



University Health System

Pharmacy and Therapeutics Committee

Pharmaceutical Industry Representative Visitation Policy

Effective June 1, 2008





PHARMACY AND THERAPEUTICS COMMITTEE POLICY

EFFECTIVE JUNE 1, 2008

TITLE: PHARMACEUTICAL INDUSTRY REPRESENTATIVE VISITATION POLICY

PURPOSE:

This policy will delineate guidelines for Pharmaceutical Industry Representative visitation at all University Health System facilities. The policy will address appropriate activities and interactions between University Health System medical facility personnel (including Community Medicine Associates (CMA) physicians, physician's assistants, nurse practitioners, Texas Diabetes Institute staff and UT Medicine staff when they practice at University Health System facilities), allied health professionals and representatives from the pharmaceutical industry. The Pharmacy and Therapeutics Committee also hereby endorses and adopts the "Guidelines for Interactions between University of Texas Health Science Center at San Antonio Clinicians and the Pharmaceutical Industry" and expects Pharmaceutical Industry Representatives and University Health System staff to adhere to those guidelines.

POLICY STATEMENT:

The goal of the University Health System is to foster an environment in which Pharmaceutical Industry Representatives provide information to medical, pharmacy, nursing staff and other allied health professionals that will promote safe and cost-effective use of formulary medications. It is considered a violation of this policy to undermine decisions of the Pharmacy and Therapeutics Committee, including promoting the use of non formulary and/or restricted medications to any of these groups.

POLICY ELABORATION:

This policy was developed by the Drug Vendor Visitation Subcommittee of the Pharmacy and Therapeutics Committee. The subcommittee met over several months and reviewed policies from health care partner facilities, such as the Veteran's Administration and the University of Texas Health Science Center at San Antonio (UTHSCSA). The following policy was developed in concert with policies in place in our health partners' facilities. This policy does not apply to training in-services on products that are admitted to the formulary, i.e, when new processes are implemented,

nor does it apply to in-services prepared and presented by University Health System, UTHSCSA or VA staff unless they are sponsored by industry.

DEFINITIONS:

(1) Pharmaceutical Industry Representative.

The term “Pharmaceutical Industry Representative(s)” (may also be referred to as representative) refers to anyone acting on behalf of a pharmaceutical manufacturer or its business partners for the purpose of promoting the use of items managed under the University Health System formulary process. These items primarily include drugs, but also include any medical supplies, nutritional supplements, and similar commodities managed under the formulary process. Pharmaceutical Industry Representative also refers to anyone acting on behalf of a pharmaceutical manufacturer or its business partners for the purpose of promoting drugs or supplies that are used in conjunction with drugs (for example, diabetic supplies) belonging to that company or one of its partners.

(2) Visit.

Refers to any contact with University Health System staff, including but not limited to clinical staff of CMA, Texas Diabetes Institute, or UT (University of Texas) medicine physicians, physicians assistants, nurse practitioners, pharmacists, nurses and other allied health professionals working in a University Health System facility/clinic. Any visit may only be through controlled access and all visits are subject to the University Health System VENDOR ACCESS/IDENTIFICATION Policy No. 6.07. This policy was established to promote patient safety, security and privacy and requires that vendors wear University Health System provided and company provided name tags at all times when they are at a University Health System facility. It further requires that vendors check in and check out at the same facility. All Pharmaceutical Industry Representatives should review the entire policy to assure compliance.

(3) University Health System Facility

This is defined as any facility owned and/or operated by the University Health System.

(4) Meal.

A “meal” is the food served and eaten at one of the customary times for eating, as in breakfast, lunch, dinner, or “on call” dinners.

(5) Presentation

The process of presenting the content of a topic to an audience.

