

 <p style="text-align: center;"><b>County of Sacramento</b>  <b>Department of Health and Human Services</b>  <b>Division of Behavioral Health Services</b>  <b>Policy and Procedure</b></p>	Policy Issuer (Unit/Program)	<b>QM</b>
	Policy Number	<b>QM-07-03</b>
	Effective Date	<b>04-01-2003</b>
	Revision Date	<b>01-01-2012</b>
Title: <b>Dispensing “Sample” Medications</b>	Functional Area: <b>Interface with Physical Health Care</b>	
Approved By: (Signature on File) <b>Signed version available upon request</b>  <b>Kathy Aposhian, RN</b> Program Manager, Quality Management  <b>Robert Hales, MD</b> County Medical Director		

**BACKGROUND/CONTEXT:**

The Sacramento County Division of Behavioral Health Services (DBHS) will pursue the “sample” medication programs offered by pharmaceutical companies to county operated and contracted providers.

**DEFINITIONS:**

“Sample” medication is defined as a unit of a prescribed medication that is not intended to be sold. “Samples” may only be ordered and received by the Physician, Nurse Practitioner, or Physician Assistant.

**PURPOSE:**

The purpose of this policy of DBHS to establish policies and procedures governing the process of dispensing and storing of “sample” pharmaceuticals. Dispensing of these “samples” shall be for the sole purpose of providing access to prescription medications and “trial” prescriptions.

**DETAILS:**

**Procedure:**

- I. Ordering and receiving “Samples”
  1. Physician, Certified Psychiatric Nurse Practitioner (CPNP), Nurse Practitioner (NP) or Physician Assistant (PA) will submit a written request/receipt to the pharmaceutical representative for a specified medication, dose, amount and manufacturer. No scheduled I, II, III or IV medications will be obtained.
  2. The Physician, Certified Psychiatric Nurse Practitioner (CPNP), Nurse Practitioner (NP), Physician Assistant (PA) or a licensed health care professional, upon receipt of the ordered medication, will verify the name, dose and amount. A licensed health care professional will be a Registered Nurse, Certified Psychiatric Nurse Practitioner (CPNP), Nurse Practitioner, Physician Assistant, Licensed Vocational Nurse or Licensed Psychiatric Technician. All medications received will be logged into a **Medication Log Book**. The following information will be documented in this log:

- Name of Medication
  - Amount
  - Dosage
  - Date
  - Lot number
  - Date of Expiration
  - Signature
3. All medications will be inspected, prior to storage, to determine that the packaging is unopened; the labeling is intact and not out of date.
  4. If multiple medications are to be kept in stock, separate Medication sheets may be maintained.

## II. Storage of Sample Medication

1. All sample medications will be stored in a double locked system.
2. Access to this storage will be limited to the physician or licensed health care professional, as described in I,2.
3. All medications intended for external use will be stored separately from medications for internal use.
4. All medications are stored separately from foodstuff.
5. All medications will be stored at proper room temperature:
  - a. Room temperature medications at 59-86 degrees F (15-30 degrees C).
  - b. Refrigerated drugs at 36-46 degrees F (2-8 degrees C)
  - c. A thermometer will be present in both locations.
6. Confirmation of a routine inspection of the temperature will be documented. The date and temperature observed will be recorded on at least a monthly basis.

## III. Dispensing of Medication Samples

1. A physician, Certified Psychiatric Nurse Practitioner\* (CPNP), Nurse Practitioner\* (NP), or Physician Assistant\* (PA) will prescribe all medications to be dispensed. This will be documented in the Progress Notes and on the Medication Summary List. The name of the medication, dose, route, frequency and quantity to be dispensed will be documented.
2. All medication samples will be dispensed in the original, unopened container with the name and dose of the medication clearly labeled.
3. All medication samples will be clearly labeled with instructions for administration by the client. This may be performed by the RN, LVN or LPT, at the direction of the Physician. The client name, date, name of medication, dose, route, and instruction for use will be documented. Relevant warnings or precautions will be identified on the label.
4. All medication samples dispensed will be logged on the Medication Log. The following information will be documented:
  - Date
  - Client name
  - Name of medication
  - Dose
  - Quantity
  - Lot number
  - Signature of person dispensing

\* Nurse Practitioner and Physician Assistant may only prescribe in accordance with the written standardized procedures and applicable laws and regulations.

**IV. Maintenance of Inventory**

1. The sample medication inventory will be inspected for expiration date, deterioration, contaminated, or damaged packaging on a monthly basis.
2. All medication samples that are deemed expired, contaminated, or damaged will be logged on a Medication Log, and prepared for disposal by an authorized hazardous waste firm. The name of the medication, dose and quantity will be documented and signed by an authorized staff.
3. This inspection may be conducted by a licensed health care professional, physician, or authorized pharmacy staff.
4. Medication Logs will be retained for a period of three years.

**REFERENCE(S)/ATTACHMENTS:**

- California Code of Regulations Title 9 §785.30, 785.31, 785.28 ,21 CFR 203 & 205
- Federal Register Docket No. 92N-0297
- Business & Professional Code §4180-4186

**RELATED POLICIES:**

- No. 03-06 Compassionate Care Pharmaceuticals
- No. 04-01 Site Certification of Provider Physical Plant
- No. 07-01 Medication Support Services
- No. 07-02 Medication Monitoring
- No. 03-04 Nurse Practitioner
- No. 03-09 Physician Assistant

**DISTRIBUTION:**

Enter X	DL Name	Enter X	DL Name
X	Mental Health Staff		
X	Mental Health Treatment Center		
X	Adult Contract Providers		
X	Children’s Contract Providers		
X	Alcohol and Drug Services		
X	Specific grant/specialty resource		

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