(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) Purpose of Policy

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 through the approved process. This requires the vendor to log in and receive a vendor permit that is good for that visit only. The method and/or location for this process will 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 within their areas, representatives lacking a valid UTMC vendor permit.
   D. Pharmaceutical and device representatives will be required to follow all requirements of the Supplier Visitation and Compliance Guidelines.

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 Pharmacy clinical pharmacists by appointment or invitation
- Patient care areas on the invitation of an attending physician or University of Toledo faculty member. This requires prior disclosure and consent by the patient, and then only to provide or receive in-service training or assistance on medical devices, equipment and materials.

3. Appointments and Purposes

A. Representatives are required 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 clinical pharmacists will provide the representative with the formulary status of a particular drug. Where applicable, drug guidelines will be shared with the representative.

B. Promotion of non-formulary drugs is prohibited

C. New drug entities, although non-formulary, may be promoted until formulary status is decided by the P & T Committee.

D. Representatives may be asked to provide the pharmacy department with copies of all informational and promotional materials disseminated in the organization.

E. 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.

G. Direct promotion to members of the P & T Committee is prohibited unless the product is specifically related to the member's area of expertise.

H. Mailboxes may not be used for unrestricted distribution of promotional materials. Only materials specifically requested by physicians may be left in mailboxes.

I. Industry drug and device representatives are prohibited from having non-faculty or staff mentored promotional interactions with pharmacy students or residents.
J. 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.

K. 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 3364-101-6-03.
   • Current law requires that a licensed physician must sign a receipt for drug samples left in the physician’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 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 on a Request for Addition to UTMC (hospital) Drug Formulary form. This form is provided directly to the members of the medical staff by the pharmacy department.

B. New dosage forms or strengths of formulary items rarely require committee action.

C. For consideration a request needs to be in the pharmacy department 2 months prior to the P&T meeting.

D. Once requested, pharmacy may contact physicians who are most likely to prescribe the drug for their input and generate a predicted utilization analysis

E. After an overview presentation to the P & T Committee, one of four following actions is taken:
   • Added to formulary
   • Added but under restricted use
   • Added but not stocked
   • Not added, but available using a Non-formulary Drug Request Form
   • Not added, and will not be available
F. All P&T decisions are subject to review/rejection 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.


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 by purchasing, pharmacy, and compliance offices. 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.

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<th>Approved by:</th>
<th>Review/Revision Date:</th>
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<tbody>
<tr>
<td>Russell Smith Pharm D, BCPS</td>
<td>7/04</td>
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<tr>
<td>Director of Pharmacy</td>
<td>3/08</td>
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<td>Dan Barbos RN</td>
<td>5/24/2011</td>
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<tr>
<td>Interim Chief Executive Officer</td>
<td>1/2014</td>
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<td>9 Nov 2016</td>
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Next Review Date: 11/1/2019

Policies Superseded by This Policy: