Policy Title: Control of Samples: Medications, Personal Medical Devices, Drug Vouchers and Starter Supplies
Policy Number: 6.1.6
Category: UW Health
Type: Ambulatory and Inpatient
Effective Date: August 25, 2016

I. PURPOSE

To establish a procedure to provide vendor-supplied samples of medications or personal medical devices without charge to patients of UW Health in compliance with federal and state laws and standards of The Joint Commission (TJC).

II. DEFINITIONS

A. Personal Medical Device (PMD): a medical device that a patient can take home. These include blood glucose monitors, blood pressure monitors, etc.
B. Sample: medications or personal medical devices provided by manufacturers free of charge for the purpose of encouraging ongoing use by patients.
C. Starter Supplies: a supply of a prescription medication provided for onsite instruction in proper medication use. Medications included in this category are inhalers, nasal sprays, oral titration packs, and injections.

III. POLICY ELEMENTS

The distribution of vendor-supplied medication and personal medical device samples are prohibited throughout UW Health. Certain exceptions are made in this policy allowing distribution only in accordance with the procedures outlined herein.

IV. PROCEDURE

A. Control of Samples
   i. Unapproved samples may not be used or stored in any UW Health facility.
   ii. Current lists of approved samples and starter supplies are maintained (Appendix D and E) and shall be published on U-Connect. Samples may not be used in cases where a patient does not have adequate insurance coverage or does not qualify for a free sample under a manufacturer's assistance program and cannot afford the medication or PMD. UW Health will provide support for these patients through existing patient assistance programs.
   iii. A printed list of approved samples and starter supplies will be kept in the locked storage cabinet where these products are stored.
   iv. Authorization to distribute approved samples is contingent on continued compliance with the procedures outlined in this policy for the control of samples.
   v. Each clinic utilizing approved samples, vouchers, or starter supplies shall designate a prescriber or nurse who is responsible for ensuring compliance with all policies and procedures related to these product categories. Recordkeeping and oversight responsibilities may be delegated to other clinic personnel as appropriate.
   vi. Providers are prohibited from storing samples in their offices.
   vii. Samples acquired for personal use by providers may not be used to treat UW Health patients.
   viii. All approved samples must meet the following requirements for appropriate methods for storing, handling, and preparing for dispensing:
      a. All samples must be labeled using the label portion of the Approved Sample Record form (Appendix A) with the following information: patient name, medical record number (MRN), prescribers name, date, directions for use, purpose of treatment, drug/device name, quantity dispensed, and clinic name, address, and phone number.
      b. The first page of the Approved Sample Record form shall be scanned into the patient's medical record to document receipt of an approved sample or starter supply.
      c. The second page of the Approved Sample Record shall be kept on file in the clinic for a minimum of three years.
      d. Any interdepartmental or clinic-to-clinic transfer of approved samples must be logged at both the distributing and receiving sites.
      e. All starter supplies, approved samples, and vouchers will be stored in a locked cabinet.

This cabinet is located in a limited access area whenever possible and is locked when unattended.

f. Industry representatives will not have access to the storage area without supervision of appropriate personnel.
g. Starter supplies and approved samples may be dispensed only with the consent and supervision of a UW Health attending staff physician or Advanced Practice Provider when acting within prescribing limitations in the state of Wisconsin.

ix. Methods for monitoring stock and evaluation of compliance with dispensing procedures:
a. A monthly review of starter supply and approved sample stock inventory will be conducted in conjunction with Pharmacy Departmental Policy #1.19, Regulatory Compliance Inspections. All samples will be checked for expiration dates and proper storage. Expired items or those that will expire prior to the next inspection will be removed and destroyed.
b. Random periodic review for compliance with dispensing procedures will be conducted by personnel designated by the UW Health Pharmacy and Therapeutics Committee.
c. Failure to comply with procedures for handling and dispensing starter supplies and approved samples may result in the removal of all such medications and personal medical devices from the clinic permanently as determined by the UW Health Pharmacy and Therapeutics Committee.

x. Clinics who do not implement the procedures for handling and dispensing samples or clinics unable to comply with procedures will not be able to stock and dispense samples.

