CDC requires each VFC-enrolled provider site to maintain a written Routine Vaccine Management Plan. The following document is a template that contains the minimum information needed to meet this requirement. Your practice may use this template or add additional information relevant to your site's day-to-day operations. None of the information contained in this template may be excluded. This plan must be reviewed and signed by the person responsible for its content annually.

(INSERT PROVIDER HEADER)

Virginia Vaccines for Children (VVFC) Routine Vaccine Management Plan

Provider Name and VVFC PIN	
Primary Vaccine Coordinator Name	
Back-up Coordinator Name	

A. Provider contact information
    a. VVFC requires that each site identify the following Key Staff:
        i. Vaccine Coordinator
        ii. Back-up Coordinator
    b. These individuals must be communicated to VVFC, initially and if any changes occur

B. Roles and Responsibilities
    a. During the enrollment process, VFC providers are required to designate a primary vaccine coordinator and at least one back-up vaccine coordinator for each facility.
    b. The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:
        i. Developing and maintaining the Vaccine Management Plan
        ii. Monitoring storage and handling and vaccine administration practices in the facility
        iii. Overseeing vaccine ordering and notifying the VA Immunization program if vaccines will expire before they are administered
        iv. Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire
        v. Participating in and documenting completion of annual training on VFC requirements
        vi. Storing all required documentation for three years, as required by CDC guidelines
    c. To effectively perform their duties, the vaccine coordinator and back-up coordinator must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management.
    d. VFC providers are required to notify the awardee anytime there is a change in vaccine coordinator staff.

C. Appropriate vaccine storage and handling
    a. Vaccine shipment should be checked upon arrival and stored in the appropriate location (refrigerator or freezer) immediately
    b. Separate refrigerators and freezer units are recommended to store product. Any currently enrolled provider who is using both compartments of a household combination unit that is consistently maintaining the required temperature ranges may continue to do so. If temperature excursions occur that can't be attributed to another

cause (e.g. power outage,) the provider must discontinue use, even if it requires the purchase of a separate freezer unit. Any newly enrolled providers will NOT be allowed to use the freezer compartment of a household combination unit.

c. Both vaccine storage units and circuit breakers must be labeled with "Do Not Disconnect" labels
d. Refrigerators and freezers must comply with the following:
    i. Maintain required storage temperatures year-round
    ii. Have enough space to hold the largest amount of inventory during busiest time (consider respiratory and back-to-school seasons)
    iii. Utilize a working, certified digital data logger inside each storage compartment
    iv. Store only vaccines (no food or drink)
    v. Dormitory-style refrigerators are **not** acceptable to store vaccines as they do not maintain appropriate temperatures (A dormitory-style refrigerator is defined as a combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Note: size is not always an indicator of this type unit.)
    vi. The use of water bottles for temperature regulation in both storage units is recommended when commercial units are used but not for pharmaceutical-grade units.
e. Separate and clearly labeled vaccine inventory for VFC and non-VFC patients is required
f. Temperature monitoring
    i. VFC providers must use a Digital Data Logger (DDL) with continuous monitoring capability and a current and valid Certificate of Calibration Testing in each unit storing public vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, temporary storage following a temperature excursion due to storage unit failure, and mass vaccination clinics.
    ii. To meet VFC program requirements, the DDL must be equipped with:
        1. A temperature probe or sensor
        2. An active temperature display outside the unit that can be easily read without opening the storage unit's door
        3. Continuous temperature monitoring and recording capabilities and the capacity to routinely download data
    iii. Certificates must contain the following:
        1. Model/Device Name or Number
        2. Serial number
        3. Date of calibration (Report or Issue date)
        4. Confirmation the instrument passed testing (Instrument in Tolerance)
        5. Calibration expiration date
    iv. A Back-up DDL is required and must be readily available in case a DDL fails or calibration testing. The back-up DDL should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time. If the backup DDL has the same calibration retesting date, providers must have the unit retested prior to expiration, ensuring that a valid DDL is available for required temperature monitoring.
    v. Back-up DDLs must be maintained on site.

