Administrative Manual		
UNC HEALTH CARE	Policy Name	**Medication Management: Drug Samples**
	Policy Number	**ADMIN 0112**
	Date this Version Effective	**July 2011**
	Responsible for Content	**Medication Safety Committee**

I. Description

To define the elements of a sample medication program in the outpatient clinics of the University of North Carolina Health Care System ("UNC HCS")

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II. Rationale

Use of medication samples requires specific documentation procedures in order to allow for effective recall procedures, expiration date checking, and compliance with the State of North Carolina Board of Pharmacy requirements and The Joint Commission Medication Management Standards.

III. Policy

This policy applies to any UNC HCS clinic, outpatient location, and the inpatient units of the University of North Carolina Hospitals (UNCH). While drug samples are not available for inpatient use, drug product samples may be solicited by UNCH physicians and stored in ambulatory care clinics for the treatment of outpatients at home.

A drug sample is defined as a unit of a prescription drug that is not intended for sale but rather to promote the sale of a drug. Under the Food, Drug and Cosmetic Act, no person may sell, purchase, trade, or offer to sell, purchase or trade a drug sample.

Only licensed health care professionals with prescribing authority may distribute drug samples to patients. **Drug samples are strictly for use of outpatients in the clinics and are not for inpatient use**.

IV. Procedure

A. Selection and Procurement

1. Only sample medications that are packaged and labeled by manufacturers in the original sealed packaging may be included in the sampling program. Drug samples must be dispensed in the same package in which they are received. UNC HCS may not repackage drug samples.

2. **Schedule II-V controlled substances are not included in the sample medication program.**
3. Medical Service Representatives (pharmaceutical representatives) may not leave unsolicited drug samples or samples of a controlled substance.
4. Physicians and licensed independent practitioners ("LIP"s) may request drug samples for patient treatment by contacting the appropriate Medical Service Representative ("MSR").
5. The MSR must deliver the drug samples to the clinic to the requesting physician or LIP, or to a staff member designated by the requesting physician or LIP. Drug samples may not be mailed or transported by any personnel other than the MSR. The MSR may not send drug samples to a personal or professional office for transport to the clinic.

B. Drug Sample Logs

1. Clinics that utilize drug samples must keep logs to record the information identified below for every drug sample delivery. The MSR or clinic personnel may record the information. The information must include, at a minimum, the following:
   a. date of delivery;
   b. company;
   c. name of drug, strength, dosage form;
   d. quantity left by the representative; and
   e. lot number(s)
2. Each clinic must retain a copy of its completed drug sample log for a minimum of three months.
3. By the tenth (10^{th}) day of each month, each clinic must forward to the Ambulatory Care Administration office a copy of its completed drug sample log for the previous month. Ambulatory Care Administration must retain the drug sample log for a period of three years. In the event of a recall, the drug sample logs will assist in identifying and notifying clinics.
4. If a physician, LIP, or nurse transfers a drug sample from one clinic to another, he or she must note the details of such transfer in the drug sample log. The name of the clinic to which the samples are transferred, as well as the name of the drug and its strength, dosage form, lot number and quantity must be recorded. If the physician, LIP, or nurse transfers a drug sample for a specific patient's use, he or she should record the name of the patient and the patient's medical record number. Physicians, LIPs, and nurses should avoid transferring drug samples from one clinic to another, instead requesting drug samples directly from the MSR as needed for a specific clinic and/or patient.

C. Storage

1. Clinics are responsible for storing drug samples in a locked cabinet or in a secure room under proper conditions, considering sanitation, temperature, light, moisture, ventilation, segregation, and security.
2. Only clinic personnel who have a job-related need for access to drug samples may have access to areas where drug samples are stored. Clinics must use appropriate security measures to ensure that, at all times, no one other than clinic personnel with a job-related need for drug sample access have access to the drug sample storage areas. Clinic and UNC HCS personnel without a job-related need to drug sample access and anyone who is not part of clinic personnel, e.g., information technology staff members, vendors, office

support staff, dietary personnel, housekeeping, may not have access to drug samples or to the storage areas where drug samples are kept.

3. MSRs may have access to the drug samples that their company distributes to evaluate inventory and to remove expired samples.
4. Drug sample storage areas must be locked when the clinic is closed and when the area is unattended.
5. Within the drug sample storage area, clinics must segregate samples of antiseptics and other external-use products from oral, optic, and ophthalmic products, by using, for example, separate shelves or separate bins
6. Within the drug sample storage area, clinics must segregate drug samples from other medication supplies that the clinic stocks.
7. Clinics must properly store drug samples that have special storage requirements. For example, clinics must store refrigerated or frozen products in a refrigerator or freezer that is capable of maintaining the appropriate temperature and that has a thermometer to monitor the temperature.