B. Approval Process for Medication Samples
i. In some specific situations, medication samples may be necessary to provide a supply of medication that cannot reasonably be provided through the Drug Voucher System (see section IV.D.). These products are designated “approved samples.”
ii. Situations where medication samples or starter supplies may be approved include:
a. Topical products where drug vouchers are not typically available.
b. Non-prescription/Over-the-Counter (OTC) products which are packaged and labeled by the manufacturer for consumer use and that are not controlled substances.
c. Other products which are approved by the UW Health Pharmacy and Therapeutics Committee for use as an approved sample or starter supplies.
iii. A list of approved medication samples is maintained for reference (Appendix D).
iv. Requests for review should be submitted to the Drug Policy Program (DPP) using the Medication Sample Request Form (Appendix F). DPP will review requests for validity. Requests should include, but not be limited to:
a. the uniqueness of the medication sample,
b. reason why drug vouchers are not feasible
c. the specific circumstances under which the medication sample is required,
1. clinic visit educational requirements
2. dose titration for initiation
3. lack of a commercially equivalent size
4. patient confidentiality concerns
v. Once the review is complete, DPP will present the request to the UW Health Pharmacy and Therapeutics Committee.
vi. Dispensing samples or starter supplies of medications must comply with all labeling, storage, and handling procedures (described in Section IV.A.) required by the Wisconsin Pharmacy, Medical Examining Boards and TJC.
vii. Drugs or products that have been denied formulary status by the UW Health Pharmacy and Therapeutics Committee will not be available as approved samples unless an exception is made by the Committee.
viii. Medication sample use is specifically prohibited in inpatient facilities.
ix. Starter supplies and samples of controlled substances are not permitted.
x. All starter supplies or approved samples of oral medication must be dispensed in child-resistant containers either provided by the manufacturer or by UW Health personnel. The patient or patient representative may waive this requirement by signing the waiver statement on the Approved Sample Record (Appendix A).

C. Approval Process for Personal Medical Device Samples
i. Distribution of personal medical devices is prohibited unless approval is granted. A list of approved personal medical device samples is maintained for reference (Appendix E).

ii. All requests for approval must be reviewed by the Vendor Liaison Office (VLO) and approved by Technology Assessment before use in any UW Health facilities.
iii. Requests for review of personal medical devices should be submitted to the VLO using the Personal Medical Device Sample Request Form (Appendix G) with information including, but not limited to:
    a. Description of the product
    b. Specific circumstances under which the personal medical device sample is required
    c. Retail cost of the device and any associated supplies
    d. Clinic or area or patient population where the product will be offered
iv. The VLO will review requests for potential conflict of interest situations, vendor registration status, unapproved vendor marketing materials, etc. to ensure compliance with UW Health Administrative Policy #11.19, Regulation of Vendor Representatives and the Vendor Liaison Office. Upon completion of VLO review, the request will be forwarded to Technology Assessment.
v. Technology Assessment will review the clinical and financial merits of providing this vendor-supplied product to the requested population. Technology Assessment will consider whether ongoing costs (such as associated supplies) are appropriate versus other alternatives.
vi. Exclusions:
    a. Personal medical equipment purchased by UW Health and given to patients to use and take home
    b. Associated supplies purchased by UW Health for patients to use and take home
    c. Personal medical equipment attained via insurance coverage

D. Drug Voucher System
i. UW Health Drug Vouchers
    a. The purpose of the UW Health Drug Voucher system is to provide an initial supply of medication at no cost.
    b. Vouchers may be available for prescription medications that can be redeemed for a pre-determined amount of drug without charge or minimal copayment.
    c. Procedure:
        1. Prescribers will determine the need for a UW Health Drug Voucher.
        2. UW Health Drug Vouchers should only be provided in situations where not having same-day access to the medication would result in a higher level of care, or unfavorable patient outcomes.
        3. When a patient requiring a UW Health Drug Voucher is identified, a Health Link InBasket message should be sent to UWRX MEDICATION ASSISTANCE PROGRAM (MAP) [Pool #2000002].
        4. The UW Health Medication Assistance Program (MAP) will explore all possible options to ensure immediate and long-term medication access needs are addressed.
        5. After resolution, the MAP will notify Patient Resources to identify and troubleshoot long-term financial assistance, if needed.
ii. Manufacturer-Provided Drug Vouchers
    a. Only manufacturer-supplied vouchers for medications which have not been denied formulary status are allowed in the clinics.
    b. A voucher may be provided for a medication which is also dispensed as a sample.
    c. Procedure:
        1. Industry representatives are to notify the UW Health MAP by email (map@uwhealth.org), when they have new product vouchers available.
        2. MAP will coordinate and distribute all manufacturer vouchers throughout UW Health.
        3. UW Health medication vouchers can be obtained by contacting the MAP.
        4. Manufacturer sponsored vouchers are to be delivered to the MAP by industry representatives. These representatives must be registered with the VLO.
        5. Designated clinic personnel will be responsible for secured storage of the vouchers in the clinic area.

