The management of publicly purchased vaccine is one of the most important responsibilities for VFC providers. Proper vaccine storage and handling procedures and sound vaccine management practices will minimize vaccine loss and waste, and the potential need to revaccinate that could results from administering compromised vaccine. Vaccine loss is costly and the majority of the time, it is preventable. The CDC Vaccine Storage and Handling Toolkit outlines guidance and best practices for vaccine storage and handling. All VFC providers must keep the most current version on the CDC Storage and Handling Toolkit available. The toolkit can be found at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

There are many reasons for vaccine loss, including: heat and/or light exposure, inappropriate freezing, broken vials and syringes, poor reconstitution practices, possible contamination, and missing inventory. The most significant cause of vaccine loss is attributed to poor vaccine management. Vaccine management, storage, and handling procedures must include proper ordering and inventory management practices to prevent vaccine waste and ensure appropriate stock is available by funding type. Maintaining the vaccine potency is a shared responsibility of manufacturers and clinic staff that handle the vaccine until the dose is administered. It is the responsibility of the Kansas Immunization Program to offer education and guidance to providers for proper vaccine management to avoid wasted vaccine.

Each provider’s vaccine management plan and emergency response policies and procedures must be updated annually (sooner if there are changes to the plan), including authorized signature and date. The policies and procedures are written to address management of VFC vaccines in each of the following areas; vaccine storage and handling, vaccine ordering, vaccine borrowing, wasted vaccine, and emergency management. KIP Regional Consultants will review each clinic’s policies and procedures as a component of the VFC compliance site visit and/or unannounced visits.

**Storage and Handling Policy**

1. The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccine in optimal condition. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain. Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless. All VFC vaccine storage and handling requirements and recommendations are in place to ensure the cold chain is maintained.
2. Providers must be available and onsite with appropriate staff to receive vaccine shipments. All staff members who might receive vaccine deliveries must be aware of the importance of maintaining the cold chain. Receiving staff should be trained to immediately notify the VFC primary or back-up coordinator when deliveries arrive so that vaccines are checked in and stored quickly.

3. Vaccines are delivered in accordance with reported clinic hours of operation. Clinic hours must be updated during the provider enrollment process in IV4. Providers may request a change in hours of operation by submitting the change of information form found in KSWebIZ (Reports>VFC Program Forms>VFC Change of Information Form).

4. Upon receipt of a vaccine shipment, providers must immediately unpack vaccines and diluents, store them at recommended temperatures, and document appropriately.

5. When unpacking deliveries, examine the shipping container and vaccines for signs of physical damage. If the provider believes that a vaccine shipment from the central distributor is compromised or there is a problem with the temperature monitors, the provider must contact the Kansas Immunization Program immediately at 877-296-0464.

6. Each facility must designate one staff member to be the primary vaccine coordinator. This person is responsible for providing oversight for all vaccine management within the office and ensuring all vaccines are stored and handled correctly.

7. Each facility must also designate at least one back-up vaccine coordinator who can assume oversight responsibilities in the absence of the primary vaccine coordinator.

8. VFC providers are required to notify the KIP when there are changes in key vaccine staff.

9. The primary and back-up VFC coordinators are required to complete the CDC “You Call the Shots” Storage and Handling module and Vaccines for Children module annually. Information can be found at: http://www.kdheks.gov/immunize/vfc_program.html Although not required, other staff including those receiving and administering vaccines can complete these modules for a better understanding of Storage and Handling and the VFC program.

10. VFC providers are responsible for training their staff on vaccine topics, including but limited to: receipt of vaccine deliveries, proper vaccine storage and handling procedures, routine and emergency vaccine management, and administration of vaccines.

