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).

For a list of acronyms used in this document, see page 13.

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

VACCINE MANAGEMENT PLAN

PRACTICE NAME	
VFC PIN	

DATES OF REVISION	SIGNATURE OF INDIVIDUAL RESPONSIBLE FOR CONTENTS OF PLAN

DIGITAL DATA LOGGERS (DDL): CALIBRATION AT A GLANCE

Use this table to quickly update calibration*due dates. Ensure your backup DDL(s) are included in this list!

DATA LOGGER ID	CALIBRATION DATE	NEXT CALIBRATION DUE	R=REFRIG F=FREEZER B=BACKUP		DATA LOGGER ID	CALIBRATION DATE	NEXT CALIBRATION DUE	R=REFRIG F=FREEZER B=BACKUP

Ensure all DDL are up to date for calibration (not expired). This information is found on the certificate of calibration and on the back of some devices. Certificates are reviewed at VFC site visits.

Section 1: Key Contacts

	NAME	PHONE	EMAIL
Vaccine Primary Coordinator			
Vaccine Backup Coordinator			
Optional/Additional Contact			
Local Health Department (LHD) VFC Contact			

Section 2: General Management

Our practice implements the following general requirements:

☐ The Michigan VFC Resource Guide is utilized to ensure up to date VFC requirements and templates are in place. The website is bookmarked on our computer: www.michigan.gov/VFC.
☐ Changes to key staff will be reported to LHD/MDHHS immediately.
☐ Documents are maintained for at least 3 years.
☐ Key staff are available for site visits: at least every 24 months (annually in some regions).

Section 3: Storage, Handling and Administration

Our practice implements the following measures for vaccine storage and handling: 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 maintain 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 temperature.
☐ Units meet CDC and MDHHS/LHD requirements outlined at www.michigan.gov/vfc.
☐ Units can store largest inventory without overcrowding (e.g., back-to-school, flu).
☐ Units are dedicated to vaccine storage- no food or beverage are in any vaccine unit.
☐ Vaccines are stored in original packaging.
☐ Vaccines are stored centrally in 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 manufacturer indicated otherwise).
☐ "Do Not Unplug" signs are present at outlets and circuit breaker.

Additional measures may be in place to prevent accidental disconnection from power:
☐ Plug guards are in placed **(required for LHDs)**.

☐ Units are hard-wired into power supply, with no outlet.
☐ Comprehensive policy in place for measures taken to prevent accidental disconnection.

Temperature monitoring:

☐ Temperature monitoring device meets all CDC and MDHHS VFC requirements.
☐ Digital Data Logger (DDLs) are in all units and have an up-to-date certificate of calibration.
☐ At least one extra/**backup** data logger is available and has an up-to-date certificate of calibration certificate.
☐ 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.
☐ Data loggers 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 are followed per VFC requirements and Emergency Response plan.
☐ **LHD-required**: External alarm system in place and weekly temperature calibration documented; protocols in place for testing.

Complete table below for ALL units storing vaccine:

UNIT & BRAND (ex: Fridge, Follet)	TYPE:		GRADE:			
	STAND-ALONE	COMBO	PHARMA.	COMMERICAL	HOUSEHOLD	DATA LOGGER?
1.	☐	☐	☐	☐	☐	☐
2.	☐	☐	☐	☐	☐	☐
3.	☐	☐	☐	☐	☐	☐
4.	☐	☐	☐	☐	☐	☐
5.	☐	☐	☐	☐	☐	☐
6.	☐	☐	☐	☐	☐	☐
7.	☐	☐	☐	☐	☐	☐
8.	☐	☐	☐	☐	☐	☐
9.	☐	☐	☐	☐	☐	☐
10.	☐	☐	☐	☐	☐	☐

Defrost Plan: If a *manual* defrost freezer is in place, outline your protocol for defrosting and provide a backup location/unit for appropriate storage and monitoring while defrosting:

Vaccine Administration:

☐ Screening for VFC eligibility is performed and documented for every immunization visit.
☐ Documentation of administration includes address of clinic, patient eligibility, date of vaccine given, date VIS given, VIS publication date, manufacturer, lot number, name & title of vaccinator (may be electronic)
☐ Doses are entered into MCIR within 72 hours for all patient under 20 years of age (per state law).
☐ Adverse events are reported to the Vaccine Adverse Event Reporting System (VAERS):

Additional Measures for Vaccine Storage, Handling and Administration:

Section 4: Vaccine Ordering and Receiving

Our practice implements the following ordering requirements:

☐ Orders are placed to maintain 1–3-month supply on hand.
- CDC recommends ordering when 1-month supply is on hand (to minimize l large loss and have inventory on-hand in case of shipping delays).

