

Policy & Procedure Title	Publicly Funded Vaccine Accountability	Issuing Date	07/17/2012
Policy & Procedure Number	14	Revision Date	04/01/2017
Policy & Procedure Approval Authority	<i>Dave Mesnick</i>		

Policy & Procedure Summary

The Vaccine Accountability Policy is intended to support the strong partnership and collaborative efforts of the Indiana State Department of Health (ISDH) Immunization Division, the Centers for Disease Control and Prevention (CDC) and all providers receiving publicly funded vaccines to promote best practices in vaccine management and helping to ensure an adequate vaccine supply by being good stewards. Together we share a common interest in ensuring that all eligible citizens in the State of Indiana have access to ACIP recommended vaccines and are protected against vaccine preventable diseases.

Policy Statement

The Indiana Immunization Division provides vaccine free of charge for providers enrolled in publicly funded vaccine programs. These vaccines are purchased through federal and state grants and require high levels of scrutiny for maintenance, administration and storage and handling of each and every dose. This means that providers must be held accountable for all doses ordered to ensure that all Indiana's eligible citizens have access to an adequate supply of vaccine.

All providers participating in Indiana's publicly funded vaccine programs must agree to the following:

Vaccine Eligibility Screening

The Immunization Division requires that all providers screen and document all children and adults (if applicable) as outlined in the Immunization Provider Agreement and the Indiana Publicly Funded Childhood and Adult Vaccine Eligibility Statements, to determine eligibility for administration of vaccines purchased with VFC, 317, and/or state funds. The screening process determines if a patient is eligible to receive a publicly funded vaccine in Indiana. Accurate and timely screening of all who present for immunizations is an essential accountability activity.

Vaccine Accountability

All immunization providers are required to account for all publicly funded vaccine. This can be done by documenting all vaccination and eligibility information in CHIRP.

All enrolled providers agree to periodic accountability audits for the evaluation of vaccine ordering patterns, inventory of vaccine, eligibility screening practices, CHIRP data entry, and vaccine management practices. Each month, a predetermined number of enrolled providers will be selected for an accountability audit. The provider(s) will be notified via email and may be required to complete additional documentation. All enrolled providers agree to fulfill all requirements as requested by a representative of the Immunization Division. Once the audit is completed, a member of the Immunization Division will notify the provider and explain the results.

Records Maintenance

All enrolled providers must maintain records of the authorized representative's responses for a minimum of 3 years.

Immunization Schedule

All enrolled providers must comply with the appropriate immunization schedule, dosage and contraindications established by the Advisory Committee on Immunization Practices (ACIP).

Vaccine Information Statements

All enrolled providers must provide the most current Vaccine Information Statements (VIS) to each patient each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA) which includes reporting significant events to the Vaccine Adverse Event Reporting System (VAERS).

Private Stock Vaccine

All enrolled providers must carry private stock vaccine to ensure that publicly funded vaccine is not administered to a fully insured client. The Indiana Immunization Division strictly enforces the Centers for Disease Control and Prevention's definition of fully insured as an individual with health insurance that covers the cost of vaccines, regardless of a high deductible or co-pay. If the fully insured population is less than 10 children, the provider may request an exemption to this provision. The request must contain the following:

1. One (1) year of data illustrating the number of VFC eligible children and fully insured children
2. A signed agreement with another healthcare provider who maintains private stock stating that they will administer all vaccines as recommended by the ACIP to your fully insured clients
3. A detailed referral plan to track all fully insured children who do not receive their vaccinations in your practice

Fees

All providers must agree to not impose a charge for the cost of the vaccine and to not charge a vaccine administration fee that exceeds that set forth by the Indiana Office of Medicaid Policy (OMP) or the Department of Health and Human Services (DHHS). Providers agree to not charge a vaccine administration fee directly to a Medicaid VFC-eligible child and will not deny administration of publicly funded vaccine due to inability of the patient to pay an administration fee.

Site Visits

All enrolled providers agree to periodic site visits for the evaluation of vaccine storage and handling, vaccine ordering patterns, inventory of vaccine, eligibility screening practices documentation, immunization record keeping and/or immunization coverage levels.

Vaccine Management

All enrolled providers agree to comply with the Indiana Immunization Division requirements for education, vaccine ordering, vaccine accountability, and vaccine management and also agree to operate within the program in a manner to avoid fraud or abuse.

Required Reporting

There are conditions under which all publicly funded vaccine providers are required to call the Immunization Division. Timely reporting allows staff to assist enrolled providers in protecting publicly funded vaccine.

The following requirements indicate when an Indiana provider should contact the Immunization Division:

1. The facility is moving or closing

Contact your field representative or the Immunization Division prior to the move. Facilities that are closing should make arrangements with the Immunization Division to transfer any publicly funded vaccine that will not be used. Providers who choose to disenroll from the program agree to return all unused publicly funded vaccine.

2. There is a power failure/storage unit failure

Power outages, equipment failure, natural disasters, or other emergencies can compromise vaccine. Notify the Immunization Division immediately for instructions on handling, transporting, or transferring of publicly funded vaccine, and then implement the Emergency Vaccine Management Plan for the facility.

3. Temperatures are out of range

Any temperatures recorded out of acceptable range should immediately be reported to the assigned Field Representative, or call the Immunization Division. Corrective action should be taken immediately and temperature fluctuations documented. Ensure that all questionable vaccines are transferred to a storage unit that can maintain the required temperatures in the interim until the viability of the vaccines can be determined.

4. There is human error resulting in improper vaccine handling

Cold chain failure can occur from improper vaccine handling due to human error such as storing vaccines in the door/drawer of the storage unit, or failure to store reconstituted vaccines properly prior to administration. CDC storage and handling guidelines should be followed to assure vaccines remain viable. If a vaccine is exposed to improper storage and handling, the assigned Field Representative should be contacted.

5. There is a change of primary providers

The Chief Medical Officer (CMO) of an enrolled facility is defined as the “official VFC program-registered provider” and/or “official publicly funded vaccine program-registered provider” who originally signed the Provider Enrollment Form. When there is a change in the primary practitioner, new enrollment forms must be completed and the new CMO must sign the Immunization Provider Agreement. When new providers/physicians, that are not the CMO, are added to the practice after initial enrollment, the Immunization Division should be contacted and the physicians must be added to the Provider Profile.

6. There is a change in the VFC Contact/Vaccine Coordinator or Back-up Coordinator

Staff changes are a common occurrence in provider offices. Any changes in this information could result in information not being received accurately and timely. Providers are required to notify the Immunization Division *immediately* when there are changes in key vaccine staff, including the need to terminate a VOMS access for a former employees within 24 hours.

7. There is a discrepancy with your publicly funded vaccine shipment

Always check the shipment against the packing slip and make sure the doses received matches the doses ordered. Also, count the diluent to make sure they match the number of vaccine doses. If discrepancies are found, please contact the Immunization Division **immediately** with any shipping problems. **Contact MUST be made within 2 hours of receiving the order.**

Vaccine Ordering

In order 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 the most recent provider profile. The provider profile is a provider-completed population estimate of the number and type of eligible children that the provider expects to see during a time period of one year.

Providers may submit vaccine orders once each month. Monthly vaccine orders require providers to account for each dose administered and submit a physical inventory in VOMS. Monthly orders are submitted using VOMS (Vaccine Ordering Management System).

The Immunization Division staff will review all submitted orders and supporting documentation to ensure that it has been completed accurately. The Immunization Division staff will contact providers to request changes, as needed, before processing the order.

Once this has been verified, staff will:

1. **Verify the provider has selected the appropriate order intention for each vaccine ordered.**
2. **Compare the current vaccine inventory and the monthly doses used last month column with the requested number of doses for each vaccine.**
3. **Assess whether or not the current provider inventory and doses requested are in alignment with the most recent provider profile population estimate.**
4. **If numbers are not equitable, contact the provider directly.**
5. **Determine if there are special circumstances (i.e. school clinic, influenza clinic, etc) that explain the number of doses requested.**
6. **If no special circumstance exists, reduce vaccine doses.**

Vaccine orders exceeding annual profiled estimated usage are flagged by the Vaccine Management staff and passed on to the Accountability Coordinator or the Director of Vaccine Operations for further review. If necessary, the Accountability Coordinator or Director of Vaccine Operations 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.

Annual Recertification

Every enrolled provider is required to submit an electronic Provider Recertification in VOMS on an annual basis. This is completed for each calendar year during the month of December for the current year. The annual Provider Recertification process affords the Immunization Division the opportunity to reinforce the program requirements and answer any questions providers might have regarding the requirements. Once providers submit the electronic Provider Recertification in VOMS, the following documents must be emailed to immunize@isdh.in.gov or faxed to 317-972-8964 in order for the recertification process to be complete:

- VFC Provider Agreement
- VFC Provider Profile Report

By signing the Provider Agreement form, providers agree to certain requirements as a condition of participation in the publicly funded vaccine program. Submission of these forms is a requirement for participation.

The Provider Profile should be completed based on actual data and should be updated on an annual basis to accurately reflect the total number of children seen at each provider site. This data is used to evaluate the provider's vaccine orders.

Vaccine Wastage and Reimbursement

The Immunization Division has a policy for management of incidents that result in the loss or wastage of any publicly funded vaccine. The policy applies to all providers who are actively enrolled in Indiana's Vaccines for Children (VFC) Program, or any other publicly funded vaccine program.

The Indiana Immunization Division defines vaccine loss or wastage as any incident or vaccine loss involving 5 or more doses that prevents a vaccine from being properly administered. **This includes all spoiled, expired, or wasted vaccines.** It includes:

Spoiled – vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold

- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure of storage unit

Expired – non-viable vaccine in its original container (vial or syringe) that was not administered prior to the expiration date. This includes vaccine that was ordered but unable to be administered or transferred prior to the expiration date.

Wasted – any vaccine that is unaccounted for which can be due to vaccine ordered but not delivered or loss of vaccine due to poor record keeping

- Vaccine drawn into the syringe but not administered (e.g., the parent refused vaccine after the dose was drawn up or a dose of Varivax could not be administered within 30 minutes of reconstitution).
- Vaccine in open vial but doses not administered
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial
- Lost or unaccounted for vaccines are also a form of wasted vaccine

Note: All vaccine losses due to expired or non-viable vaccines must be returned to McKesson for proper tax credits, with the exception of opened multi-dose vials or broken or compromised vials/syringes with needles attached. These doses should be appropriately documented as Wastage in VOMS and then discarded in a sharps container.

All providers collaborating with the Immunization Division to vaccinate the citizens of Indiana are required to document and report all incidents of vaccine loss and wastage. Providers must complete the Vaccine Return transaction in VOMS (when available), and submit it to the Immunization Division for review within 30 days of the vaccine loss. In the interim, providers are required to submit a paper form (State Form 54052) and fax to 317-972-8964. In order for inventory in CHIRP to reflect wastage, providers are also required to report vaccine wastage in CHIRP when submitting inventory. Failure to submit returns in a paper return form or in VOMS (when available), will result in vaccine ordering delays or denial. Providers experiencing a storage unit failure or those who fail to adequately monitor temperatures will be placed on a temporary ordering suspension.

Further guidance on vaccine returns and wastage procedures will be given once the Vaccine Return feature in VOMS becomes available.

In accordance with the 2017 Provider Agreement, all providers signed that he/she understands that “ISDH has the right to require dose for dose replacement of all publicly funded vaccine lost due to mismanagement”. The Indiana Immunization Division VFC Program will require providers to replace vaccine that has been wasted due to negligence or failing to correctly store or handle vaccine beginning July 1, 2012, excluding influenza vaccines.

The Immunization Division will review all instances of wasted or expired publicly funded vaccine on a case-by-case basis to determine whether restitution will be required or if extenuating circumstances prevail. This review will help determine whether negligence was involved. If negligence is found, the provider will be asked to make restitution in the form of a dose for dose replacement for any doses that have been lost due to the provider’s failure to properly receive, store or appropriately administer vaccines.

Fraud and Abuse

Public and private enrolled providers must ensure that they correctly utilize publicly funded vaccines. Providers must ensure that funded vaccines are given only to children, adolescents and adults who meet established eligibility requirements. The Immunization Division is required by the Centers for Disease Control and Prevention (CDC) to implement VFC fraud and abuse prevention policies and is required to investigate and report suspected cases to the Medicaid Surveillance Utilization Review Unit (SUR) and the Medicaid Fraud Unit (MFCU).

The following definitions, as defined in the Medicaid regulations at 42 § CFR 455.2, apply to all VFC Program Operations and all publicly funded vaccine programs through the Indiana Immunization Division:

- **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 him or some other person. It includes any act that constitutes fraud under applicable federal or state law.”
- **Abuse** is defined 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. It also includes recipient practices that result in unnecessary cost to the Medicaid program.”

Under state law, the Immunization Division is required to take specific action to address situations in which a provider engages in intentional deception or misrepresentation with the intent to achieve some unauthorized benefit for himself or some other person. This could include selling federal or state purchased vaccines or charging clients for the federal or state purchased vaccines over and above the admissible administration fee. The Medicaid Fraud Unit (MFCU) and the Medicaid Surveillance Utilization Review Unit (SUR) investigate these complaints and ensure that the services billed to the Medicaid program by the provider in question fall within the established parameters.

The Indiana Immunization Division will attempt to work collaboratively with providers to address issues of program noncompliance. The Immunization Division will consider previous compliance issues and potential extenuating circumstances in determining remedial action(s). 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. The goal is to work with providers in as positive a manner as possible to correct noncompliant behaviors and restore publicly funded vaccine program privileges. Intervention may include, but is not limited to:

- Enrollment training
- Requirement to enroll (if not already) and utilize CHIRP for ordering and managing vaccines
- More frequent reporting of requested data and/or information to the Immunization Division
- Change in ordering cycle
- Limited vaccine ordering

A provider determined to be engaged in fraud and/or abuse will be inactivated (suspended) from participating in any publicly funded vaccine 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

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

Please refer to the complete #20 Fraud and Abuse Policy for the complete policy and procedure.

References & Resources

Immunization Provider Profile (State Form 50201)

Immunization Provider Agreement (CDC Form)

Adult Immunization Provider Profile & Agreement (State Form 54625)

Vaccine Wastage and Reimbursement Policy and Procedure (Policy number 15)

Fraud and Abuse Policy and Procedure (Policy number 19)

Centers for Disease Control and Prevention. VFC Operations Guide, revised 2017. Module 5: Fraud and Abuse.

Copies of the Ops Guide are posted in the CHIRP Document Center

Revision History

07/17/2012, Created

11/19/2014, Revised

04/01/2017, Revised