

POLICY #	ALL-RX-MED MGMT-034-01A		
POLICY NAME	CODE OF CONDUCT FOR PHARMACEUTICAL REPRESENTATIVES		
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SPONSORED BY	Timothy Freeman, M.D. (signature on file)	DATE	7/10/2007
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## I. POLICY

Establish the standards to be followed by pharmaceutical representatives when interacting with the Health Alliance.

## II. PURPOSE

This Code of Conduct for Pharmaceutical Representatives is necessary to protect physician and staff efficiency and integrity in addition to patient privacy and confidentiality. It is acknowledged that pharmaceutical representatives can provide valuable information, however, they are not considered essential experts or consultants in the care of patients. The focus of this document is to give direction in regard to educational and promotional interactions to those vendors who serve and interact with the Health Alliance and its affiliated sites with respect to drug products, supplies and services purchased by Pharmacy Services. These principles of professional conduct are established to guide the vendor representative in his/her relationship with attending faculty, house staff, pharmacists, nurses, students, other health professionals, and other vendors at the Health Alliance.

## III. DEFINITIONS

Pharmaceutical representatives - agents who promote products and provide information and services to health care providers on behalf of manufacturers and suppliers.

## IV. PROCEDURE

**A. Defined Scope of Applicability**

These policies and procedures are applicable to drug-product and drug administration device vendors' representatives. Policies and procedures applying to representatives promoting medical-surgical supplies, equipment, or drug administration devices are available in the Health Alliance Purchasing Department.

**B. Authorized Drug Purchases**

Only Alliance Pharmacy Services is authorized to make drug purchases on behalf of the health care organization, unless specifically assigned to another department. Representatives may not accept any order (verbal, phone, fax or written) for pharmaceuticals unless an official purchase order is authorized and assigned by the respective pharmacy or purchasing department.

**C. Orientation of Representatives**

Pharmaceutical representatives are required to complete an orientation program with the Health Alliance prior to appointments being scheduled at any Health Alliance facility. The orientation program will review the Code of Conduct policy and procedures.

Representatives will receive an orientation packet upon their initial visit, containing a copy of the Health Alliance Code of Conduct for Pharmaceutical Representatives, the Drug Policy Development process, and the Health Alliance Conflict of Interest Policy. A formal orientation program for new representatives will include a review of the packet and meeting key people within the organization. Announcements of times and locations for orientation programs will be made by Health Alliance Pharmacy Services.

**D. Directory**

A file of current vendor contact information is maintained in the Health Alliance Pharmacy Services Corporate Office, Alliance Business Center. The following information should be provided by company representatives:

- The vendor name and address
- The name, address, telephone number(s), and drug-product assignment of each representative.
- The name, address and telephone number of the representative's managers. The names, telephone numbers, and emergency telephone numbers of the vendor's directors of distribution, sales, and product information (titles may vary).

The names and telephone numbers of the vendor's medical director and research director (titles may vary). It is the responsibility of the vendor to provide formal notification when a change of representatives occurs.

**E. Multiple Representatives**

Some vendors have multiple representatives serving the Health Alliance. All representatives are required to register with the Health Alliance Pharmacy Corporate Office. Regular contact with pharmacy services is encouraged. A designated representative is encouraged for communication with the Health Alliance Pharmacy Corporate Office.

**F. Availability of Vendor-Contact Information to Health Alliance Health Care Professionals**

Alliance Pharmacy Services will provide professional staff with vendor directory information, upon request.

**G. Vendor Registration**

All representatives must be recorded in the Health Alliance Pharmaceutical Representatives directory. Representatives and their guests must register with the pharmacy department or other designated departments upon each visit to a Health Alliance facility. At such time, the vendor representative(s) must document the time, purpose, and location of their appointments. In addition to his/her company badge, each individual will receive a visitor's badge upon arrival that must be worn in a visible location while on the premises, and returned to the applicable registration site upon departure.

**H. Appropriate Locations**

Representatives are restricted to office and meeting areas of the facility (hospital and ambulatory sites) only and are prohibited from patient care areas unless formally involved in observing a patient procedure. A patient care area is defined as any portion of the health care facility where patients are examined or where care is administered. These areas include the immediate patient room, the areas adjacent to the room, operating rooms, treatment rooms, areas used to transport patients or any other area that would interfere with patient care delivery.

**If an appointment with a professional staff member is located in a clinical area of the facility, a Health Alliance associate must escort the representative to the appropriate location.**

**I. Confidentiality of Patient Information**

Appointments must not interfere with patient care activities. Only health care professionals with the responsibility to treat patients can have access to patients and protected health information.

Patient care rounding with physician teams and attending conferences intended to discuss patient information (e.g. Morbidity and Mortality, Patient Case Conferences, Board and Registry Meetings) is strictly prohibited.

