

**Fraud and Abuse Policy
Vaccines for Children (VFC) Program
Bureau of Immunization (BOI)
New York City Department of Health & Mental Hygiene (NYC DOHMH)
December 29, 2009, revised February 11, 2010, revised April 13, 2010**

NYC DOHMH Bureau of Immunization VFC Policy on Fraud and Abuse

The New York City (NYC) Vaccines for Children (VFC) Program policy on fraud and abuse provides guidance in the monitoring and prevention of fraud, waste and abuse of VFC vaccines. This policy is consistent with standards established in the policy on fraud and abuse by the U.S. Centers for Disease Control and Prevention (CDC). This policy applies to any fraud or abuse or suspected fraud or abuse involving VFC providers.

Background:

The Federal VFC Program was created as part of the Omnibus Budget Reconciliation Act, Section 1928 of the Social Security Act, in August 1993. The goal of this federally funded program is to improve vaccine availability nationwide by providing vaccines at no cost to VFC-eligible children through public and private providers enrolled in the program: <http://www.cdc.gov/vaccines/programs/vfc/default.htm>. The VFC program is operational in all 50 states and eight territories including the U.S. Virgin Islands, Puerto Rico and Guam.

NYC began its VFC program in 1994 as part of the President's Childhood Immunization Initiative. The VFC program is a Title XIX Medicaid program. Children who are VFC eligible are those who are under 19 years-old and; Medicaid-eligible, uninsured, underinsured and seen at a Federally Qualified or Rural Health Center, or are American Indian or Alaska Native. These children are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP) through a federal entitlement created by the Omnibus Budget Reconciliation Act of 1993. Child Health Plus B (CHPlus B) is a non-Medicaid-managed care program in New York State. Effective August 1, 2006, children enrolled in CHPlus B in NYC began receiving vaccines from the NYC Immunization Program that are distributed in the same manner as vaccine for VFC-eligible children (financed with New York State funds). Similarly, vaccines are being provided for underinsured children using 317 ARRA funds (began August 1, 2009); these vaccines are also distributed through the VFC program mechanism.

Purpose of the NYC Fraud and Abuse Policy:

The purpose of the NYC fraud and abuse policy is to have a standard operating procedure in place for prevention, detection, investigation and resolution of a suspected case of provider fraud and/or abuse. All VFC providers are required to be enrolled and re-enroll in the VFC program annually. The provider must sign the VFC vaccine recipient agreement which specifies the VFC program requirements (available at <http://www.nyc.gov/html/doh/downloads/pdf/imm/imm-vaccine-recipient-agreement.pdf>). Suspected fraud and/or abuse will be identified by several mechanisms, which may include, but not be limited to: inconsistencies in reporting of vaccines

administered to the Citywide Immunization Registry, responses to high priority questions on the CDC VFC Site Visit Questionnaire, and problems identified at the time of a VFC site or PQA site visit. Reports of suspected fraud and/or abuse should be investigated immediately.

The NYC VFC Program investigates all suspected or reported cases of fraud and abuse. The VFC Fraud & Abuse policy is to ensure that all VFC vaccines are administered only to VFC-eligible patients, that vaccine loss and wastage are minimized and that fraud and abuse by VFC providers are deterred by:

- Assigning responsibility for reporting fraud and abuse.
- Making available and disseminate a VFC fraud and abuse phone line for reports of suspected cases of fraud and abuse.
- Providing guidelines to detect and conduct fraud and abuse investigations.
- Providing all employees periodic fraud and abuse awareness trainings.
- Providing new VFC employees training regarding VFC requirements and fraud and abuse policy.

For the purposes of this **NYC VFC Fraud & Abuse Policy**, the following definitions will be used:

Fraud:

Fraud is defined in the Code Federal Regulations, Title 42, Part 455, Section 455.2 (42 CFR 455.2) 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 in 42 CFR 455.2 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.**

NYC Fraud and Abuse Policy Components:

- 1. Authority for referral of suspected fraud and abuse** – In consultation with the Bureau of Immunization Assistant Commissioner, Deputy Director and the DOHMH Office of General Counsel, and the Provider Quality Assurance Unit (PQA) Unit Chief, a decision will be made whether the case needs to be referred and where potential fraud or abuse cases are to be referred. The PQA Unit Chief will serve as the primary person to: a) make the referral; and b) notify appropriate governmental agencies. The two PQA field team leaders will serve as the first and second back-up referral positions.

