

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

Purpose:

1. To establish MLH's expectations of vendors and their sales representatives in interactions with MLH 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 MLH.
4. To establish guidelines to ensure vendors and their sales representatives adhere to established MLH 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 MLH facilities.
6. To ensure that all vendor contracts are consistent with MLH patient care, academic and research missions.
7. To specify a mechanism to enforce this policy.

DEFINITIONS

- Vendor or Vendor/Sales Representatives – includes individual(s) who market and/or sell products and/or service(s) to MLH related to any supply, equipment, instrument, pharmaceutical or medical device used in any MLH affiliated entity, and/or any services including, but not limited to, the services of external consultants, employee benefit plan providers, patient care companies (e.g. Home Care, Hospice and Home Medical Equipment), auditors, attorneys and accountants.
- MLH – includes any facility or entity that operates under the governance of the MLH 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 MLH; 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 GUIDELINES

Registration:

Each Vendor/Sales Representative desiring to market and/or sell product(s) and/or service(s) to MLH 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 MLH 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 MLH may, if an appointment is agreed to by an Associate of MLH or a Physician practicing at MLH, market and/or sale approved products and/or services at a MLH facility.

To register to market and/or sell product(s) and/or service(s) at MLH, the Vendor/Sales Representative must contact the Materials Management Division of MLH at Crosstown Concourse 1350 Concourse Avenue Suite 668, Memphis, Tennessee 38104 or telephone 901-516-0625 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 Vendors/Sales Representatives must also register through RepTrax and meet/maintain indicated requirements. Approval is required to visit a MLH 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 MLH'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 MLH 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 MLH after approval by the Medical Staff of the related Clinical Department. Requests must be submitted by a Clinical Director of MLH.

All approved incoming medical technologies, equipment and supplies must be covered by a MLH Purchase Order, which is issued by Materials 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 MLH, or the product or equipment may be returned to the Company at no expense to MLH.

All new pharmaceuticals must be reviewed by the P&T Committee prior to being placed on the MLH 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 MLH by Vendor/Sales Representatives - Those Vendor/Sales Representatives with an approved registration on file and having met the requirements in RepTrax will print off a Vendor Visit pass prior to each visit at the appropriate facility location. The Vendor Visit pass will be required to be worn at all times when on any MLH affiliated campus or location. This pass will specify the Vendor/Sales Representative's name and their company affiliation. **The RepTrax 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 MLH affiliated campus or location.

Business Meetings - Vendor/Sales Representatives may schedule business appointments with the MLH 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 by the relevant Director of Pharmacy or designee. No meals will be provided in this activity.

MLH 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 MLH and offered by Vendors free-of-charge, may use the attached form for responding/registering for the program. (See Attachment A).

Access to Patient Care Areas – Non-pharmaceutical vendors will be allowed access to clinical areas of MLH affiliated entities only for specific purposes approved by the appropriate MLH 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 MLH 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 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 MLH. 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 MLH 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 MLH facility or entity.

These meetings are to take place in an area to be designated by each MLH 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 MLH 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 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:

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

Gifts and Personal Incentives - Cash or other personal incentive programs offered by Vendor/Sales Representatives to Associates are strictly prohibited at MLH.

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 MLH are not permitted to display products or product information within MLH or MLH affiliated facilities.

Samples - Pharmaceutical samples are controlled by MLH Policy S-05-71.

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 MLH 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 MLH 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 MLH 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 Crosstown Concourse, 1350 Concourse Avenue, Suite 668, Memphis, TN 38104. 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 MLH.

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 - MLH 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 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 Crosstown Concourse 1350 Concourse Avenue Suite 668, Memphis, TN 38104, 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 MLH Departments and MLH affiliated facilities and Associates are responsible for assuring that vendors interacting with MLH 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 MLH requirements are subject to losing their business privileges at MLH. MLH reserves the right to restrict the Vendor/Representatives and the company they represent from MLH 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.

ATTACHMENT A

REGISTRATION NOTICE FOR VENDOR SPONSORED EVENTS/PROGRAMS THAT ARE OFFERED FREE-OF-CHARGE

NAME OF VENDOR: _____

EVENT/PROGRAM: _____

DATE OF EVENT/PROGRAM: _____

LOCATION OF EVENT/PROGRAM: _____

Dear Vendor:

I have registered for the above-referenced program offered by your Organization to me free of charge. Methodist Le Bonheur Healthcare policy requires that the cost of any meals or food offered to me during the program be reimbursed by Methodist Le Bonheur Healthcare. Please advise me of the cost of any such food in writing prior to accepting my registration for the program. You may provide such response to the email address indicated below.

Associate Name

Email Address