If observing an invasive procedure, the representative must adhere to the following:

- Receive prior approval from the physician and department manager
- Complete patient consent for observation
- Observe patient privacy and confidentiality
- Provide drug information, but not advise on treatment or issue orders on specific patients

A representative must respect the confidential and personal nature of patient and institutional information and may not disclose such information without authorization. In unusual circumstances, where representatives have direct patient contact or access to patient information, a signed confidentiality agreement is required. Under no circumstances may patient confidentiality be compromised. Under the Health Information Portability and Accountability Act of 1996 (HIPAA), a covered entity may not use or disclose an individual's protected health information (PHI), except as otherwise permitted or required by the rules.

Educational or research programs may necessitate representatives to have access to confidential patient information. In such circumstances, representatives must also comply with the hospital, patient, and/or medical staff consent policies.

## **J. Representative Immunizations**

In circumstances where representatives have direct patient contact, they are subject to the same hospital policy as are employees, faculty, and students regarding immunizations and other health requirements when in patient care areas, e.g., rubella immunization, TB skin test.

## **K. Appointments and Purposes**

A representative should strive to provide information to health care professionals regarding pharmaceutical products truthfully, accurately, and fully and should avoid misleading healthcare professionals regarding the safety, efficacy, costs or value of services and products. The representative must be courteous dealing with medical staff and Health Alliance employees and sensitive to the length of time spent in any area of the healthcare system.

It is mandatory that representatives schedule appointments with appropriate staff. It is encouraged that appointments be made via telephone. Loitering or wandering to spontaneously deliver product information is not deemed

appropriate. When special events are scheduled, only the representative (and his/her designee) sponsoring the event should be present. Appointments are mandatory.

Pharmaceutical representatives are not permitted to meet with voting members of the Drug Policy Development (DPD) and Pharmacy & Therapeutics Committee(s) or Subcommittees regarding products under consideration for addition/deletion to the Alliance Formulary or during contract negotiations. Literature pertaining to such products may be mailed to the members' office provided the information is requested.

The purpose(s) of appointments with Alliance health care staff should be to:

- Provide accurate information useful for product use. Representatives are expected to include balanced scientific literature (journal reprints, for example) on drug product safety and efficacy, as well as documentation of likely cost benefits.
- Provide timely information on the vendor's products and services.
- Facilitate procurement and crediting transactions.
- Obtain and provide information necessary to support the organization's formulary system.
- Facilitate informational activities for the pharmacy staff and other health care professionals with respect to the vendor's products.

Food may only be provided if scheduled in advance by the appropriate department, service, patient care area or division in conjunction with an informational presentation. Take-out meals and meals to be eaten without the company of the representative being present ( e.g. "Dine and dash" programs) do not facilitate the transfer of quality information and as such are prohibited in the Health Alliance.

**L. Physician Request for Information**

Pharmaceutical representatives should respond to physicians request for information about medications with accurate and unbiased information and in accordance to this policy.

**M. Educational Programs**

Programs must be scheduled in advance with the appropriate department director or manager. Educational programs should not be scheduled in direct patient care areas and must not interfere with the delivery of patient care. Pharmaceutical representatives are not considered expert consultants and are prohibited from providing formal educational programming.

**N. Exhibits**

Pharmacy Services may provide opportunities for vendors' representatives to distribute informational material by arranging for organized, scheduled exhibits. Policies and procedures about the times, places, content and conduct of such events have been established. Display of product information that conflicts with the Health Alliance Formulary system and prescribing guidelines are prohibited. Exhibits are not permitted for non-formulary drugs. A drug is considered to be non-formulary if it has not been reviewed by the Drug Policy and Development Committee and the Pharmacy and Therapeutics Committee or was not approved after such review.

**O. Dissemination of Promotional Materials**

The dissemination by representatives of information regarding formulary products should be made only to licensed health care professionals and professional students in a training program at the Health Alliance (e.g. physicians, nurses, pharmacists, dieticians, house staff physicians). Representatives will provide Pharmacy Services with copies of all informational and promotional materials disseminated in the organization. The Food and Drug Administration (FDA) prohibits the advertising and promotion of drug products for uses not reflected in FDA-approved product labeling. Pharmacists and other health care professionals should be aware of these laws and regulations when evaluating the content of promotional materials.

The Health Alliance limits the type of materials disseminated by representatives to include company-approved, labeled material, and reprints from peer-reviewed journals. Promotional techniques in violation of FDA guidelines are subject to reporting. The promotion of Health Alliance formulary drugs must be consistent with approved guidelines for use as developed by the DPD and P & T Committee(s). Guideline materials can be obtained through the Department of Pharmacy and are not to be shared without the expressed written approval of the Health Alliance.

Representatives are expected to communicate warnings and contraindications with the same fervor as they promote indications and endorsements by medical experts.

**P. Nonformulary Drugs**

Drugs not admitted to the Health Alliance formulary or those that have not been reviewed for formulary (e.g. newly approved products from the FDA) need to be stated as "Nonformulary at the Health Alliance" when any education or promotion is conducted.

