Pharmaceuticals Storage, Handling and Dispensing

PURPOSE: To store and dispense drugs in accordance with State, Federal and Local distribution laws and regulations.

PERSONNEL: Physicians, Non-Physician Practitioners, Nurses, and Medical Assistants

DEFINITIONS:
Drug: Any chemical compound, remedy or noninfectious biological substance, the action of which is not solely mechanical, which may be administered to patients by any route as an aid for the diagnosis, treatment, or prevention of disease or other abnormal condition, for the relief of pain and suffering, or to control or improve any physiological or pathological condition.
Drug Administration: The action, which a single dose of prescribed drug is given to the patient.
Drug Dispensing: The interpretation of an order for a drug, the proper selection, measuring, packaging, labeling and issuance of the drug.

Storage and Handling

1. All drugs, will be well organized and stored in specifically designated cupboards, cabinets, closets or drawers.
2. Drugs will be stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, purity of the drug product is not affected. Room temperature drugs should not be stored above 86° F (30° C)
3. Prescription, sample, over the counter drugs, prescription pads and hypodermic needles will be securely stored in a lockable space (cabinet or room) within the office/clinic.
4. Keys to locked storage area will be available only to staff authorized by the physician to have access. (During business hours, the drawer, cabinet or room containing drugs or medication supplies may remain unlocked ONLY if there is no access to the area by unauthorized persons. Whenever drugs or supplies are unlocked, authorized clinic personnel must remain in the immediate area at all times. At all other times they will be securely locked.
5. Drugs will be prepared in a clean area, or “designated clean” area if prepared in a multipurpose room. Vaccines will not be stored in the door of refrigerator or freezer.
6. Drugs for external use in liquid, tablet, capsule or powder form shall be stored separately from medications for internal use.
7. Drugs and immunobiologics requiring refrigeration will be kept in refrigerators that shall be maintained between 2° C (35°F) and 8° C (46°F).
8. Drugs and immunobiologics requiring freezing, will be kept in freezers that shall be maintained at 5º F or -15º C, or lower.

9. **Daily** temperature readings of medication refrigerator and medication freezer will be documented. (See Appendix A).

10. Items other than medications in refrigerator/freezer will be kept in a secured, separate compartment from drugs.

11. Drugs must be kept separate from food, lab specimens, and other items that may potentially cause contamination.

12. Tests reagents, germicides, disinfectants and other household substances shall be stored separately from drugs.

**Expiration Date Compliance**

1. The manufacturer’s expiration date must appear on the labeling of all drugs. All prescription drugs not bearing the expiration date are deemed to have expired.

2. If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and unconstituted drug.

3. Expired drugs will not be distributed or dispensed.

4. All drugs including stock, vaccine, sample, emergency, controlled, infant and therapeutic formulas will be checked for expiration monthly and written documentation will be maintained. (See Appendix B).

**Controlled Substances**

1. A dose-by-dose controlled substance distribution log will be maintained, with written records that include, provider’s DEA number, name of medication, original quantity of drug, dose, date, name of patient receiving the drug, name of authorized person dispensing drug and number of remaining doses. (See Appendix C, Pages 1&2).

2. Controlled substances will be stored separately from other drugs in a securely locked, substantially constructed cabinet.

3. Controlled substances include all Schedule I, II, III IV, and V substances listed in the CA Health and Safety Code, Sections 11053-11058, and do not need to be double locked.

4. Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, physician’s assistants, licensed nurses and pharmacists.
**Disposal and Dispensing**

1. Drugs will be disposed of appropriately. Drugs may be returned to the manufacturer or disposed of in medical waste. (See disposal of controlled substances below).

2. Drugs will be dispensed only by a physician, pharmacists or other persons (e.g.; NP, CNM, RN, PA) lawfully authorized to dispense medications, upon the order of a licensed physician or surgeon.

3. Personnel such as medical assistants, office managers, and receptionists will not dispense drugs.

4. Drugs will not be offered for sale, charged or billed to Medi-Cal members.

5. All drugs that are dispensed will be labeled and will include the following:
   Provider’s name, patient’s name, drug name, dose, frequency, route, quantity dispensed, and manufacturer’s name and lot number.

   Dispensing containers will not be cracked, soiled or without secure closures. California Pharmacy Law does not prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer and no charge is made to the patient.

   All pre-filled syringes must be individually labeled with date, medication name, and dosage.

6. All drugs that are administered or dispensed will be recorded in the medical record.

7. Disposable of Controlled Substances:
   - The DEA requires providers to maintain documentation of disposal of all controlled substances.
   - Provider may return the controlled drugs to the drug manufacturer.
   - Controlled drugs may be sent to a DEA registered disposal firm (reverse distributor) for destruction.
   - Providers may conduct their own drug destruction if the DEA had previously authorized them to do so. Those authorizations will remain in effect until rescinded, revoked, or procedures are changed.