



North Dakota Immunization Program 2010 Vaccine Loss Policy

Current state and federal vaccine contracts stipulate that spoiled or expired vaccines cannot be returned to the manufacturer for credit or replacement. Such vaccine losses are absorbed directly by our program's budget. Since the Prevention Partnership Program is so important to the health and well-being of the people of North Dakota, it is essential that all of us work together to ensure that every dose of vaccine is used to provide protection against preventable diseases. As a provider responsible for state-supplied vaccines, you and your staff should continually monitor vaccine storage and handling practices. Please notify the North Dakota Immunization Program if you or your staff would like to receive an educational visit regarding vaccine storage and handling.

Prevention Partnership Providers are required to report all wasted, expired, spoiled or lost vaccine to the North Dakota Immunization Program. This document serves as the North Dakota Department of Health (NDDoH) Immunization Program's policy for management of incidents that result in loss of state-supplied vaccine. Reimbursement for state-supplied vaccine will be requested if wastage was due to the provider's failure to properly store, handle or rotate vaccine inventory.

Definitions

Wasted: Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the NDDoH before determining that the vaccine is non-viable.

Lost: Commercial carrier (FedEx or UPS) or United State Postal Service (USPS) does not deliver the vaccine or does not deliver in a timely manner.

Situations That Require Financial Restitution

Expired Vaccine

- Failure to rotate or attempt to transfer vaccine that results in expired vaccine amounting to **greater than doses of any one vaccine in a 30-day period.**

Spoiled Vaccine

- Pre-drawn vaccine that is not used. Please note the North Dakota Immunization Program strongly discourages the practice of pre-drawing vaccine.
- Handling and storage mishaps by provider staff.
- Vaccine that is left out of the refrigerator or freezer and becomes non-viable. Call the vaccine manufacturer first to help you determine the stability/viability of vaccine left out of the refrigerator/freezer.
- Freezing vaccine that is supposed to be refrigerated.

- Refrigerating vaccine that is supposed to be frozen.
- Refrigerator/freezer left unplugged.
- Refrigerator/freezer door left open or ajar.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the North Dakota Immunization Program within 30 days from the date you became aware of the situation.
- Non-weather related power outages in which the provider fails to take precautions.
- Vaccine that is considered spoiled due to the provider not checking and/or reviewing refrigerator and freezer temperatures twice daily.
- Vaccine that is considered spoiled because a provider did not take immediate or appropriate action on out-of-range temperatures.
- Replacement vaccine: health care providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of acceptable range) or improper administration will be responsible for the current CDC cost of the vaccine needed to re-vaccinate.

Wasted Vaccine

- State-provided vaccine given to children or adults who are not eligible to receive it based on the most recent NDDoH Vaccine Coverage Table.
- Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials).

Situations That Do Not Require Financial Restitution

Below is a list of situations that are NOT considered "provider negligence." This list is not exhaustive. In these situations, the provider is deemed not to be at fault. You may be required to produce a letter from the alarm/alert company or the power company.

- A commercial carrier or USPS does not deliver to the provider in a timely manner. Before making the determination that the vaccine is non-viable, first call the vaccine manufacturer.
- A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider.
- A provider moves vaccine to a nearby hospital due to anticipated inclement weather, the hospital experiences a power failure, and the North Dakota Immunization Program later deems the vaccine not viable.
- Power was interrupted or discontinued due to a storm, and after consultation with the vaccine manufacturer and the North Dakota Immunization Program, it is determined that vaccine is not viable.
- A vial that is accidentally dropped or broken by a provider.
- Vaccine that is drawn at the time of the visit but not administered due to parental refusal or a change in physician orders.
- Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).
- Extraordinary situations not listed above which are deemed by the North Dakota Immunization Program to be beyond the provider's control.

- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the North Dakota Immunization Program within 30 days from the date you became aware of the situation.

Procedures and Policy for Returning Nonviable Vaccine to McKesson Specialty

- Call the vaccine manufacturer and the North Dakota Immunization Program as soon as you suspect vaccine may not be viable.
- Failure to report wasted vaccine to the NDDoH may result in your facility no longer being able to receive state-supplied vaccine.
- Return all **unopened** vials and manufacturer's pre-filled syringes of spoiled or expired vaccine with a completed Non-Viable Vaccine Return and Wastage Form to McKesson Specialty regardless of any financial restitution status applied to the vaccine. Vaccine provided by the NDDoH should never be discarded. The only exception is open vials or syringes, including multi-dose vials, from which some doses have already been withdrawn. These can no longer be sent back to McKesson. A wastage form must still be filled out and sent to the NDDoH, and the open vials and syringes should then be discarded per your facility's policy.
- Procedure for returning unopened non-viable vaccine to McKesson:
 - Complete a Non-viable Vaccine Return and Wastage Form before returning non-viable vaccine.
 - Make two copies of the form, one for your records and one for McKesson.
 - Prior to shipping non-viable vaccine, fax the form to the NDDoH Immunization Program at 701.328.2499.
 - **Providers may NOT contact McKesson to coordinate pickup of wasted/expired vaccine.**
 - McKesson is no longer including pre-printed return labels with its shipments. You must contact the NDDoH when you need to return nonviable vaccine.
 - McKesson will send a return label via USPS. When you receive the return label, contact NDDoH.
 - For providers who do not have a regular UPS pickup, McKesson will contact UPS to arrange the pickup.
 - If the provider has a regularly scheduled UPS pickup at their facility, the provider may hand the labeled box of wasted/expired vaccine to the UPS driver.
 - Use a container from a previous vaccine shipment to send non-viable vaccine and a copy of the completed return form to McKesson.
 - **DO NOT ship viable vaccine to McKesson.**
 - DO NOT ship viable or non-viable vaccine to the NDDoH.

Procedures for Financial Restitution

This updated policy applies to any vaccine received as wasted by the North Dakota Immunization Program on or after August 1, 2006.

- The provider will receive an invoice from the NDDoH for vaccine reported as wasted to the North Dakota Immunization Program.

- The invoice will reflect the current CDC cost of the vaccine, minus the excise tax credit.
- Reimbursement for the cost of the vaccine is **due within 30 days** of receiving the invoice.
- If reimbursement is not received within 30 days, the North Dakota Immunization Program will not supply vaccine to the negligent provider until payment is received.
- IHS facilities will be required to privately purchase vaccine to replace the wasted state-supplied vaccine. A copy of the purchase order or invoice must be submitted to the NDDoH. The NDDoH must be notified immediately when the purchased vaccine arrives so that the lot numbers can be entered into the NDIIS as state-supplied vaccine.

Provider-to-Provider Transfer of Vaccines

Providers who have excess vaccine on hand that will not be used before expiration are encouraged to transfer this vaccine to other providers to utilize, and thus avoid being charged for wasted vaccine. Providers should begin this process within 3-6 months of the vaccine expiring. **It is the provider's responsibility to find another provider willing to accept the vaccine, and also to properly pack and ship the vaccine to that provider following standard cold-chain procedures.** While the NDDoH is willing to assist when possible, it is very difficult to match odd numbers of vaccines with other provider orders and to try to arrange for shipments between providers. Providers can find contact information for other VFC providers in their area in the NDIIS under the "Provider Search" tab (the list can be sorted by city, provider name, etc., by clicking on the headings). Providers must also transfer the doses in NDIIS or send a transfer form to the NDDoH so that the transfer can be made.

If you have any questions concerning this policy, please call the North Dakota Immunization Program at 701.328.3386 or toll-free at 800.472.2180.