



Policy and Procedure

| | | | |
|------------------------|--|----------------|--|
| Policy Name: | Proper Maintenance, Storage of Drugs and Distribution of Controlled Substances | | |
| Effective Date: | | Revision Date: | |
| Department(s)/Site(s): | | | |
| Document Owners: | | | |
| Approved By: | | | |
| Relevant Law/Standard: | Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL CA B&P Code, §4172, & 16 CCR, Chapter 2, Division 13, Section 1356.3). Title 22, Section 75037(d), CA Health and Safety Code, Sections 11053-11058 BPC 4172 16 CCR 1356.3 22 CCR 75032 and 75033 BPC 4051.3 16 CCR 1356.32 21 CFR 1301.75 21 CFR 1301.72 | | |

Purpose:

Drugs are stored and dispensed according to State and Federal drug distribution laws and regulations. Drugs and medication supplies are maintained secured to prevent unauthorized access.

Definition:

Controlled substances are generally a drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a Controlled Drug.

Centrally acting drugs (such as narcotics, stimulants, and certain sedatives) are divided into five classes called schedules I through V.

The Comprehensive Drug Abuse Prevention and Control Act: Law enacted in 1970 to control the distribution and use of all depressant and stimulant drugs and other drugs of abuse or potential abuse as may be designated by the Drug Enforcement Administration (DEA) of the Department of Justice. See DEA website for Drug Schedules – www.dea.gov or write link to access, <https://www.dea.gov/drug-scheduling>

Policy:

The site will maintain competent, efficient, and ethical Pharmaceutical Services According to State and Federal statues for the health and safety of its patients.

Procedure:

1. Medications are kept separate from food, lab specimens, cleaning supplies, and other items that may potentially cause contamination. Drugs are stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug product are not affected
2. Security: The Medical Board of California interprets "all drugs" to also include both sample and over-the-counter drugs. The Medical Board defines "area that is secure" to mean a locked storage area within a physician's office
 - a. All drugs (including sample and over the counter), medication supplies, hazardous substances and prescription pads are securely stored in a lockable space (room, closet, cabinet, drawer) within the office/clinic. (CA B&P Code, 4051.3)
 - b. A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. (42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25)
 - c. Keys to the locked storage area are available only to staff authorized by the physician to have access. (16 CCR, Chapter 2, Division 3, Section 1356.32)
 - d. During business hours, the lockable space may remain unlocked ONLY if there is no access to this area by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. At all other times, all drugs (including sample and over the counter), medication supplies, prescription pads and hazardous substances must be securely locked.
3. Drugs are handled safely and stores appropriately.
4. Preparation
 - a. Drugs are prepared in a clean area, or "designated clean" area if prepare in a multipurpose room.
 - b. Drugs or medication supplies are considered "adulterated" if it contains any filthy, putrid or decomposed substance, or if it has been prepared, packed or held under unsanitary conditions (21 USC, Section 351).
5. Storage:
 - a. Drugs for external use are stored separately from drugs for internal use.
 - b. Drugs are stored under appropriate conditions of temperature, humidity and light, so that the identity, strength, quality and purity of the drug product are not affected (21 CFR, Section 211.142). Room temperature where drugs are stored does not exceed 30°C (86°F)
6. Controlled drugs are stored separately from other drugs, in a secured, lockable space accessible ONLY by authorized personnel (including physicians, dentists, podiatrists, physician assistants, licensed nurses and pharmacists) There is no need for the controlled substances to be double locked. **Controlled substances include all schedules I, II, III, IV and V substances.
 - a. A dose-by-dose controlled substance distribution log is maintained (see Appendix A), including:
 - i. Provider's DEA number
 - ii. Name of medication
 - iii. Original quantity of drug
 - iv. Dose
 - v. Date
 - vi. Name of patient receiving drug
 - vii. Name of authorized person dispensing drug and
 - viii. Number of remaining doses

First Name Last Name – Title

Date

First Name Last Name – Title

Date

First Name Last Name – Title

Date

The material in this document is a knowledge-sharing tool provided by the FSR team to enhance compliance with Facility Site Review requirements. All content is for informational purposes and may be used and/or modified according to site-specific practices. Ensure appropriate review and approval by site management prior to adoption.

Appendix A

Controlled Substances Distribution Log

| Provider DEA # | Medication Name | Original Quantity of Drug | Dose | Date | Patient Receiving Drug | Authorized Person Dispensing Drug | Number of Remaining Doses |
|----------------|-----------------|---------------------------|------|------|------------------------|-----------------------------------|---------------------------|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |