Policy and Procedure for Medicaid Fraud and Abuse Chicago Vaccines for Children (VFC) Program Updated: 01/26/2024

Chicago Department of Public Health Immunization Program

I. Background

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay. VFC was created by the Omnibus Budget Reconciliation Act of 1993 as an entitlement program to be a required part of each state's Medicaid plan. The intent of VFC is to support efforts to increase immunization levels by providing publicly purchased vaccines to eligible children. Funds for the program are annually transferred from the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC) and awarded to 64 immunization programs. Approximately ninety percent of these funds are used for vaccine purchase.

The Vaccines for Children (VFC) Program was realized in Chicago in October 1994. Since that time, approximately 2,500 physicians have enrolled in the VFC Program in order to provide vaccine at no cost to eligible children throughout the City of Chicago. The VFC program saves enrolled providers out-of-pocket expenses for vaccine, eliminates or reduces vaccine cost as a barrier to immunizing eligible children.

The Centers for Medicare and Medicaid Services (CMS) have established a maximum administration fee that may be charged by health care providers for each dose of federally supplied VFC vaccine administered. That fee varies among the states. In Illinois, health care providers may not charge more than \$23.87¹ to non-Medicaid VFC-eligible children.

Providers may not charge an administration fee to Medicaid recipients. The Illinois Healthcare and Family Services (IL HFS) Medicaid Program reimburses up to \$6.40² for the administration of each vaccine to Medicaid-enrolled children. The IL HFS Medicaid Program does not reimburse providers for the cost of the vaccines that are available through the VFC program.

To participate in the Chicago VFC Program, health care providers must agree to comply with the requirements outlined in the VFC Provider Agreement, including, agreeing to operate the VFC program in a manner intended to avoid fraud and abuse.

II. Rationale:

The VFC Program is vulnerable to fraud and abuse. It is essential to have policies, procedures and processes in place to prevent and detect instances of fraud and/or abuse and to ensure that vaccines supplied by the VFC program are used and accounted for appropriately. For the purposes of consistency, definitions of fraud and abuse are derived from CMS which supplies the following definitions:

¹ As of January 1, 2020

² As of January 1, 2020

<u>Fraud</u>

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 person. It includes any act that constitutes fraud under applicable federal or state law.³"

<u>Abuse</u>

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 fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program."

Possible examples of the types of fraud and/or abuse that may occur with respect to the VFC Program may include, but are not limited to:

- 1. Providing VFC vaccine to non-VFC-eligible children
- 2. Selling or otherwise misdirecting VFC vaccine
- 3. Billing a patient or third party for VFC-funded vaccine
- 4. Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a federally vaccine-eligible child
- 5. Failing to implement provider enrollment requirements of the VFC program
- 6. Failing to screen patients and document screening results for VFC eligibility at every visit
- 7. Failing to maintain VFC records and comply with other requirements of the VFC program
- 8. Failing to properly store and handle VFC vaccine
- 9. Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering of VFC doses of vaccine

III. Procedures for Prevention Activities

A. <u>New Enrollment</u>: During initial (new) enrollment to the VFC Program, each health care provider will be asked to complete the *VFC Provider Agreement, Provider Profile* and related forms. Completed forms will be returned to Chicago VFC. The VFC staff person conducting the new enrollment visit will assure that the Policy and Procedures for Medicaid Fraud and Abuse is received by the appropriate practice staff person. The VFC staff will inform the provider staff that the policy should be reviewed and adhered to by all provider staff persons who use the VFC supplied vaccine. All questions will be referred to the Vaccine Manager or the Immunization Program Director.

<u>Annual Re-Enrollment (re-certification)</u>: To re-enroll annually as required, providers complete all required forms within the I-CARE system as per instructions. A copy of the signed Provider Agreement containing the signature of the Medical Director (or equivalent) will be returned to VFC by fax or email to complete the process.

- B. The Centers for Disease Control and Prevention (CDC) lists the following program internal practices for fraud and abuse prevention:
 - Every provider vaccine order should be compared to the Provider Profile, with orders exceeding expected usage identified and held. The provider will be contacted to determine whether the use of additional vaccines is justified.
 - Comparing the number of children serviced by eligibility category (e.g. Medicaid enrolled children) with other existing data (e.g. Medicaid data, commercial insurance

³ See 42 Code of Federal Regulations 455.2

data) assists in identifying potential fraud and/or abuse, and helps to ensure the administration of VFC-supplied vaccine to eligible children only.

