Vaccines for Children (VFC) Program Vaccine Accountability and Management Plan Year

The VFC Program requires each facility to develop and maintain a Vaccine Management Plan for routine and emergency situations involving federally and state supplied vaccine. The plan should include practice-specific guidelines, protocols, and contact information. The plan must be submitted to the Mississippi State department of Health (MSDH) annually and when changes occur. This plan should be kept near vaccine storage units and made available to the Mississippi State Department of Health (MSDH) staff upon request.

FACILITY NAME	VFC PIN	
FACILITY ADDRESS		

EMERGENCY CONTACT LIST	Name	TITLE (MD, DO, NP)	PHONE	EMAIL
MEDICAL DIRECTOR				
VACCINE COORDINATOR				
BACK-UP VACCINE COORDINATOR				
OTHER				

Vaccines must be maintained within the manufacturer's temperature requirements in order to remain viable to administer to patients.

Does your facility have a back-up or built-in generator?

Yes

No

Back-up and built-in generators **MUST** be tested quarterly, serviced annually based on manufacturer specifications for testing and maintenance schedules. The facility should have enough fuel on hand to continuously run the generator for at least 72 hours.

List the Emergency Vaccine Storage Facility below that staff will transport vaccine to in the event vaccine storage unit(s) experience a malfunction, power failure, natural disaster, or other emergency that might compromise appropriate vaccine storage.

NOTE: An emergency vaccine storage location is <u>required</u> even with the availability of a back-up or built-in generator, in case of generator or storage unit failure. <u>Residential locations are not allowed as vaccine storage locations</u>.

EMERGENCY VACCINE		EMERGENCY STORAGE	
STORAGE FACILITY		FACILITY CONTACT PERSON	
EMERGENCY STORAGE		EMERGENCY STORAGE	
FACILITY PHYSICAL			
ADDRESS		FACILITY PHONE	
	DRIVING DIRECT	TIONS	

USEFUL CONTACTS	NAME	PHONE
UTILITY/POWER COMPANY		
BUILDING MAINTENANCE		
VACCINE STORAGE UNIT MAINTENANCE & REPAIR		
TEMPERATURE MONITORING DEVICE COMPANY		
MISSISSIPPI STATE DEPARTMENT OF HEALTH	Immunization Program	601-576-7751
VACCINE MANUFACTURER	GlaxoSmithKline	866-475-8222
VACCINE MANUFACTURER	Merck	877-829-6372
VACCINE MANUFACTURER	Novartis	877-683-4732
VACCINE MANUFACTURER	Pfizer	822-438-1985
VACCINE MANUFACTURER	Protein Sciences	800-488-7099
VACCINE MANUFACTURER	Sanofi Pasteur	800-822-2463
VACCINE MANUFACTURER	Segirus USA, Inc	888-435-8633

VACCINE STORAGE UNITS & DIGITAL DATA LOGGER (DDL)	Vaccine Storage Unit #1	Vaccine Storage Unit #2	Vaccine Storage Unit #3	Vaccine Storage Unit # 4
REFRIGERATOR OR FREEZER				
LOCATION IN FACILITY				
PHARMACEUTICAL GRADE OR COMMERCIAL/HOUSEHOLD				
STORAGE UNIT'S SERIAL #				
STAND-ALONE UNIT OR COMBO UNIT DORM STYLE & FREEZER OF A COMBO UNIT NOT ALLOWED				
DATE OF LAST ROUTINE MAINTENANCE OF STORAGE UNIT				
IS THE STORAGE UNIT APPROPRIATELY LINED WITH WATER BOTTLES? YES OR NO				
DIGITAL DATA LOGGERS (DDL) DATA MUST BE DOWNLOADABLE				
DIGITAL DATA LOGGER (DDL) SERIAL #				
DATE THE DIGITAL DATA LOGGER (DDL) WAS CALIBRATED				
DATE THE CALIBRATION EXPIRES				
Dual or Single Probe?				