2. **Referral to external enforcement agencies** – If a determination is made that referral of a suspected case of fraud and abuse to an outside agency is warranted, the referral will be made within 5 working days to the New York State Office of the Medicaid Inspector General (OMIG) by email and phone contact to summarize the case. The case will then be reported to CDC’s Program Operations Branch (POB) and to the CMS Medicaid Integrity Group within 2 working days of the notification to OMIG. Following consultations with OMIG and the DOHMH Office of General Counsel, a determination will be made whether other external agencies (e.g., New York State’s Attorney General, New York City Department of Investigations, etc.) should be notified.
3. **Process for implementing activities to detect and monitor fraud and abuse** –
 - a. Examples of actions that might constitute potential fraud and abuse:
 - 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;
 - Failing to fully account for VFC vaccine;
 - Failing to comply with the VFC borrowing requirements and procedures;
 - 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.
 - b. All cases of knowing and intentional fraud and abuse situations will be referred to OMIG and CDC.
 - c. Based on a. and b. above, the CDC Non-Compliance with VFC Program Requirements Algorithm will be used to respond to specific allegations of fraud or abuse.
 - d. Once a potential case of fraud and abuse has been detected or reported, the PQA Unit Chief will review all relevant documents regarding the case including, but not limited to: the provider’s original VFC enrollment form; all subsequent re-enrollment forms; all reports and findings from site visits; any correspondence with the provider; the provider’s vaccine ordering history; doses administered report. If review of all available documentation indicates that a referral to an external agency is warranted, the referral must be made within 5 working days from identification of the potential case.
 - e. For cases with an excusable lack of knowledge or cases with extenuating circumstances related to the VFC program, the CDC Non-compliance with VFC Requirements Algorithm will be used to provide guidance on recommended actions, for example, formal education and/or follow-up. The level of follow up and response

- for all cases without an excusable lack of knowledge or cases without extenuating circumstances, will be guided by incorrectly answered high-priority question from the CDC’s VFC Site Visit Questionnaire and the actions dictated by the Non-compliance with VFC Requirements Algorithm (<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/nc-vfc-algorithm-fall08-508.pdf>). The educational process (secondary or tertiary) 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 tertiary educational process. If the answer to all questions is “no”, the provider will be enrolled in the secondary educational process.
- f. Annual training for all PQA staff will include a fraud and abuse module that addresses the detection, documentation, and reporting of cases of potential fraud and abuse. All new PQA staff will be orientated in the procedures for investigating fraud and abuse violations and policy and procedures updates will be distributed as available.
- g. Continual evaluation and enhancements of NYC’s Fraud and Abuse Policy will be initiated by: 1) outcomes of NYC cases identified as potential fraud and abuse, and 2) policy updates obtained from CDC’s website, regular VFC conference calls with grantees, and updates to CDC’s Fraud and Abuse module (Chapter 10 of the VFC Operations Guide).
4. **Detection and monitoring of fraud and abuse** – All provider site visits will include the examination and analysis of Section I of CDC’s VFC Site Visit Questionnaire. All site visit reports submitted by field staff, including all documented cases of potential of fraud and abuse, all site findings and site recommendations, will be reviewed by the respective field team leader and, if appropriate, by the PQA unit chief.
5. **Suspected cases of fraud and abuse should be reported to:**
- The Bureau of Immunization, Provider Quality Assurance Unit Chief at 212-447-3329, and
 - The New York State Office of the Medicaid Inspector General Fraud Hotline at 877-873-7283. Complaints may also be filed on-line at: <http://www.omig.state.ny.us/data/content/view/50/224/>
6. **The List of Excluded Individuals/Entities of the U.S. Department of Health & Human Services, Office of Inspector General** – this list of excluded individuals will be reviewed annually by the PQA Unit during the annual provider re-enrollment process. All providers who enroll or re-enroll in the VFC program will be checked against the list of excluded individuals. If a provider’s name is found on the list of excluded individuals, the provider will be removed from the VFC program.

7. **CDC's Program Operations Branch and the CMS Medicaid Integrity Group** – will be notified and provided all relevant documents and information, within 2 working days of the referral of any suspected case of fraud and abuse to an external agency. All documentation will be faxed to the Medicaid Integrity Group at: 1-410-786-0711.

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