

Subject: Fraud and Abuse Policy of the North Carolina Immunization Program (NCIP) for Vaccines for Children (VFC) Vaccines

Effective: March 2011

Revised: September 2011

Policy:

The North Carolina Immunization Program (NCIP) 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 US 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.

NC began its VFC program in 1994 as part of the President's Childhood Immunization Initiative. The VFC program was established by the Title XIX Medicaid program. Children who are VFC eligible are those who are under 19 years of age and are in one or more of the following categories: Medicaid-eligible; uninsured; underinsured; or 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 the federal entitlement created by the Omnibus Budget Reconciliation Act of 1993.

Purpose of the NCIP Fraud and Abuse Policy:

The purpose of the NCIP 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 www.immunize.nc.gov).

Suspected fraud and/or abuse will be identified by several mechanisms, which may include, but are not be limited to: inconsistencies in reporting of vaccines administered to the North Carolina Immunization Registry, responses to high priority questions on the CDC VFC Site Visit Questionnaire, and problems identified at the time of a VFC site visit. Reports of suspected fraud and/or abuse should be investigated immediately.

The NC VFC Program investigates all suspected or reported cases of fraud and abuse. The VFC fraud and 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 disseminating 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; and
- Providing new VFC employees training regarding VFC requirements and fraud and abuse policy.

For the purposes of this **NCIP VFC Fraud and 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.**

NCIP Fraud and Abuse Policy Components:

1. Authority for referral of suspected fraud and abuse – In consultation with the NC Immunization Program Branch Head and the DMA Provider Quality Assurance Unit, a decision will be made whether the case needs to be referred and where potential fraud or abuse cases are to be referred. The NCIP Vaccines for Children Coordinator will serve as the primary person to: a) make the referral; and b) notify appropriate governmental agencies. Program staff members 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 NC Division of Medical Assistance, Office of Program Integrity 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 DMA and the DPH attorney, a determination will be made whether other external agencies (e.g., Attorney General, Insurance Commissioner 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; and
- 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 NCIP Branch Head 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; and 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-vfcalgorithm-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 staff will include a fraud and abuse module that addresses the detection, documentation, and reporting of cases of potential fraud and abuse. All new NCIP 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 NC’s Fraud and Abuse Policy will be initiated by: 1) outcomes of NC 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*).

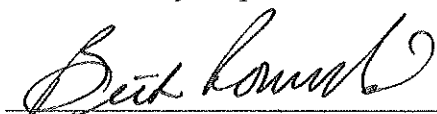
4. Detection and monitoring of fraud and abuse – All provider site visits will include the examination and analysis of Section I of CDC’s VFC Site Visit Questionnaire. All site visit reports submitted by field staff, including all documented cases of potential of fraud and abuse, all site findings and site recommendations, will be reviewed by the respective field services staff, VFC Coordinator and, if appropriate, by the NCIP Branch Head.

Any medical professional, public health official, or citizen may report suspected cases of Fraud and Abuse by contacting the NCIP at 1-877-873-6247 (Monday through Friday, 8am to 5pm, except on State holidays).

5. Suspected cases of fraud and abuse should be reported to - NCIP refers all suspected cases of VFC fraud and abuse to the Centers for Medicare & Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office. CMS/MIG will refer the suspected case to the appropriate state Medicaid agency. The NC Department of Medical Assistance (DMA) will conduct preliminary investigations and, as warranted, refer appropriate cases to NC's Medicaid Fraud Control Unit following the Federal Regulatory scheme at 42 CFR section 455.15. The referral must be sent electronically to: MIG_Fraud_Referrals@cms.hhs.gov.

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 monthly by the NCIP. 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.



Approved by

Filename: NCIP VFC fraud and abuse policy 7-11



Date