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SYSTEM POLICY

ORIGINATOR: Operations Council, Materials Management, Department of Pharmacy, Office of Compliance.

SUBJECT: Vendor/Sales Representative Relations Policy and Ethical Guidelines for Associates Interacting with Vendors

PURPOSE:

1. To establish Methodist Healthcare's (MH) expectations of vendors and their sales representatives in interactions with MH and its affiliated entities.
2. To establish guidelines to ensure high quality care, to preserve patient safety, to protect patient rights, and to provide patient privacy, dignity and confidentiality related to the presence of vendors and their sales representatives in patient care areas.
3. To establish guidelines for the introduction of new products and services to MH.
4. To establish guidelines to ensure vendors and their sales representatives adhere to established MH policies and procedures and that those vendors and their sales representatives abide by all applicable state and federal laws and regulations and other regulatory standards of practice.
5. To establish guidelines for Associates to interact with vendors in a manner that meets ethical standards and encourages the appropriate, efficient and cost-effective use of equipment, supplies, services and pharmaceuticals within MH facilities.
6. To ensure that all vendor contracts are consistent with MH patient care, academic and research missions.
7. To specify a mechanism to enforce this policy.

FUNCTIONS AFFECTED: All MH affiliated entities, including but not limited to, hospitals, outpatient services, home health agencies and all corporate departments, groups and divisions.

RELATED PROCEDURES:

- S-01-002 - Vendor Rebates
- S-05-032 - Associate Conflicts of Interest
- S-05-069 - New Medical Technology and Approval Process Policy
- S-05-071 - Drug Samples

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S-05-076 - Contractual Clinical Services & Clinical Support Services
Conflict of Interest Policy for Officers, Board Members and Certain Other Associates

01.21 - Department of Pharmacy

25.01 - Department of Pharmacy Use of Formulary and Non-Formulary Drugs

DEFINITIONS:

Vendor or Vendor/Sales Representatives – includes individual(s) who market and/or sell products and/or service(s) to MH related to any supply, equipment, instrument, pharmaceutical or medical device used in any MH affiliated entity, and/or any services including, but not limited to, the services of external consultants, employee benefit plan providers, auditors, attorneys and accountants.

Methodist Healthcare (MH) – includes any facility or entity that operates under the governance of the Methodist Healthcare Board of Directors.

New Medical Technology, Equipment or Supplies – a new invasive procedure or technique or new device or medical equipment that: (a) has final approval for prescribed use from the applicable regulatory body; (b) has not previously been reviewed and approved for use within MH; and (c) will be used in offering a treatment modality or service type previously unavailable or promoted for a different delivery venue. New Medical Technology includes devices that are determined to be Substantially Equivalent Devices by the Food and Drug Administration (FDA).

Pharmaceuticals – any and all medications, drugs and IV solutions.

Preceptorship - A preceptorship is a structured "educational" program conducted by a healthcare professional or group, in which one or more representatives of a vendor company(ies) work with, "round" or "follow" caregivers in the process of providing patient care. Other educational activities may be involved.

POLICY:

REGISTRATION:

Each Vendor/Sales Representative desiring to market and/or sell product(s) and/or service(s) to MH is required to submit registration information for themselves, pursuant to the Vendor/Sales Representative Registration Form, and their company, pursuant to the Vendor Data Sheet, including an OIG Sanctions Review. Vendors/Sales Representatives will be required to sign a statement indicating that they have received, read, and understand the Vendor/Sales Representative Relations Policy and Ethical Guidelines for Associates Interacting with Vendor and the MH Standards of Conduct and that they will comply with the policies, procedures and standards associated therewith. Each Vendor/Sales Representative whose registration is approved by MH may,

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if an appointment is agreed to by an Associate of MH or a Physician practicing at MH, market and/or sale approved products and/or services at a MH facility.

To register to market and/or sell product(s) and/or service(s) at MH, the Vendor/Sales Representative must contact the Materials Management Division of MH at 1265 Union Avenue, Suite 701, Memphis, Tennessee 38104 or telephone 901-516-2495 during normal business hours.

