**Vaccine Management & Emergency Response Plan**

All Vaccines for Children (VFC} providers must maintain a Vaccine Management Plan, including an Emergency Response Plan. These plans **must be reviewed and updated at least annually** and any time there is a change in staff responsible for vaccine management or a change in procedure. A "review date" and signature is required. **Keep this plan posted in a prominent location** (e.g., on or near the vaccine unit).

**Instructions:** Complete all sections. Review all checkboxes, selecting all that apply. Add additional items specific to your location as needed. It is recommended to complete this electronically.

**Below is a list of acronyms used in this document:**

* CDC: Centers for Disease Control and Prevention
* DDL: Digital Data Logger
* LHD: Local Health Department
* MCIR: Michigan Care Improvement Registry
* MDHHS: Michigan Department of Health and Human Services
* VFC: Vaccines for Children
* VIM: Vaccine Inventory Module

**Vaccine Management Plan**

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| Location Name |  |
| VFC PIN |  |

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| **Date of Revision** | **Signature of Individual Responsible for Contents of Plan** |
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**Digital Data Loggers (DDL): Calibration At A Glance**

Use this table to quickly update calibration due dates. Ensure backup DDL(s) are included in the list and calibration has not expired. This information is found on the certificate of calibration and on the back of some devices. Please have certificates ready for review at VFC site visits.

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| --- | --- | --- | --- |
| **DDL ID** | **Calibration Date** | **Next Calibration Date** | **R = Refrigerator**  **F = Freezer**  **B = Backup** |
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**Section 1: Key Contacts**

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|  | **Name** | **Phone** | **Email** |
| **Vaccine Primary Coordinator** |  |  |  |
| **Vaccine Backup Coordinator** |  |  |  |
| **Optional/Additional Contact** |  |  |  |
| **Local Health Department (LHD) VFC Contact** |  |  |  |

**Section 2: General Management**

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| **Our location implements the following general requirements:** | |
|  | The Michigan VFC Resource Webpage is utilized to ensure updated VFC requirements and templates are in place. The webpage is bookmarked on our computer: [Vaccines for Children (VFC)](https://www.michigan.gov/mdhhs/adult-child-serv/childrenfamilies/immunizations/healthcare/vfc). |
|  | Changes to key staff will be reported to LHD and/or MDHHS immediately. |
|  | Documents are maintained for at least 3 years. |
|  | Key staff are available for site visits. Site visits should occur at least every 11 months and not to exceed 24 months. In some regions, site visits occur annually. |

**Section 3: Storage, Handling, and Administration**

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| **Our location implements the following measures for vaccine storage and handling for units and vaccine placement:** | |
|  | Refrigerator maintains temperatures of 36.0°F to 46.0°F (2.0°C to 8.0°C); aim for 41.0°F (5.0°C). |
|  | Freezer maintains temperatures between -58.0°F to +5.0°F (-50.0°C to -15.0°C). |
|  | Ultra-cold freezer maintains a temperature between -130.0°F to -76.0°F (-90.0°C to -60.0°C). |
|  | For accurate ultra-cold temperature monitoring, it is essential to use an air-probe, or a probe designed specifically for ultra-cold temperatures. |
|  | Units meet CDC and MDHHS/LHD requirements outlined at [Vaccines for Children (VFC)](https://www.michigan.gov/mdhhs/adult-child-serv/childrenfamilies/immunizations/healthcare/vfc). |
|  | Units can store the largest amount of inventory without overcrowding (e.g., back-to-school, flu). |
|  | Units are dedicated to vaccine storage. There is no food or beverage in any vaccine unit. |
|  | Vaccines are stored in the original packaging. |
|  | Vaccines are stored centrally in the unit: 2-3 inches from walls, ceiling, floor, and door. |
|  | Private stock and VFC stock are clearly labeled and separated. |
|  | Water bottles line the walls, back, floor, and door (unless storage unit manufacturer indicated otherwise). |
|  | [Do Not Unplug](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Adult-and-Childrens-Services/Children-and-Families/Immunization-Information/VFC/Required-to-Post/Do-not-unplug.pdf?rev=612fc2a784c8457e9150e58b97a97115&hash=68B610A178B845A09BC7A48B0E59F113) signs are present at outlets and circuit breaker. |

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| **Additional measures may be in place to prevent accidental disconnection from power:** | |
|  | Plug guards are utilized. **(Required for LHDs.)** |
|  | Units with no access to an outlet are hard-wired into a power supply. |
|  | A comprehensive policy is in place for measures to be taken to prevent accidental disconnection. |

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| **Temperature Monitoring:** | |
|  | Temperature monitoring device (DDL) meets all CDC and MDHHS VFC requirements. |
|  | DDL(s) are in all units and have an up-to-date certificate of calibration. |
|  | At least one extra DDL for use as a backup is available and has an unexpired certificate of calibration. |
|  | Up-to-date certificates of calibration are available for all devices (including backup). |
|  | Temperatures are assessed and documented twice daily. |
|  | Min/Max temperature is assessed and documented at least once daily, in the morning. |
|  | Temperature documentation includes temperature readings, name/initials, time, and date. |
|  | DDLs are downloaded and reviewed weekly and anytime an alarm is triggered. |
|  | Any out-of-range temperature is acted on immediately and the LHD is notified. |
|  | All excursion measures follow VFC requirements and our location’s Emergency Response Plan. |
|  | **LHD-required**: External alarm system is in place including protocols for testing. Weekly temperature calibration is documented. |

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| **Complete table below for ALL units storing vaccine:** | | | | | | |
| **Unit & Brand**  **(ex: Fridge, Follet)** | **Type:** | | **Grade:** | | |  |
| **Stand-Alone** | **Combo** | **Pharmaceutical** | **Commercial** | **Household** | **DDL** |
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**Defrost Plan:** If a manual defrost freezer is in place, outline the protocol for defrosting and provide a backup location/unit for appropriate storage and monitoring while defrosting:

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| **Vaccine Administration:** | |
|  | Screening for VFC eligibility is performed and documented for every immunization visit. |
|  | Documentation of vaccine administration includes address of clinic, patient eligibility, date of vaccine given, date VIS given, VIS publication date, manufacturer, lot number, name and title of vaccinator. Documentation in electronic form is also acceptable. |
|  | Doses are entered into MCIR within 72 hours for all patients under 20 years of age (per state law). |
|  | Adverse events are reported to the Vaccine Adverse Event Reporting System ([VAERS](https://vaers.hhs.gov/)). |

**Additional measures for vaccine storage, handling, and administration:**

**Section 4: Vaccine Ordering and Receiving**

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| **Our location implements the following ordering requirements:** | |
|  | Orders are placed to maintain 1–3-month supply availability.   * To minimize a large loss and to account for shipping delays, CDC recommends ordering when a 1-month supply is on hand. |
|  | The Primary and Backup Coordinator are trained as “E-order Contacts” in MCIR. |
|  | A monthly inventory balance is completed in MCIR and within 10 calendar days of an order. |
|  | Orders are placed in MCIR and supporting documents are submitted timely to the LHD. This includes:   * Temperature logs, Doses Administered Report, Ending Inventory Report, and Borrowing Log. * Documents are dated within 10 calendar days of order. * Missing or out-of-range temperatures require submission of data files/graphs. Missing documents will delay orders, and excursions must have been reported to the LHD. |

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| **Our location implements the following measures for receipt of vaccine orders:** | |
|  | Staff are available to receive vaccine orders at least one weekday other than Monday for at least four consecutive hours. |
|  | The Primary and Backup Coordinator are trained in receiving and storing vaccine. |
|  | Staff is aware to never refuse a vaccine delivery and immediately store the vaccine appropriately. |
|  | Deliveries are inspected to ensure accuracy in quality, lot, expiration, etc., and inventory is uploaded into MCIR as VFC/Public Inventory. |
|  | Delivery or inventory issues must be reported to the LHD within 1 hour of receipt. |
|  | Problems with vaccine viability require contact to the distributor immediately:   * McKesson’s Vaccine Viability Line at 1-877-836-7123 * Merck Reporting Center at <https://cdcshipping.merck.com/> |

**Additional measures for vaccine ordering and receiving:**

**Section 5: Vaccine Inventory Control and Stock Rotation**

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| **Our location implements the following measures for inventory control and stock rotation:** | |
|  | Our location stocks and offers all routine ACIP-recommended vaccines for our patient population. |
|  | Our location has a written plan outlining the process for referring or outlining another option for making non-routine ACIP recommended vaccines available to VFC eligible patients. |
|  | Vaccine is clearly labeled to separate VFC and private stock. |
|  | Staff are trained to ensure they understand patient eligibility and which stock to pull from. |
|  | Staff are diligent to avoid borrowing. Borrowing is a rare, unexpected occurrence. |
|  | All borrowed doses are documented in MCIR and the vaccine borrowing log. Borrows are replaced as soon as private stock is available or within 90 days. |
|  | Vaccine is rotated weekly, placing soon-to-expire vaccine up front to be used first. |
|  | If vaccine expires in 3-6 months and there is concern about using the doses in time, a reminder/recall will be performed, the LHD will be notified regarding this concern, and the VFC Loss Policy outlined in the [VFC Provider Manual](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Adult-and-Childrens-Services/Children-and-Families/Immunization-Information/VFC/Overview/Michigan-VFC-Provider-Manual.pdf?rev=4db13c5904bb45a59782948db971155d&hash=437C4AAD0DF6AC8982605067661F666D) will be followed. |
|  | Any expired vaccine/diluent is removed immediately. Additional steps listed in Section 6 below. |
|  | For sites that use HL7/EMR transfer, transfer reports are run routinely to identify data entry errors that could result in inventory inaccuracies. Inaccuracies are corrected immediately. |

**Additional measures for inventory control and stock rotation:**

**Section 6: Vaccine Loss and Waste**

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| **Our location implements the following measures for vaccine loss and waste:** | |
|  | All vaccine loss and waste are reported in MCIR. This involves appropriate transactions to remove vaccine from inventory and generating a return/waste report for submission in MCIR. |
|  | Return/waste reports must be submitted in MCIR at the time of orders or on a monthly basis. This allows our location to identify an action plan to reduce further loss/waste. It also ensures a return label is sent to the Primary for VFC vaccine that must be returned (e.g., expired doses). Doses are replaced with privately purchased vaccine. Detailed steps can be found in the [VFC Provider Manual](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Adult-and-Childrens-Services/Children-and-Families/Immunization-Information/VFC/Overview/Michigan-VFC-Provider-Manual.pdf?rev=4db13c5904bb45a59782948db971155d&hash=437C4AAD0DF6AC8982605067661F666D). |
|  | Replacement occurs as soon as stock is available or within 90 days. |
|  | Vaccine wastage is documented in MCIR and disposed of according to [state regulations](https://www.michigan.gov/-/media/Project/Websites/mdhhs/Folder3/Folder41/Folder2/Folder141/Folder1/Folder241/Disposing_of_Unused_or_Expired_Vaccine_in_Michigan_2132018.pdf?rev=54d6da57dd5342ab931d3cc0e701084b). |
|  | The transaction “unable to locate’ is only used with LHD approval. Vaccine accountability must be ensured, and mismatches in balancing may indicate an error in data entry. |
|  | Vaccine wastage due to excursions or mishandling must be replaced dose-for-dose and reported in MCIR, as well as reported to the LHD. |
|  | Borrowed doses are documented in MCIR and on the handwritten [vaccine borrowing log](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Adult-and-Childrens-Services/Children-and-Families/Immunization-Information/VFC/Required-to-Post/Vaccine_Borrowing_Log.pdf?rev=e9678b7a92b348d9883c907ef3d9100a&hash=912E777AF47C320226B1825BF06517DF). |

**Additional measures for vaccine loss and waste:**

**Section 7: Staff Training**

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| **Our location implements the following training according to VFC requirements:** | |
|  | VFC Primary and Backup Coordinator complete the required annual training every 12 months.   * [Annual Training](https://www.michigan.gov/-/media/Project/Websites/mdhhs/Folder3/Folder39/Folder2/Folder139/Folder1/Folder239/VFC_Annual_Training.pdf?rev=bc73d6e227fb4f37b9c004e9831450a6) includes “Vaccines for Children” and “Vaccine Storage and Handling”. * Annual training meets MDHHS requirements (site visit, You Call the Shots, etc.). * The LHD may require additional trainings as needed. |
|  | The VFC Primary and Backup Coordinator have received initial MCIR VIM training.  **Note**: Train staff on routine vaccine storage and handling and emergency response. Document participants and trainings dates. A training log is supplied below in this plan. Training should be completed:   * as part of new employee orientation. * annually as a refresher for all staff involved in immunization and vaccine storage and handling. * when new vaccines are offered or when storage and handling recommendations change. |

**Additional measures for staff training:**

**Staff Vaccine Training Log**

Utilize the tool below to track trainings received. While the VFC Primary and Backup must receive annual training, it is highly recommended to train all staff involved in vaccine-related activities.

