


<b>Name of Policy:</b> Pharmaceutical Representatives <b>Policy Number:</b> 3364-133-44 <b>Approving Officer:</b> Chief Operating Officer <b>Responsible Agent:</b> Director of Pharmacy <b>Scope:</b> University of Toledo Medical Center		 <b>Effective date:</b> <b>Original effective date:</b> January 1, 2003	
Key words: Pharmaceutical Representatives, Company, Privacy, Compliance, Procedure			
<input type="checkbox"/>	New policy proposal	<input checked="" type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input type="checkbox"/>	Reaffirmation of existing policy

(A) Policy statement

It is the policy of The University of Toledo Medical Center (UTMC) to authorize, schedule and coordinate pharmaceutical company representative activities as they interact with the UTMC medical, pharmacy, nursing, other professional staff members, students, and residents.

(B) Policy Purpose

This policy is necessary for the protection of physician and staff efficiency, integrity, and to ensure patient privacy. The goal is to avoid conflicts of interest and any perception of influence or impropriety. This policy applies to physicians, residents, fellows, medical house staff and students working or studying at the UTMC. It is acknowledged that pharmaceutical representatives can provide valuable information, however, they are not considered as essential experts or consultants in the care of patients at this institution. The Director of Pharmacy is responsible for overall compliance with and enforcement of this policy and procedure.

(C) Procedure

1. Registration while on premises

- A. All vendors are required to sign in and out through the Purchasing department vendor process. This requires the vendor to log in and receive a vendor permit, which is good for that visit only. The method and/or location for this process will be determined by Purchasing.
- B. This procedure is required prior to the vendor visiting any area of the University of Toledo Health Science campus (i.e., hospital, clinics, physician offices) for business purposes.
- C. Staff will not meet with or allow representatives within their areas, that are ~~representatives~~ lacking a valid UTMC vendor permit.

## 2. Locations permitted

### A. Representatives are not permitted access to:

- Any inpatient care areas or direct patient care areas such as Patient Rooms, Procedure Rooms (i.e., OR, Cath/EP Lab, Imaging), Patient Observation Rooms, Hospital Inpatient Nursing Stations, and Emergency Room except as described in the next section.
- The only exception is the use of conference rooms for scheduled educational experiences.
- Inpatient and outpatient dispensing areas in the pharmacy department.

### B. Representatives are permitted access to:

- Outpatient nursing stations during non-patient care hours or by physician invitation at other times
- All public areas of the UTMC and clinics
- Faculty and staff offices by appointment or invitation
- Pharmacy administrative and purchasing offices by appointment or invitation.
- Office of ~~Clinical Manager or Assistant Director~~ Pharmacy Management or Clinical Pharmacists by appointment or invitation
- Patient care areas on the invitation of an attending physician or University of Toledo faculty member.
- Patient care areas for the pre-approved purposes of in-service training or assistance on medical devices, equipment, and materials.

## 3. Appointments and Purposes

### A. Representatives are encouraged to schedule appointments with appropriate pharmacy department staff to:

- Provide information useful for product evaluation and proper use.
- Provide timely information on the supplier's products and services.
- Facilitate procurement and crediting transactions.
- Obtain and provide information necessary to support the organization's formulary system or patient education. These educational materials are subject to Pharmacy review and approval prior to general distribution.
- Facilitate informational activities for the pharmacy staff and other health care professionals with respect to the supplier's products.

## 4. Dissemination of Promotional Materials

### A. The pharmacy staff will provide the representative with the formulary status of a particular drug. Where applicable, the drug guidelines will be shared with the representative.

### B. Promotion of non-formulary drugs is allowed but not encouraged. If this does occur, the representative must identify their product as such.

