**Product Storage, Dispensing, Packaging and Inventory**

**Section:** Pharmacy Operations

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** PHARM Core 4, PHARM-OP 4, 7, 13

**ACHC Standards:** DRX11-F, DRX11-H, DRX 11-I

**Policy ID:** 7.23

**Approved by:**

**POLICY**

<insert practice name> employees will store (identify and monitor inventory), dispense, package, label and ship medications in such a way as to comply with DEA and Board of Pharmacy laws and regulations as well as other applicable laws and regulations. **[PHARM Core 4][PHARM-OP 7 (a-d)]**

Proper medication storage protocols will ensure the maintenance of product potency and sterility. Pharmacists and pharmacy technicians will ensure that medications are stored within the temperature ranges specified by their respective manufacturers. Sterile products will not be opened and will be dispensed in their original sealed containers, vials or syringes so that their sterility is compromised. **[PHARM-OP 7 (b)]**

<insert practice name> uses an electronic badge and deadbolt key system which control access throughout the facility including the pharmacy area. This system allows <insert practice name> to control access levels to the facility and specific areas within the pharmacy. Access to the pharmacy area is restricted to authorized pharmacy personnel only which are Pharmacy Technicians and Pharmacists. **[PHARM-OP 13 (a-i)]** All pharmacy equipment is kept in the secured pharmacy area allowing only authorized personnel (pharmacists and pharm techs) to have access to and the ability to lock, unlock, and seal pharmacy equipment. **[PHARM-OP 13 (a-ii)]**

**PROCEDURE**

1. The manufacturer’s product storage guidelines will be followed. These guidelines include shelf life, refrigeration, prevention of cross-contamination, storage location for clean, dry products and proper segregation of products. **[PHARM-OP 7 (a)]**
2. All compounded medication will be stored in accordance with the American Compounding Pharmacist Society guidelines, commercial sources such as Paddock Laboratories’ web site or other reputable source **[PHARM-OP 7 (a-i)]**
3. Medications will be stored in the refrigerator, when required by their manufacturer, FDA, USP Guidelines or other recognized authority. Refrigerator temperature logs will be maintained daily through an electronic temperature monitoring system. **[PHARM-OP 7 (a-i)]**
4. The medication storage refrigerators will be equipped with a monitored alarm and a pharmacy staff member will be notified by the monitoring company when temperatures exceed those allowed by the manufacturers. **[PHARM-OP 13 (b-ii)(d)]**
5. In the event of a refrigerator temperature excursion that sets off the alarm, the on-call pharmacy staff member will visit the pharmacy within one hour and if temperatures continue to exceed those established by the manufacturers, transfer of medications to another monitored refrigerator will be done until repairs can be made. **[PHARM-OP 13 (b-ii)(d)]**
6. The pharmacist or their designees will contact a refrigerator repair vendor the next business day and not move medications back to their original storage refrigerator until temperatures have returned to the accepted range. **[PHARM-OP 13 (b-ii)(d)]**
7. The temperature in the pharmacy will be regulated and maintained within comfortable limits. Room temperature logs will be maintained on each day of business. **[PHARM-OP 7(a-i)]**
8. Medications will be ordered on a daily basis. When medication orders are received the contents will be matched to packing slip to monitor for discrepancies by pharmacy staff. All pharmacy staff are responsible for ordering and receiving medications. Once the order is received the perpetual inventory in <insert pharmacy software> is updated. Pharmacy staff will communicate any discrepancies with a pharmacist and resolve discrepant inventory entries by end of business that day. **[PHARM-OP 7 (a, a- ii)] [PHARM-OP 4 (b)]**
9. <insert practice name> manages its inventory by tracking quantities and NDC codes if available, determining continuous inventories of certain classes of drugs such as Class 2 and controlled drugs, determining what drugs are on the shelf, quantity, in and out date and has established a timeline to monitor and report controlled substances, if discrepancies are noted. **[PHARM-OP 7 (b)] [PHARM-OP 4 (b)]**
10. Cytotoxic agents such as cyclophosphamide, capecitabine and other cytotoxic medications listed by NIOSH are not to be touched by employees and should handling be necessary, it will only be done with use of latex (or similar) gloves. Counting trays used for counting cytotoxic chemicals are to be segregated from others and wiped with alcohol swabs after use. List of NIOSH cytotoxic and hazardous medications are posted on pharmacy drive **[PHARM-OP 7 (c)] [PHARM-OP 4 (c)]**
11. Controlled substances (CII only) will be stored in an automated dispensing cabinet whose access is limited to designated pharmacy personnel. Pharmacists will place received controlled substance inventory into the automated dispensing cabinet upon receipt. When dispensing controlled substance (CII) prescriptions, a pharmacist or designated pharmacy tech will remove inventory from the automated dispensing cabinet, double count dispensed quantities and return the unused stock to the automated dispensing cabinet. CII prescriptions are all original copies signed by prescriber and are good for 90 days from original date on prescription. This class of controlled substances may not have refills and may not be written for greater than a 30 day supply. **[PHARM-OP 7 (a- iii)] [PHARM-OP 13 (a-ii, iii, iv)] [PHARM-OP 4 (b)]**
12. CIII-CV medications are dispensed, stored, and handled just like regular medications. These classes of controlled substances will have orders accepted via paper, phone, or fax. All prescriptions in this class are valid for 6 months from the original date and may contain up to 5 refills. All controlled substances have a annual physical inventory completed in <insert month>. **[PHARM-OP 7 (a- iii)]**   **[PHARM-OP 4 (c)]**
13. Controlled substance prescription reporting is done daily through Atlantic and Associates per State of <insert state> guidelines.
14. <insert practice name>’s labeling process of medications/prescriptions is performed to meet the state and federal laws and regulations to include the following: **[PHARM-OP 4 (a)]**

