Policy

Samples should not be stored and/or dispensed in any hospital facility. In the rare event that it is necessary to do so for reasons of quality or safety, it may be done only with the express written consent of Senior Leadership (CEO or COO or CMO or CQO) and a written plan for tracking of samples submitted with the request. Vouchers or non-medication teaching kits may be given to patients in place of samples. Samples are not intended to routinely provide a full course of treatment to patients. Hospital personnel may never accept samples for personal use.

Per New York State Law, controlled substance samples may not be stocked or dispensed in any (inpatient/outpatient) area of the hospital.

1. In the rare event that samples are necessary in the inpatient setting, Pharmacy will obtain the consent of Senior Leadership and develop the plan for distribution and tracking of the samples.
2. In the rare event that samples are necessary in the outpatient setting, the following procedures must be followed after written consent is obtained from Senior Leadership:
   a) To request approval for medication samples submit the following information to the Ambulatory Care Service Office, care of Ambulatory CNS, box 680. It will then be sent to Senior Leadership for approval:
      1) Requestor Name(s)
      2) Clinical Area
      3) Name of Medication and dose
      4) Rationale for the need of the medication sample
      5) Written plan for tracking
   b) Sample drugs must be stored in a secured area.
   c) Ambulatory staff will distribute samples using the SMH 905, Ambulatory Medication Dispensation Record that details the medication and instructions, lot number, expiration date and provider name. A copy of this information is given to the patient with the sample being dispensed, a copy is placed in the patient record and a copy is filed in the unit sample log book.
   d) All areas will review their stock of sample drugs monthly. Requests for samples of drugs are reviewed by unit management for inclusion prior to requesting consent from Senior Leadership.
   e) Sample drugs are received from the pharmaceutical company on the unit. Samples should be received by appropriately licensed staff, and not directly by the physician, however, if required by the company, an accepting physician will sign the pharmaceutical voucher. The drug is logged in as delivered, by the pharmaceutical representative on the unit drug log. The drug is then placed on the shelf of the sample cupboard by the unit designee.
   f) When leaving samples, pharmaceutical representatives are responsible for documenting the following on the log book:
      1) Medication brand name, dose and form
      2) Sample lot number
      3) Expiration date (less than six months will not be accepted)
      4) Quantity
      5) Pharmaceutical representative’s signature
   g) Pharmaceutical representatives will also be responsible for filling out the SMH 905, a three-part medication record and affixing it to each sample container when distributing to the office/clinic. The pharmaceutical representative will provide the following information:
      1) Medication name
      2) Medication strength
      3) Quantity
      4) Lot number
### SECTION 7. MEDICATION STANDARDS

#### 7.20 Medication Samples

5) Expiration date

h) If approved/requested medication samples are mailed to the clinic, they must either include completed 905’s or the pharmaceutical representative must complete the 905 forms prior to use in the clinic. If the pharmaceutical representative does not complete the 905’s within 2 weeks the medication samples will be discarded and logged with a witness and the pharmaceutical representative’s name will be given to pharmacy.

i) If unapproved/unsolicited medication samples are mailed to the clinic the pharmaceutical representative is contacted to retrieve the samples. If they do not retrieve the samples within 2 weeks the medication samples will be discarded and logged with a witness and the pharmaceutical representative’s name will be given to pharmacy.

### References:

SMH Policy 12.1.1 Sales Representatives and Vendors

Approved Sample List

### History:

- **4/11** Developed
- **6/11** Reviewed and approved by Policy Management Team and Clinical Council
- **8/14** Reviewed by Pharmacy Approved Sample List link added
- **8/14** Reviewed and approved by Policy Management Team
- **9/14** Reviewed and approved by Clinical Council

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