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| <p><b>Title:</b> Fraud and Abuse</p>                  | <p><b>Policy #:</b> IDOH Immunization Division Policy 20</p>   |
| <p><b>Effective dates:</b> 01-Jan-24 to 31-Dec-24</p> | <p><b>Approvals:</b></p> <p><i>Dave McCormick</i></p> <hr/> <p>Dave McCormick, Immunization Director</p> <p>July 7, 2024</p> <hr/> <p>Date</p> |

## Policy Statement

The purpose of this policy is to provide programmatic direction for the prevention of fraud and abuse of federally and state funded vaccines. Vaccines supplied through the Indiana Department of Health (IDOH) Immunization Division are funded through the federal Vaccines for Children (VFC) Program, Section 317 federal program and state funds.

All providers administering publicly funded vaccines must complete and sign the Immunization Provider Profile and Provider Agreement, and complete the Cold Storage Unit Certification in the Vaccine Order Management System (VOMS) during the Annual Provider Recertification.

## Definitions

Fraud is defined at 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 is defined at 42 § CFR 455.2 as “provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to 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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.”

## Compliance Assessment

To receive publicly funded vaccines, enrolled providers must agree in writing to follow established Immunization Division vaccine usage, inventory management, data collection and reporting requirements. Every vaccine order submitted by a provider is compared to information disclosed in the most recent Provider Profile. The Provider Profile is a self-completed population estimate of the number and type of publicly funded vaccine recipients that the provider expects to see during a calendar year. The Provider Profile is completed on an annual basis or as needed when changes occur in the patient population. Annual vaccine usage data are routinely entered into a vaccine management system developed by the Centers for Disease Control and Prevention (CDC).

Vaccine orders exceeding annual profiled estimated usage are flagged by the vaccine management system. Immunization Division staff will contact those providers exceeding profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed. Additionally, Immunization Division staff will validate submitted provider profile data by comparing it to current usage data. Unjustified, excessive, and/or repeated discrepancies between provider profile data, vaccine orders, and vaccine usage will be evaluated and referred for further investigation.

## Fraud and Abuse Investigation

The following procedure shall be implemented whenever fraudulent use of publicly funded vaccines is suspected. Under Indiana law, fraud and/or abuse is defined as “intentional or unintentional deviation from the signed Provider Agreement with the Immunization Division.” Each case will be evaluated and referred to the proper authority or authorities for investigation. If fraudulent use of publicly funded vaccines is suspected, immediately report suspicion of fraud and/or abuse of state supplied vaccines to the accountability coordinator or designee by calling the IDOH Immunization Division at 1-800-701-0704. Ask to speak to the accountability coordinator.

The Fraud and Abuse Module in the Provider Education and Assessment Reporting (PEAR) System must be used to monitor, document and track actions related to VFC Program fraud and abuse.



Upon notification of suspected fraud and/or abuse of publicly funded vaccines:

1. The accountability coordinator will collect and prepare written documentation of the suspected fraud and/or abuse of publicly funded vaccines immediately. Documentation will include the provider's name, address, medical license number, VFC PIN, date(s) of event, manner in which the information was obtained, the name of the individual reporting the suspected fraud/abuse, and a telephone number at which the individual reporting the suspected fraud/abuse can be reached. Gathered information will also include a copy of the Immunization Provider Profile form, Provider Agreement form, provider's vaccine order history, vaccine distribution reports from the vaccine management system, and Doses Administered reports. Documentation should correspond to the time frame that fraud and/or abuse is suspected. The listed forms will be forwarded to the Office of Legal Affairs. Under the guidance of the Office of Legal Affairs, the following steps may be taken:
  - a. The accountability coordinator will notify the relevant agencies. This may include but is not limited to the Medicaid or Medicaid contractor designee, Medicaid Fraud Control Unit (MFCU), State Department of Insurance (DOI), and the Office of Inspector General (OIG).
  - b. The division director will immediately notify the CDC
  - c. The accountability coordinator will immediately contact the Indiana Professional Licensing Agency to verify the validity of the suspected abuser's medical license
2. The accountability coordinator will remain available during the case review to respond to follow-up questions, provide additional documentation and/or participate in interviews as requested.
3. Upon resolution of any formal review or investigation, the Immunization Division will develop an appropriate educational training plan for the provider in question to ensure proper administration and management of publicly funded vaccines. This may include, but is not limited to:
  - a. VFC enrollment training
  - b. Requiring the provider to enroll (if not already enrolled) and use the Children and Hoosier Immunization Registry Program (CHIRP) for ordering and managing vaccines
  - c. More frequent reporting of requested data and/or information to the Immunization Division
  - d. Change in ordering cycle
  - e. Limited vaccine ordering



