

LOCAL HEALTH DEPARTMENT RESPONSIBILITIES

In addition to the requirements expected of all VFC Providers, Local Health Departments (LHDs) must perform the following activities:

1. Work with each VFC provider to assure that their annual online enrollment is accurately completed and submitted by April 1st in MCIR.
2. Submit an online enrollment via MCIR for the LHD and each of the LHD's satellite clinics by April 1st.
3. Ensure all Vaccine Managers and Back-up Managers within your jurisdiction (including LHD staff) receive annual training. Document any changes in primary and back-up staff in PEAR and report these changes to MDHHS via email.
4. Receive vaccine orders from VFC providers and review the doses administration report (DAR), ending inventory reports and their vaccine storage temperature logs prior to approving and placing orders with MDHHS.
5. Be accountable to MDHHS for all VFC doses of vaccine administered within the LHD jurisdiction.
6. Conduct VFC site visits of no less than 50% of the VFC providers within the LHD jurisdiction each year and enter those visits into PEAR. The other 50% of VFC providers must be visited the following year. Provider sites must have a site visit at least every other year. MDHHS recommends that LHDs strive towards visiting as many VFC providers as possible every year.
Site visit objectives are to:
 - a. ensure that providers have the most current immunization resource materials available;
 - b. review VFC requirements on vaccine storage and handling, vaccine accountability, record-keeping, and compliance with VFC regulations;
 - c. assess the quality of immunization practices; and
 - d. prepare corrective action plans when necessary, including a process to track follow-up activities related to the corrective action plan.
7. Disseminate immunization information and updates about the program to all providers within their jurisdiction as needed.
8. Provide ongoing education and technical assistance to private providers and staff as needed.
 - a. Conduct on-site reviews of providers who have vaccine storage and handling problems and assist them in the resolution of these problems.
 - b. Review all incoming vaccine orders, inventory reports, temperature logs and doses administered reports. If inconsistencies are found on these reports (e.g., ordering more vaccines than usual, reports of wasted/expired vaccines), follow-up with the provider to resolve any issues.
 - c. Follow-up on problems until improvements are made and maintained.
 - d. Make referrals to the MDHHS INE program if additional provider education is indicated regarding the VFC Program and/or vaccine safety, storage and handling concerns.
9. Keep all VFC-related documents for 3 years, including: LHD temperature logs, all provider enrollments, site visit questionnaires and CA follow up documentation, and vaccine losses.
10. Assist providers with creating vaccine Returns and Wastage reports in MCIR. Provide education to ensure providers are using the correct transactions and to reduce incidence of spoiled vaccine.

11. In order to avoid expired VFC vaccine, the LHD is obligated to receive soon-to-expire provider vaccine and either use it within their own clinic or redistribute the vaccine to another clinic for use as long as appropriate storage and handling procedures were followed as evidenced by data logger files. LHDs may require that providers run MCIR patient reminder recalls prior to accepting vaccine.
12. Local Health Departments that border other states (Wisconsin, Ohio, and Indiana) must have agreements in place with those states to vaccinate VFC-eligible children with VFC vaccine regardless of which state the child resides.

LHDS AS VFC PROVIDERS

LHDs must meet all requirements of private providers. In addition, the following storage and handling requirements apply to LHDs:

1. Weekly calibration of all temperature monitoring devices which includes the date of calibration, type of monitoring devices, (use a key or legend to indicate the types of monitoring devices you have in use, temperature readings of all thermometers in use in both refrigerator and freezer units that contain VFC vaccines.
 - a. Document the certified thermometer so the reviewer can easily determine if all other devices are within acceptable range.
 - b. Fahrenheit temperatures must be within 3 degrees of certified thermometer temperature; Celsius temperatures must be within 1.5 degrees.Document adjustments, if needed. Documentation should include the device that was adjusted (e.g., Data-logger is certified thermometer, 6-17-13 DL= 40, S=46. Adjusted Sensaphone).
2. A continuous- temperature monitoring alarm notification system must be in place in each LHD storage unit.
 - a. All monitoring devices and alarm systems must be calibrated weekly to ensure they function compatibly and accurately. Readings may not always be exactly the same as the thermometer since the thermometer may react differently to changes in temperature than the alarm system does, depending on types of probes (measuring air temperature vs. liquid-filled solutions). It is best to check the calibration of the alarm system with the thermometer after the unit has been closed for an extended period of time.
 - b. An alarm system should be tested at least once a month to assure it is working correctly.

PROCESSING PROVIDER VACCINE ORDERS

VFC has two levels for data submission: VFC Private Providers to LHDs and LHDs to MDHHS. The following guidelines, by levels, highlight which documents are needed for submission. These are considered the minimal reporting requirements for document submission and review. The LHD may decide to require more frequent submission of supporting documents for those providers who are on a less frequent ordering schedule, or have issues with temperature monitoring, trouble balancing inventories, and/or issues with over and under ordering vaccine supplies.

VFC PRIVATE PROVIDERS TO LHDs

VFC providers	Submit with your vaccine order	Submission frequency
Must use MCIR VIM and E-ordering	<ol style="list-style-type: none"> 1. Doses Administered Report 2. Ending Inventory Report 3. Temperature Logs 4. Submit order in MCIR 5. Data logger documentation (if temps are out of range) 	Reports should be generated within 10 calendar days of the order, and sent with the vaccine order to the LHD based on the ordering schedule set up by the LHD (monthly, bi-monthly, or quarterly, etc.)

Prior to placing a VFC provider’s vaccine order, LHDs are responsible for collecting all supporting documents, reviewing and approving for accuracy. This must be done before the order is approved in MCIR VIM and submitted to MDHHS for processing. Submissions of VFC provider supporting documentation should be dated within 10 calendar days of the vaccine order request.

LHD staff should check MCIR for pending vaccine orders at a minimum of twice a day to ensure vaccine orders are reviewed and approved for further processing by MDHHS in a timely manner.

Section 1 - Temperature Logs

LHD reviews all temperature logs from the last vaccine order to the current date.

Overview of temperature log:

- ✓ Name of facility, VFC PIN and unit indicated on each log.
- ✓ Initials of who recorded temps are present for all temps.
- ✓ Times of temperatures recorded.
- ✓ For freezer temps, must record actual temps, not just <3 or an x in that box.

Temperatures Recorded on Log:

- ✓ Check to see if all twice daily temps are recorded.
- ✓ Best Practice (not required):
 - Check to see if MIN/MAX temps are recorded (best practice; daily MIN/MAX temps will be required January 1, 2017.)
 - Calibration: (Included for those provider offices who have more than one monitoring device)
 - Calibration should be done weekly, recording all temperature devices, with each temp labeled to identify each device. Temps must be compared to the certified thermometer (control) and calibrated based on that temperature.
 - Temps of all devices must be within 3 degrees of the certified thermometer for Fahrenheit temps or 1.5 degrees for Celsius temps. If they are not, those devices that are out of range must be adjusted to the certified temperature and documentation provided. (Example, Calibration: Sensaphone 40, Data Logger 36. The Sensaphone adjusted to 36 degrees, T. Adams, RN 1/14/14 @8:08am.)

- ✓ If any temps are missing, documentation is required to explain why: (example, office closed for holiday)
- ✓ Check to see if all temps are within proper temperature range.
- ✓ If any temps are out of range, documentation is required to explain:
 - Action taken. This means if the temp at the time it was taken was out of range, there is a brief explanation (Example: in the unit doing inventory, unpacking shipment, etc.)
 - Additional temps recorded until back to normal range (Example: Temp 56 at 10:00am, doing inventory, door shut at 10:08am. Temp 50 at 10:15am. Temp at 45 at 10:30 a.m.)
- ✓ Logs can be approved as long as documentation shows the temp back in normal range in less than 30 minutes.
- ✓ If log has temps out of range and missing documentation of actions taken, then hold order and ask for documentation or reasons for lack of. If provider is using a data logger, review the data logger documentation. Next, determine if vaccines are viable, have the provider call the manufacturers if indicated, and assess for possible vaccine loss.
- ✓ If vaccine is viable, educate provider on temp issues, offer INE session and monitor temp logs every week for one month, or per LHD protocol.
- ✓ If vaccine is not viable, work with provider to identify children who may have been vaccinated with nonviable vaccine for recall/revaccination and process loss report (in addition to steps listed above if vaccine is viable). LHDs must follow up as needed to ensure timely resolution of vaccine losses.

Section 2 - Doses Administered Reports (DAR)

Doses Administered Report (from MCIR)

- ✓ Be sure dates on DAR(s) cover period from last order to current order.
- ✓ Make sure it is VFC (public) DAR that you are reviewing.
- ✓ Assess report for accurate number of doses administered compared to ending inventory report. (Example: Used 20 doses of MMR from inventory on VFC eligible kids, DAR should show 20 doses given to 1 through 18 yrs of age.) If not, question use and educate.
- ✓ Are all doses given to age appropriate groups? (Example: DTaP only given to less than 7 yrs of age.) If not, question use and educate.
- ✓ Do the numbers in DAR compare to the number of kids being served by provider based on their annual profile?
- ✓ Check to make sure only those who are enrolled in adult programs (FQHC, Tribal HC, etc.) have doses administered to adults on the DAR. LHDs should know who can be administering adult vaccines.

Section 3 - Ending Inventory Reports (EIR)

LHD reviews all columns for all vaccines (refer to MCIR definitions for EIR column titles and the VFC 'Transfer out' Tip Sheet for more information on EIR report).

Ending Inventory Report (MCIR report generated by provider)

- ✓ Be sure dates on the EIR cover entire period since last order.
- ✓ Be sure the correct PIN is on the report.
- ✓ Be sure you are reviewing VFC/Public inventory.
- ✓ Focus on expiration dates and discuss soon-to-expire vaccine options.
- ✓ Review the numbers in each column to determine how provider is entering information into VIM and utilizing vaccines – review 'transfer out' column, LWB column, etc.

Please refer to the VFC Tip Sheet on using “Transfer Out” and the MCIR Tip Sheet on EIR column definitions. These transactions should be rare.

Question data entry if you find vaccines other than those provided by VFC (Rabies, Typhoid, PPD, etc.).

- ✓ Does the doses administered section of the EIR reflect the number of doses on the DAR?
- ✓ If the provider office balances more frequently than one time between orders, then it is necessary to view all ending inventory reports for the time period and compare to the VFC Doses Administered Report(s) run for that same time period.

Section 4 – Provider Vaccine Orders in MCIR

Providers should order vaccines based on the schedule assigned to them by the LHD (month, bi-monthly, quarterly). Most providers should order monthly, but providers with lack of adequate storage or very large volume providers may need to order more frequently.

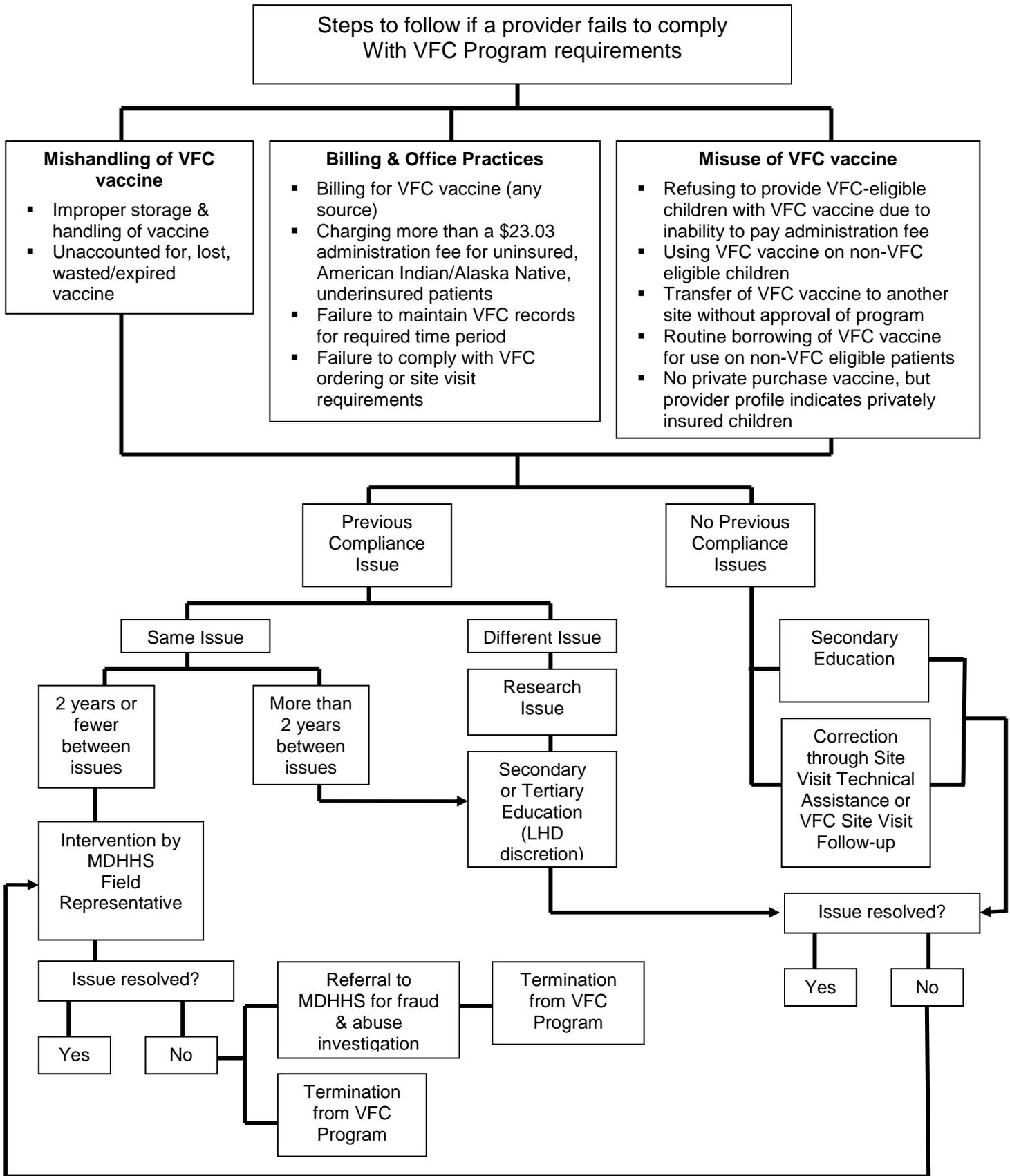
- ✓ Make sure the date on the order is within **10** calendar days of submission of supporting documents.
- ✓ Order has been assessed for appropriate amounts of vaccine based on information from the Doses Administered Report and Ending Inventory Report.
Example: Doses Administered Report shows average of 20 doses Tdap given per month, has 60 doses on hand, orders monthly, and wanted to order 20 doses because that is what they used this month. This provider has a 3 month supply on hand (60 doses), and should not order Tdap until down to 40 doses or less.
 - Educate providers on how to calculate the correct amount of vaccine to order as needed. Consider special circumstances such as back-to-school clinics, a provider conducting recalls or times of heavier vaccine use. Evaluate provider orders greater or less than 20% outside of their normal vaccine ordering patterns for inconsistencies.
- ✓ Review order for specialized vaccines, e.g. DT, Menhibrix, for appropriate quantities and any necessary supporting documentation

In addition to the Provider to LHD steps above, LHDs must submit the following to MDHHS for review of LHD vaccine orders:

LHDs to MDHHS

Local Health Departments	Submit with your vaccine order	Submission frequency
Must use MCIR VIM and E-ordering	<ol style="list-style-type: none"> 1. Doses Administered Report 2. Ending Inventory Report (Clinic and Depot) 3. Temperature/Calibration logs including satellites 4. Submit order in MCIR 5. Data logger documentation (if temps are out of range) 	LHDs should submit their MCIR vaccine order and supporting documentation to MDHHS at the same time. Do not send supporting documents unless placing an order. Supporting documents must be generated within 10 calendar days of order.

FRAUD AND ABUSE / CORRECTIVE ACTION PROCEDURE



See next page for outline of requirements of Secondary and Tertiary Education.

Secondary Education

- Provider is educated regarding VFC Program requirements
- Provider submits written corrective action (CA) plan to LHD
- LHD conducts 1-2 Follow-ups (e-mail, phone or in-person) post identification of the issue
- At LHD discretion, provider completes VFC and/or Storage and Handling INE training

Tertiary Education

- Provider is educated regarding VFC Program requirements
- LHD develops specific corrective action (CA) plan and sends written notification
- LHD conducts 2-3 Follow-ups (e-mail, phone or in-person) post notification to ensure CA plan is being followed
- Provider completes VFC and/or Storage and Handling INE training
- LHD conducts in-person visit 3-6 months after implementation of CA plan to assess provider compliance

How To Set Up A New VFC Provider

The following steps must be completed:

- 1) Provider contacts LHD with interest to become a VFC provider.
- 2) LHD verifies current MCIR site ID or requests MCIR staff issue new site ID via the MCIR Provider Site Usage Agreement. MCIR staff assigns site administrator to new sites and trains as needed on their responsibilities including adding new users.
- 3) LHD has provider complete the VFC online enrollment in MCIR and submit to LHD. LHD or MCIR Provider Site Administrator verifies the VFC Primary and VFC Backup contacts are fully trained and understand their role.
- 4) LHD reviews enrollment for completion and approves participation in the VFC program at the local level and submits to MDHHS VFC.
- 5) MDHHS VFC staff reviews and processes online enrollment and issues new VFC PIN for new provider. New provider is placed in suspended status in MCIR. New PIN & provider demographics are entered into PEAR by MDHHS VFC staff.
- 6) LHD conducts VFC new enrollment site visit and documents in PEAR.
- 7) LHD contacts MDHHS VFC staff to lift suspension & provider is directed to contact MCIR staff or trainer to schedule VIM/E-order training.
- 8) Once VFC Primary and VFC Backup have scheduled VIM/E-Order training, MCIR staff will add VFC Primary and VFC Backup E-Order contacts under the VFC, E-Order tab in MCIR immediately prior to or during training.
- 9) LHD confirms MCIR VIM training has been completed and assists provider with initial E-Order.

