Policy & Procedure Title	Publicly Funded Vaccine: Loss, Wastage and Reimbursement	**Issuing Date**	7/17/2012
Policy & Procedure Number	16	**Revision Date**	01/01/2023
Policy & Procedure Approval Authority	Dave McCormick		

Policy Statement

Indiana Immunization Division, the Centers for Disease Control and Prevention (CDC), and all Indiana's 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 Indiana's VFC and state-eligible children have access to an adequate supply of vaccine, as well as Indiana's eligible adults. It is important that all providers reimburse for returned or wasted doses so that Indiana can have a sufficient supply of vaccines and funding to continue to ensure the health of the citizens of Indiana.

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

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 5% 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, which prevents a vaccine from being properly administered. **This includes ALL spoiled, expired, or wasted vaccines.** All doses must be documented in 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 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/syringe (e.g. due to a drop causing damage to integrity or sterility), broken vial/syringe, or lost vial/syringe
- 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 those 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

Category 3 – Negligence

Category 1 – Non-preventable Loss

Vaccine loss or wastage due to non-preventable circumstances is considered to be out of the providers' control and generally do 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 – unavoidable or unanticipated when staff is not in the office
3. Transport company error (i.e. FedEx UPS, etc) when a package is not delivered in a timely manner or is otherwise damaged or stored improperly during transit

Note: Failure to notify the Immunization Division within two hours of vaccine receipt of any errors, shortages, temperature issues or damage to vaccine shipment from distributor does deem this as negligence. Also, failure of the provider to notify the Immunization Division of a change in office hours or address will not be 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 by the Immunization Division to be beyond the provider's control (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 doses administered

    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 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 in order to save the parent the cost of the deductible (a child is considered fully insured even when the deductible has not been met) or

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 FQHC/RHC or local health department with a Delegation of Authority (DOA) 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 in this category:

1. Vaccine stored improperly (i.e. refrigerating vaccine that should have been frozen, or freezing vaccine that should have been refrigerated)
2. Using dorm style refrigerators or using improper refrigeration unit to store vaccine
3. Vaccine left out of refrigerator or freezer and/or failure to store vaccine promptly upon arrival
4. Refrigerator or freezer unplugged or electrical service interrupted (circuit breaker)
5. Door of refrigerator or freezer left ajar resulting in unit temperature outside the acceptable range *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 and mark "do not use" and then 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)
   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. Not having correct/certified data loggers and/or placing them incorrectly 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-constituting vaccine, then not administering in accordance with the vaccine manufacturers/CDC recommendations

10. Not requesting prior approval from the Immunization Division for transporting vaccines and/or transferring vaccines inappropriately, thereby potentially not maintaining the cold chain

11. Failure to notify the Immunization Division within two hours of vaccine receipt of any errors, shortages, temperature issues or damage to vaccine shipment from distributor

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)
    Note: Provider may be responsible to re-vaccinate 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' stated expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used)
    Note: Properly reporting short-dated doses within 90 days prior to expiration does not guarantee transfer out. Also, late reporting of short-dated vaccine (less than 60 days until 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 those 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

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 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, with the exception of 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 VTrckS or by using a paper return form. Return submissions through VOMS is the only acceptable method.

Vaccine Loss and Wastage Reimbursement

In accordance with the 2023 Provider Agreement, all providers signed that he/she understands that "IDOH has the right to require dose for dose replacement of all publicly funded vaccine lost due to mismanagement". The Indiana Immunization Division 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 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 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. Providers must send receipts for the replacement doses they have purchased to the Immunization Division within 90 days of the event 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 is over 5% 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 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 **only eligible patients.** 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 State 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 will calculate each provider's annual ordering distribution totals for all publicly funded vaccine, as based on all orders processed in VTrcks. The totals will include the prior calendar year for a period of 12 months.

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

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

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

Step 3) On an annual basis, the Accountability Coordinator or Director of Vaccine Operations will review total vaccine wastage, excluding influenza vaccine, by provider PIN # and then compare this with the total 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.

2022 Total Distribution = $83,030.90

2022 5% Threshold = $4,151.55

2022 Vaccine Wastage annually = $15,480.40

2022 Total Percentage Vaccine Wastage = 19%

All providers will be assessed on an annual basis as to whether or not he/she has had wastage that reached the total annual wastage allowance of 5%. If the provider exceeds the total maximum annual percentage of wastage, a letter will be sent to inform them of the excessive loss or wastage. If a provider's wastage reaches between 1.25% and 5% 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. If this wastage amount exceeds 5% of the total distribution for the previous year, the Indiana Immunization Division will enforce a dose for dose reimbursement. All Covid -19 vaccine wastage and expired Influenza vaccines are not included in the wastage report

Any provider exceeding the 5%, 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.

References & Resources

Centers for Disease Control and Prevention. Vaccines for Children Operations Guide. Revised January 2017 2016

Centers for Disease Control and Prevention. (13th Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Revision History

07/17/2012, Created
03/01/2014, Revised
11/19/2014, Revised
04/01/2017, Revised
01/01/2018, Revised
02/21/2020,Revised
03/07/2022, Revised
0101/2023, Revised