vi. Note: Back-up DDLs should not be stored in the storage unit. This can result in conflicting temperature readings between the back-up and primary DDLs, which may lead to potential confusion.

vii. There are two options available to providers to log temperatures of vaccine storage units:
    1. **Option 1:** Handwrite the temperature on a paper log. The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location. A printable temperature log can be found on the VVFC website in the vaccine storage and handling section at https://www.vdh.virginia.gov/immunization/vvfc/vfcsh/.
    2. **Option 2:** Use a continuous temperature monitoring and recording system that allows providers to electronically document temperature readings. This option is at the VA Immunization program's discretion.

viii. Clinics are required to log the minimum and maximum temperatures at the *beginning* of each clinic day. If the data logger does not show min/max temperatures, then clinics must check and document temperatures *twice* each clinic day (am and pm.)

ix. Clinics are required to log the time and date of each reading as well as the name/initials of the person who assessed and recorded the reading

x. Temperature logs must be kept for three years

xi. Thermometer probes must be located in the center of the unit with the vaccine; thermometers should not be near doors, near/against walls, close to vents, or on the floor of the unit unless the unit is purpose-built

xii. Data logger reports must be downloaded and saved monthly and submitted with each order request

D. Vaccine shipping, and receiving
    a. The vaccine coordinator, back-up or the person listed above to receive the vaccine shipment is immediately contacted
    b. Examine container and contents for physical damage
    c. Check the cold chain temperature monitors to see if temperatures are within the recommended range
    d. Crosscheck contents and expiration dates with the invoice. If there are any discrepancies record store the vaccine appropriately and contact the VVFC program
    e. Check the packing list to determine how long the vaccine was in transit. Contact the VVFC program if the package was in transit more than 24 hours
    f. CDC does not recommend the reuse of the phase change material use in shipments from McKesson to provider offices
    g. McKesson Specialty ships vaccines with a postage-paid return label packed in the inside flaps of the box. Instructions for returning the shipping container to McKesson are on the return slip. If you receive a shipping container that does not include a return label, contact the VFC order center at vvfc@vdh.virginia.gov to request a label. If your clinic receives routine UPS deliveries, you can return the shipping containers by giving them to your UPS delivery person.

E. Vaccine emergency plan
    a. Each site shall fill out and post a written Emergency Response Plan (a template can be found in the vaccine storage and handling section on the VVFC website at this link: https://www.vdh.virginia.gov/immunization/vvfc/vfcsh/; this plan must be reviewed and updated at least annually or more frequently if changes occur
    b. Ensure staff are aware of appropriate procedures in the event of a power outage or mechanical failure
    c. In the event of a temperature excursion, providers must:
        i. Any staff who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor
        ii. Notify staff by labeling exposed vaccines "DO NOT USE" and placing them in a separate container apart from other vaccines (do not discard these vaccines). If these vaccines are determined to be viable, they would still need to be labeled in case they are involved in a future excursion, the manufacturer needs to be made aware of the previous one.
        iii. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem, should begin to document the event with the following information:
            1. Date and time of the temperature excursion
            2. Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
            3. Name of the person completing the report and description of the event:
                a. General description of what happened
                b. The length of time vaccine may have been affected, if using a DDL
                c. Inventory of affected vaccines
                d. List of items in the unit (including water bottles) other than vaccines
                e. Any problems with the storage unit and/or affected vaccines before the event
                f. Other relevant information
        iv. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
        v. Contact the vaccine manufacturer(s) for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.
        vi. Contact the VVFC program to report the excursion
        vii. Complete your documentation of the event, including:
            1. Action taken
                a. What you did with vaccine and how long it took to take action
                b. Whom you contacted and instructions received
                c. What you did to prevent a similar future event
            2. Results
                a. Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)

b. Other comments

d. Document each corrective action whenever temperatures are reported outside of the required range:
   i. **Refrigerator**: 36º F and 46º F (2º C and 8º C)
   ii. **Freezer**: -58º F and +5º F (-50º C and -15º C)
e. Private storage units must adhere to VFC guidelines to serve as emergency storage for VFC vaccines

F. Vaccine Ordering
   a. Conduct a physical vaccine inventory before placing a vaccine order
   b. A complete VFC vaccine inventory must be included with each order
   c. Order all the vaccines the practice needs before the next assigned order
   d. CDC recommends smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit.
   e. Place orders with sufficient inventory (four weeks) on hand to allow time for order processing and vaccine delivery
   f. Complete your VFC order using VOMS (Vaccine Ordering Management System)
   g. Self-paced training for VOMS can be found in the VFC Training section at this link: https://www.vdh.virginia.gov/immunization/vvfc/vfc-training/
   h. Providers who are not intending on stocking COVID19 or other non-routine vaccines must have a planned location for referring patients to receive these vaccines.