- C. Representatives may be asked to provide the pharmacy department with copies of all informational and promotional materials disseminated in the organization.
- D. The FDA prohibits advertising and promoting drug products for uses not reflected in FDA approved product labeling. Promotional techniques that violate FDA guidelines are subject to reporting.
- E. Direct promotion to members of the P & T Committee is prohibited unless the product is specifically related to the member's area of expertise.
- F. Mailboxes may not be used for unrestricted distribution of promotional materials. Only materials specifically requested by physician providers may be left in mailboxes.
- G. Industry drug and device representatives are prohibited from having non-faculty or staff mentored promotional interactions with pharmacy students or residents learners.
- H. Faculty, staff, fellows, residents, and students on the Health Science Campus will not be allowed to accept gifts from industry. This includes such "token items" as pens, note pads, and food.
- I. Industry support of symposia, conferences, and other events designed for post-graduate professionals in Northwest Ohio and beyond, that are sponsored totally or in part by the University of Toledo, UTMC, Pharmacy Services, or any College on the Health Science Campus will be encouraged. Sponsor support will be acknowledged. Booths, tables, and displays to provide product information and discussion with industry representatives will continue to be permitted. However, neither gifts of value nor token reminders, such as pens or pads will be permitted at these display areas.

## 5. Drug Samples

### A. Inpatient Units

- Storage and/or distribution of drug samples are prohibited in the Pharmacy department.
- The use of samples at the UTMC (hospital) is prohibited.

### B. Ambulatory Care Areas

- The representative will follow the organization's policy and procedure with respect to product samples, as stated in hospital policy # 3364-101-06-03 (available on the policies website or upon request).
- Current law requires that a licensed physician provider must sign a receipt for drug samples left in the provider's office, clinic, or procedure area.
- Pharmaceutical representatives are not allowed to put away the samples and are not allowed access to the area where samples are stored.

### C. Failure to comply with these rules may result in the removal of samples from the non-compliant area, restriction of future samples, and exclusion of the representative from University of Toledo Health Science Campus for business purposes.

## 6. Formulary Process

- A. New drug requests must be submitted for review by the P&T Committee to the Director of Pharmacy by a staff or provider at UTMC.
- B. For consideration, a request needs to be submitted to the pharmacy at least two months prior to being presented at a P&T meeting.
- C. Pharmacy may contact physicians who are most likely to prescribe the drug for their input.
- D. After an overview presentation to the P & T Committee, one of the four following actions is taken:
  - Added to formulary
  - Added but under restricted use
  - Not added, but available using a Non-formulary Drug Request Form
  - Not added, and will not be available
- E. All P&T decisions are subject to review by the Medical Executive Committee.

## 7. Gratuities

- A. The representative will not offer or provide any gifts, gratuities or entertainment to hospital and/or medical staff, students, or residents. This includes free food. This provision is not intended to interfere with materials and meals provided to UTMC faculty and staff as part of contracted services for training and education.
- B. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.
- C. Representatives are expected to abide by the American Medical Association's "Guidelines on Drug Industry Gifts" (JAMA 1991: 265:501) and Pharmaceutical Research and Manufacturers of America's "Code on Interaction with Healthcare Professionals" Effective January 2009.
- D. Educational support by unrestricted donation to a Department or College is allowed. To meet this requirement there can be no particular program, date, or topic.

## 8. Violations

- A. These policies and procedures will be strictly enforced. If this procedure is not followed, no more than one written warning will be issued, followed by the vendor being subject to exclusion from visiting the University of Toledo Health Science Campus for business purposes in the future.

<p>Approved by:</p>  <hr/> <p>Holly Smith Director, Pharmacy Services</p>  <hr/> <p>Date</p>  <hr/> <p>Russell Smith Chief Operating Officer</p>  <hr/> <p>Date</p>  <p><i>Review/Revision Completed by:</i> <i>Director of Pharmacy</i></p>	<p><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"><li>• <i>none</i></li></ul> <p>Initial effective date: January 1, 2003</p> <p>Review/Revision Date:</p> <p>7/04 3/08 5/11 1/14 11/16 4/19 6/21 3/24</p>  <p>Next review date:</p>
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