



**DEPARTMENT OF VETERANS AFFAIRS
VA Northwest Network, VISN 20**

**Policy Memorandum
10N20-2004-003
January 23, 2004**

VENDOR GRATUITY POLICY

1. **PURPOSE:** Establish guidelines for the activities of pharmaceutical and product representatives and the conduct of VA personnel in VISN 20 medical centers and outpatient clinics. This policy applies to all sales and manufacturer's representatives regardless of the type of product - medical or non-medical. This policy also applies to all VA employees, and to students and residents while on VA premises
2. **POLICY:**
 - a. Individual facilities may be more restrictive than this VISN 20 policy, but not less restrictive. This policy applies to VA personnel regardless of whether the provision of gratuities happens on VA grounds or not. Students and residents are not VA employees and are, therefore, only bound by these rules when on VA premises.
 - b. Manufacturers' representatives may provide information, literature, and reprints on their products to the staff of a VISN 20 medical center or outpatient clinic at the convenience or request of the staff. Only company approved, labeled material and reprints from major peer reviewed journals may be utilized in product promotion. Any materials on non-formulary or formulary restricted products or non-mandated standardized items where similar items are already mandated for use, must be clearly labeled in writing as such. A verbal statement to the recipient as to formulary status is insufficient.
 - c. Representatives may support facility continuing education by direct support of a facility approved speaker or by contributions to a facility education foundation established to support continuing education and continuing education activities. Contributions to the facility must be approved by Regional Counsel who will evaluate ethical considerations and conflicts of interest. The practice of bringing guest speakers to VA facilities for educational purposes is acceptable, but speakers must be approved. Pharmaceutical representatives must provide the Pharmacy manager 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. Other manufacturer's representatives must obtain approval from the manager of the appropriate department. A program's suitability will be determined by evaluation of the program's purpose, goals, and educational objectives. Handouts, a conflict of interest statement and the course outline must be reviewed by the approving authority. A statement of the applicability to VHA's mission and the clinical significance/importance of the product must be provided prior to determination of the program's suitability. This information must be submitted at least 2 weeks prior to the proposed presentation date. Programs/Presentations conflicting with VA goals, objectives and practices will be disapproved.
 - d. Unscheduled visits to a VISN 20 medical center or outpatient clinic are prohibited. Contact with employees will be limited to the employee's request and will be by advance appointment only. Representatives are not permitted in patient care areas, except as specifically provided in this policy in paragraph 3.c.(7).(a) & (b). This prohibition includes areas where patient information is discussed. Physicians and other providers may only be

**DEPARTMENT OF VETERANS AFFAIRS
VA Northwest Network, VISN 20**

**Policy Memorandum
10N20-2004-003
January 23, 2004**

visited by advance appointment in administrative offices. Representatives will not contact staff members in locations other than administrative offices.

