

Sample Drug Inventory and Distribution

Policies and procedures must be in place to ensure the safe and effective distribution, control, storage, use and disposition of drugs including sample and over-the-counter (OTC) drugs.

The Medical Board of California interprets “all drugs” to also include both sample and over-the-counter drugs (22 CCR §75032 and §75033). A list of drugs available for use in the clinic shall be maintained. Site should have written site-specific policies and procedures (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers’ representatives American Society of hospital pharmacist (ASHP) Guidelines: Minimum Standard for pharmaceutical services in ambulatory care). Each clinic, which provides drug distribution services, shall have written policy and procedures for the safe and effective distribution, control, storage, use and disposition of drugs.

- Maintain list of drug samples (see below)
- 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.
- All distribution of sample medications must be documented in the medical record for each patient. For each sample medications, the encounter note must contain the name of the medication, dosage, frequency, and quantity provided.

