Main Line Health, Inc. and Main Line Health Inc. Subsidiaries		
Working Together to Serve the Community		
This policy applicable to:	☐ **All Subsidiaries** ☒**All Hospitals** ☐ **All Acute Care Hospitals**	☐ **BMRH** ☐ **Mirmont Treatment Center**

ADMINISTRATIVE POLICY AND PROCEDURE MANUAL

Subject: Vendor Conduct -- Procedures for On-Site

No. I.56

Policy Purpose

To provide direction to vendor representatives as to their role and collaboration with Main Line Health.

Policy Statement

It is the policy of Main Line Health (MLH) and its entities to provide quality patient care while maintaining the privacy, safety and confidentiality of patients. While it is important to meet with vendor representatives to stay abreast of new medical devices, technology, equipment and/or medications, it is also necessary to ensure that vendor representatives work within the Main Line Health guidelines set forth.

It is the responsibility of all individuals who deal with vendor representatives to comply with this policy including all Main Line Health employees and medical staff.

By way of this policy, Main Line Health is establishing expectations of our business partners through a code of ethics. To provide each representative with an understanding of the specific relationship we want to establish, their role with us and to provide a channel for communication between vendor representatives and Main Line Health staff.

Equipment

MLH identification badge, vendor badge, vendor sign-in book

Procedure

A. Vendor Credentialing:

1. MLH will utilize the credentialing verification of a third party vendor. This third party website will allow MLH to stay compliant with JCAHO recommendations, confirm vendor representative credentials, track vendor representatives in and out of MLH facilities, manage and monitor representative activities in MLH hospitals.
2. All vendor representatives are required to register with the third party to complete the credentialing process.
3. The vendor will provide accurate, truthful credentials to third party.
4. MLH will have three (3) classification levels for vendors.

<u>Premium Clinical Vendor Representative</u>

A Premium vendor representative is required to submit documentation of the required credentials indicated below for clearance in order to gain access to any area of the healthcare system. Failure to

submit appropriate documentation of the credentials in a timely manner for approval will result in access to the hospital being denied.

Third Party Background Check and Proof of ID Credential Requirements:

1. Photo ID- Vendors must provide a digital headshot for their profile that accurately represents the individual. Ideally, it should follow the government's guidelines for Passport photos.
2. Proof of OIG GSA Exclusion- This credential is provided by the third party.

Third Party Vaccination and Medical Credential Requirements:

1. Immunization Documentation-Proof of PPD.
2. Immunization Documentation-Proof of Influenza Vaccination
   -Exemptions for medical or religious reasons will require documentation

Third Party Certification and Training Credential Requirements:

1. Product Training- Evidence of Representative competencies, training and/or qualifications
2. Appropriate licensure
3. Proof of Training Certificate- including competencies in aseptic principles and techniques, OR protocol training, infection control practices and blood borne pathogens

Third Party Policy Review Credential Requirements:

1. Vendor Conduct – Procedures for On-Site
2. MLH Vendor Confidentiality Agreement Signed
3. Conduct on Hospital Premises
4. Business Associate Policy
5. Patients Rights & Responsibilities
6. Loaner Implant Instrument Policy
7. Use of Cellular Phones, Two-Way Radios
8. Emergency Preparedness Information for Vendors
9. Preventing Fraud, Waste and Abuse and the Federal Claims Act (FCA)
10. Non-Retaliation Policy (Whistleblower Protections)
11. Attire in the Operating Room (Sterile Procedure Areas)
12. Error Prevention Policy

B. Sign in:

1. Vendor representatives may arrive on site between the hours 7:00 am to 5:00 pm, Monday through Friday, except for holidays. These hours of arrival are extended until 7:30pm for the operating rooms and catheterization labs due to emergent cases. All exceptions are to be approved by the administrator on call or departmental designee.
2. Representatives must proceed directly upon arrival at each hospital to the self check-in kiosk and sign in, or use the third party self check-in application as necessitated by the specific location. All representatives must sign in before proceeding to other areas in the hospital. A 'temporary' thermal printed ID badge will be issued. At BMRH: representatives must report to the Front Desk, where they will be directed to the Supply Chain Management Department. The sign in procedure will capture the representative's name, company name, email address, date, time in, department or location to be visited, and telephone number. It is recommended that appointments be arranged for in advance for all visitations.
3. New vendor representatives will be oriented to these standards by the Pharmacy or Supply Chain Management Department designee or Security.
4. For each visit, the vendor representative is required to display the thermal printed identification badge

in plain sight while in the hospital. Failure of the vendor representative to wear the proper identification badge will result in dismissal from the premises, escorted by Main Line Health Security.

