

Chicago Vaccines for Children (VFC) Program
Chicago Department of Public Health Immunization Program

Vaccine Loss and Replacement Policy

Updated: 2/13/2019

Policy

The Chicago Department of Public Health may require VFC enrolled providers to provide restitution for federally-purchased vaccine that have been lost or damaged due to the provider's failure to properly receive, store, handle, or rotate vaccine stock.

The Chicago VFC Program will determine restitution actions based on vaccine loss and circumstances under which the loss occurred. The Immunization Program Director in consultation with the VFC and the Vaccine Managers will make the final determination of provider fault after considering all related factors which led to the vaccine loss.

Definitions

Cold Chain: The vaccine cold chain is a temperature-controlled sequence of environments used to maintain and distribute vaccines in optimal condition. Appropriate storage and handling conditions must be maintained at every link in the cold chain.

Vaccine Waste: This is a general category which includes expired, spoiled, and lost vaccines.

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

Spoiled: Any vaccine exposed to a cold chain failure causing it to become unusable. This includes too much exposure to heat or cold, broken vials/syringes, vaccine drawn but not administered within appropriate time frames, and vaccine doses in open multi-dose vials that were not administered. Providers are cautioned to always consult with the Chicago VFC Program immediately upon discovery of break in cold chain before determining that the vaccine is spoiled.

Lost: Any vaccine that cannot be accounted for through use/administration, or is missing from storage.

Abuse: Provider practices that are inconsistent with sound fiscal, business, or medical practices, which may result in unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

Fraud: 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.

I. Restitution Procedures

- All instances of VFC vaccine waste must be reported to the Chicago VFC Program.
- Providers who waste VFC vaccines due to negligence will not be allowed to order VFC vaccines until the situation is satisfactorily resolved.
- The Chicago VFC Program will review all instances of VFC vaccine waste on a case-by-case basis.

- When restitution is required, the provider will receive notification from the Chicago VFC Program detailing the number of vaccine doses requiring replacement. The notice will detail number of doses by amount and type.
- The provider must commercially purchase the replacement vaccines.
- A copy of the billing invoice that shows receipt of the privately purchased vaccine shall be scanned and sent to chicagovfc@cityofchicago.org or faxed to the Chicago VFC Program at 312-746-6220, attention Vaccine Manager. The billing invoice must contain the lot number and expiration date. Chicago VFC will accept handwritten additions to the packing receipt.
- Failure to comply in a timely manner may result in the provider being suspended and/or terminated from the VFC Program, unless a mutual agreement has been made between the VFC Program and the provider. The provider may be permitted to re-enroll after the replacement of wasted VFC vaccine and other conditions are met. Re-enrollment will be at the discretion of the Chicago VFC Program.
- The replenished vaccine shall be placed in VFC inventory and used to vaccinate VFC eligible children. A log of the children vaccinated with this vaccine will be maintained and **faxed to the VFC program monthly** until all replacement doses have been successfully administered.
- If potential fraud and/or abuse are suspected, the provider may be terminated from the VFC Program and reported to authorities, including the Illinois Medicaid Fraud Control Unit and others as specified in the Chicago Department of Public Health Vaccines for Children Fraud and Abuse Policy.
- The Chicago Immunization Program reserves the right to remove a provider from the VFC program for any reason. If it is determined to remove the provider from the VFC program, the Immunization Program will collect any remaining vaccines and materials from the former VFC provider's custody; the provider must comply with all the city's demands in a timely manner.
- Withdrawal from the VFC Program does not eliminate the contractual obligation. The provider of record is still required to purchase and replace wasted vaccine doses and notify the VFC Program when they are available to be picked up.
- Failure to comply with the restitution policy will result in the clinic being terminated from the VFC Program.
- **If fraud or abuse is suspected, the provider will be reported to authorities (i.e. Illinois Medicaid) per fraud and abuse policy.**

II. Examples of Situations Requiring Restitution *(This list is not comprehensive)*

- VFC vaccine not accounted for on Doses Administered Reports
- Negligent VFC vaccine storage and handling procedures
- Failure to report temperature excursions that (potentially) damage VFC vaccines
- VFC vaccine administered to children who do not meet VFC Program eligibility criteria
- Accepting reimbursement from insurance companies, and/or patients for VFC-administered vaccine
- Storage and handling errors resulting in vaccine waste due to provider negligence
- Discarding vaccine prior to the manufacturer's stated expiration date (e.g. discarding vaccine vial 30 days after vial is first used)
- Allowing vaccines to expire and/or failing to notify the VFC program three (3) months prior to the expiration date
- Using improper vaccine storage and temperature monitoring equipment
- Any power outages in which the provider fails to act according to the posted Emergency Vaccine Management Plan, if it is determined that the provider could have taken action to avoid the wasting of VFC vaccine
- Failure to open vaccine shipments from McKesson or Merck immediately, resulting in damage to the vaccines

III. Examples of Situations Not Requiring Restitution *(This list is not comprehensive)*

- Area power outages due to severe weather or other unavoidable and unanticipated causes. The power outage must be corroborated by Commonwealth Edison for the time and location.
- Refrigerator/freezer failure-unavoidable or unanticipated. To verify actual vaccine storage equipment failure, the provider must show a properly dated invoice for a repair service call to the vaccine storage unit in question, or invoice for the purchase of a new appliance.
- Vaccine shipment is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit. Verification of improper action on part of the shipper must be validated by the shipping tracking number.
- Temperature excursions that are noted and reported promptly (within one (1) business day) to Chicago VFC.
- Extraordinary situations not listed above which are deemed by the Immunization Program to be beyond the provider's control. (When reporting wastage of any kind, providers should provide documentation that demonstrates staff's use of the Emergency Vaccine Management Plan).

IV. Procedures to Minimize Vaccine Loss

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

- Provide adequate vaccine storage in appropriate appliances
- Monitor storage temperature using a program-approved thermometer
- Avoid over-ordering or stockpiling vaccine. Over-ordering can lead to unnecessarily large volumes of vaccine being stored, increasing risk of losing a large quantity should vaccines be compromised (e.g., mechanical failure of the storage unit)
- Never assume vaccine is nonviable in the event of a storage or temperature problem. Contact the Chicago VFC Program immediately for instructions
- Conduct a full vaccine inventory at least monthly
- Check vaccine expiration dates at least monthly
- Rotate vaccine stock regularly; move earliest (soonest) expiration dates to the front
- Report vaccine that will not be used and will expire within 90 days (3 months) to the Chicago VFC Program