Revision Date: December 1, 2015

Vaccines for Children Fraud/Abuse/Wastage Policy

Primary Position: Denise Strickland, Director, VFC
Secondary Position: Chevonne Tyner, Vaccine Manager

Overview

As the cost of childhood vaccines increases and the complexity of immunization programs grows, the VFC program becomes more vulnerable to fraud and abuse. It is important that grantees' VFC programs have well-defined processes for prevention, identification, investigation and resolution of suspected cases of fraud, abuse, and wastage within the VFC program.

The VFC program, as a component of each state's medical assistance plan, is considered a Title XIX Medicaid program. Section 1928 of the Social Security Act (42 U.S.C. §1396s) provides for purchase of vaccine for administration to VFC-eligible children—"federally vaccine-eligible children" and "state vaccine-eligible children" (i.e., those children for whom states purchase vaccine; may be limited to particular vaccines)—using federal Medicaid funds and state funds (including 317 grant funds), respectively. Medicaid-eligible children and those providers who provide care for the Medicaid population (i.e., Medicaid providers) represent the majority of VFC federally vaccine-eligible children and VFC providers. However, the VFC program is different from the Medicaid medical assistance program. It also includes other VFC program–enrolled providers and the other VFC-eligible children who qualify as federally vaccine-eligible or state vaccine-eligible and who do not participate or are not eligible for the Medicaid medical assistance program. Federal fraud and abuse laws apply to the entire VFC program. In addition, for those portions of the VFC program involving state funds, state fraud and abuse/consumer protection/medical licensure laws may also apply.

A working understanding of what constitutes fraud and abuse is critical for persons working in the VFC program. Consistent with "fraud" and "abuse," as defined in the Medicaid regulations at 42 CFR § 455.2:

Fraud

Fraud is defined 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

Abuse is defined 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.

Unaccounted for vaccine (UAV)
Unaccounted for vaccine is calculated from doses administered, current inventory, wastage, transfers and records of prior inventory and shipments.

Wastage
Wastage is defined as any action at the provider level that renders the vaccine unusable (e.g., expiration, spoilage/mishandling – see "Negligence"). Shipments spoiled during shipment will not be counted as wastage by a provider and will not be included in inventory or unaccounted for vaccine.

Examples of Fraud, Abuse, and Wastage

Fraud, abuse, and wastage can occur in many ways, and some types are easier for the VFC program to prevent or detect than others. The VFC program will differentiate between intentional fraud and abuse and unintentional abuse or error due to excusable lack of knowledge. Some examples of potential fraud and abuse that VFC staff might encounter are:

- Providing VFC vaccine to 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 for administration of a VFC vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC 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;
- Failing to maintain VFC records and comply with other requirements of the VFC program;
- Failing to fully account for VFC vaccine;
- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses;
- Wastage of VFC vaccine.

On rare occasions after further assessment of an alleged fraud or abuse incident, and in conformance with the requirements of 42 CFR §455.15, if the grantee determines that there was no intentional deception, misrepresentation or negligent deception or misrepresentation of the VFC program by the provider or office staff, the situation may be corrected through an educational referral process* within the VFC program.

Determining if the alleged abuse situation is unintentional due to a clearly excusable lack of knowledge should be based on observations of the VFC staff and other appropriate investigative authorities. It should be noted that unintentional abuse or error is nevertheless still unacceptable.

The response to instances of unintentional abuse or error may vary depending on the circumstances and whether other instances of fraud or abuse (either intentional or unintentional) have occurred. In appropriate circumstances, education may be the proper response in lieu of criminal enforcement. The investigative/enforcement referral requirements of 42 CFR §455.15 must be followed to determine whether an educational intervention is adequate.

Fraud and Abuse Program Requirements:

Prior to enrolling providers into the VFC program, VFC program staff will access the Office of Inspector General website for information about parties who are excluded by HHS at http://www.oig.hhs.gov/fraud/exclusions.html under the "List of Excluded Individuals and Entities."

All examples of potential fraud and abuse described above must be reported to the VFC vaccine manager immediately. Call the Alabama VFC Program at 1-866-674-4807 and explain the circumstances to the VFC vaccine manager. Reports of potential fraud or abuse will be reviewed by the Immunization Program Manager and reported to recognized external agencies within 5 days of receiving the report.

