



New York State Vaccines for Children (NYS VFC) 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. By following NYS VFC Program storage and handling and excursion requirements, and following vaccine ordering recommendations, providers 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." The boxes below describe examples of situations that may require VFC providers to provide financial restitution and situations for which providers would not be financially responsible.

Situations Requiring Financial Restitution	
<i>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:</i>	
1	Failure to rotate or transfer vaccine close to expiration date which results in expired vaccine
2	Pre-drawn vaccine that is not used
3	Administering VFC vaccine to ineligible children or adults
4	Provider storage and handling mistakes resulting in non-viable vaccine
5	Refrigerator or freezer left unplugged, the door left open, or electrical breaker switched off
6	Failure to contact the VFC Program within 1 business day of a temperature excursion
7	Any power outages in which the provider fails to act according to the practice's vaccine emergency storage and handling plan, to the extent possible
8	Non-viable vaccine resulting from delivery of vaccine when the office is closed during provider's stated business hours
9	Loss of vaccine viability due to failure to install or maintain a certified, calibrated data logger
10	Extraordinary situations not listed above determined to be within a provider's control

Situations <i>Not</i> Requiring Financial Restitution	
<i>The following examples are situations which do not require financial restitution if vaccine is wasted, expired or non-viable. This list is not exhaustive:</i>	
1	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
2	A power outage resulting in non-viable vaccine during which the provider acted according to their vaccine emergency plan, to the extent possible, and followed VFC Program and vaccine manufacturer guidance regarding non-viable vaccine.
3	Partially-used multi-dose vials that expire before all doses in the vial can be used.
4	A vial that is accidentally dropped, broken or contaminated by the provider
5	Providers who notify the VFC Program between 60 and 90 days in advance of expiration dates with a reasonable explanation of why they have vaccine that will go unused
6	Extraordinary situations not listed above determined to be beyond the provider's control

DEFINITIONS
<p>Wasted: Any vaccine that cannot be used, including: expired, non-viable (unused multi-use vials, damaged vaccine, or vaccine which is drawn up but not administered within an acceptable time frame), and vaccine unaccounted for after delivery.</p> <p>Expired: Any vaccine with an expiration date that has passed.</p> <p>Non-viable: Any vaccine that for whatever reason (expiration, damage, or improper storage or handling) is deemed inappropriate for administration to a patient.</p>



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Annual Wastage Allowance

Standard population size VFC practices (eligible patient population > 50) will be allowed a 5% allowance toward wasted vaccine annually. Because of their proportionally smaller amount of vaccine ordered annually, small population size VFC providers (eligible patient population < 50) will have an annual wastage threshold of 10%. 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. Seasonal flu vaccine and any vaccine purchased as part of an outbreak response will not be counted as part of the annual wastage.

ANNUAL WASTAGE ALLOWANCE SUMMARY

Annual Wastage Threshold for Standard Population Size VFC Practices: the annual wastage threshold for all standard size population VFC practices (eligible patient population > 50) is 5%.

Annual Wastage Threshold for Small Population Size VFC Providers: small population size VFC provider (eligible patient population < 50) will only need to provide restitution for any vaccine wastage above 10% of their annual orders.

Outbreak Response Vaccine Exemption: wastage or returns of vaccine doses ordered as part of an outbreak response will not be counted towards VFC provider's annual wastage threshold.

Flu Vaccine Exemption: seasonal flu vaccine wastage or returns will not be counted towards VFC provider's annual wastage threshold.

Procedure for Financial Restitution

- 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.
- Providers with wastage exceeding the threshold allotments will be required to submit an invoice to the NYS VFC Program showing they purchased replacements on a dose-for-dose basis for the vaccine reported as wasted and ensure that it will be used for VFC patients.
- Although VFC providers will continue to be responsible for the cost of vaccine used to revaccinate after the administration of non-viable vaccine (i.e. wrong site, dose, or because of temperature excursion), these non-viable doses will not be included in the calculation of wasted vaccine.
- 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 CDC Storage and Handling Toolkit: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- Do not over order vaccine. New orders plus current inventory should supply VFC-eligible patients at your practice for two months. The NYS VFC Program requires all providers to utilize the inventory module in the New York State Immunization Information System (NYSIIS) to determine current inventory and adequate ordering quantities: [New York State Immunization Information System \(NYSIIS\) User Manual](#), pp 59.
- Conduct a vaccine count monthly, check vaccine expiration dates, and rotate stock regularly to prevent vaccine waste and over-ordering. See [Job Aid: Monitoring Vaccine Expiration Dates](#) for more information.
- Report vaccine that will not be used and will expire within 90 days to the NYS VFC Program using the following form: [Short-dated Vaccine Reporting Form](#). See [Job Aid: Return or Discard](#) for more information. Under no circumstances is it acceptable for providers to change or alter expiration dates on vaccines.



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- 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](#).
- For vaccine expired > 6 months, complete this form: [Nonviable Vaccine Reporting Form](#)

Vaccine Replacement 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 because of equipment failure will be required to use stand-alone storage units for publicly purchased vaccine from that point forward.

Resources

New York State Vaccine for Children Program, 1-800-543-7468 <http://www.health.ny.gov/vfc> Email: nyvfc@health.ny.gov

Centers for Disease Control and Prevention, (CDC) Vaccine Storage and Handling Toolkit:
<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

New York State Immunization Information System (NYSIIS) Returns /Wastage Training Handout
https://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/returns_wastage_training_handout.pdf