5. All vendor representatives must also wear, in plain sight, their company identification badge.
6. Prior to detailing or promoting any drug, supply, technology, equipment or device at MLH, a product information packet must be on file in the Pharmacy or Supply Chain Management office. The information packet should include product information (new and/or revised), contract pricing, as well as related clinical/technical data. All clinical studies and other material used in detailing products must be submitted to the Department of Pharmacy designee or the Supply Chain Management Operations Director prior to distribution within the institution.
7. Information on a non-formulary medication must not be distributed throughout the Institution until it has been accepted by the Pharmacy and Therapeutics Committee (P&T Committee) for formulary status at MLH.
8. Representatives are expected to leave Main Line Health promptly when their scheduled appointments are completed.
9. Vendors will not discuss or promote products or conduct appointments in patient care areas except by appointment or with authorization by the department manager.

C. Appointments:

1. When properly identified with a "Vendor" badge, representatives will have the privilege of visiting Physicians, other medical personnel, and support staff via appointment. All appointments are to be scheduled prior to the vendor representative visiting Main Line Health. The MLH credentialing vendor scheduling tool(s) may be utilized by MLH employees to assist with this process.

D. Physicians:

1. Physicians (department heads, section chiefs, etc.) with offices on Main Line Health premises are to be contacted by phone to schedule appointments.
2. Where applicable, House staff are to be contacted <u>only</u> via the Program Director's office or via a Program Director's designee.
3. Attending staff are to be contacted in their private offices instead of in the hospital.

E. Pharmacists:

1. The Pharmacy drug representative is to contact the Accountable Executive for Pharmacy Services through their respective executive assistant for an appointment; at BMRH, contact the Pharmacy Manager.
2. Pharmacy staff educational programs are also to be scheduled through the Pharmacy Department administrative assistant or designee.

F. Corporate Supply Chain Management:

1. The Vice President for Supply Chain Management is to be contacted through his/her executive assistant;
2. Contract Managers are contacted directly or via the Supply Chain Management Administrative Assistant to schedule appointments.

G. Department Heads, Nurse Managers, etc.:

1. Appointments must be made with the department representative or designee.
2. Educational programs for non-formulary medications or devices not used at MLH are not to be scheduled or promoted until a decision by MLH has been made regarding addition to the formulary or approval for use at MLH via the System Value Analysis Committees.

H. Meeting Locations:

1. Meetings with Representatives are to be conducted by Main Line Health staff in their respective office areas.
2. Vendor representatives are not permitted on any nursing station or other patient care area, Emergency Department, or clinics except by appointment or with authorization of departmental management. Business conducted in or near a patient care area must be confined to an office, conference room, or lounge. Representatives are to leave the patient care area when the appointment is over.

I. Education Meetings/Conferences:

1. Representatives will be permitted to attend Main Line Health educational meetings and conferences as are other health care personnel, provided all registration requirements if any are met and space is available.
2. Vendor representatives are asked to cooperate with moderators and other attendees, to ensure that Physicians and health care professionals have preference for seating.
3. Attendance at meetings/conferences beginning during normal business hours will include the need for the representative to follow routine sign in procedure.

J. In-Services by Vendor Representatives:

1. An in-service is defined as a pre-planned or pre-arranged group presentation that takes place in an inpatient area, and may include Physicians, pharmacists, nursing, or other patient care providers (i.e. films, videos, speakers, slides, teleconferences, etc.)
2. All in-services must be monitored by Main Line Health personnel who will report concerns or issues related to the content of the presentation to the Pharmacy Management or Supply Chain Management Operations Director.
3. In-services may only be given for medications, which have been admitted to the Main Line Health Formulary, for new indications of existing drugs on the Main Line Health Formulary, or the Investigational Review Board (IRB) approved investigational studies.
4. MLH sponsored in-service education on disease state by qualified professional staff and scientists is an acceptable means of informing staff of ongoing drug development or medications currently not on formulary.
5. In-services for new (non-drug) devices, equipment, technology or supplies may only be given for devices and supplies which have been approved through the MLH System Value Analysis Committees, the P&T Committee and/or by the IRB; at BMRH, Administration.
6. All pharmaceutical vendor representatives must inform the Accountable Executive for Pharmacy or the Purchasing Pharmacist regarding the educational program or in-service, as to the date, time and topic, so that they may attend or send a designee. Copies of materials to be used will be made available at the time of program notification.

K. Drug Samples:

1. Drug samples are not to be left for use in any area of the hospital or for use on inpatients. Distribution of samples for patient use is restricted to areas designated as a “clinic” and is limited to moderate quantities of MLH formulary products, meeting the immediate needs of each individual Physician office.
2. Samples are to be logged into the clinic inventory in accordance with the Pharmacy Policy on Samples.

L. Investigational Studies:

1. Investigational studies may be initiated only after a Physician first receives approval from the IRB.

M. Drug Product Exhibits:

1. Consistent with MLH non-solicitation policy, drug product exhibits are not permitted on MLH premises. This includes medical offices building, parking lots/garages and the MLH property.