LOCATION OF BACK-UP CERTIFIED DIGITAL DATA LOGGER (DDL)	TYPE OF DIGITAL DATA LOGGER (DDL)	SERIAL#	CALIBRATION DATE	CALIBRATION EXPIRATION DATE

On-Site Location of Emergency Transport Supplies	LOCATION OF EMERGENCY FROZEN WATER BOTTLES (CONDITION BEFORE USE)	Number of Hard-Sided Coolers	1 Inch of Insulating Material is On Hand (ex: Newspaper, Bubble Wrap, Foam)

VACCINE ACCOUNTABILITY

Submit an updated Vaccine Accountability & Management Plan when facility changes occur (including staff changes)

Facility staff members must understand, screen, and document VFC/CHIP eligibility at EVERY immunization encounter prior to selecting the vaccine stock source to utilize prior to administration

A person must be 18 years or younger, and meet one of the following criteria to be eligible to receive VFC vaccine:

- Medicaid eligible
- Uninsured
- Alaska Native (AN)
- American Indian (AI)
- Underinsured Only an FQHC, RHC, or deputized health department may administer VFC vaccine once insurance coverage for vaccine is verified by the provider prior to administration

Each dose of VFC and CHIP vaccine administered to a patient must be documented in the facility's records and decremented appropriately from vaccine inventory in the Mississippi Immunization Information eXchange (MIIX) to include the following elements:

- Patient name and appropriate identifiers
- Name of vaccine administered
- Date vaccine administered
- Date Vaccine Information Sheet (VIS) was given
- Publication date of VIS
- Name of vaccine manufacturer
- Lot number
- Name and title of person who administered the vaccine
- Address of the clinic where vaccine was administered

VFC and CHIP vaccines are provided through CDC and MSDH. These vaccines should never be charged or billed to a patient or insurance. The vaccine administration fee may be charged or billed to the patient OR insurance but may never be charged to both. VFC eligible patients may not be denied VFC vaccine or reported to collections due to inability to pay vaccine administration fees. Effective January 1, 2020, providers who choose to bill for the administration fee of a non-Medicaid, VFC eligible child may issue only a single bill to the patient within 90 days of vaccine administration.

VFC providers are required to maintain all records related to the VFC program for a minimum of three years. *This requirement applies even in the case of provider retirement or provider location closure*. Upon request, VFC Providers must make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, vaccine storage unit temperature documentation, temperature excursion information, vaccine purchase and accountability records.

VFC providers are required to distribute the current Vaccine Information Sheet (VIS) each time vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (CVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

VACCINE INVENTORY MAINTENANCE

Adequate inventory of vaccine for all patients served (VFC, CHIP, 317, Private) must be maintained and clearly marked to indicate which funding source provided the vaccine. When accidental borrowing occurs between funding sources, a borrowing report should be completed, and the vaccine repaid to the appropriate funding source. **Planned borrowing** as a replacement system is **strictly prohibited.**

VACCINE INVENTORY MAINTENANCE (CONTINUED)

A physical count of each vaccine stock in inventory must be submitted monthly and prior to each vaccine order using the Inventory Reconciliation tool in MIIX. Vaccines should be rotated to keep shorter-dated vaccines in front of longer-dated vaccines. Vaccine orders should reflect the most recent Provider Profile submitted and placed as follows:

- VFC vaccine should be ordered monthly to maintain a four-to-six-week stock of vaccine at all times. All efforts should be made to prevent borrowing from other vaccine funding sources.
- CHIP vaccine should be ordered quarterly (see MSDH Vaccine Ordering Calendar for specific dates). Should CHIP vaccine become low in between scheduled ordering windows, contact the Immunization Program Ordering Staff to request a one-time manual override order to prevent borrowing vaccine from an alternate funding source.
- Private vaccine should be ordered often enough to maintain at least a four-to-six-week supply to prevent borrowing from an alternate funding source.
- Planned borrowing is STRICTLY PROHIBITED.
- A Vaccination Tool report may be utilized in MIIX to determine quantities of vaccines administered by funding source during the same time frame last year. This report will assist you in determining appropriate amounts of vaccine needed for each funding source in the time frame you are planning and ordering for.
- Prior to order, ensure that vaccines are scheduled to be delivered during current office hours on the most recent VFC
 Provider Profile submission. Notify Immunization Program Ordering Staff if changes are needed <u>PRIOR</u> to placing an order for vaccine.

The VFC Program entitles children to the following vaccines: DTaP, Hepatitis A, Hepatitis B, HIB, HPV, Influenza, Meningococcal, MMR, Polio, Rotavirus, Tdap/Td, and Varicella. VFC Providers are also required to ensure that VFC-eligible children have access to non-routine vaccines as needed.

Expired or spoiled vaccines should <u>NEVER</u> be kept in a vaccine storage unit. Expired or spoiled vaccines should be placed in a container labeled <u>DO NOT USE</u>. A *Vaccine Return Form* (Form 131) should be completed online **within one month** of spoilage or expiration. You will receive an email with a shipping label to use for returning the vaccine to McKesson per CDC requirements.

