Certification of Capacity to Store and Manage Vaccines

I, on behalf of myself and any and all practitioners associated with this medical office, group practice, community/migrant/rural clinic, hospital, or other entity of which I am the physician-in-chief, medical director or equivalent, agree to comply with each of the California Vaccines for Adults (VFA) Program requirements

1. **Comply with Vaccine Storage Equipment Requirements**
   Providers must have appropriate equipment that can store vaccine and maintain proper conditions. Equipment must comply with **VFA vaccine storage equipment requirements**. Providers must have separate refrigerator-only and freezer-only units for storage of vaccines. Dormitory refrigerators are never allowed for vaccine storage. Vaccine storage units must be dedicated to the storage of vaccines. Providers may be required to purchase a new refrigerator or freezer unit if equipment is deemed inappropriate for vaccine storage or not able to maintain appropriate temperature.
2. **Designate an On-Site Vaccine Coordinator and Back-Up Vaccine Coordinator**
   Designate one fully trained staff member to be the primary Vaccine Coordinator and a back-up person to perform the responsibilities when the Vaccine Coordinator is unavailable. Responsibilities are outlined in the **Vaccine Coordinator Guide**. The Provider of Record is responsible for maintaining compliance with annual training requirements for the Vaccine Coordinator, Back-up Coordinator and other clinic staff handling and storing vaccines. Maintain training documentation in each staff member's personnel file.
3. **Follow Established Vaccine Storage Guidelines**
   Set up refrigerator and freezer units properly. Store vaccine in its original packaging and position it 2-3 inches away from walls and floor, and allow space for air circulation. Separate 317-supplied, VFC-supplied vaccine, State General Fund (SGF)-supplied and privately-purchased vaccine. Group vaccines by type and clearly label them. Do not store vaccine in the doors, drawers or bins. Place thermometer probes in the center of the **refrigerator** and **freezer**, in proximity with vaccines. Post "Do Not Unplug" signs to prevent interruption of power to the vaccine storage units, on the electrical outlets and circuit breakers. Plug the refrigerator and freezer into outlets that are not controlled by a light switch. Use plug guards when feasible. Do not store food or drinks in the units. Place water bottles in the refrigerator and ice packs in the freezer to stabilize the temperatures.
4. **Follow Established Guidelines for Vaccine Transport**
   Store 317-supplied vaccines only at the facility stipulated in the Provider Agreement. 317 vaccines may be transferred only in limited situations. Contact the VFA Program for approval prior to transferring vaccines to another 317 provider. Never transfer vaccines to non-317 Program providers or to sites not approved by the Program. Routine re-distribution is never allowed. Transport vaccines only when absolutely necessary and follow the guidelines for proper **refrigerated vaccine transport** and **frozen vaccine transport**. A Vaccine Transport Log for **frozen** and **refrigerated** vaccines must be completed each time vaccines are transported to an alternate or back-up location. Vaccines transported without proper documentation of temperature monitoring may be deemed non-viable.
5. **Use Certified, Calibrated Temperature Monitoring Devices: Digital Data Loggers (DDL)**
   Each storage unit must have a compliant DDL. Place the device in the center of the unit in proximity to the vaccines. Attach the digital display to outside of the storage unit to allow temperature monitoring without opening the door. The practice must have at least one compliant back-up device to use when the primary device is sent for calibration or in case it fails. Store back-up devices in an easily accessible location, and document its location on the practice's Vaccine Management Plan. Practices with multiple vaccine storage units may need more than one back-up device. All temperature monitoring devices must comply with **VFA requirements**: a digital display of current, minimum, and maximum temperatures; minimum accuracy of 1.0°F (0.5°C); a biosafe buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin), a vial filled with loose media (e.g. sand, glass beads), or a solid block of material (e.g. Teflon©, aluminum); and an out of range temperature alarm. Each device must have a valid Certificate of Calibration. Calibrate primary and back-up devices annually, or as recommended by the manufacturer. Calibration should be conducted by a laboratory with accreditation from an ILAC MRA signatory body. Certificates of Calibration conducted by non-accredited laboratories must include required information outlined in the **Program's Checklist for Certificate of Traceability and Calibration**. Keep the Certificate of Calibrations on file and make them available to CDPH Field Representatives upon request. Replace devices deemed no longer accurate within +/-1.0°F (+/-0.5°C) at the next calibration due date. Replace batteries, if required, every 6 months. Practices

needing to replace their primary or back-up thermometer will be required to purchase and use data loggers to monitor temperatures.