Procedures of detection of fraud and abuse:

- Vaccine Manager will compare vaccine orders with benchmark data
- Enter and monitor vaccine wastage reports and analyze data to determine providers who fall outside the set wastage parameters
- Investigate all verbal and written reports from outside sources
- VFC and VFC/AFIX visits (storage and handling, screening for VFC eligibility, wasted or expired vaccine)

Interventions:

After initial identification or report, the VFC program staff (Area Managers) will investigate (attachment A) the situation and report findings to the VFC Vaccine Manager. If it is determined that the provider is ordering vaccine in quantities or patterns that do not match the provider profile or otherwise involve over-ordering of VFC doses the provider will be asked to complete a new provider profile or benchmark and instructed on how to properly order their vaccine. The provider will be monitored over the next 6 months to determine if there is understanding by the provider on proper ordering. Wastage is a serious concern and proper ordering will assist in prevention. Further, if a provider has wastage of vaccine due to storage and handling issues the following steps will be implemented:

Vaccine Loss:

- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses;
- Wastage of VFC vaccine.

The vaccine manager will notify the area manager to follow up and to provide technical assistance to prevent future vaccine loss. The vaccine in question must be kept refrigerated or frozen until a decision is made concerning viability. The Area Manager will contact the vaccine manufacturer to determine if the vaccine is salvageable and provide feedback to the provider. The following information must be provided to the manufacturer:

1. Last known temperature of the refrigerator/freezer
2. Current temperature of the refrigerator/freezer
3. Duration of time vaccine stored in unacceptable temperatures
4. Name, lot number, and expiration date of vaccine in question

Documentation of the recommendations from manufacturer(s) and details of the situation should be provided in writing to the vaccine manager within 3 working days. Vaccine wastage will be determined using the following formula: A ÷ B = C. Wastage will be assessed with each wastage report filed by a provider and then again at the end of the year (12 month period).

A. Numerator: Monetary value of wastage in a single incident as reports are received (end of year analysis: wasted within the previous 12 months).

B. Denominator: Combine annual order (monetary amount) for last 2 years (VTrckS) and divide by 2.

C. Percentage of wastage

a) Providers with wastage ≥15%
   - Vaccine orders are suspended
   - Site visit required by the Area Manager to investigate possible reasons for wastage and to conduct cold chain training before the next vaccine order is processed
   - Individual providers and provider groups will be required to submit temperature logs with all subsequent vaccine orders
   - Follow up site visit required before vaccine orders can be processed
   - All children should be referred to the county health department if availability of vaccine at the providers office is interrupted

b) Providers with wastage ≥5%
   - Vaccine orders are placed on hold
   - Site visit required by the Area Manager to investigate possible reasons for wastage and to conduct cold chain training before next vaccine order is processed
   - Individual providers and provider groups will be required to submit temperature logs with all subsequent vaccine orders
   - All children should be referred to the county health department if availability of vaccine at the providers office is interrupted

c) Providers with wastage <5%

- Vaccine orders are flagged and processed
- Provider wastage and ordering are monitored

Vaccine Transfers and Wasted Vaccine Returns

1. Vaccine Transfers

If a provider experiences lower than expected vaccine demand and is faced with potential expiry of short-dated vaccine, the provider should contact the project and request a transfer.

The area manager will investigate suitable transfer destinations and coordinate the transfer in collaboration with the vaccine manager. The vaccine manager will note the transaction and update providers' inventories.

2. Wasted Vaccine Returns

A VFC provider must report wastage as soon as possible at which time the provider will receive instructions for returning the vaccine.

The Wasted Vaccine Report will note provider sites as "return pending" until the wasted vaccine arrives at the Alabama VFC Program. When the provider returns the vaccine, the VFC Program will note receipt of the wasted vaccine. The Return Pending Report will be used to identify providers who have not returned vaccine they reported as wastage.

The Doses Returned to Manufacturer Report identifies wasted vaccine sent to manufacturers for excise tax credit.

Other Program Operations Occurrences:

Determining if the alleged abuse situation is unintentional due to a clearly excusable lack of knowledge should be based on observations of the VFC staff and other appropriate investigative authorities. It should be noted that unintentional abuse or error is nevertheless still unacceptable. After thorough investigation (attachment A), it is determined that the situation is unintentional, Education Resolution will be instituted by the Area Immunization Manager. The provider will be monitored by Immunization Program staff and VFC Vaccine Manager over the next 6 months to determine if proper procedures are followed. If the situation continues or intentional abuse is determined, the provider will be reported by the Alabama Immunization Program using official procedures (Referral Process) set to prompt investigation by collaborating agencies such as, Medicaid and law enforcement agencies as described in the Referral Process section of this document.

