UMHHC Policy 07-01-045
Drug Samples and Patient Medication Financial Assistance Programs for UMHHC
(Formerly UMHHC Policy 05-03-024)

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I. POLICY STATEMENT

Drug samples, vouchers for starter medications, and copay assistance cards, while convenient for patients, often encourage or may influence prescribing of high cost, non-preferred medications without established therapeutic benefit. In addition, drug samples entail regulatory concerns and safety risks. Therefore, drug samples or sample medications are not permitted in UMHHC facilities. Prescription medication patient assistance programs may be accessed on a limited basis. Guidelines for optimal use are provided.

II. POLICY PURPOSE

This policy and these procedures have been developed to:

- Prohibit the use of drug samples at all UMHHC sites
- Provide guidelines for the optimal use of prescription medication vouchers, copay cards, and/or patient assistance programs by UMHS practitioners and service providers.

III. APPLICABILITY

This policy applies to all individuals involved in the medication use process within the health system.

IV. DEFINITIONS

**Drug Samples** - Prescription and non-prescription medications provided to the sites by pharmaceutical representatives for complimentary (i.e., without cost) distribution to patients.

**Medication Vouchers** - Coupons provided by the pharmaceutical manufacturer that provide a free supply of drug. Vouchers are used in conjunction with a legal prescription and presented to an outpatient pharmacy for dispensing.

**Copay Assistance Cards** - Cards/coupons provided by the pharmaceutical manufacturer designed to reduce the out-of-pocket expense to the patient for prescription medications. These are used in conjunction with a legal prescription and are presented to the dispensing pharmacy.
Patient Medication Financial Assistance Programs (PMFAP) - The UMHS Financial Assistance Policy (sometimes referred to as M-Support or Charity Care) has been established to identify patients who may qualify for financial assistance as determined primarily by the U.S. Federal Poverty Guidelines. For the purposes of this policy and in keeping with UMHS Financial Assistance Policy, the Patient Medication Financial Assistance Program (PMFAP) for UMHHC collectively refers to a pharmaceutical industry-sponsored program including, but not limited to, prescription drug vouchers, patient copay cards that provide financial assistance to the patient by providing free medication and/or reduced cost for a given medication.

UMHHC Sites - Applicable to all U-M Hospitals and Health Centers where care is provided to patients.

Non-Medication Containing Training Devices - Medication delivery devices containing placebo used for patient education and training (e.g., inhalers, subcutaneous injectors or "pens", etc.).

V. POLICY STANDARDS

A. Sample medications are not permitted in UMHHC sites. This includes both patient care and non-patient care areas. Limited exceptions are made for circumstances that require "first dose monitoring" in the clinic setting and/or to avoid interruption in therapy during transition of care to the ambulatory setting.

B. PMFAPs are permitted for use. When possible, practitioners consult a financial support person affiliated with their practice setting (e.g., Patient Financial Counselor, Specialty Pharmacy Financial Coordinator, Social Work, Guest Assistance Program, Patient Assistance Center, Transitions of Care Pharmacy Technician, Business Services Team, HomeMed representative) for available programs and validation of patient savings.

C. In compliance with federal and/or state prescription drug coverage programs (e.g., Medicare, Medicaid), use of PMFAPs is NOT permitted when the prescription is considered a covered benefit.

D. For claims adjudicated through the UMHS outpatient pharmacy prescription dispensing software, the Department of Pharmacy periodically retrospectively monitors use of PMFAPs to assure that recipients are not receiving prescription medication assistance through federal/state payers.

E. General guidelines for use of PMFAPs include:

1. Selection of drug therapy for a given patient is not solely dependent upon or dictated by the availability of a PMFAP;
2. Programs are not utilized for medications for which there are: (1) generic equivalents at significantly lower cost; (2) obvious therapeutic alternatives lower in cost and/or covered by third party payer of the patient;
3. Where PMFAPs are utilized, persons initiating the program assume responsibility for completion of all requirements of the sponsoring program on behalf of the patient such that upon presentation to the dispensing pharmacy, all information is completed and does not require further action by the dispensing pharmacy relative to patient-specific needs. The dispensing pharmacy assumes responsibility for compliance with the participating manufacturer and third party payer, where appropriate.

4. Access to the PMFAP is electronic, when possible, and requires active solicitation by UMHHC staff and/or patient.

5. Physical materials including, but not limited to, copay cards, vouchers, etc. exhibited in patient care areas (e.g., clinics, pharmacies, waiting areas, etc.) are prohibited. Any physical (e.g., paper, electronic) materials necessary must be obtained upon request by UMHHC staff from the manufacturer, and stored in a concealed non-patient care area.

F. Electronic links to external sites (i.e., pharmaceutical manufacturers PMFAPs) are not permitted in the electronic health record.

G. Electronic links to external sites (i.e., pharmaceutical manufacturer PMFAPs) are permitted in departmentally developed and approved web sites for patient reference.

H. Non-medication containing training devices provided by the manufacturer are permitted for use for the purpose of patient education and training.

VI. PROCEDURE ACTIONS

A. Participating pharmaceutical companies, through their pharmaceutical representatives, may alert prescribers and/or other UMHHC staff whose role it is to assist patients with prescription medication access to the availability of PMFAPs (e.g., program website and/or telephone number) per UMHHC Policy 01-04-008 Vendor Visitation and Interaction.

B. Financial assistance materials describing the program may be provided to an individual practitioner upon request. Unsolicited materials relating to financial assistance programs are not distributed to office, clinic, pharmacy, or other UMHHC staff nor left in any patient care areas, and if found, are discarded.

C. Any physical materials detailing PMFAPs identified in patient care areas are removed and the pharmaceutical manufacturer and/or representative responsible is held accountable per UMHHC Policy 01-04-008 Vendor Visitation and Interaction.

D. Requests to include external links to drug manufacturer websites for purposes of accessing PMFAPs within the electronic health record are not granted/permitted.

Approved by:

Ambulatory Formulary Committee - June 26, 2002; November 26, 2003; June 27, 2007; September 2011; May 2012
Pharmacy & Therapeutics Committee - July 16, 2002; October 18, 2011; November 17, 2015
Executive Committee on Clinical Affairs - July 23, 2002
Director and Chief Executive Officer, UMHHCC - September 20, 2002; March 31, 2004; November 19, 2007; December 17, 2012; November 29, 2015

Revised November 2015 by the Department of Pharmacy in conjunction with the Health System Legal Office and UMHS Compliance Office to permit assistance programs in a controlled setting.