LANCASTER GENERAL HOSPITAL
ACGME POLICIES

In Reference to ACGME Institutional Requirements – Effective July 1, 2022

IV.L. Vendors: The Sponsoring Institution must maintain a policy that addresses interactions between vendor representatives/corporations and residents/fellows and each of its ACGME-accredited programs. (Core)

Process Name:	GME Vendor Interactions
Effective Date:	09/25/2023
Who is the policy's expert(s):	Designated Institutional Official
To Whom does the policy apply:	All residents/fellows of ACME accredited Graduate Medical Education programs sponsored by Lancaster General Hospital
Process:	As note below.
Related policies and documents:	N/A

POLICY

Vendor access/activities to all areas of the Lancaster General Hospital (LGH) and the Lancaster General Health Physicians (LGHP) offices shall be controlled. LGH/LGHP respects patients' and their legally authorized representatives' freedom to choose post-hospital care providers and post-hospital medical equipment suppliers. Only those post-hospital vendors (as defined in Scope below) who are invited to LGH by members of the Case Management and Social Work ("CM+SW") Department to provide such services and equipment as chosen by specific patients are permitted in patient care areas.

Chosen post-hospital vendors are limited to interaction with the CM+SW staff member and the specific patient and/or patient's family/ legally authorized representative /patient representative for the purpose of transitioning the patient to the next level of care, providing associated intake services, or arranging for the post-hospital medical equipment/supplies.

Post-hospital vendors may be invited to discuss their services with the CM+SW Department, provide in-services, or for other legitimate business purposes which shall be authorized by CM+SW Department management and coordinated by the CM+SW Department administrative staff.

PURPOSE

To control vendor access/activities to all areas of LGH/LGHP and to ensure that all products and devices brought into LGH/LGHP are properly reviewed, authorized, approved and that education is in place prior to any product or device trial, distribution of product/device sample and/or demonstration. To protect patient confidentiality and to minimize disruption of patient care while facilitating preparation for patient's timely and appropriate discharge and respecting patient's freedom of choice of post-hospital care providers.

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SCOPE

This policy applies to LGH, and those parts of the clinical practices of the Lancaster General Health Physicians (LGHP) which practice at or in conjunction with LGH, operating under the LGH license. This policy also applies to practices and sites that are off campus facilities or departments of LGH and operating under its license, including ambulatory surgical facilities operating under LGH's governing body, and private entities that lease space in property owned or leased by LGH only if they provide contracted clinical services to LGH; and personnel that provide contracted clinical services to LGH patients.

This policy applies to all vendors providing services, equipment or supplies to LGH/LGHP. This policy also applies to representatives of home care agencies, home infusion providers, hospice providers, durable medical equipment companies, wound care companies, liaisons for post-acute facilities (e.g., Skilled Nursing Facility, Rehabilitation, Sub-Acute, Long-Term Acute Care Hospital, Nursing Home Long Term Care, boarding home, shelter, assisted living) who may be providing post-hospital services or equipment to patients upon discharge ("Post-hospital Vendor"), and pharmaceutical company vendor activities at LGH/LGHP.

PROCEDURE

A. Code of Conduct:

1. LGH/LGHP has the right, in its sole discretion, to approve in advance any vendor representatives assigned to provide services, equipment or products to LGH/LGHP and/or to require replacement of any such vendor representative without cause as long as it does not constitute unlawful discrimination nor violate a patient's freedom to choose post-hospital vendors.

2. Vendor representatives and their respective companies are not permitted to engage in counter-detailing activities as a means to promote their product(s), devices or services in contravention to institutional or LGH system wide initiatives. Prohibited counter-detailing includes, for example, product replacement, detailing in opposition to LGH business plans, and provision of false, misleading or inaccurate information.

3. "Shadowing" by vendor representatives is strictly prohibited.

4. **In the event that Vendor Representatives do not follow the procedures detailed in this policy, LGH/LGHP reserves the right to remove Vendors from the premises to include a Security escort from the building.**

B. Regular Vendors (other than Post-Hospital Vendors):

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1. Vendor representatives classified as "regular vendors" or "long term contractors" are vendors visiting LGH on a regular basis with inventory/consignment obligations, extended project responsibilities and/or on-going clinical product support within a specific clinical area. (The term "regular vendors" includes companies, as well as individual representatives and personnel of the company.)

2.All regular vendors requiring physical access only, must be entered into the system (Penn for People and C-CURE) in order to be eligible to obtain a Penn Medicine Lancaster General Health-issued ID badge for vendors or suppliers ("VendorMate badge"). These individuals shall be entered into the system by the respective LGH Director/Manager, or Management Sponsor one business day prior to receiving the ID badge.

Note: This shall not apply to sales reps, equipment reps, or pharmacy reps, etc. All vendor representative must be registered with VendorMate and display an approved VendorMate pass at all times. Vendors issued a Lancaster General Hospital ID badge are required to schedule and obtain approval in advance to visit a department.

3. Vendor will complete all required documents in VendorMate as required for their specific visitation purpose.

C. Post-hospital Vendors:

1. Post-hospital vendors invited into the hospital to see a specific patient (or patients) will be required to sign in to VendorMate upon entry. The post-hospital vendor will be required to provide the name of the Case Manager or Social Worker who has requested their services on behalf of the patient and are invited to the patient care area for patient evaluation. The post-hospital vendor will not visit any other units unless requested by CM + SW to do so for specific patients. Upon completion of their specific duties in the facility, they will promptly leave the floors and sign out of VendorMate. The vendors must display the VendorMate badge on their person for appropriate identification.

2. Post-hospital vendors providing Continuing Education programs will report to the CM +SW main office at LGH/LGHP on date/time as coordinated by CM+SW staff.

3. When CM+SW staff identify a post-hospital vendor not adhering to this policy, they should report this to the Director of CM +SW for follow up with the post-hospital vendor.

4. Vendor will complete all required documents in VendorMate as required for their specific visitation purpose.

F. On-Site Conduct by Vendors:

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1. Detailing shall not be permitted in public areas including: the cafeteria, telephone stations, hallways, near elevators or in parking garages.

2. Vendors are required to obtain permission to access LGH computers and LGH information systems as well as to use LGH phones to contact staff. This includes accessing LGH information systems through various remote portals. In addition, before accessing any authorized information system, vendor must ensure that all IT privacy/access policies are reviewed and all such policies must be adhered to.

3. Due to patient confidentiality concerns, regular vendors and walk-in vendor representatives are not permitted to attend any patient conferences or reports. Such vendor representatives may not see patients, review their medical records or any portion of the patient medical record, whether in electronic or paper format, go on rounds or routinely attend surgery. Vendor representatives are prohibited from unauthorized clinical areas, including inpatient units and conference rooms on inpatient units, in addition to outpatient units, where there may be a potential for patient information to be shared. Vendor representatives are permitted to meet with designated personnel in a private office setting. Post-hospital vendor representatives are only permitted to go to patient care areas for patient evaluation and to see patients, or review their charts after authorization by the CM+SW and the patient/legally authorized representative.

4. In those circumstances where there is a legitimate patient care need for the vendor representative to attend surgery or otherwise have direct patient contact, they are subject to LGH/LGHP policy regarding immunizations and other health requirements (e.g., MMR immunization and COVID-19 immunization, as described in this Policy) and with the exception of post-hospital vendors, must also have executed a Clinical Observer Agreement in VendorMate or in hard copy (see sample attached as Attachment 1).Vendor representatives must also provide documentation from the vendor's company that the vendor representative is qualified and competent to provide the necessary service.

5. Vendor representatives shall not attend programs when confidential quality assurance or risk management issues or other confidential information are presented.

6. The vendor representative must have no active cough, rash, swollen glands or fever or knowledge that they have any infectious disease that might be transmitted as a result of their attendance in the patient care or perioperative/operative area. The vendor representative must comply with all safeguards against infection and other hazards. The vendor representative must remain only in the approved areas and must leave immediately upon the request of the attending physician or their designee, Hospital administrator or CM+SW staff.

7. The vendor representative may not film, videotape, record (voice or video) any type of the staff, other guests, premises or equipment or any procedure without obtaining proper authorization and written consent.

8. In all procedure areas, the vendor representative must be dressed in appropriate surgical attire including masks, head coverings, scrubs etc.

9. Vendor Representatives are prohibited from accessing supply/equipment storage areas without consent of the department head and in accordance with rules of the department.

10. All vendors and their representatives will be subject to and must abide by LGH/LGHP and LGH policies regarding, but not limited to, patient and staff safety and security, patient confidentiality, entity parking, infection control, fraud, waste and abuse, and other policies as identified by LGH/LGHP and LGH.

11. Distribution of vendor patient educational material that may be useful to LGH/LGHP patients and staff should be left at the appropriate department. The applicable department must review all educational information before it is distributed to patients, families, visitors or staff. Vendors are strictly prohibited from providing educational materials of any type directly to patients or from leaving them in areas accessible to patients or in public areas in the hospital.

