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MODULE 10 – Fraud and Abuse

www.cms.hhs.gov/apps/mfs/statecontacts.asp
http://www.consumeraction.gov/caw_state_resources.shtml

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 and abuse 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.

It is important for state immunization programs and the state Medicaid agencies to collaborate on the development of policies and procedures regarding VFC program fraud and abuse. In addition to using the services of state Medicaid agencies and CMS, state immunization programs, in collaboration with their state Medicaid agencies, should also use the fraud and abuse–related services of other state agencies that are responsible for investigating and prosecuting fraudulent healthcare activities and misuse of government funds.

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, for the purposes of this *VFC Operations Guide*, the following definitions will be used:

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.**

Examples of Fraud and Abuse

Fraud or abuse can occur in many ways, and some types of fraud and abuse are easier for the VFC program to prevent or detect than others, depending on how the VFC program is implemented. The VFC program should try to 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. The grantee should have clear written criteria indicating when an incident may be appropriate for an educational referral. The criteria should include both objective and subjective factors such as the amount of money lost by the VFC program; inadvertent financial gain of the provider; how the incident was identified; length of time the situation was occurring; provider's willingness to replace dose for dose lost VFC vaccine with privately purchased vaccine; and the provider's willingness to participate in the educational referral and post-education follow-up.

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

Written Policy

All grantees are required to develop and implement a comprehensive written fraud and abuse policy for the VFC program that addresses prevention, detection, investigation and resolution of fraud and abuse allegations. The fraud and abuse policy must be submitted to CDC annually. **The first submission is due no later than December 31, 2007, and should be sent to the VFC policy coordinator by that date.**

Each grantee's written fraud and abuse policy should address, at a minimum, the following components and describe how the components are integrated into the daily activities of the immunization program:

1. Identify one primary position and at least two back-up positions that have the authority to 1) make decisions about where identified potential fraud/abuse situations are to be referred; 2) make the referral; and 3)notify appropriate governmental agencies (CDC, state Medicaid and others as appropriate).
2. Identify enforcement agencies that will receive referrals of potential fraud or abuse cases and the process for referral. The referral process should include

   a. How coordination occurs with the Medicaid Integrity Program within the state Medicaid agency;
   b. If appropriate, memoranda of understanding (MOU) between the grantee and each investigative/enforcement agency that detail the role of each entity and the processes to be followed in responding to allegations of fraud or abuse.

3. Describe the process for implementing activities to detect and monitor for fraud and abuse in the daily operations of the VFC program. Documentation of the following activities is required:
   a. List examples of actions that might constitute potential fraud or abuse situations for staff to use as a training and resource document.
   b. List the types of potential fraud and abuse situations to be referred to each investigative/enforcement agency.
   c. Based on items a and b above, develop an algorithm or action steps describing how to respond to particular allegations of fraud or abuse in conformance with the Medicaid investigation and referral requirements of 42 CFR §455.15 (refer to end of module for information on 42 CFR §455 .15), including when educational interventions are an appropriate response versus when referral for enforcement is necessary and including which enforcement agencies have jurisdiction over the particular allegation.
   d. Describe the process for responding to potential fraud or abuse situations identified by the VFC program staff as well as those referred to the VFC program by outside individuals. The process should include the data to be collected regarding the situation and a maximum acceptable time frame not to exceed 5 working days from identification to referral to external agency and/or to VFC educational resource staff and the documentation process.
   e. Describe the educational process, including use of corrective action plans that will be used when a provider is referred to educational resource staff for excusable lack of knowledge related to the VFC program.
   f. Describe how staff members are educated about the fraud and abuse policy, including frequency of updates. At a minimum, staff should receive education as part of new employee orientation and updates annually after completion of orientation.
   g. Develop and implement a plan for continual evaluation and enhancement of the fraud and abuse policy.
4. Describe the process for incorporating provider accountability measures and responsibilities into the daily operations of the VFC program to detect and monitor for fraud and abuse activities.
5. Make available and disseminate a VFC fraud and abuse phone line for reports of suspected cases of fraud and abuse.
6. Describe how the excluded provider list is used for identifying potential situations of fraud and abuse. Information about parties who are excluded by the HHS Office of Inspector General is found on their website

(http://www.oig.hhs.gov/fraud/exclusions.html) under "List of Excluded Individuals and Entities."

7. Describe the process for notification of CDC and CMS, as appropriate, regarding fraud and abuse activities, including mandatory reporting as described in the last section below.

Coordination of Policy Development between Urban and State Grantees

In areas with both city and state grantees (Texas, Illinois, New York and Pennsylvania), the grantees must work together to develop identical policies and procedures for the following required policy components: items #2, #3, #4, #6 and #7.
Each grantee must develop items #1 and #5 separately.

Defining the Referral Process

Each grantee must, in its policy and procedures, outline a procedure for handling potential fraud or abuse situations, including to which investigative/enforcement entities particular allegations should be referred. The policy should provide guidance to persons making referral decisions in differentiating between situations that may be corrected through educational resolution and situations that must be referred for formal investigation consistent with 42 CFR Part 455, Subpart A. Further information on each type of referral is provided 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. 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. The grantee's fraud and abuse policy should provide guidance on what types of situations would qualify for this type of referral and how to properly document the referral and the corrective action plan as well as the outcome of the educational process. Grantees are responsible for ensuring that VFC-enrolled providers and their staff have the information they need to participate in the program and fully comply with program requirements.

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. The grantee's fraud and abuse policy must provide guidance on what types of situations require this type of referral, how to properly document the referral, and what follow-up is required for this type of referral.

Investigation and Reporting of Fraud and Abuse Cases

If the VFC program determines from the information available that the situation requires referral for further investigation by an outside agency, the VFC program should make these referrals in a timely manner (i.e., within 5 working days). To accomplish this, the grantee must identify the appropriate referral agencies within its geographic area and develop a working relationship with each agency. State agencies and their responsibilities related to fraud and abuse vary by state, so the appropriate referral agency in one state may not be an appropriate agency in another state. Below is a list of potentially relevant state and federal agencies. In developing its fraud and abuse policy, each grantee must, at a minimum, consult with each entity to determine relevant laws and potential investigative and enforcement capabilities.

State Medicaid Agency

Each state Medicaid agency has a process in place to meet requirements for detecting, investigating, pursuing, and referring suspected cases of fraud and abuse to law enforcement officials. The state Medicaid agency's Program Integrity Unit and/or its Surveillance and Utilization Review Unit usually perform these functions. These units identify questionable provider practices and conduct preliminary investigations into complaints of Medicaid fraud and abuse. If there is sufficient reason to believe that an incident of fraud or abuse has occurred, a full investigation may be conducted and the case referred to the Medicaid Fraud Control Unit (MFCU) or appropriate law enforcement agency.

Medicaid Fraud Control Unit

The Medicaid Fraud Control Unit is responsible for investigating and prosecuting (or referring for prosecution) violations of all applicable state laws pertaining to fraud in the administration of the Medicaid program, including the VFC Program. The MFCU is often located in the Office of the State Attorney General or another part of state government that has statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the Medicaid program.

Office of the State Attorney General

The Office of the state Attorney General generally advises and represents state agencies that protect the rights of state consumers and may also represent other relevant state agencies.

State Consumer Protection Agency

State consumer protection agencies offer a variety of important services. They might mediate complaints, conduct investigations, prosecute offenders of consumer laws, license and regulate professional service providers, provide educational materials and advocate for consumer rights.

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. A link to each state's DOI or Insurance Commissioner can be found at http://www.naic.org/state_web_map.htm

State Secretary of State/State Medical Licensing Board/State Department of Education
Each state licenses medical providers to practice medicine within state boundaries. The agency that issues licenses and that has regulatory responsibility over healthcare providers may vary from state to state. In general, these responsibilities are implemented by the state's Secretary of State, the state medical licensing board or the state department of education. It is necessary for each grantee to determine which agency in its state has this responsibility.

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
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 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 Medicaid_Integrity_Program@cms.hhs.gov. No HIPAA-sensitive information should be e-mailed to the Medicaid Integrity Group.

Fraud and Abuse Prevention

The grantee must actively work to prevent fraud and abuse in the VFC program. The best methods to prevent fraud and abuse are strong educational components carried out during the provider enrollment process and during VFC provider site visits. Both occasions provide the opportunity to prevent situations that may develop into fraud or abuse. Along with education, well-organized and correctly administered VFC accountability programs are the cornerstones for preventing situations from developing into potential fraud and abuse incidents.

42 CFR § 455.15 Medicaid Program Integrity

PART 455--PROGRAM INTEGRITY: MEDICAID
Subpart A--Medicaid Agency Fraud Detection and Investigation Program
Sec. 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe that an incident of fraud or abuse has occurred in the Medicaid program, the agency must take the following action, as appropriate:

1. If a provider is suspected of fraud or abuse, the agency must:
    a. In States with a State Medicaid fraud control unit certified under subpart C of part 1002 of this title, refer the case to the unit under the terms of its agreement with the unit entered into under Sec. 1002.309 of this title; or
    b. In States with no certified Medicaid fraud control unit, or in cases where no referral to the state Medicaid fraud control unit is required under paragraph (a)(1) of this section, conduct a full investigation or refer the case to the appropriate law enforcement agency.
2. If there is reason to believe that a recipient has defrauded the Medicaid program, the agency must refer the case to an appropriate law enforcement agency.
3. If there is reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation of the abuse.

[48 FR 3756, Jan. 27, 1983, as amended at 51 FR 34788, Sept. 30, 1986]