

Georgia Vaccines for Children (VFC) Vaccine Loss Policy

This document will serve as the Georgia Department of Community Health, Division of Public Health - Immunization Office's policy for management of incidents that result in loss of state supplied vaccine. The action taken by the Georgia VFC Program will depend on the category of the vaccine loss. For this policy, lost vaccines fall under three categories: 1) negligence, 2) non-preventable loss, and 3) noncompliance.

Category 1

Vaccine loss due to **negligence** is defined as, but not limited to, the following:

- a) Vaccine stored improperly (i.e., refrigerating vaccine that should have been frozen, freezing vaccine that should have been refrigerated, or storing any vaccine in a dormitory style refrigerator even for day use*).
**dorm-style refrigerator change effective 1/1/2010*
- b) Vaccine left out of refrigerator or freezer.
- c) Refrigerator or freezer unplugged.
- d) Door of refrigerator or freezer left ajar resulting in unit temperatures outside the acceptable range.
- e) Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded. *(Note: Temperatures recorded on temperature logs will be considered official in making vaccine viability decisions. Also, a thermometer's margin of error will not be considered when temperatures are recorded at or below 35°F/2°C.)*
- f) Pre-drawing or premixing vaccine, then not administering.
- g) Discarding vaccine prior to the manufacturer's stated expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used).
- h) Transporting/shipping vaccine with lack of or inappropriate coolants (e.g., packing refrigerated vaccines with dry ice or frozen vaccines with ice packs only).
- i) Failure to notify the VFC Program when provider office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled.
- j) Vaccine expired due to failure of the provider to notify the VFC Program three months prior to expiration date so that vaccine might be transferred.

Action Plan

If the provider discovers: vaccine not refrigerated or frozen within the recommended temperature range, vaccine left outside the refrigerator or freezer, the refrigerator or freezer door left ajar, continued documentation of temperatures outside the recommended range, vaccine lost in transit to a satellite facility, or vaccine undeliverable and spoiled due to a change in office hours, the incident must be reported to VFC immediately. **Vaccines should be kept in the appropriate storage environment (refrigerator or freezer) until a decision is made concerning their viability.**

Call 1-800-848-3868 and explain the circumstances to the customer service representative. Be prepared to furnish the following information:

- a) Last known temperature of the refrigerator and freezer;

- b) Current temperature of the refrigerator and freezer;
- c) Duration of time the vaccines were stored out of recommended temperature range; and
- d) Lot numbers, expiration dates, and number of doses of all vaccines in question.

The VFC staff will contact the vaccine manufacturers and determine if the vaccines in question are salvageable. **If they are not, the provider may be required to purchase replacement vaccines. This decision will be made by the Vaccine Manager based on past vaccine loss history and the number of vaccine doses lost. The provider will be required to replace VFC vaccine losses due to negligence when those losses are valued at more than 5 percent of the number of doses of VFC vaccines available to be administered by the provider in the past 12 months.** For example, VFC MMR shipped to a provider in the past 12 months totals 1,000 doses. A vaccine loss of 75 doses of MMR occurs. A 5% loss would equal 50 doses. In this case, the provider would be required to purchase and replace 25 doses of MMR to be administered to VFC-eligible children.

When replacement of lost vaccine is required:

- a) The provider must mail or fax invoices for replacement vaccine to the Vaccine Manager within 10 business days;
- b) The assigned Immunization Program Consultant will verify, by site visit, the replacement of the lost vaccines within 30 days of incident; and
- c) The provider will submit a description of the incident in writing within 10 business days that discusses the circumstances of the loss and the steps taken to ensure that vaccine is protected in the future.

When replacement of vaccine is not required:

- a) The provider will submit a letter describing the incident within 10 business days that discusses the circumstances of the loss and the steps taken to ensure that vaccine is protected in the future; and
- b) Vaccine shipments will be resumed upon receipt of the aforementioned letter.

Any vaccine that is deemed not usable due to negligent circumstances should be returned to McKesson using the VFC-issued McKesson Return of Federal Vaccine Form. For more information, please call 404-657-3174. Information and instructions on returning wasted/expired vaccine (as well as the return form) can be found at <http://health.state.ga.us/programs/immunization/vfc/> or on the GRITS home page in the 'Resources' section.

Category 2

Vaccine loss due to **non-preventable** circumstances, such as:

- a) Area power outages due to severe weather or other unavoidable and unanticipated causes.
- b) Refrigerator failure.

- c) Transport company error (i.e., FedEx or Drug Transport, Inc.) Failure of the provider to notify VFC of a change in office hours or address will not be considered a transport company error.

Action Plan

If the provider discovers a power outage has occurred or the refrigerator storing vaccines has malfunctioned, the VFC program should be notified immediately by calling 1-800-848-3868.

Vaccines should be kept in the appropriate storage environment (refrigerator or freezer) until a decision is made concerning their viability (provider should enact their Vaccine Disaster Recovery Plan immediately if necessary). The provider should be prepared to supply the following information to the VFC staff:

- a) Last known temperature of the refrigerator and freezer;
- b) Current temperature of the refrigerator and freezer;
- c) Duration of time the vaccines were stored out of recommended temperature range; and
- d) Lot numbers, expiration dates, and number of doses of all vaccines in question.

The VFC staff will contact the vaccine manufacturers and determine the status of the vaccines. **If the vaccines are determined to be viable, but the power to the office has not been restored or the refrigerator is still in disrepair, , vaccines must be transported immediately to an alternate refrigerator/freezer and steps followed as noted in the provider's Vaccine Disaster Recovery Plan. If no plan is in place, the VFC staff member will assist the provider in determining a plan of action.**

If the vaccines in question are not salvageable, the VFC office will advise the provider concerning disposal or return of the spoiled vaccines. As soon as power is restored or a replacement refrigerator is acquired, the provider should monitor and document temperatures of the refrigerator and freezer for 5 days. If adequate temperatures are maintained, replacement vaccines will be shipped to the provider from VFC.

Category 3

Vaccine loss due to **noncompliance** with VFC written policies, such as:

- a) VFC vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Examples include the following:
 - Failure to document doses administered on usage log;
 - Failure to document patient eligibility on usage log;
 - Failure to report inventory;
 - Inaccurate reporting of inventory; or
 - Failure to report expired/wasted vaccine.
- b) VFC vaccine knowingly administered to children who are not eligible for the VFC program, including the following:
 - Administration of VFC vaccine to patients who are over 18 years of age;
 - Administration of VFC to every patient in the practice whether eligible or not (i.e., a provider discontinues purchasing private stocks of vaccine for administration to

- patients whose insurance covers immunizations or to patients who can afford vaccine);
 - Administration of VFC vaccine because the reimbursement rate of the child's insurance company is low;
 - Administration of VFC vaccine to a child who is fully insured (has insurance and vaccines are a covered benefit), including administration of VFC vaccine to a child who has not met their deductible in order to save the parent the cost of the deductible (a child is considered fully insured until the deductible has been met); or
 - Administration of VFC vaccine to a child even though the insurance company provides a flat rate of coverage for immunization for the year (upon exhaustion of flat rate coverage, the child is then eligible for VFC vaccine).
- c) Accepting reimbursement from insurance companies or patients for VFC vaccine as evidenced by:
- Administering VFC vaccine to a child and subsequently billing the child's insurance for the cost of the vaccine;
 - Charging the patient for the cost of the vaccine; or
 - Charging a Medicaid recipient any fee at all.

Action Plan

If a provider is found to be in violation of written VFC policies, the action taken will depend upon the policy violated, as follows:

- a) Vaccine unaccounted for in usage reports:
- Vaccine usage and inventory must be reported to the VFC office monthly. Vaccine accountability statements will be processed and remitted to the provider. These accountability statements tell the provider what their vaccine losses have been over the current reporting period.
 - If accountability statements indicate unaccounted for VFC vaccine in excess of 5% for any vaccine for 3 consecutive reporting periods:
 1. The assigned Immunization Program Consultant will be informed; and
 2. A site visit will be conducted before the next reporting period to investigate possible reasons for the vaccine inventory discrepancies.
 - Future vaccine accountability statements must reflect 5% or less of vaccine loss. Possible consequences include, but are not restricted to:
 1. A decrease in shipment of VFC vaccine; or
 2. Providers replacing unaccounted for vaccines exceeding 5% of the total number of doses of vaccine available to be administered by the provider in the past 12 months.

For example, if 10% of the provider's VFC provided Varicella vaccine is unaccounted for, then the provider may be asked to purchase 5% of the Varicella lost as replacement vaccine, or future shipments of Varicella will be decreased so that only the vaccine accounted for is replaced.

Decisions concerning the consequences of having unaccounted for vaccine will be made after receiving input from the Immunization Program Consultant, the VFC Coordinator, the Vaccine Manager and the Immunization Program Director.

- b) VFC supplied vaccines knowingly administered to children not eligible for VFC. The VFC Coordinator or Vaccine Manager will notify the provider by letter detailing the following:

- Name of child vaccinated;
- Date vaccine given;
- Each vaccine administered;
- Deadline for replacement of vaccine;
- Request for invoices for replacement vaccine;
- Request for action plan to prevent further misuse of VFC supplied vaccine; and
- Notification of future chart reviews by assigned Immunization Program Consultant.

Upon receipt of written notification, any infractions or continued administration of VFC supplied vaccine to children not eligible for VFC will result in termination from the VFC Program.

- c) Accepting reimbursement from insurance companies or patients for VFC supplied vaccine. Providers found billing insurance companies or charging patients for state supplied vaccine will be notified of the infraction by letter from the VFC Coordinator or Vaccine Manager. The letter will include the following:

- Name of child vaccinated;
- Date vaccine given;
- Each vaccine administered and billed;
- Deadline for replacement of vaccine;
- Request for invoices for replacement vaccine;
- Request for action plan to prevent further fraudulent billing; and
- Notification of future chart reviews by assigned Immunization Program Consultant.

Continued acceptance of reimbursement from insurance companies or patients for VFC supplied vaccine after receiving notification by letter will result in termination from the VFC Program.

Reports from outside sources of fraudulent use of VFC supplied vaccine will be referred to the assigned Immunization Program Consultant. A site visit and chart review will be conducted within 5 business days of the report. Findings will be reviewed with the provider and reported to the Vaccine Manager. Any action to be taken will be decided after receiving input from the Immunization Program Consultant, the VFC Coordinator, the Vaccine Manager and the Immunization Program Director.