- During site visits, data submitted by a provider can be evaluated by comparing vaccine usage and inventory data to available VFC screening documentation on file within the provider practice.
- C. A copy of the Medicaid Fraud and Abuse policy will also be placed into the VFC Provider Handbook and updated annually, as needed.
- D. The Provider Enrollment form will capture the medical license number and National Provider Identification Number (NPI) of all providers (MD, DO, NP, PA) who will use or prescribe VFC vaccine.
- E. During VFC routine site visits, AFIX visits and quality assurance visits, VFC staff will provide continuous and ongoing VFC-oriented education to office staff regarding eligibility, screening, documentation and other program compliance issues. VFC staff will be vigilant to identify any indications of fraud or abuse during these visits.
- F. Chicago Department of Public Health Immunization Program will annually train all VFC staff that has interactions with VFC-enrolled providers to:
 - Prevent situations of potential VFC fraud and/or abuse or non-compliance with VFC program requirements
 - Identify situations that involve suspected VFC fraud and/or abuse or non-compliance with VFC program requirements.
 - Follow up on situations that involve suspected VFC fraud and/or abuse or noncompliance with VFC program requirements.
- G. Working relationships with public aid and law enforcement are critical and must be continuously renewed. The Illinois Department of Healthcare and Family Services Office of Inspector General is charged with detecting, investigating and referring suspected cases of Medicaid fraud and abuse to law enforcement officials. As of the writing of this document, those contact persons are:

Inspector General Brian Dunn⁴ HFS Office of the Inspector General 2200 Churchill Rd Springfield, IL 62702 217.524.6119

Illinois also has a Certified Medicaid Fraud Control Unit (MFCU). The MFCU is responsible for investigating, prosecuting or referring for prosecution, the violations of all state laws concerning Medicaid program fraud. As of the writing of this document, that contact person is:

Heather D'Orazio, Director⁵ Office of the Illinois Attorney General, Medicaid Fraud Bureau 100 W Randolph Street, 13th Floor Chicago, IL 60601

⁴ As of 3/19/2021

⁵ As of 1/25/2024

IV. Personnel

The City of Chicago Department of Public Health, Immunization Program has identified a Fraud and Abuse Coordinator and two back-up positions that have the authority to:

- 1. Determine if situation requires immediate referral or if educational intervention and follow-up are adequate.
- 2. Make decisions to refer case to the Medicaid Integrity Group (MIG) and any other state or city agencies that is required by law to refer suspect cases.
- 3. Make the appropriate referrals; and notify CDC of referral to MIG and any other appropriate agencies.

Primary VFC Fraud and Abuse Coordinator

Kevin Hansen, Manager Vaccine Management Unit Chicago Department of Public Health 2160 W. Oaden Ave. Chicago, IL 60612 Phone: 312.746.9330 Fax: 312.746.6388 Email: kevin.hansen@cityofchicago.org

Backup:

David Juen **Projects Administrator** Chicago Department of Public Health 2160 W. Ogden Ave. Chicago, IL 60612 Phone: 312.746.9866 Fax: 312.746.6388 Email: david.juen@cityofchicago.org

<u>V. Other Notifications</u> The City of Chicago Office of the Inspector General mandates that the City of Chicago be notified for any report of fraud or abuse made by the Chicago Department of Public Health Immunization Program. As of the writing of this document, that contact information is:

Joseph Ferguson

City of Chicago Office of the Inspector General 740 N. Sedgwick, Suite 200 Chicago, IL 60654 773.478.7799

The CDC mandates that all suspected cases of VFC fraud and abuse be referred to:

Centers for Medicare and Medicaid Services (CMS) Medicaid integrity Group (MIG) Field Office Email: MIG Fraud Referrals@cms.hhs.gov

The CDC also mandates that CDC be contacted within two (2) working days of the referral to the Medicaid Integrity Group for any report of fraud or abuse. As of the writing of this document, that contact person is:

James Reiss Lueken⁶ Project Officer for Region 5A & Region 2 (New York State) Immunization Services Division Centers for Disease Control and Prevention Office: (404) 718-7232 Email: <u>oqh7@cdc.gov</u> Medicaid_Integrity_Program@cms.hhs.gov

Other government agencies involved in controlling fraudulent activities related to the provision of health care services include the State Attorneys General, the U.S. Department of Health and Human Services Office of the Inspector General and the Centers for Medicare and Medicaid Services.