The Vendor/Sales Representative Registration Information will be reviewed by Materials Management. The applicant Vendor/Sales Representative will be notified of the approval or declination of the registration. All approved Vendor/Sales Representatives will be available for reference on MOLLI. Approval is required to visit a MH facility or affiliated entity.

Vendor/Sales Representatives calling on Procedural Based Service Areas are required to submit to the Director/Manager of that area documentation of completed protocol/training required by that area of operation and any necessary health records and registration documents and adhere to any Vendor/Sales Representative requirements and/or procedures specific to that operational area.

In an operational area where a Vendor/Sales Representative may be present during a clinical procedure, informed patient consent regarding the presence and role of the Vendor/Sales Representative must be obtained and documented in the patient's medical record. If the Vendor/Sales Representative will have access to protected health information that is not related to Methodist's treatment of the patient, healthcare operations or payment, a HIPAA compliant patient authorization is required to release this information to the Vendor. Contact Legal Affairs for further information.

NEW MEDICAL TECHNOLOGY, EQUIPMENT AND SUPPLIES:

Vendor/Sales Representatives may not introduce any new technologies, equipment or supplies to any MH entity prior to review and approval by Materials Management and, as applicable, the Medical Device Management Committee (MDMC) and/or the Clinical Standards Committee (CSC).

All requests for new technology must be sponsored by or behalf of a physician credentialed at MH after approval by the Medical Staff of the related Clinical Department. Requests must be submitted by a Clinical Director of MH.

All approved incoming medical technologies, equipment and supplies must be covered by a MH Purchase Order, which is issued by Materials

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Management. Medical Equipment must be inspected and approved by Clinical Engineering prior to use. Vendors/Sales Representatives will assume all responsibility of equipment or supplies on loan or evaluation for proper operation and suitability.

Products and equipment that are delivered without a valid purchase order may be considered a donation to MH, or the product or equipment may be returned to the Company at no expense to MH.

All new pharmaceuticals must be reviewed by the P&T Committee prior to being placed on the MH formulary and Pharmaceutical Vendor/Sales Representatives must conduct themselves according to policy guidelines established by the Department of Pharmacy and the P&T Committee.

ACCESS:

Guidelines for Access to MH by Vendor/Sales Representatives

Those Vendor/Sales Representatives with an approved registration on file with MH will obtain a Methodist Healthcare Vendor/Sales Representative Identification badge if access to clinical facilities is desired. The badge will be issued by Materials Management and will be required to be worn at all times when on any MH affiliated campus or location. This badge will specify the Vendor/Sales Representative's name and their company affiliation. **The Methodist Healthcare Vendor/Sales Representative Identification badge must be visibly worn above the waist at all times.**

Any guests of an approved Vendor/Sales Representative must be accompanied by that approved Vendor/Sales Representative when on any MH affiliated campus or location.

The Vendor/Sales Representative ID Badge is the property of MH and must be surrendered upon demand or immediately upon termination of visiting privileges. Please contact the Materials Management Department in the event of any lost, stolen, or damaged ID Badges.

Business Meetings

Vendor/Sales Representatives may schedule business appointments with the MH Clinical/Department/Area Manager by calling at least 24 hours in advance. Each department will establish its own contact guidelines.

Educational Meetings with Staff (Non-Physicians)

"On site" educational meetings between Vendor/Sales Representatives and hospital staff may be conducted if consistent with hospital-defined goals, and specifically approved by the Director/Manager of the area. Meetings related to medications or drug use policy should be approved

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by the relevant Director of Pharmacy or designee. No meals will be provided in this activity.

MH Associates may attend vendor-sponsored programs that are conducted “after hours”, but such Associates must not accept provision of food or other entertainment at this meeting. The Associate may attend the meeting, and pay the cost of the relevant meal or submit for reimbursement based on approval by management. If a fee is required to attend the event, any food provided is considered included in the fee. Associates desiring to attend programs that are approved by MH and offered by Vendors free-of-charge, may use the attached form for responding/registering for the program. **(See Attachment I).**

Access to Patient Care Areas

Non-pharmaceutical vendors will be allowed access to clinical areas of MH affiliated entities only for specific purposes approved by the appropriate MH Clinical/Department/Area Manager. In this situation, the Vendor/Sales Representative should leave the premises when the purpose of his/her involvement is completed.

