

Provider Name \_\_\_\_\_

VFC/CV PIN \_\_\_\_\_

Effective Date \_\_\_\_/\_\_\_\_/\_\_\_\_/

Annual Review Date \_\_\_\_/\_\_\_\_/\_\_\_\_/

### VACCINE MANAGEMENT PLAN

This document offers guidance to:

- ✓ Develop and maintain vaccine storage and handling plans to safeguard vaccine supplies and guidance during improper vaccine storage and handling events.
- ✓ Follow appropriate vaccine-ordering procedures.
- ✓ Follow appropriate handling of expired/wasted vaccines.
- ✓ Provide for emergency-response measures.

#### VACCINE STORAGE AND HANDLING GUIDELINES

##### 1. TRAIN STAFF/POST INFORMATION

Post your Vaccine Management Plan on or near the vaccine storage equipment and ensure that all staff is trained regarding the plan.

**The Centers for Disease Control and Prevention’s (CDC’s) *Vaccine Storage & Handling Toolkit* is an excellent resource that provides guidelines on how to protect vaccine supplies. A copy may be accessed online at:**

<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

##### 2. DESIGNATED COORDINATORS

Designate primary and backup coordinators to:

- ✓ Monitor the operation of the vaccine storage equipment and systems.
- ✓ Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shutdown in power.
- ✓ Ensure the appropriate handling of the vaccine during a disaster or power outage.
- ✓ Have access to the building 24 hours a day, 7 days a week (including weekends and holidays).

**NOTE:** The primary coordinator will be responsible for the contents of this Vaccine Management Plan.

|                                     |        |
|-------------------------------------|--------|
| Primary Coordinator:                | Phone: |
| Secondary Coordinator:              | Phone: |
| Additional Staff Member: (optional) | Phone: |

### 3. STORAGE REQUIREMENTS

Follow the following measures as applicable to maintain proper temperatures in refrigerators, freezers, and/or ultra-cold freezers according to the respective requirements of the Vaccines For Children (VFC) program and COVID-19 vaccine.

- ✓ Place plastic water bottles in the refrigerator and frozen water bottles in the freezer.
  - EXCEPTION: If *pharmaceutical-grade* storage units are being used and the manufacturer does not recommend placing water bottles, follow the manufacturer's guidance.
- ✓ Store vaccine on refrigerator shelves in open containers and away from walls and the back of the unit to allow proper air circulation around the vaccine.
- ✓ Do not store vaccine in the door of the refrigerator, vegetable containers/bins (crispers), or on the bottom of the refrigerator.
- ✓ For temperature-monitoring, use on both the refrigerator and freezer units a digital data-logger thermometer with a valid, current certificate of calibration and a probe.
- ✓ Post proper storage temperatures for refrigerator and freezer on each unit.

### 4. EQUIPMENT SAFEGUARD

- ✓ Post warning signs (e.g., DO NOT UNPLUG) on the refrigerator and freezer to prevent inadvertent/accidental unplugging of the unit.
- ✓ Clearly mark fuses and circuit breakers that support vaccine-storage units and post DO NOT UNPLUG signs on these as well.
- ✓ Do not use extension cords to plug in the storage units.
- ✓ Ensure storage-unit doors close appropriately and shut tightly.

### 5. RECEIVING VACCINE

- ✓ Develop and post a protocol for accepting vaccine deliveries that indicates who in the practice may accept vaccine shipments to ensure that vaccines are stored appropriately **IMMEDIATELY** after arrival and according to VFC and COVID-19 storage requirements.
- ✓ Train staff on how to compare the vaccine received with the vaccine invoice.
- ✓ Alert the Louisiana Immunization Program at 504-568-2600 if the vaccine is not in proper condition or the number of doses is different from what is on the invoice.
- ✓ Train staff on storage and handling requirements for each vaccine.

### 6. ROTATE STOCK

- ✓ Ensure that vaccines with the shorter expiration dates are used first and are placed in front of vaccines with longer expiration dates.
- ✓ Check and rotate stock weekly with a monthly review of rotation and documentation.
- ✓ Train staff on stock rotation.
- ✓ Designate the primary coordinator to rotate stock when new vaccine is added to inventory and the backup coordinator to verify rotation and documentation.
- ✓ Contact the Louisiana Immunization Program at 504-568-2600 if vaccines are going to expire within 3-6 months.

### 7. TEMPERATURE MONITORING

- ✓ Designate the primary coordinator to check and record refrigerator and freezer temperatures on a temperature log at least twice daily (once in the morning when the practice opens, and once in the afternoon to allow for adjustments prior to the time the practice closes). Temperature monitoring allows for identifying the duration of temperature variations.
- ✓ Maintain completed temperature logs for at least 3 years.

