Vaccine Accountability Policy

This document will serve as the Georgia Department of Public Health, Immunization Program Vaccine Accountability Policy. This policy is designed to ensure:

1. Vaccine purchased with Vaccines for Children (VFC), federal and state funds are administered only to VFC-eligible and state-eligible recipients;
2. Vaccine loss and waste are minimized and measured;
3. The Georgia Immunization and VFC Programs are protected against fraud and abuse;
4. State, VFC and other federally purchased vaccines are ordered appropriately based on a provider’s VFC-eligible and state-eligible populations.

The increase in the number of ACIP recommended vaccines and a rise in their associated costs have prompted a renewed emphasis on program accountability at all levels. As part of the enrollment and annual recertification processes for VFC and state vaccine programs, providers agree to comply with VFC and Georgia Immunization Program (GIP) requirements for ordering, storage, handling and accountability of vaccine to avoid vaccine loss as outlined in the Georgia Vaccine Loss Policy (Appendix A). Providers also agree to operate in a manner intended to avoid vaccine fraud and abuse as outlined in the Georgia Vaccine Fraud and Abuse policy (Appendix B).

Georgia will help ensure vaccine accountability in provider offices by:

1. Using provider profiles to monitor provider orders;
2. Monitoring provider vaccine inventory levels to ensure adequate supplies of public and privately purchased vaccine for the population size served in provider offices;
3. Monitoring vaccine wastage and loss that occur in provider offices;
4. Monitoring provider activities to prevent and/or identify fraud and abuse against the VFC and state vaccine programs.
5. Providing clear guidance to providers regarding the return of expired and wasted public vaccine for excise tax credit.

Using Provider Profiles to Monitor Provider Orders
VFC Providers are required to submit supporting documents for the enrollment estimates produced during VFC enrollment, re-enrollment, or annual re-certification with the VFC Program. Documentation is required to verify that submitted estimates are based on previous years’:

1. Doses administered, benchmarking, Medicaid and/or other billing data; or
2. IIS (GRITS) data.

The VFC Logistics Associate will review a random provider sample on a monthly basis for accountability review purposes. Doses administered data will be reviewed over a 6 month span and data will be compared to the providers submitted profile estimates. Aggregate vaccine data exceeding annual profile estimates identified during this will result in corrective action development and implementation as necessary, including vaccine replacement for unaccounted for doses.
1. GIP staff contact providers that exceed profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed.
2. Future vaccine orders are adjusted appropriately to ensure providers receive sufficient supply to serve their VFC or State-eligible population without creating an increased risk for vaccine loss, fraud, and/or abuse.

**Monitoring of Provider Inventory Levels (Public vs. Private Supply)**

In order to receive vaccine from Georgia’s VFC program, VFC-enrolled providers must comply with reporting requirements for vaccine usage including: doses administered by eligibility category, wastage, and inventory. Georgia uses the following methods as ways to monitor provider inventory levels for both public and private vaccine supply:

1. VFC Program Representatives have been trained to routinely review monthly comprehensive reports for excessive use, underreporting, over reporting and anything that may look out of the ordinary.
2. Vaccine over- and under-reporting will be reviewed with provider(s) and unexplained amounts above the 5% allowance will be reported to the Deputy Director, who will respond accordingly.

**Monitoring Vaccine Wastage and Loss**

The Georgia Department of Public Health - Immunization Program Vaccine Loss Policy (Appendix A) details the action taken by the Georgia VFC Program for identifying, monitoring and management of incidents that result in loss of public 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

VFC staff use the CDC Non-compliance with VFC Provider Requirement Protocol (algorithm) to address all vaccine loss policy violations. Continued violation of any section of this policy will result in termination from the VFC Program.

**Prevention and Detection of Fraud and Abuse in Provider Offices**

The Georgia Department of Public Health - Immunization Program Fraud and Abuse Policy (Appendix B) details the action taken by the Georgia VFC Program to provide programmatic direction for the prevention of fraud and abuse in the utilization of state-supplied and/or VFC-funded vaccine. The Fraud and Abuse Policy is reviewed annually and updated, as necessary. Training on fraud and abuse takes place as part of new employee orientation. Additionally, program staff (VFC staff and Immunization Program Consultants [IPCs]) receives annual educational updates, led by the Deputy Director.

