

Hospital of the University of Pennsylvania
 Clinical Practices of the University of Pennsylvania
POLICY MANUAL

Number: 1-12-41

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SUBJECT: PHARMACEUTICAL COMPANY REPRESENTATIVE ACTIVITY

Effective: 9/27/06

KEY WORDS:

PhRMA
 Drug representatives
 Detail men/women
 Professional behavior
 Organizational ethics
 "Gifts to Physicians from Industry"

SEE ALSO

#1-7-10 "Guidelines for Interactions between Healthcare Professionals and Industry"

#1-12-10 "Organizational Ethics"

1-12-14 "Sample Medication Voucher Program"

Policy:

It is the policy of the Hospital of the University of Pennsylvania (HUP) and the Clinical Practices of the University of Pennsylvania (CPUP) to authorize and coordinate pharmaceutical company representative activities as they contact medical, pharmacy, nursing, administration and other professional staff members. Pharmaceutical representatives are expected to abide by the American Medical Association's "Gifts to Physicians from Industry," the PhRMA Code on Interactions with Healthcare Professionals, the Novation Code of Conduct for Pharmaceutical Representatives, and other applicable laws and regulations such as the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support and the University of Pennsylvania School of Medicine (SOM) internal Continuing Medical Education (CME) policies, while on HUP/CPUP premises or in interacting with HUP/CPUP. Gifts should not be accepted from pharmaceutical representatives.

Purpose:

The purpose of this policy is to protect physician and other medical staff and other health care providers' efficiency and integrity and to support patient safety and privacy. Pharmaceutical representatives' activity must be coordinated and this policy enforced to meet HUP/CPUP's needs for security and prudent business practices. The policy is also designed to promote an environment that ensures optimal patient care through less distractions and one that respects the integrity and confidentiality of patient privacy.

Scope:

This policy applies to all medical, nursing, pharmacy, and other healthcare workers ("professional staff") of HUP/CPUP. All pharmaceutical company representatives are also expected to abide by this policy while on HUP/CPUP premises including the Hospital of the University of Pennsylvania ("HUP" or "Hospital") or Clinical Practices of the University of Pennsylvania ("CPUP") that practice at or in conjunction with HUP (collectively "HUP/CPUP") or in interacting with HUP/CPUP.

Implementation:

Each hospital Department Director and physician and professional staff is responsible for adherence to and compliance with this policy as it applies to their respective areas of responsibility. The Director of Pharmacy Services is responsible for overall compliance with and maintenance of this policy and procedure, however compliance will be monitored through ongoing review by the Pharmacy & Therapeutics Committee in conjunction with other HUP/CPUP Department Directors, physicians, and professional staff. The Department of Pharmacy Services, Medical Staff, Nursing Staff, Medical Affairs, and Security are responsible for enforcement of this policy with pharmaceutical company representatives.

Procedure:

A. Registration and Orientation

1. Pharmaceutical company representatives, on their first visit to HUP/CPUP will be directed to the Department

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of Pharmacy Services, where they will be provided with a copy of this policy. The representative will sign a statement to the effect that he/she has received and understands this policy. The representative will then be directed to the HUP Security Department to obtain the appropriate identification badge. The representative must wear this identification badge at all times during all HUP/CPUP campus visits.

2. Pharmaceutical company representatives must provide the following information to the Department of Pharmacy Services secretary: 1) current business card; 2) immediate supervisor's name, work phone, and address. Any changes to this information must be promptly forwarded to the Department of Pharmacy Services.
3. Pharmaceutical company representatives are required to have a scheduled appointment whenever they visit the Hospital or CPUP. Representatives who arrive in the Hospital or a CPUP location without an appointment should be asked to leave the facility and subsequently reported to the Director of Pharmacy Services. Exceptions include visits to expedite removal of recalled or return products in coordination with the Pharmacy Services Department or to deliver new product information to the Pharmacy Services Department.
4. Pharmaceutical company representatives visiting HUP/CPUP for any business reason will report to the secretary in the Department of Pharmacy Services. Representatives also are required to register with the department in which they have a scheduled appointment.
5. HUP/CPUP reserves the right to limit the number of pharmaceutical representatives a single company has visiting HUP/CPUP at any given time.