**Below are frequently used vaccine training resources:**

1. CDC online web modules: [You Call The Shots | Vaccine Trainings](https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/index.html)

2. CDC [You Call the Shots - Module Eighteen - Vaccine Administration](https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp)

3. Michigan Immunization Nurse Educations sessions. Please contact your LHD for availability.

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**EMERGENCY RESPONSE PLAN**

**Post this plan on the vaccine storage unit or in another prominent location.**

The following section includes space for information and necessary actions to take in the event of an emergency such as a unit malfunction, power outage, human error, etc.

**Section 1: Emergency Contact and Backup Location**

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| --- | --- | --- |
|  | **Name** | **Phone** |
| **Primary Emergency Contact** |  |  |
| **Backup Emergency Contact** |  |  |
| **Contact with 24-hour access to backup Location** |  |  |
| **LHD VFC Contact** |  |  |

All VFC Providers must identify an appropriate backup unit/location even if a power system (e.g. generator) is on-site. This is to ensure there is a location for vaccine storage if the actual unit fails and vaccine must be re-located. **Reminder: test your emergency plan on a regular basis.**

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| **Backup Location** | **Address** | **Phone** |
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**Is an alarm system in place? If so, describe the notification process and testing frequency:**

**Is a power system (i.e. generator or back-up battery) in place? If so, describe system and testing frequency:**

**Section 2: Excursion Protocol-Responding to Out-of-Range Temperatures**

Any out-of-range temperature is considered a temperature excursion and requires immediate action. If you are not confident in identifying an excursion or any part of this process, contact you LHD for assistance. **Providers are responsible for following through on an excursion and must notify their LHD immediately**. Do not administer vaccine exposed to excursions until vaccine viability is confirmed.

Each event is unique and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar. Therefore, **all excursions** require appropriate notification and follow-up to ensure vaccine viability determinations are made. If any temperature is out of range, follow these steps:

**Identify and Notify**

1. Stop vaccination from the unit in question or with the vaccine in question.
2. Implement an immediate corrective action if able (shut door if left open, resupply power, etc.).
3. Place exposed vaccine in a separate container within the unit and label **DO NOT USE**. Do not discard the vaccine(s).
4. Notify your Primary Coordinator, Backup Coordinator, or supervisor.

**Download and Evaluate Details of Event**

1. Download DDL and review all data. If multiple excursions have occurred, manufacturers will utilize the cumulative exposure time and temperatures.
2. Document all details of the event and ensure the LHD is notified and has been provided data points.
3. If the unit is not stabilizing, implement the Emergency Response Plan for transport to the backup location or unit. Utilize CDC’s guidance when packing for emergency transport and always transport with a DDL.
   1. Ensure appropriate transport; see [MDHHS Guidance on Vaccine Transport](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Folder3/Folder16/Folder2/Folder116/Folder1/Folder216/MDHHS-Guidance-on-Vaccine-Transport.pdf?rev=6db6b53e9f2f4283b8dedb845bd5921b&hash=AF5B2A5709C7FB7A928F5B77D3504736).
   2. When packing refrigerated vaccine in an emergency, see CDC’s guidance on [Packing Vaccines for Transport during Emergencies](https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf).
   3. Print and utilize the [Vaccine Transport Temperature Log](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Adult-and-Childrens-Services/Children-and-Families/Immunization-Information/Clinical/Temp-Logs/Vaccine-Transport-Temperature-Log.pdf?rev=1ced32c75b3743b4bb0f8e86f3f10d33&hash=93FDF96ECF3E082AB1B08D5878C4D29C).

**Contact Manufacturers and LHD**

1. Contact vaccine manufacturers for viability decisions. They will request excursion temperatures, time, vaccines, etc. Contact information is located in the Emergency Response Worksheet.
2. Contact the LHD and provide all documentation, including manufacturer reports. Details for vaccine losses can be reviewed in the MDHHS VFC Loss Policy in the [VFC Provider Manual](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Adult-and-Childrens-Services/Children-and-Families/Immunization-Information/VFC/Overview/Michigan-VFC-Provider-Manual.pdf?rev=4db13c5904bb45a59782948db971155d&hash=437C4AAD0DF6AC8982605067661F666D).