11. VFC providers must develop, maintain, and implement vaccine management plans with clearly written, detailed, and up-to-date standard operating procedures (SOPs) for routine and emergency vaccine management. Plans must include, but are not limited to:
   a. Names and contact information of primary and back-up VFC coordinators
   b. Proper storage and handling practices
   c. Vaccine shipping and receiving procedures
   d. Emergency procedures (for situations such as equipment malfunctions, power failures, or natural disasters)
   e. Procedures for vaccine ordering, inventory control (stock rotation), and handling vaccine wastage, and staff training/documentation of vaccine management, storage and handling.
   f. Plans to ensure that vaccine storage and handling SOPs are easily accessible and kept near the vaccine storage units. All provider vaccine storage and handling SOPs must be reviewed and updated annually (more frequently if plans or coordinators change). A “review date” and signature of the individual responsible for the content is required on all plans.

12. VFC providers must maintain adequate inventory of vaccine for VFC and non-VFC eligible patients. VFC and non-VFC vaccine inventories must be clearly differentiated (VFC, CHIP, 317, State, Private) for reporting and within the storage unit.

13. Vaccine stock must be rotated weekly and upon receipt of new shipments.
14. Expired vaccines must be removed from the unit, packaged, and labeled “Do Not Use”. A return request must be submitted to have expired vaccines returned with the exception of open multi dose vials (which should be disposed of in accordance with clinic policy).
15. VFC providers must utilize storage equipment that properly maintains recommended temperatures at all times.
   a. Refrigerated vaccines must be stored between 36°F and 46°F (2°C - 8°C).
   b. Frozen vaccine must be stored between -58°F and +5°F (-50°C and -15°C).
16. A “dorm-style/bar-style” unit for any VFC vaccine is strictly prohibited.
17. Vaccine storage units must be of adequate size to store the largest inventory at the busiest point in the year without crowding (i.e. flu season or back to school). The CDC also recommends the unit to be large enough to store water bottles in the refrigerator and freezer to stabilize temperature. This recommendation does not apply to pharmaceutical units if the manufacturer indicates that water bottles negatively impact the functionality of the unit.
18. Storage units should be stand-alone refrigerators and freezers, preferably a vaccine or pharmaceutical grade unit.
   Household type units currently in use must have separate doors for the refrigerator and freezer, and each unit must have separate temperature controls. Household units with a single door and/or single temperature control are not acceptable unless the unit is only used for refrigerated vaccine. A separate stand-alone freezer should then be used to store frozen vaccines.
19. A “Do Not Unplug” warning sign must be placed next to the electrical outlets for each vaccine storage unit and on the electrical breaker that services these outlets. Tamper proof plugs are also recommended.
20. VFC providers must have a working thermometer with a current and valid certificate of calibration testing in each storage unit that stores public vaccines. *Note: As of January 1, 2018, all VFC providers must use continuous temperature monitoring devices (data loggers) to monitor vaccines that will be administered to VFC-eligible children. To meet VFC program requirements, the device must also be equipped with a temperature probe (a probe with buffering is recommended) and an active temperature display that can be easily read from the outside of the unit. (Other recommended features include an alarm for out-of-range temperatures, a current minimum and maximum temperature display, a low battery indicator, accuracy of +/-1°F (0.5°C), memory storage of at least 4,000 readings and a user programmable logging interval (or reading rate) recommended at a maximum time interval of every 30 minutes)
21. Calibrated thermometers as described above must have:
   a. A current and valid certificate of calibration testing, including:
      i. Name of the device
      ii. Model and Serial number
      iii. Calibration date and/or calibration expiration date
      iv. Measurement results indicating that the unit passed testing
      v. Documentation of uncertainty is within suitable range (recommended +/-1°F or .5°C).
vi. Backup thermometer calibration dates should be different than the primary thermometer’s calibration date to stagger the need for replacement on the same date.