6. **Store Vaccines at Recommended Temperatures**
   Always maintain vaccines within the recommended ranges. Vaccines stored in freezer (MMR, varicella and zoster) must be maintained between -58.0°F and 5.0°F (-50.0°C and -15.0°C). All other vaccines must be stored in a refrigerator between 35.0°F and 46.0°F (between 2.0°C and 8.0°C).
7. **Monitor and Record Refrigerator and Freezer Temperatures Twice a Day**
   The Vaccine Coordinator must monitor and record current, minimum and maximum temperatures in the **refrigerator** and **freezer** twice each day, at the beginning and end of each business day, even if a continuous monitoring device/data logger is used. If temperatures are monitored using a continuous temperature device/data logger, download and review of temperature data should occur every two-week period, or at minimum, monthly. If temperatures are not monitored and documented, or if temperature logs are falsified, the affected vaccines will be automatically deemed non-viable and will be considered a negligent vaccine loss. All employees assigned to monitor and record temperatures must be properly trained on temperature monitoring, use of the clinic's temperature monitoring equipment, and how to respond to out-of-range temperatures. Names of clinic staff with temperature monitoring responsibilities must be documented on approved temperature logs and on the clinic's Vaccine Management Plans, Training Log page. Document completion of required lessons on the training log. Record temperatures on temperature logs. Logs must be legible and completed accurately. Any inadvertent documentation error must be immediately corrected and initialed. Post the temperature logs on the vaccine storage unit doors or in an easily accessible location. When the log is complete for each 15 day period, the supervisor must certify that temperatures recorded on that log are correct and that corrective actions were taken. Maintain completed temperature logs for three years and make them available for review upon request. If a temperature is identified as out of range, take immediate action to prevent vaccine spoilage and to correct the improper storage condition. Report and document all temperature excursions.
8. **Clearly Identify 317, VFC-Supplied Vaccine from Privately-Purchased Vaccine**
   Separate 317 vaccine, VFC vaccine, SGF vaccine and private vaccine, ideally on different shelves, to prevent use on ineligible patients. Clearly label vaccines for easy identification. Maintain accurate and separate stock records, e.g., purchase invoices, for privately-purchased vaccines and make them available upon request.
9. **Maintain and Rotate Stock**
   Conduct a physical inventory of vaccine stock at least once a month and before ordering vaccine. Maintain 317 vaccine inventory to adequately serve the practice's uninsured and underinsured adult patients. Never borrow 317-supplied vaccine to supplement private stock, or vice-versa. Place vaccine with the shortest expiration dates towards the front of the unit and use it first. Store vaccine in its original packaging until it is used. Remove spoiled, expired, and wasted vaccine from the storage unit immediately to prevent inadvertent use. Submit a report of all 317-supplied expired or spoiled vaccines prior to submitting a new vaccine request. Return affected vaccines to the vaccine distributor for excise tax credit within 3 months of expiration/spoilage/wastage.
10. **Monitor Vaccine Storage Unit Capacity to Store Vaccines**
    The Vaccine Coordinator must continually monitor the capacity of the vaccine storage units to ensure adequate space for inventory, especially during flu season. The practice may need to purchase additional vaccine storage units if the size of the current unit cannot accommodate the inventory in a manner consistent with VFA requirements.
11. **Immediately Notify the VFA Program for Storage and Handling Incidents or Vaccine Shipment Issues**
    Take immediate action to prevent vaccine spoilage if the refrigerator or freezer unit experiences an out-of-range temperature, including during extended power outages or unit malfunctions. Depending on the situation, it may be necessary to transport the vaccines as outlined in the clinic's **Vaccine Management Plan**. Mark vaccines exposed to out-of-range temperatures "Do Not Use." Report and document all out-of-range temperatures. Report all shipment discrepancies or issues to the VFA Program immediately.
12. **Order and Account for 317 Vaccines in Accordance with Practice's Patient Estimates and VFA Guidelines**
    The Provider of Record is accountable for every dose of 317-supplied vaccine. Practices order vaccines according to the order frequency, vaccine usage, and inventory at the time the order is placed. Order all vaccines at once; individual vaccine orders are not permitted. Keep track of 317 vaccine doses administered within the ordering period using the **317 Vaccine Usage Log** or equivalent form. Submit a summary of vaccines administered and on-hand inventory with each

vaccine request. Vaccine doses not accounted for or lost due to negligence will be replaced dose for dose by the Provider of Record or the practice organization.

13. **Receive and Unpack Vaccine Shipments Immediately Upon Arrival**
    The practice is responsible for all 317 vaccine shipped to the site. Do not reject vaccine shipments. All staff who might accept the practice's packages must be aware that vaccine shipments require immediate attention. When new shipments arrive, vaccines must be unpacked immediately. Immediately upon receipt, inspect vaccine shipments to verify that the temperature during transport was in range and that the vaccines in the shipment match those listed on the invoice. Immediately report any shipment discrepancy to the VFA Program using the **Vaccine Receiving Log and Checklist**. Notify the VFA Program well in advance of any temporary office closures which may affect the vaccine shipments.
14. **Maintain, Update and Routinely Review Vaccine Management Plans**
    The practice must maintain a **vaccine management plan** for routine and emergency situations. Plans include practice-specific guidelines, protocols and contact information, and staff training. Review and update the plan at least once a year, and when staff with designated vaccine management responsibilities change. Staff with assigned vaccine management responsibilities must review, sign, and date the plans annually and whenever the plans are updated.

To receive 317 vaccines, you must confirm acknowledgement of this agreement. You may be held financially responsible for replacing vaccine doses lost due to negligence if you do not comply with the above requirements.