

## VACCINES FOR CHILDREN (VFC) VACCINE LOSS POLICY (4/30/18)

The Vaccines for Children (VFC) Vaccine Loss Policy applies to all providers actively enrolled in the Michigan VFC Program. This policy supersedes all policies previously issued by the Michigan Department of Health and Human Services (MDHHS) addressing lost, wasted or borrowed VFC vaccine.

MDHHS, the Centers for Disease Control and Prevention (CDC), and VFC providers share a common interest in ensuring that all eligible children receive immunizations. It is important that VFC providers account for and store VFC vaccine appropriately to avoid loss of vaccine due to expiration, storage and handling issues, and administration errors. This helps ensure that all Michigan's VFC-eligible children have access to an adequate supply of vaccine. The focus of Michigan's restitution policy is poor vaccine management, specifically, loss due to expiration and loss due to cold chain failures.

### Expired Vaccine

It is MDHHS's expectation that expired VFC vaccine is replaced dose for dose with privately purchased vaccine. CDC policy requires that the dose for dose replacement with privately purchased vaccine take place within 90 days of the expired vaccine loss.

Following these simple steps will help you avoid having to replace expired vaccine:

- Check and rotate your stock on a monthly basis
- Administer shorter-dated vaccines first
- Post a vaccine expiration date table on your refrigerator
- Use the Reminder/Recall function in MCIR to administer doses that will soon expire. Recalls must be done before requesting your LHD to redistribute the vaccine.
- Watch MCIR – vaccines expiring in six months are highlighted in green; purple means they're due to expire in only three months!
- Share MCIR expiration email notifications with all staff to ensure vaccine gets used before the expiration date
- Notify your local health department (LHD) three to six months prior to expiration if you believe you will not be able to administer the vaccine before the expiration date. Under this timeframe, and as long as appropriate storage and handling procedures were followed as evidenced by temperature logs and/or data logger files, the LHD is obligated to receive the vaccine and either use it within their own clinic or redistribute the vaccine to another clinic for use. If a LHD takes vaccine from a provider and there is less than three months to the expiration date and the doses subsequently expire, the provider who originally ordered the vaccine is responsible for replacement of the expired doses.

Due to the seasonal nature of flu vaccine and the difficulty of accurately predicting distribution of the vaccine and public demand for the vaccine, dose for dose replacement of expired flu vaccine is not required.

## Cold Chain Failures

Vaccine must be stored, handled, administered, and transported according to VFC vaccine storage and handling guidelines. Whenever the viability of a vaccine is in question due to improper storage and handling, the vaccine manufacturer(s) must be contacted. If the manufacturer determines the vaccine is acceptable to use, written documentation from the manufacturer must be obtained. If the manufacturer(s) determines that the vaccine is non-viable, the doses must be transferred out of inventory using the correct MCIR transaction:

1. Return to Distributor or
2. Non Return Open MDV – for open multi-dose vials

The vaccine must be removed from the unit and marked DO NOT USE. Once the transactions have been recorded in MCIR you must go to your MCIR home screen and under the Vaccine Mgmt section choose the Return/Waste Reporting link, select Create a New Return/Waste Report and then check the boxes of all vaccine being reported. Add a corrective action plan, including any information (lot & exp. date) on replacement of the vaccines, and submit the report for approval. Note: Once you create a report and hit submit the information cannot be changed.

Dose for dose replacement is usually required for vaccine non-viable due to a storage and handling issue, however, these are some of the things MDHHS reviews in determining the level of vaccine replacement:

- Was the provider available to accept the vaccine delivery during stated vaccine delivery hours?
- Was the vaccine stored promptly upon arrival?
- Was the vaccine stored within the appropriate temperature range?
  - Refrigerator 2 - 8°C / 36 - 46°F
  - Freezer -15°C / 5°F to -58°F
- Did the provider respond to alarms or out-of-range temperatures?
- Is the provider using data loggers and downloading and reviewing the data weekly?
- Was the emergency response plan followed?
- Did the provider do everything they could to ensure the viability of the vaccine?

