

Policy

Control of Trial Supplies of Prescription Medication: Samples, Drug Vouchers & Starter Supplies

UW Hospital and Clinics

Policy Number: 8.36

Manual: Hospital Administrative

Section: Patient Care

Effective Date: August 1, 2005

Version: Revision

I. PURPOSE

To establish a procedure to provide trial supplies of prescription medication without charge to outpatients of the University of Wisconsin Hospital and Clinics (UWHC) in compliance with the state law and JCAHO standards.

II. POLICY

Prescription medication samples shall be distributed in UWHC only in accordance with these procedures.

III. PROCEDURE

A. Samples

1. Samples are defined as a supply of prescription medication provided by a manufacturer to prescribers for the purpose of encouraging the prescriber to select the sampled medication for ongoing use by the patient. Dispensing of samples of prescription medications from a prescribers office must comply with all labeling, storage, and handling procedures required by the Wisconsin Pharmacy and Medical Examining Boards and the Joint Commission on Accreditation of Healthcare Organizations.
 - a. Samples (except as noted in section III.A.2) may not be used or stored in any facility of UWHC required to comply with JCAHO standards.
 - b. Samples are specifically prohibited in inpatient facilities per JCAHO standards. Samples found on any inpatient unit including those found in patient rooms will be removed and destroyed.
 - c. Prescribers are discouraged from accepting samples for personal use or from storing them in their offices.
 - d. Samples acquired for personal use by prescribers may not be used to treat UWHC patients.
2. Exceptions - In some specific situations, samples may be needed to provide trial supplies of medication that cannot reasonably be provided through the use of the Drug Voucher System (see section III.B). These products are designated "exempt samples."
 - a. Topical products, since commercial package sizes do not allow drug vouchers to supply an appropriate trial medication quantity, are exempt samples.
 - b. Over-the-counter, non-prescription medications that are not Schedule V controlled substances, which are packaged and labeled by the manufacturer for consumer use.
 - c. The prescriber may request that the Pharmacy and Therapeutics Committee grant an exception to allow a specific drug or product to be sampled in the clinic. The request should be in writing and include a description of the uniqueness of the drug product, the specific situations when the actual sample would be needed, and why a drug voucher for the product would not be applicable.
 - d. Drug vouchers may also be utilized for drug or drug products approved as exceptions, as there may be some situations where the drug voucher meets the needs of the patient.
 - e. The Psychiatric Clinic (WISPIC) is granted an exemption to the prohibition on physical medication samples. This exemption is granted because of the combination of the unique needs of the patients, the lack of an on-site pharmacy, and the proven history of compliance with UWHC requirements for storing, handling, and labeling of sample medications. This exemption only applies to medications used to treat psychiatric conditions and is contingent on continued compliance with the procedures outlined in this policy for the control of trial supplies of medications. See Appendix B for the list of exempt samples allowed at WISPIC.
 - f. All prescription drugs or drug products granted an exception by the Pharmacy and Therapeutics Committee must be labeled, stored, packaged, and recorded in accordance with the procedures described in Section III.E.
 - g. The list of exempt samples shall be published on the Web and periodically in the Pharmacy and Therapeutics Committee newsletter, Drug Policy Perspectives. Changes to the list of exempt samples or available vouchers will be published in the Pharmacy and Therapeutics Committee email, P&T Update. A copy of the list of exempt samples should be kept in the locked storage cabinet where these products are kept in each clinic.
3. Drugs or products that have been denied formulary status by the UWHC Pharmacy and Therapeutics Committee may not be vouchered or supplied as starter supplies or exempt samples unless an exception is made by the Committee.