- ✓ Designate the backup coordinator to review the temperature log at least on a weekly basis to ensure proper temperature recording.
- ✓ Using the IMPROPER VACCINE STORAGE AND HANDLING STANDARD OPERATING PROCEDURE below, train staff on response measures to take if temperatures are out of range.
- ✓ If a temperature outside of the recommended range is found, take immediate action to correct and document the problem as outlined in the IMPROPER VACCINE STORAGE AND HANDLING STANDARD OPERATING PROCEDURE section below.

## **8. VACCINE SPECIAL INSTRUCTIONS**

- ✓ Train staff on the current guidelines for handling individual vaccines that may include special instructions (e.g., protect from light, shelf life after reconstitution).
  - Review Vaccine Manufacturers Package inserts as the primary reference source. Online copies are available from the Immunization Action Coalition at <http://www.immunize.org/packageinserts/>.
  - An additional reference source is the 14<sup>th</sup> edition of *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("The Pink Book") published by the CDC National Center for Immunization and Respiratory Diseases. An online copy may be obtained at <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>.

### **IMPROPER VACCINE STORAGE AND HANDLING STANDARD OPERATING PROCEDURE**

#### **1. ASSESS THE SITUATION**

- ✓ Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
- ✓ Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
- ✓ Record the current temperature of the refrigerator/freezer.
- ✓ Mark the vaccine so that the potentially compromised vaccines can be easily identified.
- ✓ Collect essential data on the Emergency Vaccine Response Worksheet.
- ✓ Call the vaccine manufacturer to receive guidance on whether or not the potentially compromised vaccines are still viable. Alert the Louisiana Immunization Program at 504-568-2600 as well.

#### **2. MOVING VACCINE**

- ✓ If alternative storage is available within your facility, transfer vaccine to that storage unit. If not, contact your backup facility to notify them of your refrigerator failure and the need to store vaccine at their location.
- ✓ Prior to transporting vaccine, record the temperature of the refrigerator(s) and freezer(s). This will provide data on the maximum temperature and duration of exposure of vaccine to inappropriate temperatures.
- ✓ Conduct an inventory before you transport the vaccine.
- ✓ Transport the vaccine following proper cold-chain procedures for storage and handling.
- ✓ Isolate and maintain vaccines at appropriate temperatures and do not administer or discard vaccine until the vaccine manufacturer has been contacted for consultation as to its viability.

#### **3. PACKING VACCINE**

- ✓ Open refrigerated units only when absolutely necessary and only after all preparations for packing and moving the vaccine to alternative storage sites have been made.
- ✓ Use insulated containers.

- ✓ Pack the refrigerated vaccines first with an adequate supply of cold packs (add packing material so that cold packs are not in direct contact with the vaccine).
- ✓ Remove and pack varicella-containing vaccine and zoster vaccine, using frozen ice packs, immediately before it is to be transported.

**NOTE:** Both CDC and the Louisiana Immunization Program do not recommend transporting varicella, MMRV, and zoster vaccines, but if these vaccines must be transported during an emergency, follow the recommendations outlined in the *Vaccine Storage & Handling Toolkit* from CDC. Dry ice is not to be used for storage, even if temporarily.

#### 4. POST EVENT

- ✓ Keep exposed vaccine separated from unaffected product and any new product you receive.
- ✓ Maintain vaccines at appropriate temperatures and do not administer or discard any potentially compromised vaccine until the vaccine manufacturer has been contacted for consultation as to its viability.

### VACCINE ORDERING PROCEDURES

The Document Center of the LINKS registry homepage contains four documents detailing the procedures providers are to follow when ordering vaccines through the Vaccine Ordering and Management System (VOMS). These documents may be accessed at [https://lalinks.org/linksweb/LINKS\\_VFC.html](https://lalinks.org/linksweb/LINKS_VFC.html) and consist of the following:

- ✓ *Placing an Order through VOMS*
- ✓ *Inventory Reconciliation*
- ✓ *Vaccine Descriptions*
- ✓ *Receiving an Order through VOMS*

Providers are advised to contact their Immunization Consultant. Contact information may be found on the LINKS homepage at <https://lalinks.org/linksweb/main.jsp>.

### HANDLING OF EXPIRED/WASTED VACCINE

#### 1. VFC VACCINE

Any and all expired, damaged, and/or non-viable VFC vaccines must be returned to the Louisiana Immunization Program for accounting and reimbursement of the federal vaccine excise tax. Providers are to follow these instructions:

- ✓ Place vaccines in an appropriate shipping container such as an envelope or box.
- ✓ Include a completed copy of the *Vaccine Transfer Report* form which may be printed from LINKS at [https://lalinks.org/linksweb/LINKS\\_VFC.html](https://lalinks.org/linksweb/LINKS_VFC.html).
  - List all vaccines being returned.
  - Make sure that the form is signed and the provider name, VFC PIN, and date are entered on the form.

- ✓ Ship the vaccines to:

Office of Public Health  
 Immunization Program  
 1450 Poydras St., Ste. 1938  
 New Orleans, LA 70112-1938

**2. COVID-19 VACCINE**

Providers will dispose of any and all expired, damaged, and/or non-viable COVID-19 vaccines according to their respective disposal policies. COVID-19 vaccine is **not** to be returned to the Louisiana Immunization Program.

**EMERGENCY RESPONSE PLAN**

**1. BACKUP SUPPLIES/FACILITY**

- ✓ If your practice does not have a backup generator, identify at least one location with one. This may be a local hospital, local parish health unit, retirement home, fire station, police station, or 24-hour store.
- ✓ Make arrangements with the site to store your vaccine if your vaccine storage equipment malfunctions or there is a power outage.
- ✓ Train the primary coordinator and backup coordinator at the facility to accept your vaccine if it must be moved.
- ✓ Before moving your vaccine, call the location to ensure that their backup generator is working.
- ✓ In situations where a location with a backup generator cannot be identified within a reasonable distance (for example, if the site is more than 30 minutes away) and there is a large quantity of vaccine to transport, make preparations to obtain use of a refrigerated truck or purchase coolers and frozen ice packs to temporarily store vaccine.

**BACKUP FACILITIES CONTACT INFORMATION**

| Name of Facility | Name of Primary and Backup Contact | Contact Phone Number Work/Home/Cell |
|------------------|------------------------------------|-------------------------------------|
|                  |                                    |                                     |
|                  |                                    |                                     |
|                  |                                    |                                     |
|                  |                                    |                                     |
|                  |                                    |                                     |

**2. EMERGENCY CONTACT LIST**

Maintain a list of emergency points of contact and their respective telephone numbers. Suggested entities include:

- ✓ Electric Power Company
- ✓ Refrigerator/Freezer Repair Company
- ✓ Temperature Alarm Monitoring Company

- ✓ Transportation to Backup Storage
- ✓ Refrigerated Truck Company
- ✓ Emergency Generator Repair Company

ACKNOWLEDGEMENTS:

\_\_\_\_\_  
Primary Coordinator signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Backup Coordinator signature

\_\_\_\_\_  
Date

APPROVED:

\_\_\_\_\_  
Medical Director signature

\_\_\_\_\_  
Date

Provider Name: \_\_\_\_\_ VFC/CV PIN: \_\_\_\_\_

## EMERGENCY RESPONSE WORKSHEET

1. Date of Event: \_\_\_\_\_
2. Current temperature of refrigerator: \_\_\_\_\_ Max/min temperature reached: \_\_\_\_\_
3. Current temperature of freezer: \_\_\_\_\_ Max/min temperature reached: \_\_\_\_\_
4. Amount of time temperature was outside normal range: refrigerator \_\_\_\_\_ freezer \_\_\_\_\_

### REFRIGERATOR

| Vaccine and Manufacturer | Lot Number | Expiration Date | Amount of Vaccine | Action Taken |
|--------------------------|------------|-----------------|-------------------|--------------|
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |

### FREEZER

| Vaccine and Manufacturer | Lot Number | Expiration Date | Amount of Vaccine | Action Taken |
|--------------------------|------------|-----------------|-------------------|--------------|
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |
|                          |            |                 |                   |              |

### VACCINE MANUFACTURERS

| Manufacturer  | Telephone Number | Recommendations |
|---|------------------|-----------------|
| Sanofi Pasteur <a href="http://www.sanofipasteur.us">www.sanofipasteur.us</a>                                   | 1-800-822-2463   |                 |
| Merck <a href="http://www.merckvaccines.com">www.merckvaccines.com</a>  | 1-800-444-2080   |                 |
| GlaxoSmithKline <a href="http://www.gsk.com">www.gsk.com</a>  | 1-877-356-8368   |                 |
| Pfizer (formerly Wyeth) <a href="http://www.pfizer.com">www.pfizer.com</a>                                      | 1-800-438-1985   |                 |
| Seqirus (formerly Novartis)<br><a href="http://www.seqirus.com">www.seqirus.com</a>                             | 1-901-432-3920   |                 |
| AstraZeneca (formerly MedImmune)<br><a href="http://www.astrazeneca.com">www.astrazeneca.com</a>                | 1-877-633-4411   |                 |
| Grifols <a href="http://www.grifols.com/en/home">www.grifols.com/en/home</a>                                    | 1-888-474-3657   |                 |
| Moderna <a href="http://www.modernatx.com">www.modernatx.com</a>  | 1-866-663-3762   |                 |
| Johnson & Johnson / Janssen<br><a href="http://www.janssencovid19vaccine.com">www.janssencovid19vaccine.com</a> | 1-800-565-4008   |                 |