Georgia uses the following methods as ways to detect and/or prevent fraud and abuse of public vaccine supply:

1. Upon enrollment and on a monthly basis thereafter, provider information is cross-checked against the List of Excluded Individuals/Entities on the Department of Health and Human Services (HHS) Office of Inspector General website. If located in the Exclusion database, providers are not allowed to participate in VFC.
2. VFC Program staff has been trained to routinely review monthly comprehensive reports for excessive use, underreporting, and anything that may look out of the ordinary.
3. Georgia Immunization Representatives are required to review with the provider a vaccine accountability statement representative of at least six (6) months, which can help identify areas of potential fraud and/or abuse.
4. Vaccine over- and under-reporting will be reviewed with provider, and unexplained amounts above the 5% allowance will be reported to the Deputy Director, who will respond accordingly.
5. Any individual, group, or practice who wants to report a suspected case of fraud and/or abuse, a dedicated Fraud and Abuse Hotline has been implemented and is monitored by the Deputy Director. The Fraud and Abuse hotline number is (404) 657-5950. Reports must include (as applicable):
   1. Provider name and address;
   2. Source of the allegation;
   3. Source’s name, address, and telephone number (if available)
   4. A description of the reason for the report (suspected misconduct/violation)
   5. Specific VFC requirements violated;
6. Value of vaccine involved (if available);
7. If the report was initiated in response to a complaint, a copy and/or summary of the complaint and the
complainant’s name, address and telephone number;
8. Success of educational intervention; and
9. A summary of the result of any preliminary investigation conducted by GIO staff regarding allegations or
suspicions of fraud or abuse.

Once a report is received, the Non-compliance with VFC Provider Requirements Protocol will be used to determine the
appropriate follow up action.

At the GIP, the Deputy Director is the person with primary responsibility for responding to suspected fraud and/or abuse.
The Deputy Director will have authority to make decisions, referrals, and notifications when appropriate. In the event that
the Deputy Director is not available, the VFC Coordinator will assume responsibility. In the event that neither of these
individuals is available, the Program Director will assume responsibility.

The Deputy Director (or designated respondent) will review all information submitted and initiate an internal investigation
on all cases reported without sufficient evidence of fraud and abuse within five (5) business days of the report. All
suspected cases of VFC fraud and abuse will be forwarded electronically to the Centers for Medicare & Medicaid
Services (CMS), Medicaid Integrity Group (MIG) Field Office and CDC within ten (10) business days following
disposition. MIG will conduct preliminary investigations and, as warranted, transmit the referral to the appropriate
oversight entity and will monitor the handling of the referral by entity.

**Process for Returning Expired and/or Wasted Public Vaccine**

All vaccine received from the GIP must always be accounted for. This includes doses administered and inventory as well
as wasted and expired vaccine. Providers are required to report doses wasted or expired on their Monthly Comprehensive
Report which begins the processing of their return request and our excise tax credit process. Vaccine returns are approved
by the Vaccine Logistics Associate. The Vaccine Logistics Associate submits requests via VTrckS to McKesson for UPS
return labels. Once returns are finalized in VTrckS, McKesson will ship UPS return label(s) directly to the provider site.

Providers are asked to box returns properly to ensure safe transit of the vials. Providers submit return request monthly to
ensure vaccines are returned within 6 months following the date of expiration per VFC program requirements. The
Vaccine Logistics Associate processes and screens each return to ensure returned vaccines have been properly accounted
for and determines if replacement of the loss vaccine(s) are required according to Georgia’s Vaccine Loss Policy. The
Vaccine Logistics Associate enters all returns and wastage into VTrckS and e-mails a copy of the VTrckS Return Invoice
to the provider. Providers are to place a copy of the return invoice(s) in the box with the appropriate vaccine
return(s). Providers are reminded to mark expired or wasted vaccine(s) “DO NOT USE” and store it securely and outside
of the refrigerator to avoid accidental administration of non-viable vaccine.

Vaccine return boxes should include:

1. Full vials or manufactured pre-filled syringes (no needle attached) of unused vaccine
2. Appropriate padding to protect vials from breaking
3. VTrckS Return Invoice (copy e-mailed from the VFC office)

Vaccine return boxes should **not** include:

1. Needles or syringes with needles (vaccine that has been drawn into a syringe should be wasted on-site, not
   returned.)
2. Broken or partially used vials (including partially used multi-dose vials)
3. Paperwork or other reports intended for VFC
4. Any other objects