Upon receipt of the written documentation, the Immunization Division Policies and Procedures Committee will review the case. If abuse and/or fraud are suspected, they will refer it to the appropriate agency for investigation, such as the State of Indiana Office of Attorney General and the Medicaid Fraud Unit.

## Resolution

A provider determined to be engaged in fraud and/or abuse will be inactivated (suspended) from participating in any publicly funded vaccination program. Reinstatement in the program will be contingent on the outcome of proceedings conducted by the Attorney General's (AG) office or the Office of the Inspector General (OIG). Final resolution may include, but is not limited to, the following interventions:

- Remedial education
- Recoupment of funds
- Reimbursement of vaccines
- Reinstatement without penalty
- Referral for criminal prosecution
- Civil resolutions

If the reported or suspected violator is one of the non-Medicaid providers who is enrolled in the program, the Immunization Division will evaluate the validity of the report. If there appears to be criminal intent, the Immunization Division will report all findings to the Office of the State Attorney General.

## Medicaid Referral

Suspected fraud or knowledge of fraud and abuse, including but not limited to the false or fraudulent filings of claims and the acceptance of or failure to return money allowed or paid on claims known to be fraudulent, must be reported to Indiana Medicaid or other designees.

1. Suspected PROVIDER fraud must be reported to the:
  - a. Office of Medicaid Policy and Planning
  - b. Indiana Medicaid Fraud Control Unit (MFCU – within the Attorney General's Office)
  - c. Surveillance and Utilization Review Unit (SUR) within the Office of Medicaid Policy and Planning
2. Suspected MEMBER fraud must be reported to the:
  - a. Office of Medicaid Policy and Planning
  - b. Surveillance Utilization Review Unit



- c. Bureau of Investigation (within the Division of Family Resources)
- d. Office of the Inspector General

## Responsibility

The Immunization Division will develop training modules to educate investigative and enforcement agencies regarding the unique features and structure of the program, including the program integration of publicly purchased vaccines for Medicaid members, Alaska Natives and American Indians, and underinsured and uninsured populations.

The Immunization Division will work in collaboration with internal counsel and will seek input from State investigative and enforcement agencies to develop effective protocols for reporting allegations of fraud; share information and collaborate with all involved parties to determine the best course of action to pursue for suspected cases of fraud; and to educate staff on how to properly obtain and document information when an allegation of fraud and/or abuse is reported and how to appropriately gather additional information.

Information about parties who are excluded by the Office of Inspector General is found at this website, <http://www.oig.hhs.gov/fraud/exclusions.html>, on the List of Excluded Individuals and Entities (LEIE). Information about parties who have been placed in non-payment status by all Executive departments (including OIG's) is found at the General Services Administration website: <http://gsa.gov>. The OIG's LEIE contains approximately 17,000 names; the GSA list contains approximately 30,000 names. The OIG also issues monthly reports on its website.

A member of the Immunization Division staff will review these lists each month and cancel the enrollment of any providers identified on the list. Any publicly funded vaccine in the provider's possession should be collected and the provider should be prohibited from receiving future shipments until the exclusion is lifted. If the exclusion is lifted, the individual or entity should be required to reapply for program participation. Any allegations of fraud and abuse in the private sector will require assistance from the State Department of Insurance to determine whether there have been criminal violations of applicable state law, including commercial health care fraud and abuse, and whether to pursue prosecution or coordinate with the Office of the State Attorney General in pursuant of prosecution.

## References

Immunization Fraud and Abuse Program Contacts:

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