A., B. --
Representative
Access

B. Authorized and Unauthorized Areas

1. Pharmaceutical company representatives are not permitted to detail professional staff in any patient care unit, including inpatient units, nursing stations, conference rooms, physician lounges, outpatient clinics (patient areas), perioperative and operative areas and the Emergency Department. Representatives must conduct meetings ONLY in private offices. Public areas such as the cafeteria and non-patient care areas may be used by representatives subject to the approval of the professional staff who are in charge of the area provided it is not in an inpatient area. Representatives must have a scheduled meeting. Detailing shall not be permitted in public telephone areas, hallways, inpatient care units, near elevators or in parking garages.
2. Due to patient confidentiality concerns, pharmaceutical company representatives are not permitted to attend any conferences or reports. Representatives may not see patients, review their charts or any portion of the patient medical record, whether in electronic or paper format, go on rounds or attend surgery. Pharmaceutical representatives are prohibited from all clinical areas, including inpatient units and conference rooms on inpatient units, where there may be a potential for patient information to be shared.
3. In those rare circumstances where a pharmaceutical company representative has direct patient contact, they are subject to hospital policy regarding immunizations and other health requirements (e.g. MMR immunization, TB skin testing) and must also have executed a Clinical Observer Agreement.

C. Non-Formulary Drugs

1. Pharmaceutical company representatives may contact the Department of Pharmacy Services with drug

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information at any time in accordance with this policy. If the drug has been evaluated by the Pharmacy & Therapeutics Committee and thereafter denied formulary addition (non-formulary drug), the pharmaceutical company representatives are prohibited from detailing professional staff on HUP/CPUP premises about these drugs.

2. Pharmaceutical company representatives may detail staff about formulary medications, but may do so only after the representative has provided the Pharmacy Drug Information Service with formulary packets and information about the medication that will be detailed. Representatives must comply with the directives of the UPHS Center for Evidence Based Practice and the Pharmacy and Therapeutics Committee in their marketing activities. Representatives must notify physicians and professional staff when a medication is under restriction or guidelines and provide information on its average wholesale price. The Pharmacy Drug Information Service will notify the representatives of a formulary status change, restriction, or guidelines.

D. Sample Medications and Promotional Items

1. No physical medication samples are allowed within HUP and CPUP practices. The distribution of sample medication vouchers in inpatient areas is prohibited. Personnel discovering sample medication vouchers in inpatient care areas must forward them to the Department of Pharmacy Services. For information regarding outpatient use of sample medication vouchers, see HUP/CPUP Policy #1-12-14 "Sample Medication Voucher Program in the Clinical Practices of the University of Pennsylvania". HUP/CPUP physicians and professional staff should be wary of using sample medication vouchers as a means to obtain access to medications for their patients, since the purpose of the sample voucher may be to induce physicians to prescribe newer, more expensive products.
2. Promotional items may not be distributed (e.g. pens, note pads, and similar "reminder" items). Promotion of drug products may not be for uses not reflected in FDA approved product labeling. Information regarding such uses may be provided to the Pharmacy Services Department if consistent with UPHS Center for Evidence Based Practice and Pharmacy and Therapeutics Committee directives. Educational grants may not be made or conditioned or related in any way to any pre-existing or future business relationship with the pharmaceutical company or any business or other decisions HUP/CPUP has or may make relating to the pharmaceutical company or its products (including coverage or formulary status decisions). The content of the educational program, educational methods and materials should be consistent with applicable rules and requirements that govern certified CME. The educational content must be controlled by the Course Director (for a non-CME program) or, by the U of Penn SOM Office of CME (for a CME program), and not by the pharmaceutical company providing the educational grant.
3. Pharmaceutical company representatives are expected to communicate warnings and contraindications with the same fervor with which they promote indications and endorsements by medical experts.

D. --
Samples

D.2. --
Fellowships and Travel;
Continuing Medical Education (CME)

E. Educational Programs

1. All in-services, lectures, or other presentations to the HUP/CPUP staff members by pharmaceutical representatives must be registered with the Department of Pharmacy Services and/or the Clinical Effectiveness and Quality Improvement (CEQI) Department at least one month prior to the date of the presentation. These programs must also be approved by the director of the Hospital department for which the program is being held, and this shall be noted when the program is registered with the Pharmacy Services or

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CEQI Departments.