12. Vendors are prohibited from distributing promotional or marketing materials in public areas of LGH/LGHP. All such material for products or services offered by non-LGH entities must be sent or delivered to the CM+SW Department office. The availability of such material to LGH/LGHP's patients, families, visitors or staff will be at the sole discretion of CM+SW and placement will be limited to the immediate proximity within the CM+SW office. Material deemed inappropriate for distribution to LGH/LGHP patients, their families, visitors or staff may be disposed of with no obligation to notify the organization and no obligation to return the material.

G. Controlled Clinical Areas:

1. Controlled clinical areas are defined as: perioperative services, sterile processing, procedure areas and all other departments as defined by Senior LGH/LGHP Leadership.

2. Vendor representatives engaged within all Controlled Clinical Areas will be required to wear designated appropriate clinical clothing that will identify the vendor as distinct from regular LGH/LGHP clinical staff.

3. All vendor representatives will have a verifiable appointment or be engaged in verifiable clinical support of a specific physician or clinical service. All vendor representatives engaged in clinical support of a product must have prior approval by the specific director of that service and must be approved by the Director of Value Analysis.

4. Vendor representatives not in direct support of a specific physician or clinical service must have an appointment. Failure to have a set appointment will result in that vendor representative being removed from the facility on that date. Subsequent episodes related to vendor

representatives being removed due to failure to have a set appointment may result in LGH Supply Chain vendor disciplinary procedures.

H. Regulatory Requirements:

1. Vendor representatives will be required to review and acknowledge that they are aware of key Penn Medicine LGH/LGHP policies regarding, but not limited to: this Vendor Visitation/Management Policy, the LGH Fraud, Waste and Abuse Policy, Safety and Security, HIPAA, Loaner Instrument Sets Process (document present in VendorMate), and other policies as defined by Senior Hospital Leadership. These policies have been uploaded into the VendorMate Vendor Credentialing System and are part of each sales representative's required compliances needed to obtain access badges (VendorMate badges). Indication that the policies have been read must be confirmed within the VendorMate System.

2. "Regular vendor" representatives or vendor companies, on behalf of their respective vendor representatives, must provide documentation (upon request) that certifies training and education in:

a. Product or device supported,
b. HIPAA compliance and all matters related to patients' rights and confidentiality,
c. Appropriate conduct and attire in the perioperative or invasive procedure environment,
d. Aseptic principals and sterile techniques,
e. Infectious disease and blood borne pathogens, and
f. Occupational safety: biohazardous waste, fire, electrical, radiation and other safety protocols.
g. Vendor representatives are required to participate in an orientation.
h. These documents will be kept on file within the requesting department.

I. Conflict of Interest:

1. Vendors or vendor representatives conducting business at LGH/LGHP shall avoid any conflict of interest with employees or physicians of LGH and LGHP.

J. Violation/Sanctions:

1. Vendors violating the LGH/LGHP Vendor Visitation/Management (or any LGH/LGHP Policy) may be subject to disciplinary action, up to and including termination of visitation privileges from LGH/LGHP and LGH in the sole discretion of LGH/LGHP administration.

Policy Owner

- Director of Corporate Supply Chain

References

- Health Insurance Portability and Accountability Act of 1996

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ATTACHMENT 1
Sample Clinical Observer Agreement

These Terms and Conditions must be signed and submitted to the _ [fill in the appropriate Hospital representative] no less than 24 hours prior to the scheduled start time of the surgical or medical procedure/office visit, and a copy must be placed in the Log [fill in the name of the log where these clinical observer agreements will be maintained].

Clinical Observer Agreement Terms and Conditions

This Clinical Observer's Terms and Conditions ("**Terms and Conditions**") between _____ _____ *[fill in the name of the applicable hospital]* ("**Hospital**") and _____ *[fill in the individual's name]* ("**Clinical Observer**") specifies the Terms and Conditions under which Hospital will permit Clinical Observer to be present in the specified patient care area.

1. **Location, Time, and Purpose**. Clinical Observer is permitted to be present in ____ *[fill in the location]* ("Approved Area") on _____, 200 ___ *[specify the date]*, during the*[fill in the specific surgical or medical procedure]* of the following patient: _____ (*insert name and medical record number of patient*). Clinical Observer will remain only in the Approved Area and will leave immediately upon the request of any hospital staff. Clinical Observer's presence has been approved for the purpose of: *[clearly and precisely state the reason the Clinical Observer is permitted in the Approved Area]* _____ (the "Purpose"). Hospital may withdraw its approval at any time for any reason. Clinical Observer understands and agrees that Hospital reserves the right to terminate Clinical Observers' access and this Agreement at any time for any reason that does not constitute discrimination, including for example violation of this Agreement.

