

Georgia Vaccines for Children (VFC) Provider Agreement Policy

This document shall serve as the Georgia Department of Community Health (DCH), Division of Public Health (DPH) Immunization Office's policy for program compliance. Non-compliance is defined as any intentional deviation from the signed Provider Agreement with the Georgia Vaccines for Children (VFC) Program. Each VFC enrolled provider is required to sign a Provider Agreement stating that they agree to the following conditions:

Provider Requirements

1. **Vaccine supplied by Georgia Immunization Office will be administered only to a child ≤ 18 years of age who:**
 - a) **Is enrolled in Medicaid (or qualifies through a Medicaid waiver).**
 - b) **Has no health insurance (uninsured).**
 - c) **Is American Indian or an Alaska Native.**
 - d) **Has health insurance that does not pay for the vaccine (underinsured).**
 - e) **Is enrolled in the PeachCare for Kids Program.**

Definitions for VFC eligible children:

- a) Medicaid – has a current Medicaid card or Medicaid waiver at the time of service.
- b) Uninsured - has no health insurance.
- c) American Indian/Alaska Native – self-reported by the patient.
- d) Underinsured - has insurance but vaccines are not a covered benefit.
 - Example: An insurance company may not cover certain immunizations, such as the pneumococcal conjugate vaccine. The child will qualify for VFC for that particular vaccine.
 - Example: An insurance company may cover immunizations up to a certain age. Until that age, the child is fully insured. After that age, the child is considered underinsured (has insurance, but vaccines are not a covered benefit).
 - Example: An insurance company may only provide \$100 per year to cover the costs of immunizations. The child is fully insured up to \$100. Once this amount is exhausted, the child is then eligible to receive VFC vaccine.
- e) PeachCare for Kids – has a current PeachCare for Kids card at the time of service.

Program Violations

- a) A provider administers vaccine to patients who are > 18 years of age.
- b) A provider fails to purchase private stock vaccine for patients whose insurance covers immunizations and gives every patient in the practice VFC vaccine regardless of eligibility.
- c) A provider administers VFC vaccine to a child then bills the child's insurance for the cost of the vaccine.
- d) A provider administers VFC vaccine because the insurance company's reimbursement rate is low.

- Example: An insurance company's reimbursement rate for a particular vaccine may be \$55 per dose; however, the vaccine may actually cost \$58 per dose. The child does not qualify for VFC vaccine because immunizations are a covered benefit. Reimbursement rates are not a consideration when determining VFC eligibility. The child is still considered to be fully insured and privately purchased vaccine must be administered.
- e) A provider administers VFC vaccine to a child even though the insurance company provides a flat rate of coverage for the year.
 - Example: An insurance company may only provide \$100 per year to cover the costs of immunizations. Privately purchased vaccine should be administered up the \$100. Once this amount is exhausted, the child is then eligible to receive VFC vaccine.
 - f) A provider administers VFC vaccine to a child who has private insurance with a high deductible.
 - Example: Parent has a policy with a \$1,000 deductible. The child is still considered fully insured and privately purchased vaccine should be administered.
 - g) A provider charges the patient for the cost of the vaccine.
 - h) A provider charges a fee to a Medicaid recipient.
 - i) A provider violates applicable laws, rules, regulations, or policies.

These examples should not be considered all-inclusive.

Actions

- a) Educational training and follow-up visits will be conducted by a Georgia Immunization Office Representative.
 - b) Vaccine shipments will be suspended until VFC vaccine is replaced by the provider. **See Appendix A, Georgia Vaccines for Children (VFC) Vaccine Loss Policy.**
 - c) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.
- 2. Assess patient eligibility status during the initial visit for each patient receiving vaccines provided by the VFC Program. Subsequent screenings will be conducted to determine whether the child's VFC eligibility status has changed. Eligibility Screening Records will be maintained for a period of three (3) years. If requested, the records will be made available to the Georgia Department of Community Health (DCH) or the United States Department of Health and Human Services (DHHS).**

Program Violations

- a) Failure to maintain records of patient eligibility for at least three years.
- b) Failure to share records with DCH or DHHS.

Actions

- a) Educational training and follow-up visits will be conducted by a Georgia Immunization Program Consultant (IPC).
- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

- 3. Participate in a VFC site visit conducted by an Immunization Program Consultant at least once every two years as measured from the date of the enrollment in the VFC Program of the practice named below.**

Program Violations

Provider does not allow a site visit.

Actions

- a) If a site visit is not allowed within 60 days of request, a provider will be terminated and any remaining vaccines removed.
- b) Additional time may be allowed due to justifiable and extenuating circumstances.
- c) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

- 4. Participate in an assessment of my practice's immunization levels using the Comprehensive Clinical Assessment Software Application (CoCASA) at least once every two years.**

Program Violation

Provider does not allow a CoCASA assessment.

Actions

- a) If a CoCASA assessment is not allowed within 60 days of request, a provider will be terminated and any remaining vaccines removed.
- b) Additional time may be allowed due to justifiable and extenuating circumstances.
- c) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program

- 5. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the DHHS Advisory Committee on Immunization Practices (ACIP) unless (a) in making a medical judgment in accordance with accepted medical practice, the practitioner deems such compliance to be medically inappropriate or (b) the particular requirement is not in compliance with state law(s) including laws relating to religious or other exemptions.**

Program Violations

- a) Inappropriate administration of vaccine.
 - Example: Mixing two vaccines in the same syringe (i.e., MMR and DTaP) for the purpose of reducing the number of injections needed.
 - Example: Administering pneumococcal conjugate vaccine to a 12 year old, when VFC guidelines allow for administration to children less than 5 years of age.
- b) Non-compliance with ACIP recommendations for age and dose intervals.
 - Example: Administering vaccines before the proper age (i.e., vaccinating a child with MMR and Varicella vaccine before the age of one year).
- c) Provider fails to assess for immunization status and immunize children at the time they are seen.

- Example: Provider sees child for well-child visits but does not review immunization status and/or simply refers child to another facility for immunizations.
- Example: Provider sees child for sick visit but does not review immunization status to be administered once child is well.

Actions

- a) Mandatory participation in educational training provided by a Georgia IPC.
- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.
- c) Any provider who does not administer at least one vaccine in a six-month period of time will be terminated and any remaining vaccines removed.

6. Provide Vaccine Information Statements and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Program Violation

Failure to provide and document distribution of current Vaccine Information Statements to patients.

Actions

- a) Educational training and follow-up visits will be conducted by a Georgia IPC.
- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

7. Not impose a charge for the cost of the vaccine.

Program Violation

Imposing a charge for the cost of vaccine.

- Example: An office visit fee and administration fee can be charged to the patient, but a fee **cannot** be charged for the cost of the vaccine.

Actions

- a) Educational training and follow-up visits will be conducted by a Georgia IPC.
- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

8. Not impose a charge to the patient for administration of the vaccine in any amount higher than the current state fee cap of \$14.81 per injection. (Your practice may charge less than \$14.81 per injection).

Program Violation

Imposing a charge greater than \$14.81 per injection.

Actions

- a) Educational Training and follow-up visits will be conducted by a Georgia IPC.

- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

- 9. Not deny administration of a VFC supplied vaccine to a VFC eligible child due to the inability of the child's parent/guardian/individual of record to pay an administration fee. If the parent/guardian/individual of record is unable to pay, the administration fee must be waived. Other visit or office fees may be charged as applicable.**

Program Violations

- a) Denying vaccine to a VFC eligible child due to inability to pay.
- b) Denying a child/parent/guardian access to vaccine administration records due to an outstanding bill on the part of the parent/guardian.
- c) Carrying a balance for unpaid administration fees.

Actions

- a) Educational training and follow-up visits will be conducted by a Georgia IPC.
- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

- 10. Comply with the DCH's requirements for ordering vaccine, for reporting vaccine usage, spoilage, expiration and physical inventories, and all other requirements as outlined on the monthly reporting forms.**

Program Violation

- a) Failure to submit a monthly comprehensive report detailing vaccine usage, inventory, expiration, and spoilage on a monthly basis.

Actions

- a) Educational training and follow-up visits will be conducted by a Georgia IPC.
- b) Non-reporting of vaccine usage, inventory, expired, spoiled, and returned vaccine may result in termination from the VFC Program. **See Appendix A, Georgia Vaccines for Children (VFC) Vaccine Loss Policy.**
- c) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

- 11. Not prohibited by Georgia law (i.e., O.C.G.A. Chapters 43-34, 26-4, and 16-13) or any other applicable law from possessing dangerous drugs (i.e., vaccines).**

Program Violations

- a) Drug Enforcement Agency number has been revoked.
- b) License to practice medicine has been revoked, suspended, or annulled.
- c) Failure to report changes in license status.

Action

- a) Immediate termination from the VFC Program

- 12. Accept the responsibility of maintaining the integrity of the drugs (i.e., vaccines) in accordance with all laws, regulations, and VFC program recommendations pertaining to vaccine storage and handling procedures.**

Program Violations

- a) Failure to properly store vaccine in accordance with CDC guidelines. As of January 1, 2010, VFC-supplied vaccines may not be stored in a dorm-style refrigerator, even for short periods of time. VFC-supplied vaccines must be moved to a CDC-approved storage unit (stand alone refrigerator or freezer unit; household style unit with separate refrigerator and freezer doors). **See Appendix A, Georgia Vaccines for Children (VFC) Vaccine Loss Policy.**
- b) Failure to identify primary and backup staff members responsible for vaccine storage and handling.
- c) Failure to document temperatures twice daily.
- d) Failure to complete and utilize the Vaccine Disaster Recovery Plan.

Actions

- a) Educational training and follow-up visits will be conducted by Georgia IPC.
- b) As of January 1, 2010 providers storing vaccine in a dorm-style refrigerator will have vaccine shipment suspended until vaccines are moved to an approved unit.
- c) Vaccine replacement by provider. **See Appendix A, Georgia Vaccines for Children (VFC) Vaccine Loss Policy.**
- d) May result in termination from the program.
- e) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

- 13. Complete and submit to the VFC office the annual Provider Profile Update within 30 days of receipt. Failure to submit this update can lead to deactivation from the VFC program.**

- 14. Comply will all requirements of VFC's Vaccine Tracking System (VTrckS). VTrckS will replace VACMAN, the current CDC software.**

- a) **Should the practitioner, staff or representatives of the facility or practitioner named below access VTrckS, each user agrees to be bound by CDC's terms of use for interacting with the online ordering system. Each user further agrees to be bound by any applicable federal laws, regulations, or guidelines related to accessing a CDC system and ordering publically funded vaccines.**
- b) **Upon execution of this contract, the name of each member of the facility or practitioner's staff or any person representing the facility or practitioner that will access VTrckS to order vaccines on behalf of the practitioner or facility will be submitted to DCH. In addition, the practitioner or facility will maintain a record of each staff member authorized to order vaccines on behalf of the practitioner or facility. The practitioner or facility will designate a contact person responsible for informing the CDC of changes in the status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of**

any new staff authorized to order on behalf of the practitioner or facility within 24 hours of such change.

Program Violations

- a) Provider fails to designate primary and backup staff members responsible for vaccine management in VTrckS.
- b) Provider fails to notify CDC and VFC of staff changes within 24 hours.

Actions

- a) Vaccine shipments may be suspended until a new staff person has been certified.
- b) May result in termination from the program.

15. Pursuant to O.C.G.A. §31-12-3, the vaccination data for every dose of vaccine administered by the clinic will be entered into the Georgia Registry of Immunization Transactions and Services (GRITS) within ten (10) business days of the service being rendered. See Appendix B, Georgia Immunization Registry Law – O.C.G.A. §31-12-3.1.

Program Violation

- a) Provider fails to submit vaccination data within 10 business days.

Actions

- a) Provider orders may be suspended until all vaccination data has been entered into GRITS.
- b) More than three (3) program violations (of the same type or a combination of types) will result in termination from the VFC Program.

16. Understand that this agreement may be terminated by either party at any time for any reason. DCH has the discretion to terminate this agreement for convenience or for failure of the provider to comply with any of the requirements.

- a) Termination by either party must be in writing.
- b) The clinic will contact GIO to schedule delivery of any remaining vaccines.
- c) If the practitioner or facility terminates the agreement, the practitioner or facility will notify VFC for vaccine pickup.
- d) If DCH terminates, GIO staff will contact the provider to arrange for vaccine pickup.

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.

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.

Provider Agreement
Vaccines for Children Program

In order to participate in the Vaccines for Children (VFC) Program and/or receive other state or federally funded vaccine at no cost, all provider(s) enrolling in the VFC Program (including those associated with the medical office, group practice, health department, community/migrant/rural clinic, or other facility named below), must agree to the following conditions which are further defined in the enclosed Provider Agreement Policy document:

1. Vaccine supplied by VFC will be administered only to a child ≤ 18 years of age who: (a) is enrolled in Medicaid (or qualifies through a Medicaid waiver), (b) has no health insurance, (c) who is an American Indian or Alaska native, (d) has health insurance that does not pay for the vaccine, or (e) is enrolled in the PeachCare for Kids Program.
2. Assess patient eligibility status during the initial visit for each patient receiving vaccines provided by the VFC Program. Subsequent screenings will be conducted to determine whether the child's VFC eligibility status has changed. Eligibility Screening Records will be maintained for a period of three (3) years. If requested, the records will be made available to the Georgia Department of Community Health (DCH) or the United States Department of Health and Human Services (DHHS).
3. Participate in a VFC site visit conducted by an Immunization Program Consultant at least once every two years as measured from the date of the enrollment in the VFC Program of the practice named below.
4. Participate in an assessment of my practice's immunization levels using the Comprehensive Clinical Assessment Software Application (CoCASA) at least once every two years.
5. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the DHHS Advisory Committee on Immunization Practices (ACIP) unless (a) in making a medical judgment in accordance with accepted medical practice, I deem such compliance to be medically inappropriate or (b) the particular requirement is not in compliance with state law(s) including laws relating to religious or other exemptions.
6. Provide Vaccine Information Statements and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
7. Not impose a charge for the cost of the vaccine.
8. Not impose a charge to the patient for administration of the vaccine in any amount higher than the current state fee cap of \$14.81 per injection.
9. Not deny administration of a VFC supplied vaccine to a VFC eligible child due to the inability of the child's parent/guardian/individual of record to pay an administration fee. If the parent/guardian/individual of record is unable to pay, the administration fee must be waived. Other visit or office fees may be charged as applicable.
10. Comply with DCH's requirements for ordering vaccine, for reporting vaccine usage, spoilage, expiration and physical inventories, and all other requirements as outlined on the monthly reporting forms.
11. Not be prohibited by Georgia law (i.e., O.C.G.A. Chapters 43-34, 26-4, and 16-13) or any other applicable law from possessing dangerous drugs (i.e., vaccines).
12. Accept the responsibility of maintaining the integrity of the drugs (i.e., vaccines) in accordance with all laws, regulations, and VFC program recommendations pertaining to vaccine storage and handling procedures.
13. Complete and submit to the VFC office the annual Provider Profile Update within 30 days of receipt. Failure to submit this update can lead to deactivation from the VFC program.
14. Comply with all requirements of VFC's Vaccine Tracking System (VTrckS).
 - a) Should the practitioner, staff or representatives of the facility or practitioner named below access VTrckS, each user agrees to be bound by CDC's terms of use for interacting with the online ordering system. Each user further agrees to be bound by any applicable federal laws, regulations, or guidelines related to accessing a CDC system and ordering publically funded vaccines.
 - b) Upon execution of this contract, the name of each member of the facility or practitioner's staff or any person representing the facility or practitioner that will access VTrckS to order vaccines on behalf of the practitioner or facility will be submitted to DCH. In addition, the practitioner or facility will maintain a record of each staff member authorized to order vaccines on behalf of the practitioner or facility. The practitioner or facility will designate a contact person responsible for informing the CDC of changes in the status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff

authorized to order on behalf of the practitioner or facility within 24 hours of such change.

15. Pursuant to O.C.G.A. §31-12-3, the vaccination data for every dose of vaccine administered by the clinic will be entered into the Georgia Registry of Immunization Transactions and Services (GRITS) within **10** business days of the service being rendered. See Appendix B, Georgia Immunization Registry Law – O.C.G.A. §31-12-3.1.
16. Understand that this agreement may be terminated by either party at any time for any reason. DCH has the discretion to terminate this agreement for convenience or for the failure of the provider to comply with all requirements.

Provider Agreement
(continued)

Facility Name _____

Mailing Address _____

Street Address and/or P.O. Box Number

City

State

Zip Code

If this enrollment is for a hospital, either a hospital pharmacist or administrator must sign this agreement. For other facilities enrolling in VFC, all physicians and mid-level practitioners (nurse practitioners, nurse midwives, and physician assistants) providing service at this location must sign. Also, in order to prevent fraud, abuse, and for other related purposes, a copy of the professional license(s) of the individual(s) listed below and, if applicable, a pharmacy license for the aforementioned facility must be submitted with this enrollment package.

By signing below, I agree to follow the 16 conditions listed in this Provider Agreement. Failure to abide by any of these conditions may result in termination of enrollment and applicable professional license review.

Please print or type

Name: (include middle initial and title)

Medicaid Number/License #

Signature

EXAMPLE: Oscar D. Grouch, MD

11122233A/012345

_____	_____	_____
_____	_____	_____
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_____	_____	_____

Specialty: (Check one only)

_____ Pediatrics (Ped)

_____ General Practice (GP)

_____ Family Practice (FP)

_____ Internal Medicine (IM)

_____ Hospital (Hosp)

_____ Multiple Specialties (MULT)

_____ Other, Please Specify: _____