**Q. Dissemination of Hospital/Pharmacy Policy**

No pharmaceutical representative shall attempt to interpret or communicate policies of The Health Alliance Pharmacy Services, Pharmacy & Therapeutics Committee or Drug Policy Development Committee to any member of the hospital or medical staff. All such questions must be referred to the appropriate member of the pharmacy department.

**R. Dissemination of Drug Price Information**

Pharmaceutical representatives may not provide Health Alliance comparative cost data to physicians. Representatives do not have access to the actual acquisition prices of The Health Alliance and, therefore, cannot provide accurate price comparisons between their drug and a competitive drug.

The Health Alliance will not provide a competitor's price, or sufficient information to calculate a competitor's price, to any representative or representative's agent.

Contract information may only be discussed with Health Alliance Directors of Pharmacy. Details of contract negotiations are not to be disseminated to any other members of the Health Alliance staff at any time.

**S. New Information on Products**

The pharmaceutical representative is responsible for communicating any and all changes in the legal or therapeutic status, new labeling, or product formulation to the pharmacy department for all drug products currently stocked and included in the hospital formulary.

**T. Drugs That Cannot Be Promoted**

The Health Alliance may have a list of drugs that cannot be detailed. Check the Health Alliance Intranet and/or contact the Director of Clinical Pharmacy Programs for more information.

**U. Samples**

The representative will follow the organization's policies and procedures with respect to product samples. The use of drug samples within the organization is discouraged and should be eliminated to the extent possible. Any sampling program should (1) incorporate the elements of pharmaceutical care, (2) result in appropriate drug control, allowing patients to receive drugs that are properly labeled and packaged, within their expiration dating, not recalled, not deteriorated, and properly recorded, (3) provide access to prescription drugs only to authorized and properly trained personnel, (4) encourage appropriate prescribing, and (5) not increase the cost of treatment to patients.

## **V. Gratuities**

The Health Alliance supports the Pharmaceutical Research and Manufactures of America's (PhRMA) marketing code established to govern the pharmaceutical industry's relationship with physicians and other health care professional. PhRMA guidelines prohibit the distribution of gifts and promotional material that are not primarily associated with health care professionals' scope of practice.

The representative will abide by the Health Alliance Conflict of Interest Policy. Gifts given with the intent of having a physician or staff member influence decisions made by committees, physicians or other healthcare professionals are prohibited. No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing/recommending products or for commitment for continued prescribing/recommending. Nothing should be offered or provided in a manner or condition that would interfere with the independence of a healthcare professional's professional practice.

Gifts of a nominal value (e.g. pens, notepads) or educational in nature (e.g. textbooks, software) are permitted, but must be related to an individual's work. Items may only promote those drugs on the formulary.

Entertainment must be reasonable in nature, time, frequency, and cost (not in excess of \$125). The essential purpose of the activity must be to better coordinate the absolute needs of the Health Alliance. Invitations to excessively elaborate social activities indicate overt persuasion tactics.

## **W. Research Cost Disclosure**

Pharmaceutical vendors must disclose research protocols under consideration to the pharmacy department for the purpose of assessing the impact of such protocols on drug usage and expenses. The hospitals of the Health Alliance conduct research adherent to Policies and Procedures of its Institutional Review Board. Pharmacists, physicians and representatives must clearly differentiate research from sales and promotional activities, applying appropriate policies and procedures accordingly. Generally, scientific research involving drug products is coordinated through research or clinical departments of product manufacturers rather than through sales and promotional representatives.

## **X. Noncompliance**

When a representative is known to be in non-compliance with these policies and procedures and basic rules of courtesy and professional conduct, the representative will be given oral notification. The representative's manager may also be contacted for correction of the non-compliant behavior. If the representative continues non-compliant behavior he/she will be prohibited from



doing business in any affiliated site of the Health Alliance upon consultation of the DPD Committee as appropriate. Formal discussion with the representative's manager(s) will be carried out to determine future business relationships. The Health Alliance's group purchasing organization (GPO) will consider compliance by company representatives with these policies and procedures, in various partnership agreements.

## V. RESPONSIBILITY

Physician  
Pharmacist  
RN/Clinician  
Administration

## VI. KEY WORDS

## VII. REFERENCES

**The Health Alliance Code of Conduct for Pharmaceutical Representatives** is based on the American Society of Health-System Pharmacists' document, "ASHP guidelines for pharmacists on the activities of vendors' representatives in organized health care systems" *Am J Hosp Pharm.* 1994; 51:520-1.

PhRMA Code on interactions with Healthcare Professionals  
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JAMA 1191: 265:501

ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Health Care Systems  
[http://www.ashp.org/bestpractices/pharmaceutical/Marketing\\_Gdl\\_Vendors.pdf](http://www.ashp.org/bestpractices/pharmaceutical/Marketing_Gdl_Vendors.pdf)

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