Guide to Inactivating a VFC Provider from the VFC Program and MCIR VFC VIM

The following steps must be completed:

- 1) LHD to send an email to MDHHS VFC, MDHHS Field Rep and Regional MCIR Staff advising that a provider is leaving the program. Notification should include the reason for and date of termination.
- 2) LHD and/or MCIR staff (depending on how each local jurisdiction has it set up) has the provider complete the following in VIM:
 - balance and perform an Ending Inventory report and submit that report to the LHD
 - Submit in MCIR an online Returns and Wastage report for any lost, wasted or expired doses
 - Transfer out to the LHD any remaining viable doses using transaction return to Local Health Department –Excess Inventory for each vaccine to be returned
 - Return all VFC vaccine with temperature logs to LHD
 - After all lots are brought to zero a final balance will need to be completed a minimum of one day past initial balance
 - Inactivate all the VFC lots in VIM
 - When above steps complete LHD will notify Regional MCIR staff who will remove checks from default and active boxes
 - This step is often missing when the request to inactivate a provider is received by MDHHS
- 3) Following removal of checks for active and default boxes MCIR Regional staff will send an email advising MDHHS VFC that the provider is ready for VFC inactivation in MCIR.
- 4) MDHHS VFC inactivates VFC PIN in MCIR
- 5) MDHHS VFC documents in MCIR, VTrckS and PEAR the date of and reason for inactivation

MDHHS VFC Program staff must be notified of any provider who no longer wants to participate in the program, for whatever reason.

Providers may continue to use MCIR VIM for their private stock vaccine even if they are no longer a VFC provider.

PEDIATRIC DIPHTHERIA-TETANUS TOXOID (DT) VACCINE ORDERING PROTOCOL

The federal VFC program does not supply DT vaccine to VFC providers. Michigan purchases DT vaccine with special vaccine funds and places the vaccine at McKesson for distribution to MI VFC providers. Very few patients should need DT vaccine and MI has been historically wasting more DT vaccine than is administered. MDHHS has developed the following policy to limit the use of DT and possibly avoid vaccine wastage.

MDHHS VFC program will continue to allow VFC providers to order single dose DT vaccine in MCIR E-ordering. However, a VFC provider must have a VFC-eligible patient who is younger than 7 years of age and has a documented valid contraindication, precaution or reason for delay from a previous dose of pertussis containing vaccine before ordering.

Contraindications to further vaccinations with DTaP are a severe allergic reaction (anaphylaxis) to a vaccine component or following prior dose of vaccine, and encephalopathy (coma, decreased level of consciousness, prolonged seizures not due to another identifiable cause within 7 days after DTaP vaccination.

Precautions to further doses of pertussis vaccines are moderate to severe illness, temperature 105°F or higher within 48 hours with no other identifiable cause, collapse or shock-like state (hypotonic hypo-responsive episode) within 48 hours, persistent, inconsolable crying lasting 3 hours or longer, occurring within 48 hours, seizure or convulsions with or without fever occurring within 3 days.

Valid Reasons to Delay DTaP vaccine include progressive or unstable neurologic disorder (including infantile spasms), uncontrolled seizures or progressive encephalopathy. Providers should defer DTaP until a treatment regimen has been established and the condition is stabilized. DT can be ordered and given.

A family history of seizures or other neurologic diseases, stable or resolved neurologic conditions (e.g., controlled idiopathic epilepsy, cerebral palsy, and developmental delay) are not contraindications to pertussis vaccinations.

When a provider request for DT is received by an LHD, the LHD staff must contact the provider to assure that the provider has a specific child with a contraindication, precaution or valid reason to delay from a previous pertussis-containing vaccine before approving the order for a single dose of DT vaccine. This information from the provider must be provided to MDHHS before the DT vaccine order will be approved at the MDHHS level.

Providers or LHDs will not be allowed to have DT vaccine on hand for possible future need. DT vaccine will only be approved for a specific child.

This policy will assure that all doses of DT that are shipped to MI VFC providers will be used and will prevent expired doses in provider and LHD sites.