G. Inventory Control
   a. Conduct a physical vaccine inventory at least once a month and before ordering vaccines
   b. Maintain enough vaccine supply to meet the needs of the practice's VFC-eligible patients
   c. Maintain accurate records, including purchase invoices, for privately purchased vaccines and make them available upon request to VFC Consultants
   d. Records must be kept for a minimum of three years
   e. Ensure that vaccine that is drawn up and not used is disposed of properly (Refer to Section H, *Vaccine Wastage*, item *f* for vaccine supplies that should not be returned to the distributor.)
   f. Organize vaccines so those with the earliest expiration dates are used first

H. Vaccine Wastage
   a. CDC's expectation is that vaccine wastage remains below 5%
   b. Return expired and/or spoiled vaccine to McKesson for excise tax credit within six months of expiration/spoilage using the DOI Returns/Transfer form
   c. If the practice has vaccine due to expire within three months and will not use it:
      i. Notify the VVFC program about the vaccine;
      ii. Identify VVFC providers in the area to contact and inquire if they may be able to use the soon-to- expire vaccines (the VVFC program may be able to assist); and
      iii. After the transfer is complete, submit the Return/Transfer Form
   d. If vaccine becomes spoiled or expires, remove it immediately from the storage unit, report it to the VVFC program, and complete the Return/Transfer Form
   e. Return unused vials/prefilled syringes to McKesson if unopened and in original packaging
   f. Report but do not return the following vaccine supplies:
      i. Used syringes with or without needles
      ii. Syringes with vaccine drawn up and not used
      iii. Broken or damaged vaccine vials

iv. Multi-dose vials that have already been withdrawn

g. Report spoiled or expired vaccines to the VVFC program before placing a new vaccine order

I. Vaccine Restitution

a. The VVFC Provider Agreement states, "I will comply with the requirements for vaccine management including: Ordering vaccine and maintaining appropriate vaccine inventories, and Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration."
b. The VVFC Provider Agreement also states, "I agree to operate within the VFC program in a manner intended to avoid fraud and abuse as defined in the Medicaid regulations…"
c. Excessive wastage is considered abusive when it is due to negligent inventory management.
d. The agreement states, "I agree to replace vaccine purchased with state and federal funds (VFC, 317), that are deemed non-viable due to provider negligence on a dose-for-dose basis."

J. Employee training

a. All key staff must complete required annual training
    i. Key staff includes the Vaccine Coordinator and Back-up Coordinator
b. Participating in and documenting VFC-related training annually is **REQUIRED** for every vaccine coordinator and their back-up coordinator.
c. There are 4 options for completing annual training:
   1-Participating in a VFC compliance visit.
   2-Completing the Vaccines for Children and Vaccine Storage & Handling Modules of the CDC's You Call the Shots online training.
   3-Complete the CDC's VFC Pre-Test found here:
   https://www2.cdc.gov/vaccines/ed/vfc/vfc/
   4-Review the Annual Training Document.
d. For access to the training and additional information, refer to the VFC Training link found here: https://www.vdh.virginia.gov/immunization/vvfc/vfc-training/
e. Once training is completed, certificates/letters of completion are faxed or emailed to the VVFC regional consultant. To verify a site received a compliance visit, contact the VVFC Regional Consultant or email vvfc@vdh.virginia.gov.

The Vaccine Management plan must be reviewed and/or updated annually or more frequently if changes occur. All information in the plan must be current. A "review date" and signature is required in order to verify that it is current.

Review Date	**Signature of individual responsible for the content**