All examples of potential fraud and abuse described must be reported to the VFC vaccine manager immediately. Call the Alabama VFC Program at 1-866-674-4807 and explain the circumstances to the VFC vaccine manager.

- Providing VFC vaccine to 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 for administration of a VFC vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC 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;
- Failing to maintain VFC records and comply with other requirements of the VFC program;
- Failing to fully account for VFC vaccine;

Referral Process

Based on investigation by program staff one or all of the following will be performed. If education and training can resolve the issue the process will be completed at that level. If the issue is determined to be intentional, or warrants further investigation, a formal referral to other collaborative agencies will be implemented. A list of identified agencies and their contacts are listed below.

Educational Resolution Referral

Certain situations may initially appear to be potential cases of fraud or abuse, but when assessed further, there may be no purposeful intent to misrepresent or defraud the VFC program and no negligence regarding VFC responsibilities. The situation can be attributed to an excusable lack of knowledge or understanding of the VFC program. In this circumstance, the CDC's VFC Site Visit Questionnaire and PEAR (Provider Education Assessment and Reporting) system will be used to provide guidance on recommended actions, for example, formal education and/or follow-up. The first intervention in these situations can be education regarding the requirements of the VFC program, consistent with the requirements of 42 CFR Part 455, Subpart A. Most infractions involve instituting an educational plan for providers, especially with the first report or observation by Immunization staff of improper storage and handling, incorrect paperwork or inaccurate ordering procedures. Serious fraudulent billing or unwillingness by the provider to change their behavior after education and re-training will result in suspending vaccine ordering until the problem is corrected or reporting or referral to outside agencies such as Medicaid and law enforcement.

The level of follow-up for all cases without an excusable lack of knowledge or cases without extenuating circumstances will be guided by incorrectly answered high-priority questions from the CDC's VFC Site Visit Questionnaire and the actions dictated by the CDC PEAR system. The educational process that a non-compliant provider will be enrolled in will be determined by the answers to the following questions: 1) Is the non-compliant behavior causing or has it caused loss of VFC vaccine? 2) Is the behavior placing the VFC program in danger if the behavior is

not stopped immediately: 3) Has the provider received unintentional financial gain because of the behavior? If the answer is "yes" to any of the questions, then the provider will be enrolled in the follow-up and educational process determined by PEAR. If the answer to all questions is "no," the provider will be enrolled in the follow-up and educational process determined by PEAR.

Formal Investigation/Referral

Situations identified by VFC staff or reported by the public that are not related to excusable lack of knowledge or understanding of the VFC program must be referred in conformance with 42 CFR §455.15 to the appropriate agencies for further investigation and potential enforcement of relevant laws, including fraud and abuse, consumer protection and professional licensure.

If the VFC program determines from the information available that the situation requires referral for further investigation by an outside agency, the VFC program will make these referrals within 5 working days.

State Medicaid Agency

Verbal reports within 5 days initial investigation will be made to the Alabama State Medicaid Agency followed with a written report to:

Jacqueline Thomas
Director
Program Integrity Medicaid
334-242-5318
PO Box 5624
Montgomery, AL 36103-5624

Office of the State Attorney General

Office of the Attorney General
500 Dexter Avenue
Montgomery, AL 36130
334-242-7300

Department of Insurance or State Insurance Commissioner

The Department of Insurance (DOI) or the State Insurance Commissioner is responsible for enforcing insurance-related laws of the state.

Alabama
334-269-3550
201 Monroe Street
Montgomery, AL 36104

State Medical Licensing Board

848 Washington Avenue
Montgomery, AL 36104
334-242-4116

Federal Agencies

CDC
All suspected cases of VFC fraud and abuse that are referred to an external agency for further follow-up must be reported to the grantee's Program Operations Branch (POB) project officer within 2 working days of the referral to the external agency. The grantee must submit to the VFC policy coordinator a copy of the information supplied to the external agency where the case was referred.

CMS and the Department of Health and Human Services Office of Inspector General

Prior to enrolling providers into the VFC program, VFC program staff will access the Office of Inspector General website for information about parties who are excluded by HHS at http://www.oig.hhs.gov/fraud/exclusions.html under the "List of Excluded Individuals and Entities." This site will monitored monthly by program staff for additional names of providers.