**Additional measures for excursions:**

**Section 3: Emergency Response Worksheet**

Utilize this worksheet to track transported vaccine or vaccines exposed to out-of-range temperatures. Document temperature information, and decision on viability after contacting the manufacturers.

|  |  |  |
| --- | --- | --- |
| **Excursion Discovered** | **Time at Discovery:** | **Temp at Discovery:** |
| **Review Details** | **Total time out-of-range:** | **Max or min temp reached:** |
| **If transport occurs** | **Time at start of transport:** | **Temp at start of transport:** |
| **Time at end of transport:** | **Temp at end of transport:** |

**Excursion follow-up:** Utilize the tool below for vaccine exposed to out-of-range temperatures.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Vaccine** | **VFC or Private** | **Lot** | **Number of Doses** | **Manufacturer Decision Regarding Viability** |
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| **Manufacturer Contacts** | **Phone** | **URL or Email** |
| AstraZeneca | 1-800-221-1638 | - |
| Bavarian Nordic | 1-844-422-8274 | medical.information\_NA@bavarian-nordic.com |
| CSL Seqirus | 1-855-358-8966 | customerservice.us@seqirus.com |
| Dynavax | 1-877-848-5100 | contact@dynavax.com |
| GlaxoSmithKline (GSK) | 1-888-825-5249 or  1-866-475-8222 | [Home | GSK US Medical Affairs](https://gskusmedicalaffairs.com/) |
| MassBiologics | 1-800-457-4626 | - |
| Merck | 1-877-829-6372 | <https://cdcshipping.merck.com/> |
| Moderna | 1-866-663-3762 | [ModernaPV@modernatx.com](mailto:ModernaPV@modernatx.com) |
| Novavax | 1-844-668-2829 | <https://www.novavax.com/contact-us/email-us> |
| Pfizer | 1-800-438-1985 | <https://www.pfizermedicalinformation.com/> |
| Sanofi Pasteur | 1-800-822-2463 | <http://www.sanofiusmedicalinformation.com> |

**Section 4: Transport**

The requirements below apply to vaccine monitoring during transport. Transporting vaccine is not recommended and should only occur in an emergency. Improper packing can affect the viability of vaccine.

* Notify the LHD before any transport of VFC vaccine (or ASAP if transport occurs after-hours).
* **Important**: Different transport situations necessitate different methods of packing. For example, methods differ between emergency transport versus planned transport.
* Follow guidance for methods, packing, and temperature monitoring found in the [MDHHS Guidance on Vaccine Transport](https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Folder3/Folder16/Folder2/Folder116/Folder1/Folder216/MDHHS-Guidance-on-Vaccine-Transport.pdf?rev=6db6b53e9f2f4283b8dedb845bd5921b&hash=AF5B2A5709C7FB7A928F5B77D3504736) and [CDC Storage and Handling Toolkit](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf).
* **DO NOT USE** dry ice, cold packs from vaccine shipments, or soft-sided food/beverage coolers.

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| **Our location utilizes the following materials for transport:** | |
|  | Portable vaccine refrigerator/freezer units (preferred option). |
|  | Qualified cooler built for vaccine transport (cool cube, TempArmour, etc.). |
|  | Hard-sided cooler/container or Styrofoam (for emergency transport only). |
|  | Proper coolant materials such as frozen water bottles that can be conditioned (for emergency transport only), or qualified materials such as inserts for vaccine orders. |
|  | Certified, calibrated continuous monitoring DDL for all coolers utilized. |
|  | Insulation materials: bubble wrap and cardboard (for emergency transport only). |
|  | Printed copy of the [CDC Packing for Emergency Transport](https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf) guidance. |
|  | Printed copies of Vaccine Temperature Logs:   * Frozen vaccine transport: MDHHS, CDC, and Merck **DO NOT RECOMMEND** transporting frozen varicella-containing vaccines. * If frozen vaccine must be transported in an emergency, use a portable vaccine freezer unit or qualified container and pack-out that maintains temperatures between -58.0°F to +5.0°F (-50.0°C to -15.0°C). |

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| **Our location implements the following measures for monitoring temperatures in transport:** | |
|  | A certified, calibrated DDL must be used to monitor and record temperatures. |
|  | Temperatures are recorded at the start and end of transport. Temperatures must be documented hourly if longer than 1 hour. |
|  | If an excursion occurs due to improper packing, manufacturers must be contacted to determine vaccine viability. |

**Additional measures for transport:**

This document was updated by the Michigan Department of Health and Human Services – Division of Immunization. Please visit the [Vaccines for Children (VFC)](https://www.michigan.gov/mdhhs/adult-child-serv/childrenfamilies/immunizations/healthcare/vfc) Resource Webpage for more information. Questions regarding this document can be sent to the LHD within the provider’s county or jurisdiction or to MDHHS at [checcimms@michigan.gov](mailto:checcimms@michigan.gov).