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Title: Publicly Funded Vaccine: Loss, Wastage and Reimbursement	**Policy #**: IDOH Immunizations Division Policy 16
Effective dates: 01-Aug-25 to 31-Dec-26	**Approvals**: Dave McCormick Dave McCormick, Immunization Director January 22, 2026 Date

Policy Statement

The Indiana Immunization Division, the Centers for Disease Control and Prevention (CDC), and Indiana providers share a common interest in ensuring that all eligible citizens receive immunizations. Although enrolled providers receive vaccine free of charge through the Immunization Division, these vaccines are purchased through federal and state grants. This means that providers must be held accountable for all doses ordered to ensure that all VFC (Vaccines for Children) and state eligible children have access to an adequate supply of vaccine, as do eligible adults. It is important that all providers reimburse the Immunization Division for returned or wasted doses so that the state can maintain a sufficient supply of vaccines and funding to continue to ensure the health of Hoosiers.

Non-viable vaccine in its original container (vial or syringe) needs to be returned for excise tax credit following the Vaccine Returns Policy (Policy 17).

Procedures and Responsibilities

Vaccine Loss and Wastage

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 any Indiana publicly funded vaccine program. This policy supersedes all policies previously issued by the Indiana Immunization Division addressing wasted vaccine.

If a provider's office has vaccine wastage of five (5) percent or greater, the Immunization Division can ask for restitution of the cost of the vaccine wastage.
The Indiana Immunization Division defines vaccine loss or wastage as any incident or vaccine loss that prevents a vaccine from being properly administered. This includes ALL spoiled, expired, or wasted vaccines. All doses must be documented in the Vaccine Order Management System (VOMS) under the correct reason code and description. 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 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 unable to be 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 doses are required to be reported in VOMS. Every effort should be made to reconcile unaccounted for doses of VFC vaccine. In those circumstances where you are unable to reconcile your current vaccine inventory with what is reflected in VOMS, doses that cannot be accounted for are considered lost doses. These lost and unaccounted doses are a form of wasted vaccine and will count towards the total vaccine loss and wastage amounts.

All providers collaborating with the Immunization Division to vaccinate the citizens of Indiana are responsible for maintaining vaccine quality from the time a shipment arrives until the moment the vaccine is administered. Providers are also required to document and report all incidents of vaccine loss or wastage. All providers experiencing vaccine loss or wastage due to negligent vaccine management are accountable for all the doses and could be required to replace vaccine through private purchase.

The Indiana Immunization Division may withhold vaccine orders until improved accountability is demonstrated by the provider office. If accountability for expired, spoiled and/or wasted public doses does not improve, dose for dose replacement of lost doses with private stock vaccine will be required. All doses must be recorded in VOMS and reported to CDC through the Returns/Wastage reporting process.

Vaccine loss or wastage is both costly and preventable, but the Immunization Division understands that some losses (e.g. due to equipment failure and power outages) are unavoidable. The action taken by the Immunization Division will depend on the category of the vaccine loss. For this policy, loss of vaccine is divided into three categories: Category 1 – Non-preventable Loss, Category 2 – Non-compliance, and Category 3 – Negligence.

Category 1 – Non-preventable Loss

Vaccine loss or wastage due to non-preventable circumstances is out of the providers' control and generally does not require financial restitution. The provider is not negligent in his/her handling of the publicly funded doses if the incident is truly non-preventable. This list is not exhaustive, but does include the following:

1. Area power outages due to severe weather or other unavoidable and unanticipated causes in which the provider acts according to the site's emergency response plan.
2. Refrigerator/freezer failure that is unavoidable or unanticipated when staff is not in the office.
3. Transport company error (i.e. FedEx UPS, etc.) in which a package is not delivered in a timely manner or is otherwise damaged or stored improperly during transit.
    a. Failure to notify the Immunization Division of any errors, shortages, temperature issues or damage to vaccine shipment from distributor within two (2) hours of vaccine receipt does deem this as negligence.
    b. A provider's failure to notify the Immunization Division of a change in office hours or address is not considered a transport company error.
4. Single dose spoilage not related to improper storage, or vaccine that could not be administered once removed from storage (e.g., the parent refused vaccine after the dose was drawn up, or Varivax could not be administered within 30 minutes of reconstitution).
5. Extraordinary situations not listed above which are deemed to be beyond the provider's control by the Immunization Division. When reporting wastage of any kind, providers should provide documentation that demonstrates staff's use of the site's emergency response plan.