All suspected cases of VFC fraud and abuse that are referred to an external agency for further follow-up must be reported to CMS' Medicaid Integrity Group (MIG) and, as appropriate, to the DHHS Office of Inspector General, within 2 working days of the referral to the external agency. An example of a case that should be reported to the Office of Inspector General would be discovery of a provider that has not disclosed information regarding conviction of a crime under the Medicare, Medicaid or Title XX programs. The grantee must submit to the Medicaid Integrity Group a copy of the information supplied to the external agency to which the case was referred **by fax to 410-786-0711.** Questions regarding this requirement may be directed by e-mail to MIG_Fraud_Referrals@cms.hhs.gov. No HIPAA-sensitive information should be e-mailed to the Medicaid Integrity Group.

Fraud and Abuse Prevention Activities

All new providers enrolled in the program receive an enrollment visit establishing the provider's capacity to support the program, training on storage and handling, program requirements, including required forms and ordering processes, followed by a VFC-AFIX visit within 3 months of their enrollment. At minimum, program staff visit 50% of private providers enrolled into the program annually and perform additional visits on providers that exhibit educational needs during the visit. As educational needs are identified, staff provides issue specific training for VFC providers. Vaccine spoiled and wastage reports will be analyzed on each provider to determine the level of follow up required (percentage of loss). In addition, the providers agree to the following program activities as listed on the enrollment form:

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In order to participate in the Alabama Vaccines for Children (VFC) Program, providers agree to the following:

1. I will administer VFC vaccine only to children, newborn through 18 years of age, who meet one or more of the following criteria:
    a. Enrolled in the Alabama Medicaid program
    b. Not insured
    c. Is an American Indian or Alaskan Native

2. I will not administer VFC vaccine to underinsured patients unless my practice is a rural health center (RHC) or a federally-qualified health center (FQHC).

3. I will maintain all patient eligibility screening records for a period of three years after the date of the last dose of vaccine administered. I will make patient eligibility screening records available to Alabama VFC staff or the Department of Health and Human Services (DHHS) upon request.

4. I will comply with VFC site visits, and I will make patient records available upon request.

5. I will comply with the current immunization schedule, vaccine dosage recommendations, and contraindications to vaccination as recommended by the Advisory Committee on Immunization Practices, and included in the VFC program, unless
    a. I deem such compliance to be medically inappropriate based on my medical judgment in accordance with accepted medical practice, or
    b. The patient has a religious exemption.

6. I will provide current Vaccine Information Statements (VIS) at every immunization visit, and I will maintain records in accordance with the National Childhood Vaccine Compensation Injury Act which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). I will document the name of the VIS and the date of the VIS in the medical record.

7. I will not charge for VFC vaccine. I will not deny VFC-supplied vaccine if the patient is unable to pay an administration fee. I can opt to charge an administration fee up to $19.79 per dose for VFC-eligible children. I may request payment for an administration fee from all VFC-eligible patients except Medicaid patients. Administration fees for Medicaid-covered children must be billed to the Alabama Medicaid Agency.

8. I will designate one staff member to be the primary vaccine coordinator and designate at least one back-up vaccine coordinator who is able to perform the same responsibilities as the primary coordinator in the event the primary coordinator is unavailable. I agree that the vaccine coordinator will be responsible for:
    a. Adjusting the temperature of a vaccine storage unit;
    b. Documenting the temperature on the temperature logs for each storage unit:

c. The primary vaccine coordinator will review temperature logs weekly if daily monitoring is being conducted by a back-up person to ensure proper temperature recording. The back-up staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures;
d. The primary and back-up vaccine coordinators are responsible for training other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training should be kept as documentation.

9. I understand that it is my responsibility to maintain proper vaccine storage and handling procedures. I understand that my responsibility for proper vaccine storage and handling begins when a VFC vaccine delivery is accepted. I will assess and document refrigerator and freezer temperatures twice daily (once in the A.M. and once in the P.M.). I will provide proof of documented temperatures upon request. I will cooperate with the Alabama VFC program to recall patients if VFC vaccine doses are mishandled or administered incorrectly. I will manage vaccine storage in the following:

a. Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates and check for short-dated vaccine;
b. Store vaccines that require refrigeration in the middle of the refrigerator compartment, away from the walls, coils and peripheral areas;
c. Space stored vaccine to allow for cold air circulation around the vaccine;
d. Do not store vaccines in the door of the storage unit;
e. Post the temperature log on the vaccine storage unit door;
f. Record refrigerator and freezer temperatures twice a day (beginning and end) ensuring that refrigerator temperatures are between 35° and 46° F (2° C and 8° C). The freezer temperatures should be 5° F or lower (-15° C or lower);
g. Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside of the recommended ranges. Contact the immunization program for further instruction. Document actions taken on the temperature log. In the event the vaccine is wasted or spoiled, the vaccine should be returned to the vaccine distribution center with a completed vaccine spoiled and wastage report;
h. Maintain an ongoing file of temperature logs, and store completed logs for 3 years;
i. Immediately check vaccine cold chain monitors and document the temperature inside the transport;