* Discard date
* Appropriate warning labels
* Pharmacy and provider contact information
* Patient name
* Directions
* Drug name
* Dispense date
* Doctor Name/Prescriber’s name
* Any other appropriate information

1. The pharmacy ensures appropriate handling, storage, and disposal of hazardous materials to ensure safety for employees and consumers. The safety of employees and consumers is ensured by the appropriate handling, storage and disposed of hazardous materials. The pharmacy inventory is managed to ensure all products are received handled and stored and disposed of properly. **[PHARM-OP 7 (c)] [PHARM-OP 13 (c-i)]**

* Handling of Hazardous Material
  1. Employees are to take special care when handling hazardous materials which include chemicals used in compounding and cleaning supplies as well as chemotherapeutic drugs and expired and unsafe pharmaceuticals.
  2. Employees should use gloves when handling chemotherapeutic and chemicals used in compounding. Employees not training in compounding should not perform this function for safety reasons.
  3. Employees have access to MSDS **[PHARM-OP 13 (c-ii)]**
  4. Eye Wash Kits and Spills Kits are available **[PHARM-OP 13 (e-i, e-ii)]**
* Storage of Hazardous Materials
  1. Cleaning products should be in the manufactures bottle to ensure that they are clearly labeled and should never be stored with medications, food or items such a silverware, cups and plates.
  2. Chemotherapeutic drugs are stored away from other medications
  3. Chemicals used in compounding are kept in labeled containers and stored only in the compounding area.
* Disposal of Hazardous Materials **[PHARM-OP 11 (f)]**
  1. The pharmacy uses Stericycle to dispose of unacceptable medications and hazardous materials. Unacceptable medications and hazardous materials are placed in a hazardous waste container provided by Stericycle which is the picked up by Stericycle and properly disposed of.

1. The packaging for dispensing will include the following if necessary. Patients requesting non-safety caps will be flagged in computer system. A reminder will print on these patients’ labels for staff to place appropriate closure on bottle. Unit dose packaging and Tamper evident seals are placed by the manufacturer. Patients receiving medications in unit of use packaging from manufacturer will receive tamper evident sealing and/or unit dose packaging as deemed appropriate by the manufacturer. Medications requiring a controlled cold temperature (refrigeration) will have appropriate safety stickers detailing storage requirements. Temperature excursion questions will be directed to a pharmacist: **[PHARM-OP 4 (b, c, d)]**
2. All of the above procedures are to be done within compliance of DEA and Board of Pharmacy laws and regulations and other applicable laws or regulations. **[PHARM Core 4]**
3. In event of natural and or manmade disaster that eliminates functionality of any individual <insert practice name> pharmacy operations can be immediately moved to another <insert practice name> pharmacy location.

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