

DIVISION OF PUBLIC HEALTH

Policy Memorandum Number 58

Subject : Immunization Program Vaccine Fraud and Abuse Policy

Page 1 of 3

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Approved by:  _____

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I. POSITION STATEMENT

The purpose of this policy is to provide guidance for the reporting and referral for investigation of cases of fraud and/or abuse involving the utilization of vaccine purchased with public funds.

This policy does not cover private purchase vaccine in private provider offices. Such vaccine is used at the discretion of the provider and issues of abuse/misuse will be handled by the relevant licensing authorities.

II. BACKGROUND

The Division of Public Health is required by federal granting authorities to implement a vaccine fraud and abuse prevention policy. Through a strong provider education component, the program actively works to prevent fraud and/or abuse from occurring. Certain situations may be considered excusable because they are deemed to be due to a genuine lack of knowledge or understanding of State and/or Federal regulations and requirements. Such situations are addressed in detail in the program standard operating procedures (SOPs) through provider education, site audits and other measures to ensure compliance with State and Federal regulations and requirements.

III. DEFINITIONS

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 "...practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost..."

The definitions of "fraud" and "abuse" are taken directly from 42 CFR § 455.2, the Code of Federal Regulations (CFR), Medicaid Regulations.

IV. REVIEW AND REFERRAL PROCESS

Education and Resolution

All fraud and abuse reports will initially be reviewed by the Immunization Program. If it is determined that there is no purposeful intent to misrepresent or defraud, a corrective action plan will be developed and implemented. The provider will be required to sign an acknowledgement indicating receipt of additional education, and that any recurrence of the situation could result in disenrollment from the Vaccines for Children (VFC) program and/or referral for further investigation.

Formal Investigation Referral

Situations determined by the Immunization Program to constitute potential fraud and/or abuse must be referred to the appropriate agency for further investigation and potential enforcement of relevant laws.

V. PROCEDURES

Outlined below is the process to manage potential fraud or abuse situations. The process includes:

- (A) Reporting of potential/fraud/abuse
- (B) Determination that a situation constitutes fraud and/or abuse.
- (C) Referral of a suspected case to investigative/enforcement agencies.

A. Reporting of Potential Fraud/Abuse

Investigation of vaccine fraud and/or abuse is not a primary responsibility of the Immunization Program. However, the Program is required to report all suspected fraud and/or abuse to relevant authorities after first determining the action was not due to excusable lack of knowledge or understanding of State and/or Federal regulations

Any individual, group, or practice may report a suspected case of fraud and/or abuse. All such reports will be recorded by receiving Immunization Program staff on the Delaware Immunization Program Suspected Fraud and Abuse Report Form (Appendix A) which must then be forwarded within one (1) business day to the key personnel listed below.

Reports may be made anonymously or otherwise to the Delaware Immunization Program through any of the following:

- Program Hotline 1-800-282-8672,
- Program Tel# 302-744-1060,
- Program resource e-mail: Immunizedph@state.de.us
- State Fraud Hotline 1-800-55-FRAUD

Any staff member may receive and document a report of fraud and/or abuse. Such reports must then be forwarded within one (1) business day to key personnel identified as authorized to make decisions and referral determinations. The key personnel authorized to make decisions, referral determinations and notifications where appropriate are:

Primary: Immunization Program Manager
 540 S DuPont Hwy, Ste 4
 Dover, DE 19901
 (P) 302-744-1060 (F) 302-739-2555
 Immunizedph@state.de.us

1st Back Up: Deputy Immunization Program Manager
 540 S DuPont Hwy, Ste 4
 Dover, DE 19901
 (P) 302-744-1060 (F) 302-739-2555
 Immunizedph@state.de.us

2nd Back Up: Vaccines for Children Coordinator
540 S DuPont Hwy, Ste 4
Dover, DE 19901
(P) 302-744-1060 (F) 302-739-2555
Immunizedph@state.de.us

3rd Back Up: Communicable Disease Bureau Chief
540 S DuPont Hwy, Ste 12
Dover, DE 19901
(P) 302-744-1050 (F) 302-739-2549

B. Determination of Fraud/Abuse

The Immunization Program will determine if a situation is due to an excusable error or lack of knowledge that is amenable to education and/or re-training as outlined in detail in the Program SOPs. If the situation does not fit into this category, the Program will proceed with the referral process.