10. I understand in order to receive VFC purchased vaccine, that vaccine can be stored in two acceptable storage units: 1) a refrigerator that has a separate freezer compartment with a separate exterior door, or 2) stand-alone refrigerators and freezers. The units must be able to maintain required vaccine storage temperatures year-round and be large enough to hold the year's largest inventory, have a working thermometer certified in accordance with National Institute of Standards and Technology or the American Society for Testing and Materials standards placed in a central area inside each storage

compartment, and be dedicated to the storage of vaccines. Post warning notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.

11. I agree to develop a written routine and emergency storage and handling plan. The Alabama Department of Public Health, Immunization Program will provide a template if needed to assist in the creation of the plan. The plan should be reviewed at minimum annually (or as needed) or when there is a change in staff that has responsibilities specified in the plan. The plan must include:

    a. A description of the process for ordering vaccine;
    b. A description of the process for controlling inventory;
    c. A description of the process for storing vaccines and monitoring storage conditions;
    d. A description of the plan to minimize vaccine wastage;
    e. A description of the plan involving vaccine shipping, including receiving, and packing and transporting vaccines;
    f. The emergency vaccine storage and handling should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. This portion of the plan should include: the name and contact information of the person(s) responsible for preparing and transporting vaccine, how this person will be notified that vaccine needs to be moved, the location that will receive the vaccine, how the receiving location will be notified of the vaccines arrival, and the maintenance of a worksheet to document vaccine involved in the power or equipment failure.

12. I will notify the Alabama VFC program at least 30 days before the vaccine expiration date of VFC vaccine that I will not use. I will return spoiled or wasted VFC vaccine to the Alabama VFC program.

13. I understand that vaccine orders will only be processed if the orders are submitted on the official Alabama VFC order form. **I understand that I have a choice regarding vaccine brands, but my order may be filled with another vaccine brand if the brand I request is not available**. I understand that some types may be on backorder; in such case, I understand that the vaccine brands I ordered will be shipped to me if and when they are available.

14. I understand that vaccine should be ordered in accordance with actual need and to avoid stock-piling of vaccine.

15. I understand that I must complete a new provider benchmark upon enrollment in the Alabama VFC program and an annual provider benchmark and provider profile every year and more frequently if necessary (e.g., if my practice size increases or the number of VFC-eligible children in my practice increases).

16. I, or the Alabama VFC program, may terminate this agreement in writing, at any time. The Alabama VFC program may terminate this agreement for failure to comply with

VFC requirements. Should this happen, I agree to return VFC-supplied vaccine to the Alabama VFC program.

17. I agree to operate and manage vaccine in a manner to avoid possible fraud and abuse of VFC purchased vaccine. Separate stock records for both public and private purchased vaccines should be maintained. This requirement does not necessitate having separate storage units for public and private vaccine however, the provider must be able to distinguish between the stock.

Immunization staff attends training quarterly to maintain up to date knowledge of VFC program requirements and implementation of the fraud and abuse policy.

Fraud and Abuse Evaluation Policy

The Alabama Department of Public Health, Immunization Division, will review the fraud and abuse policy by committee annually to review existing procedures. Review will also be based on continual feedback from field staff based on implementation of the procedures.

Appendix A

VFC Investigation Form with Corrective Action Plan

Pin Number:_____

Provider Name:_____

Clinic Name:_____

Address:_____

Phone Number:_____Fax Number:_____

Identify possible infraction:

- Providing VFC vaccine to 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 for administration of a VFC vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC 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;
- Failing to maintain VFC records and comply with other requirements of the VFC program;
- Failing to fully account for VFC vaccine;
- Other_____
  _____

Describe situation:_____
_____
_____
_____
_____
_____

Provider's description of situation:_____
_____
_____
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_____
_____

Please call Chevonne Tyner, Vaccine Manager at 334-206-2024. Proceed to Corrective Action Plan after consulting with VFC Vaccine Manager. After completing investigation and corrective action plan, please send a copy to the state office within 3 days.

Corrective Action Plan:

_____
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_____
_____
_____

_____ _____
Immunization Program Manager **Date**

_____ _____
VFC Program Manager **Date**

_____ _____
Immunization Staff **Date**