Eric J. Holcomb
Governor
Lindsay M. Weaver, MD, FACEP
State Health Commissioner

Title: Publicly Funded Vaccine Accountability	**Policy #**: IDOH Immunization Division Policy 14
Effective dates: 01-Jan-25 to 31-Dec-25	**Approvals**: Dave McCormick Dave McCormick, Immunization Director January 1, 2025 Date

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 of 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

Accurate and timely screening of all patients who present for immunization is an essential accountability activity and must be conducted at the onset of each encounter. **The Immunization Division requires that all providers screen and document eligibility for all children and adults (if applicable) as outlined in the Immunization Provider Agreement prior to administration of publicly purchased vaccines.**

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 the Children and Hoosier Immunization Registry Program (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. When the provider is audited, they 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 of the audit. If you do not receive a face-to-face audit, you will be notified via email and may be required to complete other training to remain compliant.

Records Maintenance

All enrolled providers must maintain records of the authorized representative's responses for a minimum of three years, as well as all documents regarding the Vaccines for Children (VFC) Program.

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 and parent 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 patient. 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 ACIP to your fully insured clients.

3. A detailed referral plan to track all fully insured children who do not receive their vaccinations at 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 the amount 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. A provider 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 rates.

Vaccine Management

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

Required Reporting

All publicly funded vaccine providers are required to notify the Immunization Division of certain events. 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.
    a. Contact your Regional Quality Assurance Specialist or the Immunization Division prior to the move. Facilities that are closing must make arrangements with the Immunization Division to transfer any unused, publicly funded vaccine. 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.
    a. Power outages, equipment failure, natural disasters or other emergencies can compromise vaccine.

b. Notify the Regional Quality Assurance Specialist immediately when these situations occur. In an emergency, you do not need to wait for approval prior to moving vaccines. If after hours, notify the next business day. **Refer to your Emergency Transport and Emergency Vaccine Management Plan** for packing and transporting instructions and procedures on relocating the vaccine as designated for your facility.

3. Temperatures are out of range.
    a. Any temperatures recorded out of acceptable range should immediately be reported to the assigned Regional Quality Assurance Specialist, Vaccine Ordering and Accountability Specialist, or the Immunization Division. **Corrective action should be taken immediately, using the checklist in the Vaccine Management Plan:**
        i. Determine the duration of the excursion along with the temperature range.
        ii. Mark vaccines as "Do NOT Use" until a determination is made regarding viability.
        iii. Contact the manufacturers for guidance. You must obtain a case number.
        iv. Document the reference number given by the manufacturer.
        v. Contact field staff with information and further plan of action.
        vi. Do not use websites for guidance on viability of vaccines.
4. There is human error resulting in improper vaccine handling.
    a. Cold chain failure can occur due to improper vaccine handling resulting from 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 regional quality assurance specialist should be contacted.
5. There is a change in the primary providers.
    a. 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 Agreement. 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.
6. There is a change in the VFC contact/primary vaccine coordinator or back-up coordinator.
    a. 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 their regional quality assurance specialist or

ordering and accountability specialist **immediately** when there are changes in key CMO, the primary vaccine coordinator, and/or the back-up coordinator, including the need to terminate the VOMS access for former employees within 24 hours.

7. There is a discrepancy with your publicly funded vaccine shipment.
    a. Always check the shipment against the packing slip and make sure the doses received match the doses ordered. Also, count the diluent to make sure the amount matches the number of vaccine doses. If discrepancies are found, please contact the Immunization Division **immediately** with any shipping problems. **Contact the Immunization Division at 800-701-0704 or immunize@health.in.gov within two (2) hours of receiving the order.**

Vaccine Ordering

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 whom the provider expects to see during a period of one (1) 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 the Vaccine Ordering Management System (VOMS). Monthly orders are submitted using VOMS.
The Regional Vaccine Ordering and Accountability Specialist will review all submitted orders and supporting documentation to ensure that it has been completed accurately. Providers will be contacted if additional information is needed prior to approving orders.
Once this information 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 doses used last month with the requested number of doses for each vaccine.
3. Assess whether the current provider inventory and doses requested are in alignment with the most recent provider profile population estimate.
    a. If numbers are not equitable, the provider will be contacted directly.
4. Determine if there are special circumstances (i.e. school clinic, influenza clinic, etc) that explain the number of doses requested.
    a. If no special circumstance exists, reduce vaccine doses as needed.

Vaccine orders exceeding annual profile 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 annually. This is completed each calendar year during the month of December for the coming year. The annual Provider Recertification process affords the quality assurance specialists 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@health.in.gov or faxed to 317-972-8964 to complete the recertification process:

- VFC Provider Agreement.
- VFC Provider Profile Report.
- Pictures of the inside and outside of your storage units.
- *IDOH may require additional information during recertification.*

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's 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 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 any number of doses that prevents a vaccine from being properly administered. This includes all spoiled, expired or wasted vaccines:

- **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 vaccine 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 was not administered or transferred prior to the expiration date.
- **Wasted** – any vaccine that is unaccounted for, which can be due to vaccine shipments that were never delivered or loss of vaccine due to poor record keeping. Some examples include:
    - 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, except for 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 within 30 days of the vaccine loss. Failure to submit returns in VOMS 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 interruption.

In accordance with the 2017 Provider Agreement, all providers attest that "IDOH has the right to require **dose for dose replacement** of all publicly funded vaccine lost due to mismanagement".

The Indiana Immunization Division VFC Program may require providers to replace vaccine that has been wasted due to negligence or failing to correctly store or handle vaccine, excluding influenza and COVID-19 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 is 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

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 themselves or some other person. This could include selling federal or state purchased vaccines or charging clients more than the admissible administration fee for federal or state purchased vaccines. 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.

A provider determined to be engaged in fraud and/or abuse will be inactivated (interrupted) 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).

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

References

Vaccine Wastage and Reimbursement Policy and Procedure (15).
Fraud and Abuse Policy and Procedure (20).

Immunization Provider Profile and Provider Agreement: http://www.chirp.in.gov.