N. Pharmacy Information:

1. Representatives are asked to keep the Pharmacy Department informed of matters related to their products, e.g. recalls, price adjustments, package insert updates, new products.
2. The preparation and submission of formulary addition requests is the responsibility of the Physician or his/her designee. Formulary addition request forms will be sent directly to the staff Physician for requesting a drug to be added to the Main Line Health formulary.
3. Representatives will be contacted by Pharmacy personnel responsible for inventory and/or a member of the Pharmacy management team to schedule an appointment to address outdated medication, problem medications, contracting issues or for medical information.
4. A non-formulary drug must never be represented as being stocked and/or on formulary.
5. The Main Line Health name will not be used in detailing any product so as to imply endorsement.

O. Medical Product Samples:

1. Equipment, samples or supplies requested by hospital personnel, that have been approved through the System Value Analysis Committees, to be brought in for evaluation purposes must follow appropriate purchasing procedures to allow the execution of a "no charge" purchase order. Please note that any product brought into a MLH facility without the proper purchase order prior to use will not be paid for by MLH.
2. Under no circumstances should products be left with Main Line Health staff to be used on a patient without approval of the Supply Chain Management Department and the System Value Analysis Committees.
3. Medical equipment to be brought into Main Line Health for evaluation must have a "no charge" purchase order approved in advance by the Director of Biomedical Engineering and have been approved, in advance, by the System Value Analysis Committees.
4. Line powered electrical equipment that will be used directly on patients must also be safety inspected by Biomedical Engineering prior to use.

P. Vendor Representative Participation in Clinical Care:

1. At times, vendor representatives may request, or be requested to participate in or observe direct patient care. The appropriate Main Line Health Departmental Clinical Director, Manager or Supervisor will ensure that:

    a) The vendor representative is appropriately credentialed or otherwise approved to participate in the care of the patient or patients (see “Vendor Credentialing;)(Premium Clinical Vendor Representative)
    b) The vendor representative has signed the necessary confidentiality agreement(s)
    c) Any clinical information obtained by the vendor representative complies with Main Line Health, state, federal and JCAHO confidentiality and privacy regulations including HIPAA.
    d) If the vendor representative will participate in a procedure or direct patient care they must also have the appropriate state license, even if on a temporary basis.
    e) The vendor representative must retain and demonstrate upon arrival certification of compliance that they have received instruction in the principles of asepsis, appropriate conduct in restricted procedural environments, emergency preparedness Information for vendors (fire and safety), infection control practices- blood born pathogens, patients’ rights and confidentiality. In addition, the representative should provide proof of current PPD.

f) In the operating room procedural areas, vendor representatives, excluding pharmaceutical representatives, may verbally assist with set-up and education of equipment and supplies. They are not permitted to perform a surgical scrub and assist with a surgical or invasive/noninvasive procedure. They should not open products for the surgical or procedural field or operate equipment for the procedure. Representatives are permitted to calibrate programmable devices under the direction of the Physician; these include ICD's, pacemakers, sacral nerve stimulators, and lasers.
g) Vendor representatives must present a list of implants used to the circulating nurse to obtain written approval. The vendor representative must then contact the Inventory Control Coordinator for issuance of a requisition for purchasing. Payment will not be rendered unless a Purchase Order has been issued by MLH.
h) The vendor representative's name and company name must be documented in the medical record in areas where procedures are performed.

Q. Telephones:

1. Representatives are to adhere to the Main Line Health cellular device policy (No. I.53) while on campus premises. Use of hospital designated phones is prohibited. The use of hospital paging system is not permitted.

R. Meals:

1. Vendor representatives may purchase meals in the hospital coffee shop/cafeteria in conjunction with an appointment.

S. Enforcement:

1. Vendor representatives who violate this policy will be asked to leave the premises immediately.
2. The Main Line Health Manager, Director or Administrator identifying the violation may ask the vendor representative directly, or may request assistance from Security.
3. The vendor representative's violation will be reported to the management for the Pharmacy or Supply Chain Management.
4. The Pharmacy Management or Supply Chain Management will initiate a graded response for repeated violations. This will include:
   a) A letter to the vendor representative explaining the violation, and reiterating Main Line Health policy
   b) A letter to the vendor representative's supervisor explaining the violation, and reiterating Main Line Health policy
   c) Banning of the offending vendor representative from Main Line Health for a defined period of time from 30 days to one year.
   d) Removal from the Main Line Health accounts.

Replaces the following Policies/Procedures: Pharmacy Policy I.50
Reference: AORN Position Statement, "Role of the Health Care Industry Representative in the OR," 2001 Standards, Practices and Guidelines. HLA Newsletter "Manufacturer's Reps in the OR," Fall 2000. MLH OR Policy "Authorization of Observers and Representatives in the OR," November 1999.

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