GUIDELINES FOR VISITATION:

I. REGISTRATION

A. Any visit may only be through controlled access and all visits are subject to the University Health System **VENDOR ACCESS/IDENTIFICATION** Policy No. 6.07. This policy was established to promote patient safety, security and privacy and requires that vendors wear University Health System provided and company provided name tags at all times when they are at a University Health System facility. It further requires that vendors check in and check out at the respective facility. Pharmaceutical Industry Representatives should review the entire policy to assure compliance.

Prior to visiting a physician/health care provider within University Health System facilities, the representative must register at the appropriate office to receive a vendor badge which must be returned at the conclusion of the visit. This registration is for a **ONE-TIME VISIT ONLY**. It **DOES NOT** provide authorization to visit other areas or other individuals encountered within the area. Individuals in the designated registration area (Protective Services at the Hospital and Clinic Administration at the ambulatory care clinics) will verify an appointment before the vendor is given a badge to proceed to the visit. Access to University Health System facilities by sales representatives who have not made a previously scheduled appointment is not permitted.

B. University Health System staff/clinic personnel may develop a list of individuals or departments that do not wish to be called upon by sales representatives. These lists should be given to the Protective Services, Purchasing and Pharmacy departments, as well as to administration in that facility. Pharmaceutical representatives must not attempt to make appointments with individuals or departments on the list.

C. Representatives are encouraged to schedule appointments in University Health System facilities between the business hours of 8:00 AM and 5:00 PM, Monday through Friday. However, if necessary for the convenience of University Health System staff, appointments at other times are permissible. The requesting physician or allied health professional must request this exception and receive approval through the Director of Pharmacy. If approval is received, the Chief of Police will be notified regarding the after hours visit. This process may require up to a 3-day lead time to make the arrangements/receive approval.

D. To respect patient privacy, representatives are not permitted in patient care areas. Examples of patient care areas at the hospital include, but are not limited to, the following:

1. Inpatient units and outpatient clinics;
2. Clinic examination rooms;

3. Nursing stations;
 4. Intensive care units;
 5. Operating room suites;
 6. Emergency Center;
 7. Dialysis areas; and
 8. Cardiac Cath Lab
- E. In the University Health System Ambulatory Care Clinics, drug representatives will schedule appointments by calling the physicians through Clinic Administration or at their specific clinics. Meeting areas can be designated by each clinic to avoid visitation in the patient care clinics and each clinic can designate specific meeting times with representatives if so desired.

II. SPECIFIC PROHIBITED OR REGULATED ACTIVITIES

- A. Representatives related to any University Health System employee and/or physician should not call on that person in the course of their business. In this situation, the drug company must provide another representative to call on a physician or University Health System employee.
- B. University Health System employees, including physicians practicing in University Health System facilities, may not accept any form of personal gift from industry or its representatives.
- C. Distribution of pads, pens, any items that promote the use of a drug or product, may not be distributed within University Health System.
- D. Meals funded directly by industry will not be provided at any University Health System facility unless the program will provide at least one (1) hour of Continuing Education (CME, CNE or ACPE). Prior to presentation of any program, there must be prior review and approval by the Pharmacy Academic Programs Oversight Committee—please refer to Appendix 1.
- E. Representatives are not allowed to attend medical care treatment facility conferences where patient-specific material is discussed or presented.
- F. Representatives are prohibited from marketing to medical, pharmacy, nursing and other health profession students without the presence of a faculty or licensed professional (pharmacist, nurse, etc.).

III. ACCEPTABLE PROMOTIONAL ACTIVITIES

- A. Presentation of programs through donation of unrestricted educational grants is allowed. These programs may be planned and carried out by University Health System/UTHSCSA staff or by a speaker sponsored by the

- company. In these instances, a reasonable portion of the grant may be used for food to the extent that this is required by the timing or nature of the educational program.
- B. Presentations may be made by speakers brought in from outside the Health System. In these cases, the representative must submit a statement of non-bias and the syllabus that will be presented to the Pharmacy Academic Programs Oversight Committee (located in the Administrative Offices of Pharmacy at University Hospital). This should be done two (2) weeks prior to the presentation. If there is no statement of non-bias, the Oversight Committee will decide based on review of the material.
 - C. In-services for use of a specific product that has been approved for the formulary are allowed.
 - D. Presentations sponsored by drug industry (not including inservices for new products or for patient safety training, etc.), must be prior reviewed and approved by the Pharmacy Academic Programs Oversight Committee to assure there is non-commercialism and no bias. (see Appendix 1). If a statement of non-bias has been prepared, this may be presented to the Committee with the materials.