All patient care areas are “off limits” to pharmaceutical representatives at all times. Patient care areas include any area where patients are being seen for diagnostic or treatment purposes (e.g. inpatient units, surgery suites, emergency departments, diagnostic laboratories, and outpatient treatment centers).

Vendor/Sales Representatives may conduct educational meetings if invited by hospital personnel or medical staff and if the session is conducted in conference room or meeting area (outside of patient care areas) or similarly dedicated non-patient-care space. If drug related, such sessions may not address non-formulary drugs and must be approved by the Director of Pharmacy, or designee, at each respective MH Hospital. If relevant, the Vendor/Sales Representative will be provided information regarding formulary and/or restriction status of the drug(s) that will be addressed in the education. The presentation should include and be supportive of this information. Reference and/or educational material may be distributed only if the drug(s) involved are on formulary and approved by a Department Manager.

Access to Medical Education Conferences including Graduate Medical Education

Vendor/Sales Representatives may sponsor speakers for Medical Education conferences. Topic(s) to be addressed must be approved by the Director for Medical Education, or designee. The date, topic, and time of any drug-related presentation should be communicated to the Director of Pharmacy, or designee. Vendor/Sales Representatives may not provide meals for educational programs conducted in Medical

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Education.

Vendor/Sales Representatives shall not attend programs/meetings in which specific patients are identified or when quality assurance or risk management issues are presented. This does not apply to Vendor/Sales Representatives who have been specifically requested to consult with Associates and/or Medical Staff Members regarding a specific patient or group of patients.

Preceptorships

Preceptorships involving Vendor/Sales Representatives may not be conducted at MH. Nothing in this section shall prevent the conduct of IRB-approved activities, or the consultation or collaboration of visiting medical staff or visiting faculty in the conduct of educational efforts.

Physician Lounges

Vendor/Sales Representatives will not have access to physician lounges at any MH facility or entity.

“On Site” Meetings Between Medical Staff & Representatives

A physician may specifically request to meet with a Vendor/Sales Representative while “on site” at a MH facility or entity. These meetings are to take place in an area to be designated by each MH Hospital Administrator at each facility.

Emergency Department Physicians and Related Programs

It is recognized that Emergency Department physicians do not have offices from which to work or in which to meet with representatives, if so desired. Meetings with Vendor/Sales Representatives will not be allowed in the Emergency Department. However, physicians may schedule a meeting with the Vendor/Sales Representative in the area designated at that hospital for this purpose. Promotional materials may be shared with the requesting physician but may not be left in the area.

Drug-related educational programs that are provided by Vendor/Sales Representatives for the purpose of educating ED (Physician and Non-Physician) staff may be scheduled in non-patient-care areas. The Director of Pharmacy, or designee, must approve these conferences at each respective MH facility or entity. If relevant, the Vendor/Sales Representative will be provided information regarding formulary and/or restriction status of the drug(s) that will be addressed in the education. The presentation should include and be supportive of this information.

Nursing and Other Clinical Departments

Vendor/Sales Representatives may not provide promotional, educational

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and/or reference material unless it is specifically in support of a hospital initiative. As previously noted, the scheduling of pharmaceutical related educational conferences must be communicated to the Director of Pharmacy or designee, and content must be reviewed and approved as noted.

ETHICAL GUIDELINES FOR ASSOCIATES INTERACTING WITH VENDORS:

MH expects Vendors/Sales Representatives to respect and abide by the MH Standards of Conduct and applicable organizational policies and procedures. MH also stipulates that Companies with contracts or agreements with MH and any of its affiliates adhere to the provisions of the MH Standards of Conduct and policies and procedures that address Vendor Sales/Representative interaction with MH colleagues and facilities.

Gifts and Personal Incentives

Cash or other personal incentive programs offered by Vendor/Sales Representatives to Associates are strictly prohibited at MH.