E. Industry Representative Responsibilities
i. Approved samples provided by industry representatives may be left only at:
    a. Clinics with designated locked sample storage areas
    b. Prescriber's offices if in non-patient care areas, or

c. Designated UW Health Pharmacies (when appropriate)

ii. Representatives may provide samples only when requested by licensed prescribers or pharmacists.

iii. The industry representative will be responsible for logging the generic name, brand name, company name, representative's name, delivery date, clinic location, quantity, lot number and expiration date on a form maintained in the individual off-site clinic (Appendix B). All starter supplies and exempt samples must be logged as designated. Representatives are responsible for ensuring that the remaining shelf life for samples is at least 6 months.

iv. Any interdepartmental or clinic-to-clinic transfer of approved samples must be logged appropriately by UW Health staff.

v. Starter supplies and approved samples should be supplied at the discretion of clinic staff.

vi. Industry representatives will be responsible for notifying the VLO for any manufacturer recalls of personal medical device samples.

vii. Unsolicited starter supplies and approved samples are unauthorized and will be removed by the VLO in conjunction with the Pharmacy Department.

viii. Any representative(s) found to be violating these procedures will be subject to the disciplinary process outlined in UW Health Administrative Policy #11.19. The company representative will be held responsible for any and all unapproved sample products they have supplied. If it is impossible to ascertain which company representative violated the sample policy, every representative responsible for the sale of the product identified will be disciplined.

F. Recall Process for Medication Samples

i. The Pharmacy Purchasing personnel shall notify all outpatient clinics of a recall. (See Pharmacy Departmental Policy #9.2, Medication Recalls)

ii. The Approved Sample Log-In Form (Appendix B) shall be reviewed to determine if any recalled product has been stocked. Remaining stock will be located, removed, and returned to the pharmacy for proper disposal.

a. For any UW Health location with a UW Health outpatient pharmacy, pharmacy personnel will remove recalled stock.

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 address the recall along with the name and phone number of the pharmacy personnel managing the recall.

iii. If a Class I 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 Approved Sample Record will be reviewed for the names of patients who have received the recalled sample product. These names should be placed on the Recall Form (Appendix C).

b. The patient should be contacted and informed of the recall. Patients should be encouraged to return any remaining supply 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 provide the patient with any information or instructions provided by the FDA regarding the recall.

G. Compliance

i. A copy of this policy shall be posted in each clinic sample storage area and will be distributed to industry representatives.

ii. Infractions of this policy shall be reported to the VLO per UW Health Administrative Policy #11.19.

V. FORMS

Approved Sample Record Form (Appendix A)
Approved Sample Log-In Form (Appendix B)
Recall Form for Samples (Appendix C)
Medication Sample Request Form (Appendix F)
Personal Medical Device Sample Request Form (Appendix G)

VI. COORDINATION

Author: Director, Center for Clinical Knowledge Management

Senior Management Sponsor: VP, Professional and Support Services
Reviewers: Program Manager, Vendor Liaison Office; Program Manager, Technology Assessment; Manager, Ambulatory Pharmacy Services; Pharmacy Manager, Drug Policy Program; Director, Pharmacy Services
Approval committees: UWISCO; Pharmacy and Therapeutics Committee; UW Health Clinical Policy Committee; Medical Board
UW Health Clinical Policy Committee Approval: July 18, 2016

UW Health is a cohesive, united and integrated academic medical enterprise comprised of several entities. This policy applies to facilities and programs operated by the University of Wisconsin Hospitals and Clinics and the University of Wisconsin Medical Foundation, Inc., and to clinical facilities and programs administered by the University of Wisconsin School of Medicine and Public Health. Each entity is responsible for enforcement of this policy in relation to the facilities and programs that it operates.

VII. APPROVAL

Peter Newcomer, MD
UW Health Chief Medical Officer

J. Scott McMurray, MD
Chair, UW Health Clinical Policy Committee

VIII. REFERENCES

Approved Medication Sample List (Appendix D)
Approved Personal Medical Device Sample List (Appendix E)
UW Health Administrative policy #11.19, Regulation of Vendor Representatives and the Vendor Liaison Office
Pharmacy Departmental policy #1.19, Regulatory Compliance Inspections
Pharmacy Departmental policy #9.2, Medication Recalls

IX. REVIEW DETAILS

Version: Revision
Next Revision Due: August 2019
Formerly Known as: Hospital Administrative policy #8.36, Control of Trial Supplies of Prescription Medication: Samples, Drug Vouchers and Starter Supplies