

Georgia Vaccines for Children (VFC) Program Fraud and Abuse Policy

I. Background

The purpose of this policy is to provide programmatic direction for the prevention of fraud and abuse in the utilization of state-supplied and/or Vaccines for Children (VFC)-funded vaccine. The Georgia Immunization Office (GIO) is required by federal granting authorities to implement VFC fraud and abuse prevention policies.

Vaccine supplied through GIO is funded through several federal sources. For simplification purposes, those funding sources can be divided into two primary groups: VFC and non-VFC funds. VFC funds may be used to purchase vaccine for children and adolescents who are birth through 18 years of age (less than 19), and who are:

- Medicaid eligible
- Uninsured (have no health insurance)
- American Indian/Alaskan Native
- Underinsured (have health insurance that does not pay for vaccinations), seen in Federally Qualified Health Centers (FQHC) or Rural Health Centers (RHC)

Non-VFC funds are utilized to purchase vaccines for children and adolescents who are birth through 18 years of age (less than 19), and who are:

- Underinsured, seen in their medical home
- PeachCare for Kids™

Georgia VFC providers must adhere to the vaccine usage constraints relative to vaccine funding. Providers must administer GIO-supplied vaccine only to the aforementioned categories of adolescents and children. Misuse of VFC-funded vaccine may result in civil and/or criminal penalties.

The Fraud and Abuse Policy will be reviewed annually and updated, if necessary. Training on fraud and abuse will take place as part of new employee orientation. Additionally, program staff (VFC staff and Immunization Program Consultants [IPCs]) will receive annual educational updates, led by the Vaccine Manager.

II. Definitions

Fraud is defined by Medicaid as “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.”

Abuse is defined by Medicaid as “provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, [and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient]; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.”

Examples of fraud and abuse include, but are not limited to the following:

- Providing VFC vaccine to non VFC non-VFC-eligible children;
- Selling or otherwise misdirecting VFC vaccine;
- Billing a patient or third party for VFC vaccine;
- Charging more than the established maximum regional charge (\$14.81) for administration of a VFC-funded vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee;
- Not implementing provider enrollment requirements of the VFC program;
- Failing to screen patients for VFC eligibility at every visit;
- Failing to maintain VFC records for a minimum of three (3) years and/or comply with other requirements of the VFC program;
- Failing to fully account for VFC-funded vaccine through required monthly reporting of doses administered, doses wasted, and inventory on hand;
- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine or reporting vaccine usage in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses;
- Waste of VFC vaccine due to negligence.

III. Compliance Assessment

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. Every vaccine order submitted is compared to the most recent provider profile calculated by GIP and approved by the provider. The provider profile is an estimate of the number of VFC-eligible children the provider expects to see in a given year by eligibility category. These estimates are entered into the Centers for Disease Control and Prevention (CDC)-developed Vaccine Management System (VACMAN). Aggregate vaccine orders exceeding annual profile data are identified by VACMAN. GIO staff contact providers that exceed profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed.

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.

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. In addition, IPCs 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. Vaccine over- and under-reporting will be reviewed with provider, and unexplained amounts above the 5% allowance will be reported to the Vaccine Manager, who will respond accordingly.

VFC fraud or abuse determination is not a responsibility of GIO. However, GIO is required to report suspected VFC fraud and abuse to state and federal authorities. Unjustified, excessive, and/or repeated discrepancies between provider profile data, vaccine orders, and vaccine usage will be referred for further investigation as is required of the program.

IV. Referrals

At the Georgia Immunization Program, the Vaccine Manager is the person with primary responsibility for responding to suspected fraud and/or abuse. The Vaccine Manager will have authority to make decisions, referrals, and notification when appropriate. In the event that the Vaccine Manager 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.

Should any individual, group, or practice want to report a suspected case of fraud and/or abuse, a dedicated Fraud and Abuse Hotline has been implemented and is monitored by the Vaccine Manager. 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. This protocol has two levels of formal education –

secondary and tertiary. Each level requires a minimum amount of education intervention and follow-up. For a provider to successfully complete the Secondary Education process, the provider must have corrected the situation. Tertiary Education requires a full VFC compliance site visit, and the compliance issue must be resolved for the provider to be released from the educational intervention. For example, if an employee from a practice calls to report that the practice is failing to properly store vaccine, the IPC assigned to the provider will be notified that a storage and handling visit needs to be made. It is expected that the IPC will enter the provider into secondary education and take steps to resolve the issue, which may involve suspending vaccine shipment until the situation is resolved. If the issue is not resolved the provider will be entered into Tertiary Education. If the issue remains unresolved, the provider has more than three instances with the same issue, or any allegation where it is discovered that a provider is billing Medicaid inappropriately (inaccurate services, ineligible clients, etc.), then the IPC will notify the Vaccine Manager immediately and provide the following information (as applicable):

1. Provider name and address;
2. Specific VFC requirements violated;
3. Value of vaccine involved (if available);
4. 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;
5. Success of educational intervention; and
6. A summary of the result of any preliminary investigation conducted by GIO staff regarding allegations or suspicions of fraud or abuse.

The Vaccine Manager will review all information submitted. The Vaccine Manager will initiate an internal investigation on all cases reported without sufficient evidence of fraud and abuse within five 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.

V. Allegation and Referral Database

GIO will maintain a database to monitor and document all actions taken on allegations related to fraud and abuse of the VFC program requirements, including actions taken to address identified situations. As requested, database will be made available to CDC. The following data will be collected for the database:

1. Provider's name (Medicaid ID if known);

2. Address;
3. Source of allegation;
4. Date allegation reported to program;
5. Description of suspected misconduct;
6. Specific VFC requirements violated;
7. Value of vaccine involved if available;
8. Success of educational intervention;
9. Disposition (closed, referred, entered into educational process) of case;
and
10. Date of disposition

V. Resolution

Determination of fraud or abuse is made by the appropriate oversight entity. Providers identified to be engaged in VFC fraud or abuse will be suspended from the VFC program. Reinstatement to the VFC program will be contingent on the outcome of proceedings conducted by the appropriate oversight entity. Final resolution may include the following (not all-inclusive) interventions: remedial education, recoupment of funds, reinstatement without penalty, or referral for criminal prosecution or civil resolution.

Providers who have been cleared of suspected fraud due to excusable lack of knowledge will be required to work with IPC staff to complete corrective action training sessions prior to reinstatement to the program. Trainings may include: Provider Refresher, Vaccine Storage and Handling, and Vaccine Administration. IPC will be required to document all steps taken and will have authority to reinstate providers, which will then be reviewed by the Vaccine Manager. In all cases, providers will be required to submit a corrective action plan in which the practice will be expected to outline how to avoid a similar situation in the future. In those instances where provider activities do not involve Medicaid or billing agencies, GIO will work with the provider directly within the VFC policy guidelines. This may include requiring education, suspending vaccine shipments until corrective actions are taken, or termination from the VFC program. In any event that a provider's activities violate Medicaid requirements, the abovementioned notification steps will be taken to inform MIG and CDC.