



Policy and Procedure

Policy Name:	Drug Samples		
Effective Date:		Revision Date:	
Department(s)/Site(s):			
Document Owners:			
Approved By:			
Relevant Law/Standard:	<p>California Department of Health Care Services under Title 22, California Code of Regulations, Section 75032 and 75033. (Requires the review and certification of Primary Care Practitioner (PCP) sites.)</p> <p>Department of Health Care Services (DHCS) All Plan Letter 20-006, Site Reviews: Facility Site Review and Medical Record Review or any superseding APL</p> <p>CA B&P Code, 4051.3</p> <p>42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25</p> <p>16 CCR, Chapter 2, Division 3, Section 1356.32</p> <p>16 CCR, Chapter 2, Division 3, Section 1356.32</p>		

Purpose:

To ensure the safe and effective distribution, control, storage, use and disposition of drugs including sample and over-the-counter (OTC) drugs.

Definition:

A prescription drug not intended to be sold, given by drug representatives in sub-prescription-sized amount to promote the drug's sales. The Medical Board of California interprets "all drugs" to also include both sample and over-the-counter drugs

Policy:

- 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)
- 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)
- 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)

- 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.

Procedure:

- Maintain list of drug samples (see Appendix A)
- Store drug samples in secure area at all times
- Maintain proper temperature, light, humidity, conditions of sanitation, ventilation, and segregation.
 - Room temperature where drugs are stored does not exceed 30 ° C
- Maintain product integrity
- Maintain compliance with all applicable packaging and labeling laws, regulations, standards, and patient education requirements. Pharmacists should be involved in the organization’s efforts to secure safe and effective low-cost medication for low-income patients.

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