If dose for dose replacement of non-viable doses is determined, the replacement must take place within 90 days of the vaccine loss. If private vaccine was stored in the same storage unit as the compromised VFC vaccine, the provider must submit a paid invoice for private vaccine used to replace lost VFC doses.

Providers with losses that exceed a VFC dollar value of \$1500 are required to complete a Vaccine Accountability INE training session before the loss is considered resolved. If the provider site received a Vaccine Accountability INE session within 90 days of the vaccine loss, this requirement can be waived unless the LHD feels the provider staff would benefit from a repeated training.

If a provider has vaccinated patients with non-viable vaccine (expired vaccine or non-viable from a temperature excursion), they must re-vaccinate the child with private stock vaccine. Under the VFC Program, running titers is not acceptable. You must revaccinate.

### Wasted Doses

Dependent upon the storage and handling practices conducted by the clinic, dose for dose replacement of the vaccine is not usually required for the following types of vaccine loss:

- Accidental breakage
- Drawn but not used (which includes parent changed mind; vaccine/syringe/needle compromised; child moved and dose was unable to be administered)

These types of vaccine wastage should be recorded in MCIR using the corresponding transaction under Adjustment. An educational training/intervention may be required if a provider office has an above average occurrence of these types of vaccine losses.

All wastage must now be reported to CDC. At minimum once per month you should create a Wastage report in MCIR and submit that report for approval.

### Withholding VFC Vaccine Due to an Unresolved Vaccine Loss

The LHD and MDHHS have the authority to withhold VFC vaccines from a clinic with an open, unresolved (90 days or older) vaccine loss until doses are replaced and all corrective action to avoid occurrence of another loss is completed.

### Medical Errors Requiring Revaccination

When a vaccine has been administered in error (incorrect vaccine, wrong age group, improper administration, using non-viable vaccine, etc.) and the patient is required to be re-vaccinated, a provider must re-vaccinate the patient with privately purchased vaccine. Under the VFC Program, running titers is not acceptable.

### Short-Dated Vaccine

If vaccine has been assigned a shortened expiration date by the manufacturer due to an out-of-range temperature excursion, the vaccine cannot be re-distributed to another clinic unless the receiving clinic is notified of the circumstances and agrees to accept the vaccine. If the receiving clinic is unable to administer the vaccine prior to the shortened expiration date, the original provider shall be responsible for the dose for dose replacement of that vaccine.

### Borrowed Vaccine

VFC providers must maintain an adequate inventory of vaccine to administer to both

privately insured and VFC-eligible children. CDC allows borrowing of vaccine between two vaccine inventories only as a rare, unplanned occurrence. Borrowing can occur only when there is:

1. A lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment,
2. Vaccine spoiled in-transit to the provider, or
3. New staff calculated ordering time incorrectly.

Replacement of VFC vaccine with private vaccine stock is required upon receipt of the private vaccine stock. Vaccine doses must be replaced with like-kind vaccine (e.g., if one dose of VFC ActHIB vaccine is used, one dose of privately purchased vaccine stock ActHIB must be used for replacement). Providers must have private stock inventory in VIM in order to accurately replace borrowed VFC doses under these guidelines. Providers must not borrow VFC vaccine that they are unable to replace with private stock vaccine. The Vaccine Borrowing Report developed by MDHHS must be used to record/document all borrowed doses. These reports must be kept for three years, as with all other VFC documentation, and made available during a VFC compliance site visit.

**Providers who have occurrences of borrowing (even just one dose) must store, monitor, and maintain their private stock vaccine under the same storage and temperature monitoring requirements of the VFC Program: use of appropriate storage units, use of data loggers with current calibration certificates, twice daily temperature documentation on a temperature log, daily MIN/MAX documentation, monthly balancing of inventory, etc.**

For seasonal flu vaccine, providers may use private-stock seasonal flu vaccine to vaccinate VFC-eligible children if VFC seasonal flu stock is not yet available. Those private stock doses used on VFC-eligible children can later be replaced when VFC stock becomes available. The replacement must be for the exact same product including the same presentation (Fluzone for Fluzone, prefilled syringes for prefilled syringes, single antigen vials with single antigen vials, etc.). You should not borrow more private stock vaccine than what you have pre-booked through VFC. VFC flu vaccine should never be used on private pay patients. **This one-directional borrowing exception is unique to seasonal flu vaccine and a new requirement of CDC.**

If at the time of service the child was reported as fully insured, private pay vaccine administered and insurance was billed with eligibility code of “private pay/fully insured” recorded in MCIR, but 3-6 months later vaccine payment was rejected by insurance, VFC will replace the private vaccine doses with VFC vaccine doses. This is because the child at the time of service was actually VFC eligible as “underinsured” but parent/guardian was unaware. Provider office staff must change this child’s eligibility in MCIR for the doses rejected from “private pay” to “underinsured”, which will create a borrowed transaction from the private inventory. Now VFC owes vaccine to the private stock and provider office staff must go into MCIR VFC inventory and create a “replace

borrowed” transaction for the doses that were rejected and now have eligibility changed to “underinsured”. VFC vaccine must also be physically moved from VFC vaccine inventory to private vaccine inventory in the vaccine storage units. Replacing doses for underinsured rejections must be completed in a 6-8 months from time of service or as soon as rejection is received.

## Lost VFC Vaccine Doses

Pursuant to *Public Health Act 540 of 1996*, all healthcare providers are required to enter vaccine doses administered into the Michigan Care Improvement Registry (MCIR) within 72 hours. MCIR is the primary system used by the VFC Program to account for VFC vaccine doses received and administered by VFC providers. Based on the data entered by providers, MCIR tracks the number of doses that are received, administered, wasted, returned to McKesson, and borrowed.

Prior to submitting a VFC vaccine order, it is required that an *Ending Inventory Report* be completed in MCIR. To do this, providers must conduct a physical inventory of the vaccines stored in their refrigerator(s) and freezer(s) and enter these numbers into MCIR. Ideally, the number of doses in your refrigerator(s) and freezer(s) will match what is reflected in MCIR. In the event the numbers do not match, it is necessary to thoroughly review the administration history of your vaccines and determine if all data has been entered into MCIR and if a data entry error has occurred regarding doses administered or wasted. It is also recommended that you physically re-count your vaccines. 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 MCIR, doses that cannot be accounted for are considered lost doses. You must have approval from your LHD before using the Unable to Locate/Lost transaction in MCIR. LHDs and MDHHS may withhold vaccine orders until improved accountability is demonstrated by the provider office. If accountability for lost VFC doses does not improve, dose for dose replacement of those lost doses with private stock vaccine will be required. Lost doses must be recorded in MCIR and reported to CDC through the Returns/Wastage reporting process.

## Returning Non-viable Vaccine to McKesson (what to do with the vaccine vials)

1. Record transactions in MCIR for vaccines that have expired or have not been stored according to CDC’s guidelines. If you don’t know the correct transaction please contact your LHD or MCIR Region Contact. Incorrect transactions cannot be corrected once a loss report has been submitted.
2. Under Vaccine Mgmt on your MCIR home page, select the Return/Waste Reporting link
3. Create the report and submit the report to your LHD for approval. Be sure to add a corrective action plan. In addition, if doses have been replaced with private stock vaccine, add the lot number and expiration date of the replaced doses as well as the date they were transferred into your VFC inventory.

4. Once the report has been processed at the MDHHS level, a return label will be emailed to the VFC Primary Contact as outlined under the VFC Enrollment section in MCIR.