D. Ordering and Dispensing

1. When deciding to use a drug sample to fulfill a patient's medication needs, the physician or LIP must screen the patient's medical history and current drug therapy for:
   a. drug-allergy contraindications;
   b. potential drug-drug interactions;
   c. drug-disease contraindications; and
   d. drug-food interactions.
2. The physician or LIP must dispense the sample to the patient and counsel the patient on directions for administration, potential side effects, potential drug-drug interactions, and potential drug-food interactions, as appropriate for safe and accurate use. Whenever possible, the physician or LIP should give instructions for self-administration in writing.
3. The physician or LIP is responsible for recording the dispensation of a drug sample to a patient in two separate records:
   a. The Patient's Clinic Record
      i. The physician or LIP must document that he or she has dispense a drug sample to the patient by recording the name, strength, and dosage regimen of the drug sample on the appropriate clinic record for insertion into the patient's medical record. Entering the sample medication into the medication list in WebCIS meets this requirement.
   b. Drug Sample Dispensing Log
      i. The physician, LIP or his or her designee must document that the patient has received a drug sample by recording the following information in a drug sample dispensing log:
         (1) date the physician or LIP dispensed the drug sample;
         (2) name and medical record number of the patient receiving the drug sample;
         (3) name of the physician or LIP dispensing the drug sample;
         (4) name, strength, and dosage form of drug dispensed;

(5) lot number(s) of drug dispensed; and

(6) quantity of drug sample dispensed.

4. Only the prescriber may dispense a drug sample during a face-to-face visit with the patient. Nurses, office assistants, medical office assistants, and any other support personnel may not dispense drug samples.

5. Clinics must abide by the following rules with regard to the dispensation of drug samples:

   a. Clinics may not package drug samples ahead of time in anticipation of patient needs or in advance of a particular patient appointment.

   b. Clinics may not dispense drug samples without the patient having a verified, documented visit to the prescriber.

   c. Clinics may not dispense drug samples without proper documentation, as indicated in this policy.

   d. Clinics may not package drug samples for dispensing to patients outside of a clinic appointment.

   e. Clinics may not mail drug samples to the patient.

E. Drug Sample Labeling

1. Legible labels for each drug sample dispensed shall include the following:

   a. clinic name and physical address

   b. date

   c. prescriber's name

   d. patient name

   e. name of the drug

   f. strength

   g. quantity given

   h. frequency of use

   i. special precautions as appropriate

F. Administration

1. The licensed professional prescribing a drug sample to a patient is responsible for the ordering, dispensing, and administration of the drug consistent with the terms of this policy, and for all documentation required by this policy.

G. Returned Medication

1. Clinic personnel must immediately return to the Pharmacy Support Service on the ground floor of Memorial Hospital or to the MSR any drug sample medications that are outdated or returned by patients.

H. Recalls

1. In the event of a drug sample recall, the Department of Pharmacy in conjunction with the Ambulatory Care Administration shall determine which clinics have stocked and dispensed the recalled product by consulting the appropriate MSR and reviewing Drug Sample Logs and Drug Sample Dispensing Logs.

2. The Department of Pharmacy and the Ambulatory Care Administration shall review Drug Sample Logs and Drug Sample Dispensing Logs to identify patients who have received the recalled product, and will contact such patients to provide information explaining the nature of the recall and the appropriate corrective action.
3. The Department of Pharmacy and/or the Ambulatory Care Administration shall quarantine recalled samples that are retrieved from clinics and patients and shall return such samples to the manufacturer according to instructions in the recall notice.

I. Medication Storage Area Reviews

1. The UNCH Department of Pharmacy shall perform regular, unannounced inspections of drug sample medications.
2. During inspections of medication storage areas in clinics, the Department of Pharmacy will inspect Drug Sample Logs, Drug Sample Dispensing Logs, and overall medication security. Spot checks are made for expired or adulterated drug samples.
3. During inspections, the Department of Pharmacy will reconcile the actual inventory in the clinic's drug sample storage with information from the clinic's Drug Sample Logs, Drug Sample Dispensing Logs, and patient medical records. Additionally, the Department of Pharmacy shall inspect all logs to assure the clinics are recording the required information thoroughly and accurately.
4. The Department of Pharmacy shall maintain documentation of compliance with this policy, in accordance with the Department of Pharmacy Quality Assurance Program.
5. If any clinic is out of compliance with this policy for three (3) consecutive inspections within any 24-month period, the clinic will no longer be permitted to stock, handle or request sample medications for a period of two years.
6. Areas where a clinic may be out of compliance include but are not limited to the following:
    a. Inappropriate storage of drug samples
        i. Unsecured drug samples
        ii. Drug samples not separated by route
        iii. Drug samples not separated from stock supply of medications
        iv. Drug samples being present in exam rooms, consult rooms, unsecured storage areas, or any location where the patient or the patient's authorized representative or anyone without a job-related need for drug sample access may have access to the drug sample
    b. Expired samples
    c. Drug samples of controlled substances
    d. Missing, incomplete, or incorrect log entries
    e. Evidence of a drug sample being dispensed to a patient without a clinic visit to a physician on the same day
    f. Evidence of samples being prepared in advance of a patient visit
    g. Inappropriate labeling of samples for dispensing
    h. Samples being dispensed by a medical office assistant, office support staff, nursing assistant, nurse, or anyone other than the prescriber

7. When a clinic is out of compliance with this policy, the Department of Pharmacy shall notify the Chair of the Department, as well as the clinic manager, clinic medical director and lead clinic nurse. The format will be as follows:

   a. notification of the first instance of non-compliance within a 24-month period will be sent via e-mail, with a read receipt;
   b. notification of the second instance of non-compliance within a 24-month period will be sent via letter, certified mail with a return receipt requested;
   c. notification of the third instance of non-compliance within a 24-month period will be sent from UNCH's Pharmacy and Therapeutics Committee via written letter, certified mail with return receipt requested, and will include notification that the clinic has lost privileges to stock, request or handle drug sample medications for 24-month period.

V. Reviewed/Approved by

Medication Safety Committee
Ambulatory Care Administration
Pharmacy and Therapeutics Committee
Medical Staff Executive Committee