*Note: KIP supplied datalogger (DDL) will be required as the primary thermometer by 1/1/18.

b. One or more of the following items documented regarding the calibration testing:
   i. Conforms to ISO 17025
   ii. Performed by an ILAC/MRA Signatory body accredited Laboratory List of the ILAC/MRA signatories may be found at: http://ilac.org/ilac-mra-and-signatories/
   iii. Traceable to the standards maintained by NIST
   iv. Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F ($\leq 0.5 \, ^\circ C$) or better
   v. Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.

22. VFC Providers must provide a backup thermometer with a buffered probe that has a certificate of calibration testing meeting requirements. At a minimum, the backup thermometer must be a digital thermometer. DDL must monitor the temperatures of the vaccine during routine storage, time in transport and off site storage.

23. The thermometer must be placed in the center of the unit with vaccines surrounding it. Thermometers must not be placed in unit doors, near or against walls, or close to the floor, ceiling, or vents.

24. VFC providers must have established protocols for reviewing and recording temperature readings twice daily when the office is open. The temperatures of the vaccine storage units, must be manually checked and recorded on a temperature log at in the AM when the clinic opens and in the PM just prior clinic closing. Alarm systems with certified calibrated probes are recommended for notification of out of range temperatures when the clinic is closed.

25. If a cold chain failure is suspected, or there is evidence vaccine has been exposed to temperatures outside the recommended temperature range, providers must follow the instructions found on the KIP Temperature Excursion Worksheet found at: http://www.kdheks.gov/immunize/storage.htm

26. VFC providers must develop contingency plans to assure vaccine viability in the case of natural disasters, power outages, or other emergencies. Such emergency plans might include a backup generator or transporting vaccines to another location which has a generator. Templates for routine storage, handling, and emergency procedures can be found at: http://www.kdheks.gov/immunize/storage.htm. Emergency Response facilities must have vaccine storage units that will maintain proper temperatures and vaccines must be monitored with a certified calibrated thermometer. Vaccine storage units must be appropriate size to accommodate additional vaccine inventories without overcrowding. The staff must have a clear understanding of proper vaccine management while the vaccine is being stored in their facility. It is the responsibly of the VFC provider to ensure that temperature excursions are avoided regardless of where vaccines are stored.
27. Any incident which may call into question the vaccine viability, including incidents of improper vaccine storage and handling, must be reported by phone to the Regional Immunization Consultant immediately. The vaccine manufacturers must be contacted and their written recommendations sent by fax or email to the Regional Immunization Consultant or Consultant on call. Information to report includes: vaccine antigens, length of time vaccines were exposed to temperatures out of recommended range, and the exact temperatures to which the vaccines were exposed. Not all vaccines are non-viable if the temperature excursion and time factors are minimal. Mark vaccines DO NOT USE and leave refrigerated or frozen until the manufacturer and KIP have been notified. The Provider Temperature Excursion Worksheet can be found at: http://www.kdheks.gov/immunize/storage.htm

If the vaccines are determined to be non-viable, please reference the KIP Wasted VFC Vaccine Policy.

Temperature Logs
1. All VFC providers are required to maintain a paper temperature log. Manual temperature logs must be submitted monthly to KIP, unless the VFC provider downloads the appropriate information from a KIP supplied data logger.
2. Temperature logs must be kept on file for a minimum of 3 years, and be available upon request.
3. Temperatures logs must be filled out completely. This includes: exact time temperatures were checked, temperature of the unit, staff initials, etc. In the event a facility is closed, no more than 3 days may pass without the twice daily temperature documentation.
4. Temperatures need to be assessed and documented in the AM when the clinic opens and in the PM just prior to clinic closing. If temperatures are out of range, the Regional Consultant must be contacted immediately by phone. Temperatures will need to return to range, or vaccine moved per emergency plan.

Vaccine Storage Units
There are several manufacturers of vaccine storage units. Samples of these can be found on the KIP website at: http://www.kdheks.gov/immunize/storage.htm.

The KIP does not endorse any specific product or manufacturer. The examples provided are for demonstration purposes only. Each provider is responsible for the terms and conditions of any purchase made.