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2. All non-CME programs must be limited to discussion of formulary drugs. Any restrictions or guidelines that pertain to use of the drug at HUP/CPUP must be stated in the context of the program. These programs must be attended by a pharmacist. Programs must not be scheduled in any patient care unit, including inpatient units, nursing stations, conference rooms, physician lounges, or outpatient clinics.

F. Meals and Gifts

F.1. -- Gifts

1. Gifts to professional staff are prohibited, including but not limited to tickets or vouchers for entertainment events, cash or other gifts.

F.2. -- Meals

2. Food is not to be provided directly by pharmaceutical representatives. Support for continuing medical education (CME) may only be made through educational grants made directly to the Trustees of the University of Pennsylvania/CME. All commercial support grants associated with a CME program must be given with the full knowledge and approval of the U of Penn SOM Office of CME. The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter and the U of Penn SOM Office of CME. Educational grants may not be made or conditioned or related in any way to any pre-existing or future business relationship with the pharmaceutical company or any business or other decisions HUP/CPUP has or may make relating to the pharmaceutical company or its products (including coverage or formulary status decisions). The educational content must be controlled by the Course Director (for a non-CME program) or, by the U of Penn SOM Office of CME (for a CME program), and not by the pharmaceutical company providing the educational grant.
3. Pharmaceutical representatives may not use HUP/CPUP personnel or resources to distribute information about promotional pharmaceutical-sponsored events. This includes UPHS or University of Pennsylvania e-mail, mailings, e-page, or other mass notification methods. Departmental and division offices, including residency and fellowship programs, will not circulate announcements of promotional pharmaceutical-sponsored events or provide e-mail lists or address lists of HUP/CPUP physicians or housestaff.
4. Pharmaceutical representatives should not compensate HUP/CPUP personnel for time spent listening to them detail their product or accessing websites.

G. HUP/CPUP-Based Training Programs

1. Occasionally physicians, pharmacists, nurses, or other professional staff are asked by pharmaceutical companies to provide HUP/CPUP based training for representatives about new drugs or procedures. While HUP/CPUP is interested in educating members of the pharmaceutical industry, physicians and pharmaceutical representatives must comply with the following:
 - a. The pharmaceutical company, physician or professional staff member will notify the Director of Pharmacy Services as soon as an educational program becomes a possibility.
 - b. The Director of Pharmacy Services will require the pharmaceutical company to have on file a brief outline of the project from the pharmaceutical company that includes the intent, scope and time line of the educational program.

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- c. Pharmaceutical representatives are not allowed direct contact with patients or their medical records for reasons of confidentiality, nor are they allowed in any patient care area unless the patient has authorized access or the pharmaceutical company has appropriately executed a Business Associate Agreement (and is providing treatment, payment or healthcare operations services to UPHS).
- d. While on HUP/CPUP premises pharmaceutical representatives must wear appropriate identification badges so that patients, visitor, staff and physicians can identify them as visitors from the pharmaceutical industry.

H. Compliance by Pharmaceutical Company Representatives

1. Pharmaceutical company representatives shall comply with all applicable rules, regulations, policies and procedures of HUP/CPUP as they exist now and as they may be amended from time to time, including, but not limited to, all policies and procedures relating to ingress and egress to and from the HUP/CPUP campus and HUP/CPUP premises, parking, confidentiality of patient information, safety, smoking, waste disposal, and infection control.
 - a. When Security or HUP/CPUP personnel identify a pharmaceutical company not adhering to this policy, they should report this to the Director of Pharmacy Services, who then notifies the representative of the infraction. Restriction, up to and including the removal of the pharmaceutical representative from HUP/CPUP premises, is possible based upon the type of infraction or the number of reoccurring infractions of the policy.
2. HUP/CPUP reserves the right to immediately have any pharmaceutical company representative removed from HUP/CPUP premises as determined in HUP/CPUP's sole discretion.
3. Pharmaceutical companies that are not participants in the UPHS Center for Evidence Based Practice or that violate this policy shall not be permitted to market or detail at HUP/CPUP.

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