B. Drug Voucher System

1. With the Drug Voucher System, the prescriber has access to vouchers that, when given to the patient with a traditional prescription, are redeemed at a pharmacy for a pre-determined amount of drug without charge. Vouchers for generic drug products may only be redeemed at a UWHC pharmacy.
2. With the exception of drugs which have been denied formulary status, any manufacturer-supplied brand name vouchers and UWHC generic medication vouchers are allowed in the clinics.
3. Procedure
 - a. Pharmaceutical representatives are to notify the Center for Drug Policy when they have new product vouchers which they would like to place in UWHC clinics.
 - b. UWHC generic medication vouchers can be obtained by clinic representatives by contacting the Medication Assistance Program office at 262-6443.
 - c. Vouchers are delivered to the clinics by the representatives in accordance with procedures described in Section F.
 - d. The designated prescriber or nurse will be responsible for secured storage of the vouchers in the clinic area.
 - e. Each voucher will be for a specific drug in a predetermined amount.
 - e. When a prescription is written, the prescriber determines if there is a need for a drug voucher. If needed, the patient is given the prescription with the voucher and instructed that the voucher can be redeemed for the predetermined amount of drug at any participating outpatient pharmacy.
 - f. When the patient presents the prescription and voucher at a pharmacy, the pharmacist prepares the predetermined quantity of vouchered medication in accordance with all legal procedures.
 - g. At dispensing, the patient receives the predetermined quantity without charge.

C. Starter Supplies

1. Starter supplies are defined as a trial supply of a prescription medication provided to the clinic for use during a clinic visit to instruct the patients in proper medication use or when packaging provides compliance with dosage titration during the initiation of therapy.
 - a. Medications included in this category are inhalers, nasal sprays, and injections.
 - b. A request to consider other products or dosage forms as starter supplies should be forwarded to the Center for Drug Policy . Included with the request should be the actual drug or drug product proposed for consideration as a starter sample.
 - c. If remaining medication in the starter package after the clinic visit is dispensed to the patient for use at home, the package must be labeled and medication recorded in compliance with procedures. (See Section E. Appropriate methods for storing, handling, and preparing starter supplies or exempt samples for dispensing.)
 - d. The list of starter supplies shall be kept in the locked storage cabinet where these products are kept in each clinic.

D. Each clinic utilizing starter supplies, exempt samples, or vouchers shall designate a prescriber or nurse who is responsible for implementation and compliance with all policies and procedures regarding the sample process for that clinic. They may delegate recordkeeping and oversight responsibilities to other clinic personnel as appropriate.

E. Appropriate methods for storing, handling, and preparing starter supplies or exempt samples for dispensing.

1. All prescription drugs should be labeled using the label portion of the Drug Sample Record form (Appendix A) complete with the following information: patient name, medical record number (MRN), prescribers name, date, directions for use, purpose for treatment, drug name, quantity, and clinic name, address, and phone number.
2. The first page of the Drug Sample Record form shall be placed in the patient's chart to document that the sample was dispensed as is any medication prescribed to a patient.
3. The second page of the Drug Sample Record form shall be kept on file in the clinic for use, if needed, in accordance with the recall procedure for a minimum of three years.. (See III.H. Recall Process.)
4. All starter supplies or exempt samples of oral medication should be dispensed in child-resistant containers either provided by the manufacturer or by UWHC personnel. The patient or patient representative may waive this requirement by signing the waiver statement on the Drug Sample Record.
5. All starter supplies, exempt samples, and controlled substance vouchers will be stored in a locked cabinet. This cabinet shall be placed in a limited access area whenever possible. The cabinet will be locked at any time it is unattended.
6. Pharmaceutical representatives should not have access to the storage area without supervision by the dispensing prescriber or nurse responsible for the cabinet.
7. Starter supplies and exempt samples may be dispensed only with the consent and supervision of a UWHC attending staff physician. Prescriber consent is required for dispensing of prescription drugs.
8. No controlled substance starter supplies or exempt samples shall be permitted unless authorized under special circumstances by the Pharmacy Department.

F. Pharmaceutical Representative Responsibilities:

1. Medication samples provided by pharmaceutical representative may only be left at clinics with a designated locked sample storage areas, at the prescribers office if in non-patient care areas, or in the central pharmacy office; and then only by the request of licensed prescribers or licensed pharmacists.
2. The pharmaceutical representative will be responsible for logging in generic name, brand name, pharmaceutical company, representative's name, delivery date, clinic location, quantity, lot number and expiration date on a

form maintained in the individual off-site clinic (See Appendix D). All starter supplies and exempt samples distributed to UWHC must be logged on these forms.

3. Drug vouchers, starter supplies, and exempt samples should be supplied during periods when patient traffic in the clinic is light as determined by clinic staff.
4. Unsolicited starter supplies and exempt samples are unauthorized and will be removed by the Pharmacy Department.
5. A representative(s) found to be in violation of these procedures at UWHC will be subject to the disciplinary process outlined in Administrative Policy 11.19 Regulation of Sales Representatives. The company representative will be held responsible for any and all unapproved sample products they have supplied that are identified at UWHC. If it is impossible to ascertain which company representative has violated the sample policy, every representative responsible for the sale of the product identified will be disciplined as outlined.

G. Methods for monitoring stock and evaluation of compliance with dispensing procedures.

1. A monthly review of starter supply and exempt sample stock will be conducted. Samples will be checked for expiration dates, proper storage, and lack of use. Any item that has expired or has not been used in the last six months will be removed and returned to the pharmaceutical company or destroyed.
 - a. A pharmacy technician performs the review at the Main Campus and selected clinic sites. (See Appendix D.) A report listing any discrepancies will be forwarded to the designated prescriber or nurse staff and to the clinic liaison pharmacist for review and follow up of problem areas.
 - b. For other clinics, the designated prescriber or nurse will perform the review. A copy of Clinic Monthly Starter Supply and Exempt Sample Review Form (Appendix E) will be forwarded to the pharmacy department. These clinics will have an additional review done by the pharmacy on a semi-annual basis with a reports of any expired or removed samples forwarded to the designated prescriber or nurse and liaison pharmacist for review and follow up of any problem areas.
2. Random periodic review for compliance with dispensing procedures will be conducted by personnel designated by the Pharmacy and Therapeutics Committee.
 - a. The review will include compliance with labeling, packaging, and recording procedures as described in Section III.E. (See Appendix F.)
 - b. The report of the review shall be forwarded to the designated prescriber or nurse for the specific clinic and to the Pharmacy and Therapeutics Committee. Failure to comply with procedures for handling and dispensing starter supplies and exempt samples may result in the removal of all starter supplies and exempt samples from the clinic permanently as determined by the Pharmacy and Therapeutics Committee.

H. Recall Process:

1. The Pharmacy Purchasing personnel shall notify all outpatient clinics of a recall. (See Department of Pharmacy Services Policy 9.6 Medication Recalls)
2. The Drug Exempt Sample Log-In Form (Appendix C) shall be reviewed to determine if the recalled product has been stocked. The recalled drug stock remaining in the clinic will be located, removed, and returned to the pharmacy stockroom for proper disposal.
 - a. For the Main Campus clinics and off-site clinics with an UWHC outpatient pharmacy, pharmacy personnel will conduct this procedure.
 - b. For all other clinics, a designated clinic staff member will notify the designated prescriber or nurse at all locations and provide information needed to carry out the recall along with the name and phone number of the pharmacy personnel in charge of the recall.
3. If a patient specific recall is required, pharmacy personnel will notify the designated prescriber or nurse at all locations and provide information needed to carry out the recall along with the name and phone number of the pharmacy personnel in charge of the recall.
 - a. The designated prescriber or nurse should review the copies of the Drug Sample Record for the names of patients who have received the recalled sample product. Names of patients who have received the recalled drug should be placed on the Recall Form (Appendix G).
 - b. The patient should be contacted and informed of the recall. If the patient still has a supply of the drug, the patient should be encouraged to return them to the clinic for proper disposal. Record of contact and disposition of the drug shall be recorded on the Recall Form.
 - c. The clinic personnel contacting the patient should also provide the patient with any information or instructions provided by the FDA regarding the recall.
4. When the clinic staff has completed the patient level recall, the completed Recall Form shall be delivered to or faxed to the pharmacy personnel in charge of the recall.

I. Compliance with Sample Procedures

1. Clinics who do not wish to implement the procedures for handling and dispensing samples or clinics found unable to comply with procedures shall not continue to stock and dispense samples.
2. In these situations, the drug voucher system is available to provide the benefits of receiving medication without required payment.

- J. A copy of this policy shall be posted in each clinic sample storage area and will be distributed to pharmaceutical representatives.
- K. Infractions of this policy shall be reported to the UWHC Pharmacy & Therapeutics Committee.

IV. COORDINATION

Sr. Management Sponsor: VP, Professional & Support Services

Author: Director of Pharmacy Services

Review/Approval Committees: Pharmacy and Therapeutics Committee, Administrative Policy and Procedure Committee, Medical Board

SIGNED BY

Donna K. Sollenberger,
President & CEO