

October 21, 2003

**BUSINESS RELATIONSHIPS BETWEEN VHA STAFF AND PHARMACEUTICAL
INDUSTRY REPRESENTATIVES**

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes VHA system-wide guidance governing the business relationships between Department of Veterans Affairs (VA) medical facility personnel and representatives from the pharmaceutical industry.

2. BACKGROUND

a. This policy was developed by VHA with considerable input from pharmaceutical industry representatives, Veterans Integrated Service Networks (VISN) Formulary Leaders, Medical Advisory Panel members, and field-based clinical staff. It is intended to outline appropriate activities and interactions between VA medical facility personnel and representatives from the pharmaceutical industry. These activities include the review of product information, sponsorship of medical education, coordination of studies for new and existing drugs and products, and responses to requests for procurement, or recall, of specific products.

b. **Definitions**

(1) **Pharmaceutical Sales Representative.** The term “Pharmaceutical Sales Representative(s)” 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 VA formulary process. These items primarily include drugs, but to a lesser extent also include any medical supplies, nutritional supplements, and similar commodities managed under the VA formulary process. In consideration of VA staff time, patient privacy, formulary management goals, physical plant security and government ethics rules as set out in the Standards of Ethical Conduct for Employees of the Executive Branch, it is VHA policy to control access to all its medical care facilities and staff by Pharmaceutical Sales Representatives. Standards of Ethical Conduct for Employees of the Executive Branch are hereafter are referred to as “government ethics rules.”

(2) **Visit.** The term “visit,” as it applies to Pharmaceutical Sales Representatives, refers to any contact with VHA staff, to include drug fairs, drug displays, and other multi-vendor events.

(3) **Meal.** A “meal” is the food served and eaten at one of the customary, regular occasions for taking food during the day; breakfast, lunch, or supper.

3. POLICY: It is VHA policy that Pharmaceutical Sales Representatives, hereafter are referred to as “sales representatives,” may only have controlled access to all medical care facilities and staff.

THIS VHA DIRECTIVE EXPIRES OCTOBER 31, 2008

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4. ACTION

a. Responsibilities

(1) **Deputy Under Secretary for Health (10A).** The Deputy Under Secretary for Health (10A), is responsible for oversight of business relationships between VA medical facility personnel and representatives from the pharmaceutical industry.

(2) **Medical Center Director.** The Medical Center Director, or designee, is responsible for:

(a) Monitoring business relationships between VA medical facility personnel and representatives from the pharmaceutical industry, and

(b) Ensuring the facility personnel and representatives from the pharmaceutical industry adhere to the procedures outlined in subparagraph 4b.

(3) **Chief of Pharmacy, the Pharmacy Manager.** The Chief of Pharmacy, the Pharmacy Manager, or the person with similar responsibilities, in each VA medical care facility is responsible for:

(a) Monitoring business relationships between VA medical facility personnel and representatives from the pharmaceutical industry.

(b) Educating sales representatives about the VHA policy regarding business relationships between VA medical facility personnel and representatives from the pharmaceutical industry.

(c) Providing a copy of this Directive to each sales representative, and documenting with a signed receipt that the sales representative has received a copy.

b. Procedures

(1) **Sales Representatives Contacts with VA staff**

(a) In order to minimize the potential for disruption of patient care activities, sales representatives must schedule an appointment prior to each specific visit. Appointments may be made by either telephone or e-mail, but must be made in advance of visiting the medical center. Sales representatives may not use the overhead public address paging system to locate any member of the medical staff, house staff, pharmacy staff, or nursing staff. Contacts using the VA electronic paging system (beepers) is generally discouraged, but is permissible if specifically requested by an individual VA staff member.

1. Access to VA health care facilities by sales representatives who have not made a previously scheduled appointment is not permitted under any circumstances.

2. Sales representatives visiting VA facilities for previously scheduled appointments may not initiate requests for impromptu meetings with other VA staff whom they may happen to

encounter during their scheduled visit, but may respond to requests for meetings initiated by VA staff during the visit.

3. VA health care facilities are permitted to develop a list of individuals or departments that do not wish to be called upon by sales representatives. Facility personnel may provide such lists to each sales representative. Sales representatives must not attempt to make appointments with individuals or departments on the list.

(b) To maximize learning opportunities and minimize potential confusion on the part of students (including residents) still serving in their primary educational programs, sales representatives are prohibited from marketing to medical, pharmacy, nursing and other health profession students without the presence of a faculty professional.

(c) Sales representatives are not allowed to attend medical care treatment facility conferences where patient-specific material is discussed or presented.

(d) In the interests of physical plant security, each VISN is responsible for developing written guidance establishing reasonable procedures for accurately accounting for:

1. The whereabouts of sales representatives who are visiting VISN medical care facilities (such as log in and log out sheets, photo identification badges, etc.), and

2. Compliance with VA security requirements.

(e) Sales representatives are encouraged to schedule appointments in VA medical care facilities between the business hours of 8:00 a.m. and 3:30 p.m., Monday through Friday; however, if necessary for the convenience of VA staff, appointments at other times are permissible. **NOTE:** *VISN guidance needs to address access and security procedures needed during off business hours.*

(f) In respect of patient privacy, sales representatives are not permitted to make presentations in patient care areas. Restricted patient care areas include, but are not limited to:

1. Patient rooms and ward areas when patients may be encountered,

2. Clinic examination rooms,

3. Nursing stations,

4. Intensive care units,

5. Operating room suites, and

6. Emergency rooms, urgent care centers, ambulatory treatment centers.

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(g) Provided there are no breaches of patient privacy, exceptions to prohibiting access to patient care areas is permissible if a VA staff member's office is located in a patient care area and it is necessary to meet with the sales representative in the office. Sales representatives may not wait for appointments in patient care areas, but may briefly travel through them, when necessary, to meet in a staff member's office.

(2) **Promotional Materials, Promotional Activities, and Medical Literature**

(a) Sales representatives may only promote products that are included on the VA National Formulary and/or VISN Formulary, and only in accordance with applicable Food and Drug Administration (FDA) and VA guidelines, and/or VA restrictions and criteria which may exist for those products, except as outlined in following subparagraph 4b(2)(b). It is the sales representative's responsibility to ensure that the formulary status of all drug products discussed and/or displayed is represented accurately. Educational materials or literature for new drug products that have not yet been reviewed by the VA Medical Advisory Panel VISN Formulary Leaders Committee, or the VISN Formulary Committee, or new therapeutic indications for products already on the formulary, may only be displayed and discussed according to the processes outlined in following subparagraph 4b(2)(b).

(b) All educational materials or literature (including journal articles, etc.) and/or discussions regarding any drug that has a status of "Formulary with Restrictions," "Non-formulary," or other similar status designations, or has not yet been reviewed, must be clearly articulated and conspicuously identified as such by the sales representative. Promotional Materials are not to be placed in any patient care area.

(c) The practice of bringing guest speakers to VA facilities for educational purposes is acceptable, but must be at the invitation of VA staff and must be approved by the Pharmacy Manager or Chief of Staff, or as specified in local policy. Sales representatives must provide the Pharmacy Manager, Chair of the Facility Education Committee or other similarly responsible VA staff member a summary of such plans well in advance of the proposed visit, so that a determination of the program's suitability can be made. An education activity may be subject to further requirements by continuing education providers that have certified the activity for credit for pharmacists, physicians, or other health professionals.

(d) Disclosure of industry sponsorship of any educational program conducted at VA medical care facilities must be included in the introductory remarks and in the announcement brochures for educational programs. It is the responsibility of the sales representative to ensure adequate disclosure is provided. Sponsorship includes any contribution, whether in the form of staple goods, personnel, or legal tender, intended to support the program. Sales representatives are prohibited from conducting marketing activities during a sponsored educational program. An educational activity may be subject to further requirements by continuing education providers.

(3) **Drug Samples and "Free Goods."** Drugs and medical supply items donated to VHA which are intended for patient use, such as starter packs or free goods, must be delivered to the Chief, Pharmacy Service, or person with similar responsibilities, for proper storage, dispensing and documentation, using the normal VHA prescription delivery processes. The medical center

Director, or designee, is the individual authorized to approve receipt of donations of drugs or supply items to VA. If donated drugs are intended to be used solely to allow VA clinicians to gain familiarity with the product, such use must be pre-approved by the Chief, Pharmacy Service and the local Pharmacy and Therapeutics (P&T) Committee. Information pertaining to the trial use must be forwarded to the VISN Pharmacy Benefits Management Office or VISN Formulary Committee. Drugs dispensed to VA patients from donated drug stock are ordinarily not labeled with the words "sample," "professional sample," or similar wording. Rare exceptions to labeling as samples, such as in the case of product shortages, are permissible if such use is in the best interests of VA patients.

(4) Gifts to VA Staff including Refreshments

(a) In order to avoid violating or giving the appearance of violating government ethics rules, VA employees must exercise careful judgment when considering the acceptance of any gift, gratuity, favor, entertainment, loan, or anything of monetary value from a sales representative or any other person seeking to become involved, or who is currently involved, in business interactions with VA. Sales representatives may provide food items of nominal value (e.g., soft drinks, coffee, donuts, and other light refreshments are permissible; meals are not) to VA employees when incidental to a scheduled meeting or legitimate educational interchange and are not otherwise prohibited by government ethics rules and/or education accreditation requirements. VISNs may impose additional restrictive measures on sales representatives regarding food and/or refreshments incidental to meetings.

(b) In the interest of patient safety and/or facility accreditation processes, sales representatives may not provide samples of medications to VA providers for their personal use or the use of their families on VA property. Samples may be provided to VA staff via their home addresses or other non-VA property; such samples are regulated by applicable ethics rules. Current government ethics rules restrict gifts to a value of no more than \$20 per occurrence, and no more than \$50 in aggregate value over a given consecutive 12-month period from any one source. Different sales representatives from the same company are considered one source for the purposes of determining the appropriateness of gifts. Sales representatives must be aware that government ethics rules apply to VA staff regardless of whether the staff are located on VA or off VA property, or are on duty or off duty.

(c) Sales representatives may offer donations to a VA medical facility to support education or VA research in accordance with existing VHA, Employee Education System (EES), and VISN policies on accepting donations for education and research. Special rules may apply if the donation is for VA staff travel expenses. **NOTE:** *Generally, VHA deposits into the general post fund, or an approved VA Not-for-Profit Research and/or Education Corporation, any monetary donation that is accepted.*

(d) Continuing education materials and textbooks that exceed the value permissible for acceptance under government ethics rules may not be given to individual employees, but may be donated to the medical care facility library or individual departments for use by all employees in those departments.

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(5) Non-adherence with Policy Requirements

(a) Failure of sales representatives to comply with the provisions outlined in this Directive may result in the suspension, limitation, and temporary or permanent revocation of visiting privileges for one or more VA medical care facilities.

(b) Suspension of sales representatives consisting of a 3-month, 6-month, or 12-month suspension; limitation of visiting privileges; or the permanent removal of a sales representative may be evoked if deemed appropriate by the Chief of Pharmacy, VISN Formulary Leader, or designee(s). If a sales representative's visiting privileges are suspended, a determination must be made by the facility Chief of Staff or the VISN Chief Medical Officer (as appropriate), as to whether the sales representative's employer will be permitted to replace its suspended sales representative with a different sales representative. **NOTE:** *Suspension and/or limitation of visiting privileges are considered significant sanctions and need to be used judiciously and only with good cause.*

(c) When evidence exists that a pharmaceutical manufacturer, or other similar vendor, conducting business with VA permits, endorses or encourages its' sales representatives to engage in widespread and serious misconduct in violation of this Directive, or in any actions which are perceived to be in conflict with VA's drug therapy and formulary management goals, VA may impose a VHA-wide or VISN-wide suspension or limitation of visiting privileges for that manufacturer's sales representatives. Such a VHA-wide or VISN-wide revocation of privileges must consist of a minimum 12-month suspension, or limitation of visiting privileges as deemed appropriate and recommended by the:

1. Chief Consultant, Pharmacy Benefits Management Strategic Healthcare Group, for a VHA-wide suspension or limitation of privileges; or

2. VISN Formulary Leader for a VISN-wide suspension or limitation of privileges.

NOTE: *Final decisions regarding limitation or suspension of visiting privileges rest with the Chief Officer, Patient Care Services and VISN Chief Medical Officers, respectively.*

5. REFERENCES

a. Title 5 Code of Federal Regulations (CFR), Part 2635.

b. Title 38 CFR, Part 0.

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11), is responsible for the content of this Directive. Questions may be addressed to the Associate Chief Consultant, Pharmacy Benefits Management Strategic Healthcare Group at 708-786-7862.

7. RESCISSIONS: None. This VHA Directive will expire October 31, 2008.

S/ Jacquelyn Vassanelli for
Robert H. Roswell, M.D.
Under Secretary for Health

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