Wasted vaccines should be disposed of appropriately and documented on the *Vaccine Wastage Form* (Form 132) online. The following vaccines should **NOT BE** returned to McKesson:

- Vaccine syringes that have been opened (with OR without needles)
- Broken or damaged vaccine vials or syringes
- Vaccine vials that do not have the original sealed cap intact

VACCINE TRANSPORT

Accessing Your Building After Hours – An emergency can arise outside of business hours. Your storage and handling SOPs should have written instruction for accessing your vaccine storage units when the building is closed. Keep information on after-hours building access and security procedures (including alarm codes) with the SOPs, and make sure relevant staff members, including building management and security staff, if appropriate, have copies of this information available at home.

VACCINE STORAGE AND HANDLING

Refrigerated vaccine storage units must maintain a temperature range of $36^{\circ}F$ and $46^{\circ}F$ (2° C and 8°). Freezer vaccine storage unit must maintain a temperature range of -58° F and $+5^{\circ}$ F (-50° C and -15° C). Vaccine storage units must have sufficient storage space to accommodate vaccine stock at the busiest times of the year without overcrowding.

CDC recommends the following vaccine storage unit types (in order of preference: pharmaceutical grade standalone or combination units (preferred); household/commercial standalone units; household combination units using the refrigerator section only.

CDC strictly prohibits the use of all dorm-style and bar-style units for vaccine storage. Any VFC or CHIP vaccines stored in these types of units are considered non-viable.

Beginning January 1, 2023, MSDH prohibits the use of the freezer section of household combination units.

Each vaccine storage unit is required to have a **continuous temperature monitoring thermometer device (digital data logger – DDL)** with:

- A current certificate of calibration,
- Buffered temperature probe placed in the central are of unit,
- Ability to display daily minimum and maximum temps,
- Capacity to continuously monitor and record temp data that can be downloaded, and
- Temp display that can be seen outside of the storage unit

One extra digital data logger that also meets these criteria is required to serve as a back-up digital data logger at each facility. The back-up DDL should have a different calibration date from the DDLs in use.

VACCINE STORAGE AND HANDLING (CONTINUED)

The certificate of calibration for each thermometer must contain:

- Model/device name or number
- Serial number
- Date of calibration testing (report or issue date)
- Instrument Passed or Instrument I Tolerance testing

Vaccine must always be stored under appropriate temps as described in the package inserts. Vaccine storage unit temperatures must be monitored and documented to include the following:

- At least one temperature reading per day
- Time and date of each reading
- Name (or initials) of the person who assessed and recorded the readings
- Minimum and maximum temps of each unit once per workday (preferably in the morning)

Temperature Excursions – Complete the following items when vaccine storage unit temperatures deviate from appropriate ranges listed in vaccine package inserts:

- 1. Quarantine and label vaccines as "DO NOT USE"
- 2. Place vaccines in a storage unit where they can be stored under proper conditions
- 3. Contact the vaccine manufacturer(s) to obtain documentation supporting the viability and usability of the vaccine
- 4. Contact the MSDH Immunization Program at 601-576-7751
- 5. Document the information above on your vaccine storage unit temperature logs

Vaccine should only be transported from the physical location of a VFC Provider during an emergency, expected power outage, or with the permission of the Immunization Program to prevent vaccine wastage. The VFC Provider should follow the guidance of the <u>Packing Vaccines for Transport During Emergencies</u> by the CDC at all times during transport. The MSDH District Immunization Representative should be notified as soon as possible when vaccines have been transported for emergent or power outage incidents.

Power Outages – During a power outage, never open the storage unit door until power is restored or it is determined that vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility. If you are unsure how long the power interruption will last, or you determine that power will not be restored in time to maintain proper temperatures inside the unit, implement your emergency vaccine storage, handling, and transport procedures.

