

# MONTEFIORE HEALTH SYSTEM ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: MEDICAL VENDOR REPRESENTATIVES NUMBER: JP54.1

OWNER: OFFICE OF THE MEDICAL DIRECTOR, MHS DEPARTMENT OF

COMPLIANCE AND THE MHS PURCHASING DEPARTMENT

EFFECTIVE: REVIEW/REVISED: SUPERSEDES: 11/21, 6/22 12/16, 5/16, 5/13, 6/11,12/08

CROSS-REFERENCES: Administrative Policies and Procedures: JH20.1 - Conflict of Interest; JP31.1 – Vendor Credentialing and Access; Patient Care Manual OR-V-2 Procedures for Visitors in the Operating Room; Network Care Management Policy VP1.1 – Post-Acute Service Provider's Access to Montefiore Medical Center

REFERENCE: American College of Physicians Guidelines on Physician-Industry Relations, PhRMA Code on Interactions with Health Care Industries, Accreditation Council for Continuing Medical Education Standards for Commercial Support

# Scope:

Applies to all Medical Vendor Representatives, Montefiore associates, medical staff and trainees throughout Montefiore Health System's delivery system. Interactions with non-medical vendors are covered exclusively under the Conflict of Interest Policy.

# **Policy Statement:**

The purpose of this policy is to ensure that the best interest of the patient is the principal factor in any decisions to use pharmaceuticals, medical equipment and devices or clinical services in patient care. Circumstances in which commerce and care planning coexist are ethically challenging. At times care providers are involved in the development or marketing of a product and will derive benefit from its use. This creates a conflict of interest that is precluded by medical codes of conduct and by standards of medical professionalism. Furthermore, the acceptance of gifts—even very small gifts—may also create conflict of interest, because of relationships and sense of obligation these gifts engender. Choices of marketed products present opportunities to meet the needs of the patients with the most recent and appropriate technology. But the uncritical acceptance of promotional material may lead providers to overlook data about less innovative and less profitable products that may be as good or better for the patient. This policy is designed to assist physicians and other care providers in balancing potential influences with benefits, including knowledge of new treatments and devices, by providing guidance for the conduct of medical vendor representatives as well as providing guidance for Montefiore clinical and business decisions involving medical vendor representatives.

#### **Definitions:**

**Medical Vendor Representatives (MVRs):** Defined as vendors' representatives from pharmaceutical companies, manufacturers and distributors of medical device and durable medical equipment, recruiting and marketing personnel from nursing homes and home health Page 1 of 6

 $\ \ \, \text{vendors, and other patient care vendors.}$ 

#### PROCEDURE FOR VENDOR REGISTRATION:

- 1. All MVRs must be approved and pre-registered prior to seeking access to any Montefiore site. Access is sought on a per visit basis or as a standing appointment for a specific period of time, at the discretion of the specific clinical or administrative department and as approved as follows:
  - Pharmaceutical Vendors: Pursuant to the Vendor Credentialing and Access policy the Pharmacy Department for each Montefiore Member is responsible for screening and approval of all pharmaceutical representatives;
    - Pharmacy Sales Representatives are not permitted on Montefiore premises, unless to meet with the Member's Director of Pharmacy or Designee. Pharmaceutical Scientific Liaisons, or other similar position whose specific job responsibilities explicitly prohibit the detailing of medications, may be permitted to have access to Montefiore with appropriate approval.
  - ii. Medical Device Vendors: Pursuant to the Vendor Credentialing and Access policy the Montefiore Health System Purchasing Department ("Purchasing Department") will screen and approve medical device representatives;
  - iii. Durable Medical Equipment, Home Health and Nursing Home Vendors: Pursuant to the Vendor Credentialing and Access policy the Care Management Organization (CMO) will screen for approval of these representatives, except that Montefiore Home Health will screen and approve its own related vendors;
  - iv. Post-Acute Service Providers: All liaisons from post-acute service providers must comply with the provisions contained in the Network Care Management policy VP1.1, Post-Acute Service Provider's Access to Montefiore Medical Center or corresponding Member's policies and procedures.
  - v. Other: Other patient care vendors not explicitly covered above are obligated to comply with the Vendor Credentialing and Access policy.
  - b. The Purchasing Department is responsible for ensuring that the MVRs receive a copy of the application package, including but not limited to this policy and procedure, and that they sign an attestation that they have read and will abide by the conditions outlined. MVRs are responsible for signing and submitting this attestation to the Purchasing department annually or as required. Copies of these attestations must be sent to the Montefiore Health System Purchasing Department prior to the start of any contractual agreement.

# **VENDOR ACCESS AND AUTHORIZATION:**

- 1. MVRs must enter Montefiore facilities through a designated entrance. Please see Appendix A: Designated MVR Entrances for Montefiore Facilities
- 2. Montefiore shall not grant access to former Montefiore associates now acting in a MVR capacity without explicit approval of the Department of Compliance responsible for the oversight of the MVR's Montefiore-related activities).
- 3. MVRs are not authorized to be present on any Montefiore outpatient site—including, but not limited to Montefiore Medical Group (MMG) sites, unless written permission is received in advance from the MMG Director of Clinical Services or their counterparts if the access would relate to Member Hospitals' outpatient sites, or to educate nursing and pharmacy staff prior to the use of a new drug if prior approval was received.
- 4. MVRs are not permitted in any patient care area, including waiting rooms, inpatient units or faculty practice sites, unless to provide in-service training on devices or other equipment and then, only by appointment and with the appropriate approval.

- 5. MVRs may not loiter in common hospital areas, such as lobbies, cafeterias, Medical Library, etc, for the purpose of initiating unsolicited contact with health care professionals and detailing products. Under no circumstances may MVRs initiate contact with house staff or medical students on Montefiore premises.
- 6. Access to patient information:
  - a. MVRs will not be permitted access to any patient information, clinical data or billing information unless covered by a BAA or where a purpose-specific authorization for the release of information from the patient is in place. Montefiore associates and medical staff shall not provide such information to MVRs. In the event that provision of such information is required for patient care reasons, patient consent to release information to the MVRs shall be sought in all instances.
  - Proprietary information related to prescribing practices, product consumption or prices may not be provided to MVRs except by individuals authorized by Purchasing to negotiate contracts.

#### **VENDOR OBLIGATIONS AND AUTHORIZED ACTIVITIES:**

- 1. MVRs will abide by the policies and procedures of Montefiore Health System, its members and subsidiaries, including, but not limited to, the Montefiore Compliance Plan and compliance policies, the determinations of the Pharmacy and Therapeutics Committee and the Medical Device Committee, the Medical Staff By-laws and Rules and Regulations. MVRs are not permitted to promote medications, supplies or equipment contrary to Montefiore policies or guidelines as approved by the applicable Health System committees.
- 2. MVRs are required to wear their ID at all times when on Montefiore premises. They must also wear a Photo ID issued by their employer. MVRs are required to return their Montefiore or Member ID badge to the appropriate Security Department in the event they leave their job or they no longer require access to Montefiore premises for any reason.
- 3. Authorized MVRs are only permitted to discuss drugs available through the Montefiore Hospital Formulary for the specific site they are visiting or with which they are otherwise communicating. Distribution of literature or promotional materials for non-formulary products to the house staff or the Health System community at large is prohibited. Authorized MVRs may, however, discuss non-formulary products with healthcare professionals during office appointments arranged in advance, provided, however, that all promotional literature and materials being detailed are first provided to and approved by the associated (System or Member) Department of Pharmacy prior to any discussions.
- 4. New drugs for consideration by the Pharmacy & Therapeutics (P&T) Committee (or equivalent body) shall be discussed with the appropriate Director of Pharmacy Services or designee. That Director of Pharmacy may then schedule a discussion of the new drug for addition to the Formulary on the agenda of the P&T Committee meeting after completion of the application process. No statement may be made to any health care professional as to the availability of a product/medication at that Montefiore facility until such time as it has been approved by the P&T committee.
- 5. Sample medications and/or devices are not permitted at all and may not be distributed or left in any area within Montefiore facilities. In rare circumstances, a sample may be permitted if approved by the appropriate Director of Pharmacy or other authorized party.
- 6. MVRs are not permitted to solicit business via displays or organize gatherings of the professional staff for the purpose of presenting their products; nor may a representative post any brochures, notices, or promotional material in any part of any Montefiore facility.

Appropriately scheduled in-services or educational programs, such as for approved devices, must be coordinated and approved by the departmental supervisor.

- 7. No food shall be provided by an MVR at any educational program offered at Montefiore.
- 8. No gifts or inducements of any kind, even of nominal value, may be distributed by MVR on Montefiore premises. Examples of banned items include pens, stick pads, mousepads, conversion charts or food or meals of any kind, even in connection with an educational program.
- 9. Patient education materials produced by vendors may be used provided they have been reviewed and approved by the Montefiore Patient Education Department.
- 10. Off-sites activities arranged specifically for clinical or administrative departments that are sponsored or otherwise supported by MVRs, such as educational lunches or dinners for Montefiore medical staff, house staff or associates, also are not permitted.
- 11. No expenses for travel or attendance at lectures of conferences of any type may be provided by MVRs.
- 12. MVRs seeking to contribute to continuing education may do so by coordinating through the Montefiore Office of Continuing Medical Education. Those seeking to provide grant money for trials should coordinate through the Office of Sponsored Research.

### **VIOLATIONS**:

Montefiore Health System associates and medical staff who observe vendor representatives violating this policy and procedure, or any of the requirements of the Montefiore Compliance Program, should notify the Department of Compliance responsible for the oversight of the MVR's Montefiore-related activities. Violations of this policy by MVRs may result in suspension or termination of access privileges at Montefiore. In the event violations occur, appropriate notice will be sent to the MVR's employer. Montefiore associates and medical staff found to incite or assist any MVR in violating the terms of this policy also may be subject to disciplinary action, including warning, suspension or discharge.

# **Appendix A: Designated MVR Entrances for Montefiore Facilities IN DEVELOPMENT**