☐ The Primary and Backup Coordinator are training "E-order contacts" in MCIR.
☐ A "balance" is completed on MCIR monthly and within 10 calendar days of an order.
☐ Orders are placed in MCIR and supporting documents are submitted timely to the LHD.
- Temperature logs, Doses Administered Report, Ending Inventory Report, and Borrowing Log
- Documents submitted and dated to reflect within 10 calendar days of order.
- Missing or out-of-range temps require submission of data files/graphs. Missing documents will delay orders, and excursions must have been reported to the LHD.

Our practice 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 appropriately.
☐ Deliveries are inspected to ensure accuracy in quality, lot, expiration, etc., and that the inventory uploaded into MCIR "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 Loss and Waste

Our practice implements the following measures for inventory control and stock rotation:

☐ Our clinic stocks and offers all ACIP-recommended vaccine for our patient population.

☐ vaccine is clearly labeled to separate VFC and private stock.

☐ Staff is trained to ensure they understand patient eligibility and which stock to pull from.

☐ Staff is diligent to avoid borrowing. Borrowing is a rare, unexpected occurrence.

☐ All borrows are documented in MCIR and the borrow log. Borrows are replaced as soon as private stock in available (and 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 we are concerned about using the doses in time, we will perform reminder/recall, notify the LHD and take steps in the VFC Loss Policy at www.michigan.gov/vfc.

☐ Any expired vaccine/diluent is removed immediately. Additional steps in section 6.

☐ For site that use HL7/EMR transfer, transfer reports are run routinely to identify data entry errors that could results in inventory inaccuracies. These are corrected immediately.

Additional Measures for Inventory Control and Stock Rotation:

Section 6: Vaccine Loss and Waste

Our practice implements the following measure for vaccine loss and waste:

☐ All vaccine loss and waste are reported in MCIR. This involves appropriate transactions to remove 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 monthly. This allows our practice 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 (eg., expired doses). Doses are replaced with privately purchased vaccine. Steps detailed at www.michigan.gov/VFC.

☐ Replacement occurs as soon as stock is available and within 90 days.

☐ Vaccine wastage is documented in MCIR and disposed of according to state regulations.

☐ 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 LHD.
☐ Borrowed doses are documented in MCIR and on the handwritten borrow log (www.michigan.gov/vfc).

Additional Measures for Vaccine Loss and Waste:

Section 7: Staff Training

Our practice implements the following training according to VFC requirements:

☐ VFC Primary and Backup Coordinator receive required annual training, every 12 months.

- Annual Training covers 'Vaccines for Children" and "Vaccine Storage and handling".
- Accomplished according to 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.
☐ The Primary and Backup Coordinator follow routine and emergency procedures for vaccine shipments, storage and handling, transport, and inventory management.
FYI: Train staff on routine vaccine storage and handling and emergency response. Document trainings with dates and participants. A training log is supplied 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

Utilized this tool for tracking your staff's trainings received. While VFC Primary and Backup MUST receive annual training and document this, it is highly recommended to train all staff.

Below are some resources frequently used for vaccine training:

1. CDC online web modules You Call the Shots
2. CDC Vaccine Administration E-Learn
3. Michigan Immunization Nurse Education session (free and may provide CEU's, Contact your LHD)

NAME	DATE	TRAINING TYPE

EMERGENCY RESPONSE PLAN

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.

POST THIS PLAN ON THE VACCINE STORAGE UNIT OR IN ANOTHER PROMINENT LOCATION.

Section 1: Emergency Contact and backup Location

	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 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 to ensure it works when needed!