VI. Allegation and Referral Database

The Chicago Department of Public Health Immunization Program maintains a database to monitor and document all actions taken on allegations related to fraud and abuse of the VFC program requirements, including actions taken to address the identified situations. The database is shared periodically with CDC. This database includes any external reports received and issues identified by VFC program staff during site visits. The following elements are collected in the database:

- a. Subject's name, address and contact information (Medicaid ID and other identifiers), if applicable
- b. VFC Provider Name
- c. VFC Provider Address
- d. Source of allegation
- e. Date allegation reported to program
- f. Description of suspected misconduct
- g. Specific VFC requirements violated
- h. Specific dates and actions taken with provider (specific follow-up activities: education, site visit, suspension, removal of vaccine, or other actions taken prior to disposition)
- i. Value of vaccine involved, if available
- j. Application of education intervention(s), if applicable
- k. Disposition (closed, referred, entered into educational process) of case and date of disposition.

VII. Procedures for Detection Activities

- A. At least once each year, VFC staff will conduct a VFC Compliance Site Visit (also known as a Quality Assurance Review-QAR) with all enrolled VFC providers.
- B. Providers who are newly enrolled will receive a VFC Compliance Site Visit within 6 months of enrolling.
- C. At least three (3) times each year, VFC staff will conduct a site visit to check that vaccines are being properly stored and maintained and that temperature logs are available for review for at least three (3) months.
- D. VFC providers will be interviewed on any occasion when AFIX or VFC visits are conducted as to the vaccine use practices for VFC and other patients. At any time during these visits, the policies and practices of the VFC provider will be assessed to determine if VFC supplied vaccine is being used appropriately.

⁶ As of 1/31/2024

VIII. Procedures for Responding to Fraud and/or Abuse Allegations

- A. The Chicago VFC Program will respond to any allegation of fraud and/or abuse by conducting a site visit to the provider in question within five (5) working days of the allegation being brought by any reporting party including VFC staff or an external source. VFC staff is required to report any issues/complaints to the VFC Program Manager who is their immediate supervisor.
- B. Any allegation of fraud and/or abuse will require the collection of certain facts to substantiate the allegation. The following information will be collected and added to the Allegation and Referral Database:
 - 1. The name of the VFC provider and/or name of the practice, the address and phone number.
 - 2. The name of the enrolled physician, named as the primary medical director or physician(s) involved in the allegation, the Medical License number and NPI.
 - 3. Source of the allegation
 - 4. Date allegation reported to program
 - 5. Description of suspected misconduct with specific details including:
 - Complete description of alleged behavior, persons involved and contact information, if available; include actions taken by program.
 - Specific VFC program compliance requirements violated and how conduct of provider violated the requirements
 - Value of VFC vaccine involved, when available.
 - 6. Educational intervention, if applicable, required to correct misconduct or inappropriate behavior, and/or non-compliance with VFC.
 - 7. Success or failure of educational intervention
 - 8. Disposition (closed, referred, entered into educational process) of case and date of disposition.
 - 9. All documents supporting the allegation of fraud or abuse will be protected and conserved for evaluation by managerial staff. All allegations will be held in strict confidence.
 - 10. All reports derived from the vaccine management software program, VTrcks and/or I-CARE, will be included for evaluation including Doses Administered Reports, Vaccine Monthly Inventory, and Doses Distributed Reports. Furthermore, the written report from the site visit will be included.
- C. VFC supplied vaccine may be removed from the VFC provider and the provider may be terminated when wrongful use of vaccine may cause potential physical or financial harm to patients, parents/guardians or the VFC program.
- D. If the identified issue/complaint is determined to result from an excusable lack of knowledge or understanding of the VFC Program, education and a corrective action plan will be required. Elements to be included in this will be made on an individual basis depending on factors leading up to the investigation. Once education is completed and the corrective action plan is implemented, the VFC program will monitor the VFC provider for a one-year period (12 months). If the provider practices demonstrate the similar or related issues of non-compliance, fraud or abuse, the provider may be terminated and reported as specified.
- E. Allegations of fraud or abuse by VFC providers will be evaluated by the Immunization Program Director, Immunization Program Medical Director and lead CDC Public Health Advisor within five (5) working days of the site visit (above section VIII. A). If the identified issue/complaint is determined to be substantive, all documentation will be gathered and

immediately reported to the City of Chicago Office of Inspector General and the Centers for Medicare and Medicaid Services.

F. An instance of fraud and/or abuse will be referred to the appropriate agency/ies as indicated previously. Instances of Medicaid fraud/abuse will be reported to the Medicaid Integrity Group (MIG).

This policy will be reviewed annually and updated, as needed, based on CDC guidance and personnel changes.