



MOUNT SINAI  
SCHOOL OF  
MEDICINE

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## Mount Sinai Medical Center Policy

### **BUSINESS RELATIONSHIPS BETWEEN MOUNT SINAI MEDICAL CENTER STAFF AND SALES REPRESENTATIVES**

#### **1. Purpose**

This Mount Sinai Medical Center (MSMC) policy establishes MSMC system wide guidance governing the business relationships between MSMC personnel and medical sales representatives. The purpose of this policy is to ensure that decisions regarding the use or purchase of pharmaceutical products, medical or research supplies or equipment are made based on the best available scientific knowledge and that neither medical education, patient care or research are unduly biased by the activities of sales representatives. **For purposes of this policy the term Medical Sales Representative (MSR) will be utilized to reference all sales representatives identified above.** In addition to assuring this level of professionalism and impartiality, this policy is designed to:

- Ensure patient confidentiality, compliance with regulatory standards, and a collaborative approach to promote safe and effective product use throughout MSMC.
- Facilitate appropriate MSR interaction with medical center personnel and dissemination of information without causing a disruption in the care of patients, research or education, or interfering in the work performance of MSMC staff.
- Ensure marketing of products that is consistent with policies and guidelines established by MSMC committees and the Medical Board.
- Ensure that sample products are accepted and evaluated by appropriate MSMC committees/officials and do not violate conflict of interest rules.
- Ensure that hospital owned donated products are provided only to recognized organizations and are carefully tracked.
- **This policy is a complement to the MSMC policy titled, "Interactions with Vendors and Other Commercial Entities" and other MSMC policies.**

## **2. Policy**

Access to MSMC by MSRs is a privilege provided to allow mutually beneficial interactions. As invited guests, MSRs are expected to strictly adhere to this policy as well as guidelines outlined by the Food and Drug Administration (FDA), the American Medical Association (AMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). It is MSMC policy that MSR's may only have controlled access to all medical care facilities and staff. Violation of these policies and procedures will result in disciplinary action up to and including termination of privileges of the MSR.

## **3. Responsibilities**

- A. The *Chief Compliance Officer*, or designee, is responsible for:
- (a) Monitoring business relationships between MSMC medical facility personnel and representatives from the pharmaceutical and medical supply industries.
  - (b) Ensuring the facility personnel and MSRs adhere to the procedures outlined in this policy.
  - (c) Monitoring adherence to this policy by all pertinent MSMC organizations.
- B. The *Director, Purchasing Department* is responsible for ensuring that the registration of all MSR's is completed in a timely manner and that an accurate and current list of registered MSRs is maintained. As part of the registration package, all MSR's must receive and sign receipt for a copy of this policy.
- C. The *Director of Pharmacy* is responsible for monitoring business relationships between MSMC personnel and MSRs from the pharmaceutical industry.
- D. The *Chief Audit Executive* is responsible for conducting periodic audits and investigations to determine if the systems implemented to monitor the activities of MSRs are functioning properly and if MSRs are complying with this policy.

## **PROCEDURE**

### **1. Registration**

Each commercial enterprise desiring to do business with MSMC must register their MSR's with the Purchasing Department.

- A. At the first visit to the Purchasing Department, each MSR will receive a registration packet with a copy of this policy and be registered with Vendor Credentialing Service.

- B. Every MSR must complete registration online at [www.VCSdatabase.com](http://www.VCSdatabase.com), sign all MSMC policies, and return them to VCS by fax (866-839-1647) or email to [credentials@vcsdatabase.com](mailto:credentials@vcsdatabase.com)
- C. MSRs must read this policy and sign that he/she understands and agrees to abide by the policy and procedure while visiting the MSMC. MSRs are encouraged to meet with a representative of the Purchasing Department or Department of Pharmacy if they need clarification on any part of the policy and procedure.
- D. It is the responsibility of each commercial enterprise to ensure that the names of their registered representatives are accurate. The Purchasing Department is to be informed, in writing, of any MSRs that no longer represent their enterprise at MSMC. A "Medical Sales Representative Registry Form" must be completed for each new individual that represents the commercial enterprise.
- E. Once registered, VCS will issue the MSR a permanent, color-coded identification badge. It is the MSR's responsibility to keep their credentials up to date to ensure that they are not denied access to the facility because of expired credentials.

## **2. Access to MSMC Buildings**

- A. MSRs are permitted to access MSMC buildings only when they have an appointment with a member of the faculty, a management employee in an applicable area, or a member of the purchasing staff. MSRs are prohibited from setting up appointments with students, house staff, nursing staff, pharmacy staff, or laboratory staff. Appointments may be made by either telephone or e-mail, but must be made in advance of visiting the medical center. MSRs may not use the overhead public address paging system to locate any member of the medical staff, house staff, pharmacy staff, nursing staff, or laboratory staff. Unannounced visits to any area of the medical center are not allowed.
- B. All MSRs must wear their VCS Badge at all times when they are on MSMC property.
- C. The VCS badge must be presented to the Security Officer upon entrance to the medical center.
- D. An entry in the "Medical Sales Representative Visitation Log" must be completed by the MSR before they enter the building. The name and location of all individuals that the MSR is scheduled to visit and the purpose of their visit must be logged in the "MSR Visitation Log." Visitation by a MSR to any area not included in the Visitation Log will be considered a violation of this policy.
- E. It is the responsibility of the MSR to sign out in the "Medical Sales Representative Visitation Log" when they leave the medical center.

- F. On occasion, MSR's may bring with them members from their commercial enterprises who do not regularly visit our medical center. These individuals **MUST** be accompanied by a registered MSR at all times and must wear a Photo ID issued by their commercial enterprise. Individuals who may visit the medical center more than two times a year with a registered MSR are required to register with VCS.
- G. MSMC healthcare facilities are permitted to develop a list of individuals or departments that do not wish to be called upon by MSRs. Facility personnel may provide such lists to each MSR. MSRs must not attempt to make appointments with individuals or departments on the list.
- H. To maximize learning opportunities and minimize potential confusion on the part of trainees (including residents) still serving in their primary educational programs, sales representatives are prohibited from marketing to medical, pharmacy, nursing and other trainees without the presence of a faculty professional.
- I. Sales representatives are not allowed to attend medical care treatment facility conferences where patient-specific material is discussed or presented.

### **3. Visitation Hours**

MSRs should conduct business from 9AM-5PM on weekdays unless a duly authorized individual from MSMC specifically requests visitation or the conduct of business during alternative hours of the day or on weekends.

### **4. Areas of Visitation**

MSRs are not allowed in patient care areas, either inpatient or ambulatory (including nursing units and clinics), or in work areas (Pharmacy distribution areas, Microbiology work areas, Laboratories, FPA etc.)

- A. Meetings with MSRs shall be held only in public or administrative areas.
- B. MSRs may be present but shall not wait in common medical center areas (such as building lobby areas, eating areas, parking areas, public telephone areas, etc.) for the purpose of initiating unsolicited contact with health care professionals and detailing the individuals or their products.
- C. Provided there are no breaches of patient privacy, exceptions to prohibiting access to patient care areas is permissible if a MSMC 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.

## 5. Patient Confidentiality and Privacy

- A. MSRs should not be present in any patient care area or at meetings or function where patient specific information is discussed.
- B. Training by MSRs for new equipment or devices that involves exposure to patients is highly discouraged. When training by an MSR is necessary that involves exposure to a patient or information about a patient, approval from the Departmental Chair AND patient consent, documented in the patient's chart, are required. The Operating Room has specific policies related to training provided by MSRs that must be followed in that area.
- C. MSRs shall not have access to any electronic or paper information that is patient specific, or could be associated with a particular patient. This includes patient charts, laboratory information, patient bills, etc.

## 6. Marketing Activities

MSRs are authorized to promote their products and disseminate information within the following parameters:

- A. MSRs should confine their promotional activities within the MSMC to attending medical staff, pharmacy management staff, research faculty and staff, management staff in areas where the commercial enterprise's supplies and equipment could be used, and the Purchasing Department.
- B. MSRs will respect and abide by the decision of the appropriate MSMC committees. MSRs are not permitted to promote medications, supplies or equipment contrary to MSMC policies. Before visiting members of the medical staff to promote medications, MSRs should meet with a member of the Director of Pharmacy to inform/provide them with any of the information they will be using to promote their product(s). Any information/materials deemed inappropriate or biased by the Director of Pharmacy may not be used as information provided to individuals in the MSMC.

Examples of policies/guidelines MSRs are expected to follow include:

- Promotion of restricted products to only those attending physicians who are authorized to prescribe them
  - Promotion of products within guidelines where MSMC recommends specific dosing, the agents are restricted at MSMC for specific indications, clinical parameters must be met prior to use of the agent at MSMC, etc.
- C. The following are **acceptable** forms of information for dissemination by MSRs within the MSMC provided that the drug is a Formulary item and the materials are

approved for distribution by the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Food and Drug Administration:

- Reprints of primary literature from peer-reviewed journals
  - Promotional materials that are deemed unbiased
- D. The following are **unacceptable** forms of information for dissemination by MSRs at the MSMC:
- Abstracts related to potential benefits of a drug marketed by the commercial enterprise
  - Information related to the unapproved use of medications as determined by the Food and Drug Administration.
  - Any comparative cost analysis related to the product being promoted.
- E. Provision of food and beverages by MSRs or payment for food and beverages by MSRs is prohibited.
- F. Gifts, **including de minimis items** such as pens and notepads, may not be distributed within the medical center and/or to Mount Sinai employees.
- G. MSRs may not post any notices in the medical center that promote their products or a program that they are sponsoring. Program notices must be posted by the MSMC representative responsible for that program in concordance with MSMC policies for posting notices. Promotional materials may only be given to an individual during an appointment and may not be left in hospital areas, including public areas.
- H. Violations of applicable laws governing the promotion and marketing of drug products will be reported by representatives of the institution to the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Food and Drug Administration.

