

## Vaccine Restitution Policy

**Effective November 1, 2011, the Iowa Immunization Program implemented the following vaccine restitution policy as mandated by the Centers for Disease Control and Prevention, Vaccines for Children Program requirements.**

The purpose of this policy is to establish requirements for VFC Program providers to replace, at the provider expense, VFC vaccine that is unaccounted and wasted (expired, spoiled or improperly stored) due to negligence on behalf of the provider. The intent is to apply this policy to address instances of extreme/on-going negligence resulting in the wastage of VFC Program vaccine.

### RESTITUTION PROCESS

1. The Iowa VFC Program will review incidents of vaccine wastage to determine if restitution will be required. Restitution will be required for negligent provider activities or recurring issues that result in vaccine wastage.

**Situations that may require provider restitution include, but are not limited to:**

- Storage and handling errors not consistent with the agency/practice's Emergency Vaccine Storage and Handling Plan resulting in vaccine wastage.
- Provider failing to act according to the agency/practice's Emergency Vaccine Storage and Handling Plan.
- Situations resulting in re-vaccination due to either improper vaccine administration or improper vaccine storage and handling resulting in the administration of non-viable vaccine. The provider may be responsible for purchasing private vaccine to re-vaccinate VFC eligible children.
- Excessive vaccine ordering leading to overstock resulting in vaccine wastage.
- Ordering combination vaccines which results in wastage of single antigen vaccines.

**Situations that may not require restitution include, but are not limited to:**

- A package not delivered to the provider in a timely manner or is otherwise damaged or exposed to improper temperatures during transit.
- A provider experiences a refrigerator/freezer malfunction, and the contracted alarm company does not notify the provider. The clinic should document the event and include a plan to prevent this from occurring in the future. (This situation is reviewed on a case-by-case basis by the Iowa VFC Program. If the necessary steps to assure notification of equipment malfunction was not taken or negligence by the provider resulting in wastage of VFC vaccine is found, restitution would be implemented.)
- Power is lost due to inclement weather or natural disaster.
- A vial is accidentally dropped or broken by a provider.
- Given the uncertainty with COVID-19 vaccine demand and potential for packaging size concerns, the Iowa VFC Program may not penalize VFC providers for COVID-19 vaccine wastage due to expiration.
- Extraordinary situations, not listed above, deemed by the Iowa VFC Program to be beyond the provider's control.

2. When restitution is required, the provider will receive notification from the Iowa VFC Program detailing the number of vaccine doses requiring restitution.
  - The invoice will detail the number of doses by vaccine manufacturer, type, and presentation (vials, syringes).
3. The replenished vaccine shall consist of the same manufacturer, type, and presentation of vaccines identified for dose-for-dose restitution by the Iowa VFC Program.
  - Substitutions for vaccine manufacturer and presentation must be agreed upon by clinic staff and Iowa VFC Program prior to purchasing the vaccine.
4. The provider will purchase vaccine doses equivalent to the notification received from the Iowa VFC Program. The vaccine shall be replaced within 30 days from the date of the notification unless mutually agreed upon by clinic staff and VFC program staff.
5. The replenished vaccine shall be placed in the clinic's VFC vaccine inventory and used to vaccinate VFC eligible children.
6. A copy of the packing slip demonstrating all VFC vaccine doses were replaced appropriately by privately purchased vaccine shall be faxed to the Iowa VFC Program at 1-800-831-6292 attention VFC Program Coordinator or emailed to [IowaVFC@idph.iowa.gov](mailto:IowaVFC@idph.iowa.gov) within 30 days from the date of notification.
7. The provider and VFC Program will use IRIS to track replenished doses from entry into IRIS inventory to final administration to a VFC eligible child. The provider must notify the VFC Program once doses have been entered into IRIS inventory. IRIS will be used to monitor replaced doses to assure they are administered to eligible children.
8. Failure to comply with the restitution policy will result in suspension from the VFC Program. Suspended clinics will not be able to order VFC vaccine until the vaccine has been replaced.
9. Failure to replace wasted VFC vaccine within 90 days of the clinic being placed on suspension will result in the clinic being terminated from the VFC Program. The provider may be permitted to re-enroll after the replacement of wasted VFC vaccine. Re-enrollment will be at the discretion of the Iowa VFC Program.
10. Providers who fail to comply with the Vaccine Restitution Policy may be referred to the Iowa Department of Health and Human Services, Medicaid Program for further investigation of fraud and abuse.
11. Providers may appeal the decision by the Iowa VFC Program to require restitution of wasted vaccine. Follow these steps to submit the appeal:
  - The appeal shall be submitted in writing by mail or fax on the clinic's letterhead within 10 business days of receipt of notification.
  - Appeals shall be submitted in writing to Bureau Chief, Bureau of Immunization and Tuberculosis, Iowa Department of Health and Human Services, Lucas State Office Building, Des Moines, Iowa 50319 or fax to: Bureau Chief at 1-800-831-6292.
  - Appeals must provide a detailed explanation of the circumstances which demonstrate the wastage situation is not due to provider negligence resulting in financial responsibility for the wasted vaccine. Include any information or attachments to be considered in the appeal.
  - The appeal must be signed by the clinic medical director.
  - Each appeal will be considered on a case-by-case basis.

- Written notification regarding the outcome of the appeal will be returned within 30 business days of receipt.

## PROCEDURES TO MINIMIZE VACCINE LOSS

Healthcare providers should implement and adhere to the following items to minimize vaccine loss:

- Provide adequate vaccine storage and monitor storage conditions.
- Do not over-order or stockpile vaccine.
- Never assume vaccine is nonviable in the event of a storage problem. Contact the Iowa VFC Program immediately for instructions.
- Conduct count of vaccine inventory at least monthly.
- Check vaccine expiration dates at least monthly.
- Rotate vaccine stock regularly; move earliest expiration dates to the front.
- Report vaccine that will not be used and will expire within 2-3 months to the Iowa VFC Program.