chain.
- A power outage resulting in non-viable vaccine during which the provider acted according to the vaccine emergency plan and NYS VFC Program and vaccine manufacturer guidance regarding non-viable vaccine is followed.
- Partially-used multi-dose vials that expire before all doses in the vial can be used.
- A vial that is accidentally dropped, broken or contaminated by the provider.
- A provider notifies the NYS VFC Program of vaccine scheduled to expire within 90 days but the NYS VFC Program is unable to redistribute vaccine prior to expiration.
- Refrigerator/freezer equipment is consistent with the NYS VFC Program requirements but has a temperature excursion that results in non-viable vaccine when equipment failure is reported within 1 business day.
- Extraordinary situations not listed above which are deemed by the NYS VFC 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 Emergency Plan).

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Annual Wastage Allowance

Practices will be allowed a 5% allowance toward wasted vaccine for the first year of policy implementation excluding expiration of seasonal influenza vaccine. During the second year of policy implementation, providers will be allowed a 2.5% allowance toward wasted vaccine and 1% in the third year. The allowance will be based on the total doses of vaccine wasted compared to the total doses of vaccine ordered over the previous 12-month period for the practice.

- Once a practice has reached the 5% allowance it will need to participate in the NYS VFC Program without incident. Any additional doses wasted beyond the 5% allowance will need to be replaced at provider's cost on a dose-for-dose basis.
 - Example – a delivery of 75 doses of vaccine is left outside the refrigerator and is determined to be non-viable. The practice has ordered 1000 doses over the past 12-months. 50 doses [5% of 1000] would be considered the provider's wastage allowance and the practice would be responsible to replace 25 doses of vaccine [75 doses wasted – 50 dose allowance]. Any additional events during the 2014 calendar year that result in losses above the 5% allowance would require 100% restitution for the vaccine lost.

Loss of Vaccine Viability and Wastage Resulting in the Need for Revaccination

- Situations in which health care providers must revaccinate due to administration of non-viable vaccine or improper administration (i.e. wrong site, dose or needle). Provider will be responsible for the cost of vaccine for re-vaccination but this will not be included in the calculation of wasted vaccine.

Procedure for Financial Restitution

This policy applies to any vaccine reported to the NYS VFC Program as wasted on or after January 1, 2015:

- Each incident reported will be reviewed on a case-by-case basis by the NYS VFC Program to determine whether restitution will be required or if extenuating circumstances prevail.

The provider will be required to submit an invoice to the NYS VFC Program showing they purchased replacements for the vaccine reported as wasted and that it will be used for VFC patients. Failure to replace any wasted vaccine will result in a suspension of VFC ordering privileges or forfeiture of future VFC Program enrollment for the practice.

Strategies to Minimize Vaccine Loss

- Always adhere to appropriate storage and handling procedures as described in the NYS VFC Provider Manual and CDC Storage and Handling Toolkit.

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- Do not over order vaccine. When ordering vaccine, only order enough so that your current inventory plus new stock will supply VFC-eligible children for two months. The NYS VFC Program strongly encourages all providers to utilize the inventory module in the New York State Immunization Information System (NYSIIS) to assist with determining current physical inventory and proper ordering.
- Conduct a vaccine count monthly, check vaccine expiration dates, and rotate stock regularly to ensure that vaccine is not ordered while adequate supplies are currently in stock.
- Report vaccine that will not be used and will expire within 90 days to the NYS VFC Program.
- Contact the NYS VFC Program and vaccine manufacturers immediately whenever a temperature excursion is identified.

Procedure for Returning Vaccine

- Call the NYS VFC Program as soon as you suspect vaccine may be non-viable to determine viability status.
- Complete and fax a copy of the **Expired/Loss Report** to the NYS VFC Program for any expired or other non-viable vaccine. The 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 and pre-filled syringes of wasted vaccine to McKesson along with a copy of the **Expired/Loss Report**.

Replacing Vaccine and Follow Up

- Providers who are required to replace vaccine must do so by purchasing vaccines from manufacturers at their own expense on a dose-for-dose basis. The replacement vaccine must only be used for VFC-eligible children.
- If a provider is required to replace a portion of vaccine doses lost, that portion will reflect the variety of vaccine lost at equal percentages.
 - For example, if a provider is required to replace 50% of three different brands of vaccine, the provider should replace 50% of all three different vaccines or their equivalent.
- Providers who replace lost vaccine will be required to provide the NYS VFC Program with a receipt or invoice as proof of vaccine replacement.
- Providers who lose vaccine due to equipment failure will be required to use stand-alone storage units for publicly purchased vaccine.

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References

- New York State Vaccine for Children Provider manual:
http://www.health.ny.gov/prevention/immunization/providers/vfc_provider_manual/
- The Centers for Disease Control and Prevention Recommendations and Guidelines-
Vaccine Storage and Handling: <http://www.cdc.gov/vaccines/recs/storage/default.htm>
- The Centers for Disease Control and Prevention Storage and Handling Toolkit:
<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>