Items to maintain vaccine viability and avoid temperature excursions include:

- Completely line each vaccine storage unit, unless pharmaceutical grade, with water bottles to stabilize or extend temps during a power outage.
- Plug each unit directly into a wall outlet and ensure unit is not controlled by a light switch, power strips, or surge protectors with an on/off switch. Never use an extension cord.
- Place a DO NOT Unplug sign near each vaccine storage unit's plug-in.
- Place a CAUTION sign near the circuit breaker box label to indicate which breaker(s) are associated with vaccine storage
 units, and who to contact if power is disconnected.
- Store vaccines in the middle of the unit with space between the vaccines and the side/back of the unit to allow cold air to circulate.
- DO NOT store vaccines in storage unit doors, vegetable bins, drawers, on floor of unit, or near cooling vents.
- NEVER store food, beverages, or laboratory specimens in the units.
- Routinely clean storage unit interiors, keep the outside dust-free, ensure doors have proper seals and follow routine maintenance tasks in the manufacturer's product information.
- Review and follow the CDC Vaccine Storage & Handing Toolkit at: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

SCHEDULE ORDERING

The vaccine coordinator or back-up coordinator will review the facility's schedule for any upcoming, expected facility closures, or staffing shortages that may prevent the completion of vaccine receipt protocols. The coordinator(s) will delay ordering until they can ensure a coordinator will be available to receive the vaccine delivery.

RECEIVING AND INSPECTING VACCINE SHIPMENTS

When a vaccine order has been placed, the vaccine coordinator or back-up coordinator will monitor the tracking number for the expected delivery date. In the event of an unexpected closure when a vaccine delivery is scheduled, the vaccine coordinator or back-up coordinator will be available to receive the vaccine delivery. On receipt of the delivery, the inspection protocols below will be followed.

The vaccine coordinator or back-up should follow the steps outlined below to receive and inspect vaccine deliveries:

NOTE: if **problems** are encountered during any of the following steps or there are any **doubts** that the vaccines may not have been shipped properly, immediately **contact the MSDH Immunization Program Ordering Staff at (601-576-7751 ad the vaccine distributor listed on the packing slip.** *Vaccine deliveries should NOT be refused.*

- 1. Inspect the shipping container and vaccines for signs of damage.
- 2. Determine when the vaccine container was shipped and the amount of time it was in transit to your facility. Compare the acceptable transit time listed on the packing slip to the actual transit time to ensure that the vaccines were delivered in an appropriate amount of time.
- 3. Compare the number of vaccines/diluents received, lot numbers, manufacturers, and expiration dates to the enclosed packing slip.
- 4. Compare the number of vaccines received, lot numbers, manufacturers, and expiration dates of vaccines to the shipment information in MIIX.
- 5. Document receipt of vaccines in MIIX.
- 6. IMMEDIATELY store vaccines in the appropriate refrigerator or freezer vaccine storage unit. Be certain to store vaccines in the appropriately labeled sections of the unit(s) according to the vaccine funding source listed on the packing slip (VFC, CHIP, 317)

Attach copies of the following items to your Vaccine Accountability & Management Plan:

- Vaccine Coordinator's You Call the Shots Certificates of Completion
- Back-Up Coordinator's You Call the Shots Certificates of Completion
- Certificate of Calibration for EACH Vaccine Storage Unit's Digital Data Logger (DDL)
 Certificate of Calibration for the Back-Up Digital Data Logger (DDL)

Please list any facility staff members who have received training related to vaccine storage and handling protocols (optional):

ADDITIONAL STAFF MEMBERS TRAINED TO PERFORM ANY ASPECT OF VACCINE STORAGE AND HANDLING INCLUDING BUT NOT LIMITED TO: TEMPERATURE MONITORING, APPROPRIATE STORAGE AND HANDLING ON RECEIPT, AND / OR EMERGENCY PACK AND TRANSPORT	ANNUAL TRAINING DATE	SIGNATURE OF VACCINE COORDINATOR OR BACK-UP COORDINATOR

By signing this form, I certify that I have read and agree to the Vaccine Accountability & Management Plan items listed and understand I am accountable for compliance with these requirements.		
Primary Vaccine Coordinator Name (print):		
SIGNATURE:	DATE:	
•		
BY SIGNING THIS FORM, I CERTIFY THAT I HAVE READ AND AGREE TO THE VACCINE ACCOUNTABILITY & MANAGEMENT PLAN ITEMS LI. AM ACCOUNTABLE FOR COMPLIANCE WITH THESE REQUIREMENTS.	STED AND UNDERSTAND I	
Back-Up Vaccine Coordinator Name (print):		
SIGNATURE:	DATE:	
•		
By signing this form, I certify on behalf of myself and all immunization providers in this facility as listed on the VFC Provider Agreement, I have read and agree to the Vaccine Accountability & Management Plan items listed and understand I am accountable, and each listed provider is individually accountable, for compliance with these requirements		
Medical Director or Equivalent Name (print):		
SIGNATURE:	DATE:	

Providers must maintain all VFC records for a minimum of three (3) years, regardless of VFC enrollment status.