BACKUP LOCATION	ADDRESS	PHONE

Is an alarm system in place? If so, describe notification process and testing frequency:

Is a generator or backup battery system 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 to follow through on excursion and **notify their LHD immediately**. Do not administer vaccine exposed to excursions unless/until the LHD advises.

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 temperate 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 immediate correctional action if able (shut door if left open, resupply power, etc.).
3. Please exposed vaccine in a separate container within the unit and label "DO NOT USE" Do not discard these vaccines.
4. Notify your clinic's Primary/Backup Coordinator and/or supervisor.

DOWNLOAD AND EVALUATE DETAILS OF EVENT

5. Download data logger and review all data. If multiple excursions have occurred, manufacturers will utilize the cumulative exposure time/temperatures.
6. Document all details of the event and ensure the LHD is notified and provided the data.
7. If unit is not stabilizing, implement Emergency Plan for transport to backup location/unit. Utilize CDC's guidance when packing for emergency transport, and always transport with data logger.

- Ensure appropriate transport; see MDHHS Guidance on Vaccine Transport.
- For packing refrigerated vaccine in an emergency, see CDC Guidance on Packing Vaccine for Transport During Emergencies.
- Print and utilize Transport Temperature Logs.
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CONTACT MANUFACTURERS AND LOCAL HEALTH DEPARTMENT

8. Contact vaccine manufacturers for viability decisions. They will request excursion temperatures, time,

vaccines, etc. Contact information is in the Emergency Response Worksheet.
9. Contact the LHD and provide all documentation, including manufacturer reports. Details for vaccine losses can be reviewed in the MDHHS VFC Loss Policy at www.michigan.gov/vfc.

Additional Measures for Excursions:

Section 3: Emergency Response Worksheet

Utilize this worksheet to track transported vaccine or vaccines exposed to out-of-range temperature. Document temperature information, and decision on viability when call 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 this for vaccine transported or exposed to out-of-range temperatures.

VACCINE	VFC OR PRIVATE	LOT	DOSES	MANUFACTURER DECISION

MANUFACTURER CONTACTS

Dynavax: 1.844.375.4728
GlaxoSmithKline: 1.888.825.5249 **or** https://gskusmedicalaffairs.com/
Janssen (Johnson & Johnson): 1.800.565.4008
AstraZenica: 1.877.633.4411
Merck: https://cdcshipping.merck.com/
Moderna: 1.866.663.3762
Novavax: 1.844.668.2829
Pfizer: 1.800.438.1985
Sanofi Pasteur: 1.800.822.2463 **or** http://www.sanofiusmedicalinformation.com
Seqirus: 1.855.358.8966

Section 4: Transport

The below requirements apply to vaccine monitoring during transport. Transporting vaccine is not recommended and should only occur in an emergency. Improper packing is as risky as a failed unit.

- 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. MDHHS Guidance on Vaccine Transport and CDC Storage and Handling Toolkit.
- Do **NOT** use dry ice, cold pack from vaccine shipments, or soft-sided food/beverage coolers.

Our clinic utilizes the following materials for transport:

☐Portable vaccine refrigerator/freezer units (preferred option)
☐Qualified cooler built for vaccine transport (cool cube, temp Armour, 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 data logger for all coolers utilized.
☐Insulating materials: bubble wrap and cardboard (for emergency transport only)
☐A print-out of the CDC Packing for Emergency Transport (put into coolers and with this plan)
☐Printed copies of Vaccine Temperature Logs

- Frozen vaccine transport: MDHHS, CDC and Merck do NOT recommend transporting frozen varicella, containing vaccines. If these 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 +50.0°F (-50.0°C to -15.0°C).

Our practice implements the following measure for monitoring temperatures in transport:

☐A certified, calibrated data logger must be used to monitor and record temperatures.

☐Temperatures are recorded at start and end of transport (hourly if longer than 1 hour)

☐If an excursion occurs due to improper packing, manufacturers are contacted for stability.

Additional Measures for transport:

LIST OF ACRONYMS

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 & Human Services
VFC	Vaccines for Children
VIM	Vaccine Inventory Module