## **7. Educational programs**

The Post Graduate School has a well-defined policy on commercial support for continuing medical education programs. Please refer to the MSMC Interactions with Vendors and Other Commercial Entities Policy for details.

## **8. Prohibited Contacts**

- A. MSRs are not allowed to attend non-CME approved teaching sessions that are attended by students, residents, pharmacy, nursing, or laboratory staff. Meals may **not** be sponsored, **and** all funds must be unrestricted and must be channeled through the Department, which will in turn make all arrangements.

- B. MSMC does not allow MSRs to meet with students, residents, pharmacy, nursing, or laboratory staff on medical center property. Please refer to the MSMC Interactions with Vendors and Other Commercial Entities Policy for details.
- C. MSMC will not provide the names or addresses of students or staff to MSRs. MSMC does not allow house staff or fellows to accept direct gifts, favors, or trips from MSRs. Any donations from MSRs must be made in accordance with the MSMC Interactions with Vendors and Other Commercial Entities policy.
- D. Faculty and MSMC employees who are offered speaking engagements, consultantships, etc., must follow policies as outlined in MSMC Interactions with Vendors and Other Commercial Entities policy.

#### **9. MSR Access to MSMC Information**

MSRs are not allowed access to verbal or written information that refers to patient specific information, quality of care issues, or information that would jeopardize the process for product selection or competitive pricing.

- A. Information discussed or distributed at Medical Board Subcommittees (e.g., Formulary and Therapeutics Committee) or their Subcommittees may NOT be provided to or obtained by MSRs.
- B. Institution specific data related to prescribing practices, product consumption, or prices may not be provided to MSR's except by individuals authorized by MSMC to negotiate contracts.

#### **10. Process for Product Review and Selection**

Only attending medical staff can request the addition of a medication to the MSMC formulary.

#### **11. Drug and Medical Device Samples**

##### **DRUG SAMPLES**

Please refer to the MSMC Interactions with Vendors and Other Commercial Entities Policy for details regarding pharmaceutical samples.

##### **MEDICAL DEVICES**

To protect the integrity and objectivity of transactions between employees of MSMC and its past, present or future vendors, employees (physician or otherwise) are not permitted to directly accept any medical device from any vendor. Please refer to the MSMC Interactions with Vendors and Other Commercial Entities Policy for details.

## **Donations of Expired Products**

Medical device donations save lives and are much needed, especially in times of crisis. The indirect benefits should not be underestimated either. The collection of drugs and medical products can act as a focal activity for supporters and donors, promoting interest in the work of a mission hospital or relief organization and a sense of meaningful participation.

The World Health Organization (WHO) recently updated its guidelines on medical device donations. The guidelines urge donors to ensure that their donations are of maximum benefit to the recipient; respect the wishes and authority of the recipient; strictly avoid any double standards in quality; and are based on effective communication between donor and recipient. Six donor countries and 13 recipient countries have now developed their own drug donation guidelines. These guidelines were established to deter well intentioned, but inappropriate donating that can turn developing world hospitals into dumping zones for pharmaceutical junk, sent on the basis of "anything must be better than nothing."

Therefore it is important that all donations of expired product meet both the WHO and the recipient country's guidelines for acceptance. In addition, a well-documented audit trail must be established for each device donated, particularly in the event of a product recall. It is preferred that all MSMC foreign bound-donations go directly to either the recipient government or through recognized non-profit relief agencies.

Direct MSMC to hospital donations should be avoided; particularly when a member of the staff or faculty has a financial interest in the recipient organization. In this scenario, potential conflict of interest problems could mask the nobility of the mission, no matter how charitable and needy the donation may be.

In no instances should an employee or physician directly donate expired product him/herself.

## **DEFINITIONS**

- (a) **Medical Sales Representatives (MSRs) as defined in this policy** are vendors' representatives who promote medical, pharmaceutical, research or educational supplies, equipment or other products or services and provide information and services to health care providers on behalf of manufacturers and suppliers. This definition includes positions also known as Medical Service Representatives, Pharmaceutical Representatives, Drug Representatives, etc.
- (b) **Visit** - The term "visit" as it applies to MSRs, refers to any contact with MSMC staff, to include drug fairs, drug displays, and other multi-vendor events.

(c) Medical Device is defined as: *“An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man” (adopted from section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act).*