C. Referral Process

If the Program determines, based on the available information, that a situation is not due to excusable error or lack of knowledge, referral must occur within ten (10) working days from the date of assessment.

State-Funded Vaccine Purchases: All suspected cases of fraud and/or abuse involving vaccine purchased with State funds shall be referred to the Deputy Attorney General (DAG). The DAG will advise on the investigative course of action.

Federally-Funded Vaccine Purchases: Suspected cases involving Federally-funded vaccine must be referred by the Program (as per the Centers for Disease Control and Prevention's (CDC) VFC Operations Guide, Module 10- Fraud and Abuse), to the Medicaid Integrity Group (MIG) via e-mail at: MIG_Fraud_Referrals@cms.hss.gov with a copy to:

1. The CDC Program Operations Branch project officer.
2. The Deputy Attorney General (DAG).

No information shall be e-mailed to the MIG that violates HIPAA rules and regulations.

The MIG will refer the case to the appropriate Delaware State Medicaid agency. The following information shall be included in the referral to the MIG:

- Name, Medicaid provider ID (if known), address, provider type (e.g., private provider).
- Source of report (e.g., provider office staff, public, immunization program staff, anonymous).
- Date and time information was received.
- Detail of suspect activity with specific details including:
 - Person/s involved and contact information if available;
 - Specific statutes, rules, regulations violated
 - Monetary value of the vaccine involved.
- Contact information for Immunization Program Fraud and Abuse Coordinator
- Have available all records pertaining to the case including any communication between the Immunization Program and the affected provider concerning the situation, signed provider enrollment forms, all previous site visit audit reports if available (including any education given or remedial action taken) and any general communication with the provider (current and in the past).



Delaware Immunization Program Suspected Vaccine Fraud and/or Abuse Report Form

Complete this **Suspected Vaccine Fraud and Abuse Form** in its entirety to report suspected vaccine fraud and/or abuse. Please provide as much information as possible.

<i>This information is optional – you may choose to remain anonymous</i>	
Name of person reporting:	Date Reporting:
Address:	
Telephone Number:	Email Address:

Person or Company Suspected of Fraud and/or Abuse <i>(This information is required)</i>	
Name of Physician's Office, Practice Clinic:	
Type of Provider (e.g., private) if known:	Medicaid ID (if available)
Name of person(s) suspected of fraud and/or abuse: (Including names of staff that may be involved)	
Business Address:	
Telephone Number:	Date of Incident:
Please explain how you became aware of the suspected fraud and abuse:	

Which of following best describes the type of fraud and/or abuse?

- Providing VFC vaccine to non-VFC-eligible children.
- Selling or otherwise misdirecting VFC and/or State-funded vaccine.
- Billing a patient or third party for VFC vaccine.
- Charging the parent/guardian/patient for administration of a VFC vaccine to a Federally vaccine-eligible child.
- Not providing VFC-eligible children VFC vaccines due to parent/guardian's inability to pay.
- 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 and State-funded vaccine.
- Failing to properly store and handle State supplied vaccine.
- Ordering VFC or State-funded vaccine in quantities or patterns that do not match provider profile or otherwise involves over-ordering of VFC or State-funded doses.
- Wastage of VFC or State-funded vaccine.
- Other: _____

**Please PRINT or TYPE report in detail. You may add additional sheets if necessary:
Attach COPIES, not originals, of all documents that relate to this report.**

Signature of person completing this form:	Printed name & title:

RETURN THIS FORM TO:

Delaware Immunization Program
540 S. DuPont Hwy, Ste 4
Dover, DE 19901
Phone: 1-800-282-8672
Outside of Delaware: (302) 744-1060
Fax: 1-800-318-0810

FOR OFFICE USE:	
CASE #:	
Immunization Program Staff:	