

Alabama Department of Public Health

Immunization Division

VFC Vaccine Replacement Policy

Purpose

The Alabama Department of Public Health, Immunization Division (IMM), manages the federal entitlement program Vaccines for Children (VFC) and the distribution of approximately \$67 million dollars of vaccine each year. This vaccine is distributed at no cost to VFC providers. Due to an increase in vaccine cost and over \$1 million dollars wastage per year, it has become necessary for the AL VFC Program to implement the *VFC Vaccine Replacement Policy* effective April 1, 2018. Providers who conform to the VFC Program requirements and recommendations, e.g. vaccine storage and handling, excursion reporting, and vaccine ordering requirements will protect VFC vaccine from wastage. These same requirements and recommendations will also protect private-stock vaccine from wastage.

Policy

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

Definitions

- **Wasted:** Any vaccine not used, which includes expired and non-viable vaccines, vaccine that is pre-drawn, reconstituted and unused within acceptable time frames, and vaccine unaccounted for after delivery.
- **Expired:** Any unused vaccine past its expiration date.
- **Non-viable:** Any vaccine expired, damaged, or improperly stored and handled is deemed inappropriate for administration.

Negligent Situations Requiring Replacement

The following negligent situation examples may require financial replacement if vaccine is wasted, expired, or non-viable. This list includes, but is not limited to:

- Not using stand alone refrigerator, stand alone freezer (e.g., chest freezer, frost-free freezer, manual defrost freezer), household refrigerator with separate compartments for refrigerator and freezer with separate exterior doors (refrigerator portion is the only section that may be used), commercial refrigerator with separate compartments for refrigerator and freezer with separate exterior doors (refrigerator portion is the only section that may be used).
- Failure to maintain a primary and back-up certified calibrated digital data logger (DDL) defined by the Centers for Disease Control and Prevention (CDC) and VFC guidelines.
- Temperature excursion which results in vaccine loss when equipment failure and loss is not reported within 1 business day.
- Failure to rotate or transfer vaccine close to expiration.
- Pre-drawing vaccine prior to screening patient and not administering.
- Storage and handling mistakes by provider staff.

- Vaccine left out of the refrigerator or freezer.
- 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, time-temperature limits are exceeded, and vaccine is determined to be non-viable.
- Any power outages in which the provider fails to act according to the practice's VFC Vaccine Emergency Plan.
- Ordering habits resulting in overstock that leads 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.

Situations Not Requiring Replacement

Providers should always contact the AL VFC Program for a determination regarding the viability of suspect vaccine and when reporting providers should document the staff's use of the practice's VFC Vaccine Emergency Plan. Some situations are considered out of the providers' control, and generally do not require financial replacement. The following examples include but are not limited to:

- Damaged or improperly stored vaccine during transit to the provider, or vaccine is not delivered by the distributor to the provider in a timely manner.
- Provider followed their VFC Vaccine Emergency Plan, AL VFC Program, and vaccine manufacturer guidance during power outage.
- Expired partially-used multi-dose vials.
- A vial that is accidentally dropped, broken, or contaminated.
- Reported within 1 business day that the required refrigerator/freezer has a temperature excursion.
- Extraordinary situations not listed above which are deemed by the AL VFC Program to be beyond the provider's control.

Annual Wastage Allowance

Practices should not exceed 5% wasted vaccine for the first year of replacement policy implementation, excluding expiration of seasonal influenza vaccine. 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, 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 practice has ordered 1,000 doses over the past 12-months and 75 doses of vaccine were left outside the refrigerator and determined to be non-viable. The 5% of 1,000 doses (50), 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 calendar year would result in losses above the 5% allowance and 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) by their practice. Provider will be responsible for the cost of vaccine for re-vaccination, but this will not be included in the calculation of wasted vaccine. Medicaid will not pay for the revaccination for an incorrectly administered dose.

Procedure for Financial Replacement

This policy applies to any vaccine reported to the AL VFC Program as wasted on or after April 1, 2018. Each incident reported will be reviewed on a case-by-case basis by the AL 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 AL VFC Program showing they purchased replacements for the wasted vaccine reported and 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 CDC Storage and Handling Toolkit.
- 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 one month.
- 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 unused vaccine that will expire within 90 days to the AL VFC Program.
- Contact the AL VFC Program and vaccine manufacturers immediately whenever a temperature excursion is identified.

Procedure for Returning Vaccine

- Call the AL VFC Program as soon as you suspect vaccine may be non-viable to determine viability status.
- Complete a copy of the VTrckS Expired/Loss Report to the AL 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.

- Providers who replace lost vaccine will be required to provide the AL 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 public-purchased vaccine.

References

- 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>