

Overview of the
Regulations and Recommendations
made by various organizations and state licensing boards
concerning the handling of Drug Samples by physician offices and clinics

Besides following your state's pharmacy and medical licensing board's regulations, concerning the storage, dispensing and labeling of prescription medications (*such as drug samples*), some other organizations have their own recommendations and policies concerning drug samples that you should follow to *minimize your professional liability*. A few of these organizations include;

1. The Joint Commission (TJC)
2. Institute for Safe Medication Practices (ISMP)
3. The National Coordinating Council (member ship includes the FDA and TJC)

State licensing board's rules are concerned with obvious things like the proper storage, tracking and labeling of prescription medications. Labeling typically requires that the patient name, drug name and strength, quantity provided, directions, date dispensed, and drug expiration date and lot number be affixed to the packaging. ***Everyone needs to follow these regulations to minimize their legal liability.***

Of the three organizations listed the TJC Medication Management Standards for hospital affiliated physician offices and clinics are the most important to follow. Everyone wants to avoid receiving Requirements for Improvements (RFIs) after a survey during your Exit Conference.

TJC recommendations for drug samples can be found at:

<http://www.jointcommission.org> search "sample" or "drug sample"

Some of the Medication Management Standards that apply are

- **Medications are dispensed safely. Note: Note: This standard is applicable to all practices that dispense medications, including those practices that dispense sample medications. Quantities of medications are dispensed and minimize diversion yet are still consistent with the patient's needs. (Standard MM.4.40 B1)**
- **Procedures supporting safe medication prescribing or ordering address the following: Ordering, procuring, storing, controlling, labeling, preparing, and dispensing medications according to law or regulation (Standard MM.5.30 B1)**
- **Medication orders must be written clearly (MM.3.20)**
- **Medication orders or prescriptions are clear and accurate (MM.04.01.01)**
- **The patient record contains information that reflects the patients care, treatment or services (RC.02.01.01)**
- **Medications are appropriately labeled, Element of Performance #3 at a minimum - this information is usually included on the container (MM.4.30)**
- **The organization follows a process to retrieve recalled or discontinued medications (MM.0501.17).**

- Medications dispensed by the practice are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration for safety reasons. (Standard MM.4.70) B 4. The practice has procedures for retrieving and safely disposing of recalled medications including the following:
 - 1) Identifying each patient who is receiving or has received recalled medications
 - 2) Identifying the source of the medication
 - 3) Providing for the retrieval and safe disposal of medications subject to recall
 - 4) Providing for external reporting of medication product defects
- The organization responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors (MM.07.01.03).
- If the patient is transferred to another Provider, setting, level of care, a complete list of current medications, must be communicated (National Patient Safety Goal 8B).
- Look-alike/sound-alike drugs are identified (NPSG 3, Requirement 3C). *Drug Sample uses tall man lettering*

The *National Coordinating Council Recommendations for Avoiding Medication Errors with Drug Samples* are found at <http://www.nccmerp.org/council/council2008-01.html>

A few of their recommendations are;

6. Multiple doses should be packaged in a manner that preserves labeling for each dose (e.g., the label or backing of each dose should contain the drug's name, strength of medication, lot number, and expiration date).
7. Unique National Drug Code (NDC) numbers should be assigned to each drug sample to facilitate electronic documentation and tracing of products.
12. For each drug sample, the patient instructions should be written in language appropriate for the patient. At a minimum, a drug sample should be labeled to include:
 - the name of the patient;
 - the brand and/or generic name of the drug;
 - the strength of the drug per dosage unit;
 - clear directions for use by the patient; and
 - any necessary cautionary statements or use instructions such as, 'May cause drowsiness' or 'Take with food'.
17. Prescribers should document in the patient's medical record drug samples given to patients as they would any other medication.
18. Drug samples should be included in any list of medications that is communicated to another provider or care setting.