Category 2 – Non-compliance

Vaccine loss due to non-compliance is defined as:

1. Publicly funded vaccine not accounted for in the online ordering system, VOMS. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Examples include the following:
    a. Failure to document administered doses.
    b. Failure to report inventory.
    c. Inaccurate reporting of inventory.
    d. Failure to report expired/wasted vaccine within 30 days.
2. Publicly funded vaccine knowingly administered to children and/or adults who do not meet the Immunization Division eligibility criteria, including the following:
    a. Administration of VFC or state funded vaccine to patients who are older than 18 years of age (only approved adult providers are permitted to administer public vaccine to individuals 19 years of age or older).
    b. Administration of publicly funded vaccine to every patient in the practice whether eligible or not (i.e. a provider discontinues purchasing private stocks of vaccine for administration to patients whose insurance covers immunizations.)
    c. Administration of publicly funded vaccine in lieu of privately purchased vaccine because the reimbursement rate of the insurance company is low.
    d. Administration of publicly funded vaccine to a child and/or adult who is fully insured (has private insurance that covers vaccinations), including the administration of publicly funded vaccine to a child who has not met their deductible to save the parent the cost of the deductible (a child is considered fully insured even when the deductible has not been met).
    e. Administration of publicly funded vaccine to a child even though the insurance company provides a maximum amount of reimbursement for immunizations for the year. Upon reaching the maximum amount, the child is then eligible for VFC vaccines in a Rural Health Clinic (RHC), Federally Qualified Health Center (FQHC), or local health department with a Delegation of Authority (DOA) and is then eligible for state-funded vaccine in any other Indiana VFC providers' office.
3. Accepting reimbursement, above and beyond the allowable administration fee, from patients and/or insurance companies for publicly funded vaccines as evidenced by:
    a. Administering publicly funded vaccine and subsequently billing the insurance for the cost of the vaccine.
    b. Charging the patient for the cost of the vaccine.
    c. Directly charging a Medicaid-eligible patient ANY fee.

Category 3 – Negligence

Negligence is defined as loss of vaccine on the part of the provider/clinic staff. The following situations qualify as negligence:

1. Vaccine is stored improperly (i.e. refrigerating vaccine that should have been frozen, or freezing vaccine that should have been refrigerated).
2. Use of dorm style refrigerators or use of improper refrigeration unit to store vaccine.
3. Vaccine is left out of refrigerator or freezer and/or vaccine is not stored promptly upon arrival.
4. Refrigerator or freezer is unplugged, or electrical service is interrupted (circuit breaker).
5. Door of refrigerator or freezer is left ajar resulting in unit temperature outside the acceptable range.
    a. *Note: Whenever the viability of ANY vaccine is in question due to improper or questionable storage and handling, all providers must first move the vaccine in question to a unit that can maintain temperatures within the required range, quarantine the vaccine, mark the vaccine "Do NOT Use," and contact the vaccine manufacturers to determine each vaccine's viability. Some vaccines may be simply short-dated and will not require discarding.*
6. Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded (e.g., failure to respond to temperature alarms).
    a. *Note: Temperatures recorded on temperature logs will be considered official in making vaccine viability decisions. Also, a thermometer's margin of error will not be considered when temperatures are recorded below 36°F or 2°C for refrigerators and at or above 5°F or -15°C for freezers.*
7. Absence of correct/certified data loggers and/or incorrectly placing data loggers in each vaccine refrigerator and freezer compartment.
8. Failure to properly read and record refrigerator(s) and freezer(s) temperatures, and/or failure to take immediate corrective actions when temperatures are determined to be out of required range.
9. Pre-drawing or pre-reconstituting vaccine, then failing to administer it in accordance with the vaccine manufacturer/CDC recommendations.
10. Failing to request prior approval from the Immunization Division for transporting vaccines and/or transferring vaccines inappropriately, thereby potentially failing to maintain the cold chain.
11. Failure to notify the Immunization Division of any errors, shortages, temperature issues or damage to vaccine shipment from distributor within two (2) hours of vaccine receipt.
12. Failure to notify the Immunization Division when provider office hours change or the provider moves, resulting in vaccines being undeliverable and consequently becoming non-viable.
13. Situations in which healthcare providers must re-vaccinate due to failure to keep vaccine viable (temperatures out of acceptable range) or an administration error (incorrect vaccine, wrong age, improper administration).