No gifts of any kind from Vendor/Sales Representative to Associates and/or Board Members are permitted. Medical Staff members are strongly encouraged not to accept such gifts.

Pre-printed prescription pads, pens, post-it notes, and other promotional items may not be distributed by vendors to Associates or accepted by Associates, including, employed physicians.

Expenses Incurred to Evaluate a Vendor's Products and/or Services

Vendor/Sales Representative may provide training, information and/or a site visit to another location regarding new products and/or services it wishes to promote and associated travel, meal and entertainment costs provided the arrangement has been reviewed by an appropriate Vice President or above Senior Leader and it is determined that such training, information and/or site visit is necessary and the substantive portions of the event outweigh any entertainment portions.

Company Display of Products and/or Promotional Information

Companies not directly owned by or directly affiliated with Methodist Le Bonheur Healthcare are not permitted to display products or product information within MH or MH affiliated facilities.

Samples

Pharmaceutical samples are controlled by MH Policy S-05-71.

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Educational/Informational Programs and Meetings

Vendor/Sales Representatives shall not provide monetary support for any educational programs developed and/or intended only for use by Methodist Associates. This is not intended to address programs to train Associates and clinical staff on use of the Vendor/Sales Representative products and/or services. Educational programs and other support offered by MH to the community outside our Organization may receive vendor support. Vendor/Sales Representatives shall not attend programs intended specifically for medical students, residents, Medical Staff Members or Associates without clearance from the Materials Management Department.

Associates Acting as Speakers or Consultants for Vendors

Associates must comply with existing MH Policy regarding conflicts of interest (S-05-032). Associates may speak for and/or consult with industry, manufacturers or suppliers outside of worked hours, but Associates must provide quarterly updates disclosing such activities to their Director/Administrator. The Associate engaged in such activity is responsible for also forwarding a copy of such disclosure to the Vice President of Materials Management located at University Hospital, 1265 Union Avenue Crews Wing Suite 701. Full disclosure by the Associate of such relationship is required to be made before any internal discussion or meeting addressing any product(s) and/or service(s) in which the Associate has been engaged in any speaking and/or consulting activity for the company being addressed. The Director/Administrator is responsible for recognition of potential conflicts of interest and for counseling the Associate regarding the need to refrain from or limit such activities. When engaged in consulting or speaking, the Associate must avoid representation that the activity/information being shared is supported by MH.

Donations

The solicitation of donations from Vendor/Sales Representative is strictly prohibited unless conducted under the fund raising activities of the Organization's charitable foundations. Associates may not solicit Vendor/Sales Representative to provide support for attending educational and/or professional association conferences and programs.

Vendor Support for Continuing Medical Education

MH endorses the Standards of Commercial Support of the Accreditation Council for CME, which address institutional responsibility, handling of funds, reasonableness of payments, disclosure, and other issues.

Rebates, Discounts & Credits

All rebates, discounts, credits and any other payments received from a Vendor must be structured to comply with the Discount Safe Harbor

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Regulations and GPO Safe Harbor Regulations. The Materials Management Department has responsibility for tracking and reporting such information in accordance with regulatory requirements. Any Vendor/Sales Representative remitting rebates, discounts, credits or other payment vouchers to facility departments other than the Materials Management Department located at University Hospital, 701 Crews Wing, shall be subject to disqualification as an approved vendor. Any Associate receiving rebates, discount and/or credit vouchers must ensure that these are promptly reported and forwarded to the Materials Management Department.

Responsibility Departments And Staff

All MH Departments and MH affiliated facilities and Associates are responsible for assuring that vendors interacting with MH comply with this policy. Non-compliant vendors are to be immediately reported to the Vice President of Materials Management.

Compliance

- 1) The Materials Management Department shall thoroughly investigate any reported violations of this policy.
- 2) Vendor/Sales Representatives who fail to comply with MH requirements are subject to losing their business privileges at MH. MH reserves the right to restrict the Vendor/Representatives and the company they represent from MH property.

Associates found not to be in compliance with this policy will be reported to their supervisor for action. Depending on the severity of the situation, corrective action up to and including discharge may be warranted.

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