IV. DRUG SAMPLES

Drug samples are not allowed in any Health System facilities/clinics, either inpatient or outpatient. Drug representatives shall not provide drug samples on the premises of any University Health System facility.

V. NON-FORMULARY/RESTRICTED PRESCRIPTION DRUGS

- A. If a faculty physician asks for medical literature for a non-formulary drug, the representatives must write on the literature that the drug is non-formulary. The use of a non formulary drug may not be discussed or promoted.
- B. Representatives may not complete or participate in the completion of Formulary Admission Request in any manner, nor should they request the Formulary Admission Request for the physician.
- C. Representatives may not detail non formulary drugs to residents or fellows, physicians in training, Physician's Assistants, Nurse Practitioners, or other allied health professionals.
- D. Representatives may not detail their restricted product if the detailing is not in accordance with the restriction.

VI. INFRACTIONS AND DISCIPLINARY ACTION

- A. All vendors must ensure that their representatives who provide services to the University Health System meet and adhere to all requirements, rules, policies, procedures, regulations and vendor protocol of the Health System.
- B. Vendor representatives who violate any of these rules, policies, procedures and regulations will be subject to removal, refusal of entry and all sanctions allowed by Health System policy and law.
- C. Vendors who are not properly identified and have not completed the vendor check-in process must be referred to the Vendor Registration area.
- D. The Directors of Pharmacy and/or Purchasing will follow up on complaints regarding representatives and the Directors of Purchasing may take action up to and including banning the individual and/or company for a specified period of time.

VII. DEPARTMENTAL/EMPLOYEE RESPONSIBILITIES

- A. Directors, managers, and supervisors of departments must ensure that all Vendors meet Health System requirements and follow all Health System policies, procedures, rules, and regulations while on Health System premises.
- B. Employees must be vigilant regarding the presence of unauthorized personnel in the workplace. Persons not displaying appropriate identification shall be referred to Protective Services.

REFERENCES/BIBLIOGRAPHY:

UTHSCSA Policy
 Health System Policy # **6.07** Vendor Access/Identification
 Health System Policy #5.02 *Protection of the Work Environment*
 Health System Policy #6.01, *Purchasing*
 Health System Purchasing Vendor Protocol Handbook
 Pharmacy and Therapeutics Committee policies—Drug Sample Policy

OFFICE OF PRIMARY RESPONSIBILITY:

Pharmacy and Therapeutics Committee, University Health System

OFFICE(S) OF SECONDARY RESPONSIBILITY:

Director of Pharmacy
 Director of Purchasing
 Chief of Police, University Health System

Appendix 1

A Pharmacy Academic Programs Oversight Committee will be established to review program content from outside (not University Health System, UTHSCSA or VA staff) prior to presentation to assure that bias for a particular product does not appear in a program (such as when a speaker is a member of an industry-based speaker's bureau). The speaker and/or representative sponsoring the presentation must present handouts/slides to the Committee so that the information may be reviewed **prior** to the presentation. This will apply to presentation of programs involving drugs, pathways, processes, etc., where drugs are included.

Patient Care Services currently has a process such that all presentations are prior reviewed for content for accreditation, as well as conflict of interest through their Continuing Education Division and they will continue to review their programs. The Pharmacy Academic Oversight Committee is available for consult to Patient Care Services. Prior review of presentations must occur for all programs sponsored by industry for CNE, ACPE, CME or presentations for other allied health professionals.

Minimum of two (2) weeks time is requested for this review, but review may occur in less time.