   a. Note: Provider may be responsible for re-vaccinating the patient with privately purchased vaccine.
14. Ordering habits resulting in excess inventory or overstock that leads to expiration of vaccines (i.e., maintaining an inventory of more than 90-days inventory).
15. Failure to follow an emergency response plan.
16. Discarding ANY vaccine prior the manufacturer's stated expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used).
   a. *Note: Properly reporting short-dated doses 90 days prior to expiration does not guarantee transfer out. Also, late reporting of short-dated vaccine (less than 60 days before expiration) can be considered vaccine wastage.*
17. Failure to rotate vaccine stock and administering longer dated vaccine before short-dated doses.
18. Poor accountability processes when vaccines cannot be located or accounted for or are missing from provider inventory. The immunization program determines the provider did not make every effort to follow required accountability and/or storage and handling procedures resulting in lost or missing vaccine, or the provider is repeatedly unable to reconcile the clinic's vaccine inventory with vaccine use.

The Indiana Immunization Division may withhold vaccine orders until improved accountability is demonstrated by the provider office. If accountability for expired, spoiled and/or wasted public doses does not improve, dose for dose replacement of lost doses with private stock vaccine will be required. All doses must be recorded in VOMS and reported to CDC through the Returns/Wastage reporting process. Depending on the severity of the issue, the provider's ordering privileges may be withdrawn until there is an investigation or mandated educational visit by the Immunization Division, and the provider is cleared to receive vaccine again.
Vaccine Loss and Wastage Reporting

Vaccine Loss and Wastage Reporting

All providers collaborating with the Immunization Division to vaccinate Indiana citizens are required to document and report ALL incidents of vaccine loss and wastage. Providers must complete a Vaccine Return transaction in the Vaccine Ordering Management System (VOMS) within 30 days of the vaccine loss.

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 in VOMS as Wastage and then discarded in a sharps container. See Policy 17, Provider Vaccine Returns, for special guidance on completing vaccine returns.

Providers are no longer able to submit vaccine returns in the Vaccine Tracking System (VTrckS) or by using a paper return form. Completing return submissions through VOMS is the only acceptable method.

Vaccine Loss and Wastage Reimbursement

In accordance with the 2024 Provider Agreement, all providers attest that the "IDOH has the right to require dose for dose replacement of all publicly funded vaccine lost due to mismanagement." The Indiana Immunization Division may require providers to replace vaccine that has been wasted due to negligence or failure to correctly store or handle vaccine beginning July 1, 2012, excluding influenza vaccines.

The Immunization Division will review all instances of vaccine loss or wastage of publicly funded vaccine on a case-by-case basis to determine whether restitution will be required or if extenuating circumstances occurred. 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. Providers must send receipts for the replacement doses they have purchased to the Immunization Division within 90 days of the event's occurrence.

The Immunization Division will assess the provider's annual ordering distribution totals for all publicly funded vaccine and will require providers to make restitution for any doses that equal an amount that exceeds five (5) percent of the total distribution for the previous calendar year.

The following guidelines are followed if a provider is asked to reimburse the Immunization Division for wasted/expired doses of vaccine:

1. If negligence is found and restitution is necessary, the Immunization Division will send the provider a letter and invoice for any vaccine loss or wastage.
2. All providers who have been required to provide restitution must make arrangements with the appropriate vaccine manufacturers to privately purchase replacement doses of vaccine, as instructed by the Immunization Division. All replacement doses should have at least a one-year (1-year) expiration date.
3. Once the replacement doses have been purchased, the provider must submit a copy of the invoice, showing the vaccines purchased, lot number(s), and the number of doses purchased to the Indiana Immunization Division within 90 days of the event occurrence. Proof of payment will also be required.
4. The provider must show that all replacement doses have been transferred appropriately into the provider's publicly funded inventory and that the privately purchased

replacement vaccine is used to vaccinate **eligible patients only**. These doses should be entered into VOMS. The Immunization Division may ask to see records documenting administration of these replacement doses to eligible children.

Depending on the severity of the issue, the provider's ordering privileges may be withdrawn until there is an investigation or mandated educational visit by the Immunization Division, and the provider is cleared to receive vaccine again.

Appeals Policy

Each provider is entitled to an administrative hearing on this matter. A written request must be filed with Indiana's Immunization Division within ten (10) business days of receipt of this notice.

All requests for an administrative hearing must meet the following criteria:

1. The request must be addressed to:
   Director of the Immunization Division
   Indiana Department of Health
   2 N. Meridian Street, 6th Floor
   Indianapolis, Indiana 46204
2. The request must outline the reason that the vaccine was wasted.
3. The request must contain a corrective action plan that will ensure that future wastage will not occur.
4. The request must be signed by the medical officer registered with the Indiana Immunization Division.

Procedure Details

Step 1: At the end of each calendar year, the Immunization Division calculates each provider's annual ordering distribution totals for all publicly funded vaccine based on all orders processed in VTrckS. The totals will include the prior calendar year for a period of 12 months.

Step 2: On a monthly basis, all Vaccine Return transactions will be reviewed and approved in VOMS by provider PIN # and total vaccine loss.

Step 3: On an annual basis, the accountability coordinator or director of vaccine operations will review total vaccine wastage, excluding COVID-19 and influenza vaccine, by provider PIN # and then compare this with the distribution totals to determine the wastage rate. This rate, with the corresponding amount owed (if over the wastage threshold for that year), will be communicated via a letter from the division director to each provider.

All providers will be assessed annually on their total wastage for the year:

- If the provider exceeds the maximum annual total percentage of wastage, five (5) percent, the Indiana Immunization Division will:
  - Send a letter informing them of the excessive loss or wastage.
  - Enforce a dose for dose reimbursement. All COVID-19 vaccine wastage and expired Influenza vaccines are not included in the wastage report.
- If a provider's wastage reaches between 1.25 percent and five (5) percent of the total distribution for the previous year, a warning letter will be sent to inform the provider that wastage levels last year almost exceed the annual allowance. This will provide an opportunity for the provider to consult with the Immunization Division for assistance in managing vaccine inventory and ordering.

Any provider exceeding the five (5) percent maximum, at any point throughout the year, will continue to have to reimburse, dose for dose, any vaccine loss or wastage in the remainder of that same calendar year.

For Calendar Year - 1/1/XXXX -12/31/XXXX	
Provider PIN #	Total $$
MXXLXX	$83,030.9000

The table above depicts a medical center's total annual distribution of 83,030.90.

Pin #	Provider Name	Vaccine Returned	Reason	# of Doses	$/per Dose	Loss
MXXLXX	XYZ Medical Center	DTaP - Infanrix	Expired	26	$14.85	$386.10
MXXLXX	XYZ Medical Center	IPV - IPOL	Expired	10	$11.97	$119.70
MXXLXX	XYZ Medical Center	MCV4 - Menactra	Expired	135	$82.12	$11,086.20
MXXLXX	XYZ Medical Center	PCV13 - Prevnar	Expired	40	$97.21	$3,888.40
Total						$15,480.40

The table above depicts a medical center's annual vaccine wastage. Its total wastage loss amounted to $15,480.40, and its wastage rate reached 19 percent. To waste less than the five (5) percent wastage threshold, the medical center would have to have losses amounting to less than $4,151.55.

References

Centers for Disease Control and Prevention. Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2021. http://www.cdc.gov/vaccines/pubs/pinkbook/index.htm.

https://www.in.gov/health/immunization/vaccines-for-children/policies-and-procedures/