- e. Drug samples and donated drugs will not be brought into VISN 20 facilities unless approved by the VISN 20 Pharmacy and Therapeutics (P&T) Committee and distributed through normal pharmacy dispensing and distribution systems (labeled appropriately, recorded, reviewed, profiled with other medications). Products other than pharmaceutical samples will not be brought into VISN 20 facilities unless approved by the local Chair of the Commodity Standards Committee.
- f. Pharmacy is responsible for the selection and purchase of all pharmaceuticals in the medical centers. All contract proposals and quotations for pharmaceuticals will be submitted to the VISN Pharmacy Benefits Manager for review and acceptance prior to discussion with medical staff. The Chief, Pharmacy or designee will review and approve drug price information before distribution to medical staff.
- g. Pursuant to the enactment of Section 27 of the Office of Federal Procurement Policy Act (41 U. S. C. 423) and regulations pertaining to conflict of interest (5 C.F.R. Part 2635), manufacturers' representatives are prohibited from offering or providing gratuities to any employee of a VISN 20 medical center or outpatient clinic or trainees while at the VA.
 - (1) Employees may accept gifts other than cash from prohibited sources when the gifts have an aggregate market value of less than \$20 per occasion and do not exceed \$50 in a year from any one person or company. Items of nominal value (e.g., pens, note pads, soft drinks, coffee, donuts, and other refreshments offered other than as part of a meal) are permissible. 5 C.F.R. § 2635.204(a). As to attendance at widely attended gatherings, when the employee's attendance is in the interest of the agency because it will further agency programs, a specific exception to the Standards of Ethical Conduct permits an employee to accept from an event sponsor an unsolicited gift of free attendance to a widely attended gathering. 5 C.F.R. § 2635.204(g). However, "widely attended gatherings" do not include meetings targeting only VA employees. Under this narrow exception, free attendance may include waiver of fees, as well as food, entertainment, instruction and materials furnished to all as an integral part of the event, despite the value of the "gift" exceeding \$20.
 - (2) According to the General Counsel, despite the \$20 rule, physicians and other VA employees may not accept or solicit lunches or other meals from any companies or other affiliates at Grand Rounds or other scheduled meetings without creating the appearance of using their public office for private gain in violation of the Standards of Ethical Conduct for Employees of the Executive Branch. Where staff education or business meetings are regularly held at the facility at the behest of physicians and staff for the direct purpose of improving their performance of official duties, the meetings are directed at VA employees in their official status. Acceptance or solicitation of free lunches at those meetings involves a personal benefit in connection with their official position. Therefore, acceptance or solicitation of free lunches at those meetings is prohibited.

**DEPARTMENT OF VETERANS AFFAIRS
VA Northwest Network, VISN 20**

**Policy Memorandum
10N20-2004-003
January 23, 2004**

- (3) Subject to availability of space, representatives may attend medical center conferences where any training is conducted, but will adhere to section 2.(g).(4).
- (4) Commercial exhibits, displays, or discussion of promotional materials referring to any product names are not allowed during Continuing Medical Education and Graduate Medical Education activities.
- (5) Representatives may contribute to a facility education or research foundation to support Education or Research.
- (6) Continuing education materials and textbooks will not be given to specific employees but may be donated to the medical center library or unique departments for use by all employees in those departments.
- h. Representatives will not contact members of the facility Pharmacy and Therapeutics Committee, the VISN Pharmacy and Therapeutics (P&T) Committee or the Commodity Standards Committees (either local or VISN 20) to discuss their products unless the member has requested information.
- i. VA staff members will submit requests for formulary consideration based on the clinical merits of the drug and the need of VA patients, not based on a request from pharmaceutical representatives.
- j. Pharmaceutical displays, that are not associated with any educational activities, will only be conducted as part of a periodic (e.g. monthly) display at the discretion/approval of the local VA medical center Pharmacy Service.
- k. Medical centers and outpatient clinics may use patient education materials, provided by manufacturer's representatives, only after the local patient education committee has approved those materials for use.
- l. Pharmaceutical representatives will promote the use of their products only in accordance with VISN 20 prescribing restrictions, criteria for use, and guidelines for use.
- m. Failure of manufacturer's sales representatives to comply with the provisions outlined herein may result in the suspension or revocation of all VISN 20 medical center visitation privileges. Suspension of representatives will consist of either a 3-month, 6-month, 12-month interval or permanent removal of a representative as deemed appropriate by the Chief of the affected department. During a suspension, no company will be permitted to replace their suspended representative with another person.

3. PROCEDURES:

- a. All representatives must first register with the department they are visiting or other designated department (as specified by the medical center) and obtain appropriate identification badge before proceeding to any other location within the medical center.

**DEPARTMENT OF VETERANS AFFAIRS
VA Northwest Network, VISN 20**

**Policy Memorandum
10N20-2004-003
January 23, 2004**

- b. All representatives will wear their company nametag plus the VA issued identification tag on their outer garments at all times.
- c. Representatives will contact medical center staff by advance appointment only. Representatives will not wait, without an appointment, to visit with any staff member.
 - (1) In order to minimize the potential for disruption of patient care and facility activities, sales representatives must schedule an appointment prior to each specific visit. Appointments 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 staff or trainees. Contacts using the VA electronic paging system (beepers) is discouraged, but is permissible if specifically requested by an individual VA staff member.
 - (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. Such lists may be provided to each sales representative by facility personnel. Sales representatives should not attempt to make appointments with individuals or departments on the list.
 - (4) To maximize learning opportunities and minimize potential confusion on the part of students still serving in their primary educational programs, sales representatives are prohibited from contacting medical, pharmacy, nursing and other health profession students without the presence of a faculty professional.
 - (5) Sales representatives will not attend facility medical care treatment conferences or any other meetings where patient specific material will be discussed or presented.
 - (6) In respect of patient privacy, sales representatives are not permitted in patient care areas. Representatives will not enter restricted patient care areas, including but not limited to:
 - (a) Patient rooms, wards, hallways, and nursing stations
 - (b) Intensive care units, operating room suites, emergency room
 - (c) Outpatient triage and urgent care centers
 - (d) Mail rooms, copy rooms, medical libraries, and employee lounges/break rooms
 - (e) All outpatient clinics
 - (7) Exceptions to prohibiting access to patient care areas are permissible if:
 - (a) The 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, provided there are no breaches of patient privacy. 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.

**DEPARTMENT OF VETERANS AFFAIRS
VA Northwest Network, VISN 20**

**Policy Memorandum
10N20-2004-003
January 23, 2004**

- (b) The second exception is when the representative provides assistance at the request of VA staff. Examples of this exception would include providing technical support for equipment or prosthetic device size selection.
- d. Pharmaceutical representatives will be aware of which of their products are on the VISN formulary and any prescribing restrictions or criteria.
- e. Each pharmaceutical representative is expected to make clear to prescribers those products that are non-formulary or under restricted use. Non-formulary drugs can be considered for formulary status only when data suggests increased effectiveness, increased safety, or lower cost when compared to formulary alternatives. It is the sales representative's responsibility to assure that the formulary status of all drug products discussed 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 or new therapeutic indications for products already on the formulary, may only be displayed and discussed as non-formulary products or indications.
- f. Pharmaceutical representatives will not be involved in any way with the completion, delivery to Service Chiefs and/or Pharmacy Service, and ultimate submission to the P & T Committee of requests for formulary addition.

4. RESPONSIBILITY:

- a. The appropriate service chief at each VISN 20 facility will:
 - (1) Inform manufacturer's representatives of the applicable rules, regulations, and policies regarding the promotion and procurement of drugs and other products.
 - (2) Inform staff of the provisions of this policy.
 - (3) Enforce the provisions of this policy.
- b. The Police and Security Service will assist in enforcement of this policy.
- c. The ACOS/Education or designee will make information regarding this policy available to all residents, students, and trainees rotating through the facility.
- d. All sales representatives will adhere to these policies and procedures.
- e. VA employees and students/residents performing duties at VA medical facilities are responsible for knowing the content of this policy and adhering to it.

5. REFERENCES:

- a. Title 5, Code of Federal Regulations, Part 2635, Standards of Ethical Conduct for Employees of the Executive Branch; specifically, Title 5, Code of Federal Regulations, Part 2635, Subpart B - Gifts From Outside Sources, 5 C.F.R. §§ 2635.201-2635.205.

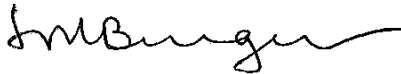
**DEPARTMENT OF VETERANS AFFAIRS
VA Northwest Network, VISN 20**

**Policy Memorandum
10N20-2004-003
January 23, 2004**

- b. Title 38, Code of Federal Regulations, Sections 0.735 and 1.218.
- c. Office of Regional Counsel Letter on Gifts from Pharmaceutical Companies, March 15, 2000.
- d. VHA Directive 2003-060, Business Relationships between VA Staff and Pharmaceutical Industry Representatives dated October 21, 2003.

6. REVIEW DATE: January 2007

7. FOLLOW-UP RESPONSIBILITY: VISN 20 Chief Logistics Officer



LESLIE M. BURGER, MD, FACP
Network Director, VISN 20