2. Confidentiality. Clinical Observer will have access to patient information and Hospital information of a confidential and/or proprietary nature, including but not limited to patient medical information, patient demographic information, and information regarding Hospital's provision of health care and practices ("Confidential Information"). Clinical Observer will (a) secure and protect the Confidential

Information consistent with standards and laws applying to the security and protection of patient information, including, but not limited to any such regulations under the Health Insurance Portability and Accountability Act of 1996, and any applicable state privacy and security legislation or regulations, (b) will not use the Confidential Information except to achieve the Purpose under these Terms and Conditions, and (c) will not disclose the Confidential Information except to those individuals providing medical care to the patient. This restriction will not apply to Confidential Information the Clinical Observer is required by law, regulation, rule, or court order of any governmental authority to disclose if Clinical Observer first notifies Hospital as soon as possible, but in no event less than fifteen (15) days, prior to disclosure, and cooperates with Hospital in any response to such required disclosure. In addition, Clinical Observer will immediately inform Hospital of any disclosure of Confidential Information to

anyone, whether or not permitted by this agreement or any other agreement between Clinical Observer and Hospital. If Clinical Observer receives any Confidential Information, it will return it to Hospital or destroy it the sooner of the end of the procedure or upon Hospital's request.

3. Covenants, Representations, and Warranties.

a. Clinical Observer covenants that he/she is aware of Hospital's safeguards against the introduction of infection and that he/she is not aware that he/she has any infectious disease. Clinical Observer represents and warrants that he/she will comply with all safeguards against infection and other hazards.

b. Clinical Observer represents and warrants that he/she will comply with Hospital's rules, policies, and procedures.

c. If the Clinical Observer is to participate in the surgery or otherwise come into physical contact with the above named patient, the Clinical Observer represents and warrants that he/she has received the requisite approval from Medical Affairs and has the appropriate licensure, insurance coverage, qualifications, and competencies to participate, which are: *[insert the appropriate licensure, insurance coverage, qualifications, and competencies]*
_____
_____. Unless specifically approved through Medical Affairs, Clinical Observer represents and warrants that he/she will not directly or indirectly touch the patient, will in no way interfere with the provision of health care in the Hospital and, will not enter _____*[fill in specific locations if desired e.g.* the sterile field, the sterile supply area, or the scheduling office*]* and will not touch any equipment or supplies in the Approved Area with the exception of the following: (*list anything the Clinical Observer may touch, and make sure that each item matches the Purpose described in paragraph 1 and the competencies in paragraph 3 (c)*).
_____ .

d. Clinical Observer represents and warrants that he/she will not photograph, audiotape, videotape, or otherwise record any aspect of the surgical procedure or recovery unless expressly permitted pursuant to a hospital policy.

e. Clinical Observer represents and warrants that he/she will respect the privacy of all patients.

4. Miscellaneous. These Terms and Conditions will be governed by and construed and enforced in accordance with the laws of the Commonwealth of Pennsylvania. If any provision of these Terms and Conditions is rendered invalid or unenforceable by the enactment of any applicable statute or ordinance or by any regulations duly promulgated or is made or declared unenforceable by any court of competent jurisdiction, the provision will be deemed stricken from these Terms and Conditions and the remainder of these Terms and Conditions will remain in fully force and effect. No waiver will be binding unless executed in writing by the party making the waiver. No waiver of any provision of these Terms and Conditions will be deemed or will constitute a waiver of any other provisions, whether or not similar, nor will any waiver constitute a

continuing waiver. Neither party may assign these Terms and Conditions or any rights hereunder, not may it delegate any of its duties to be performed hereunder, without the prior written consent of the other party. These Terms and Conditions will be binding upon, and will inure to the benefit of, the parties and their respective legal representatives, successors and assigns.

The parties consent to the terms of these Terms and Conditions.

[Fill in legal name for the applicable LGH hospital]
By: _____
(Signature)
Printed: _____
(Printed name)
Its: _____
(Print title)

Clinical Observer

_____
(Print Clinical Observer's name)

_____
(Print Clinical Observer's Title)

_____
(Clinical Observer's Affiliation)

_____
(Clinical Observer's Address)

_____
(Clinical Observer's Signature)