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Owner	Diane Artieri: Purchasing VP
Area	Purchasing
Applicability	Erie County Medical Center
References	PUR-001

Vendor Access Policy

I. Policy Purpose, Statement of Policy, and Policy Goals:

The intent of this policy is to manage access to ECMCC sites in a manner that will ensure the rights of the Corporation, all of its employees, the safety of its patients and the confidentiality of their health information. ECMCC is committed to maintaining corporate compliance and appropriate business ethics. In addition, we adhere to Project Sunlight, as a component of the Public Integrity Reform Act of 2011, relating to our interactions with vendors.

a. The term "vendor" is defined by this policy as a company that provides goods or services to ECMCC (including but not limited to medical devices, products, services or equipment) and the employees, subcontractors, agents and representatives of such company.

II. Policy Implementation-

The VP Supply Chain or designee, shall communicate this policy to ECMCC vendors and will be posted to our website. In addition, this policy must be followed according to contract with the various vendors.

III. Procedure

a. **Vendor Requirements for Access**

   A. All vendors requiring access to ECMCC premises must enroll in the Symplr Vendor Credentialing Program which can be completed through the Symplr web-site. Symplr is utilized to perform and to monitor screening and credentialing compliance. In addition, Symplr monitors access to our facility.

b. **Vendors must comply with ECMCC requirements for levels of access:**

A. Provider Access: Access only to Physician offices.

B. Adminstrative Access: Access to patient care areas but having no patient contact.

C. Patient Care Access: Access to patient care areas with non-interventional patient contact

D. All Access: Access to patient care areas and having interventional patient contact

c. **Vendors shall not have access to medical records containing Protected Health Information (PHI),** regardless of format. If a Vendor incidentally gains access to PHI during a site visit, such PHI shall be kept confidential in the manner described in the Vendor Access Agreement.

A. At no time is a vendor to review PHI/cases that they have not been requested to be involved.

B. Only in specifics cases are vendors allowed to fax PHI to comply with FDA regulations. A secure fax in our Prep and Pack area is the designated fax to be utilized only for these circumstances.

C. Examples of unacceptable practices include, but not limited to:

1. Reviewing surgery schedule
2. Reviewing add on cases
3. Utilizing fax machines in undesignated areas (e.g. Main OR, Radiology, Surgery Scheduling office)
4. Emailing any information with PHI

d. **Vendor representatives are required to display their Symplr badge, and are expected to conduct themselves in a professional manner at all times while at ECMCC. ECMCC may reserve the right to terminate our contract for non-compliance.**

e. **Sign In Procedure** (NOTE: ECMCC reserves the right to deny a vendor meeting if necessary)

A. Vendor representatives must check in at a Symplr kiosk located at the front of DK Miller Building or the receiving/loading dock entrances of the hospital. Vendor representative who fails to check-in may be denied further access to our facilities and the incident shall be reported to the VP Materials Managment and the Director of Corporate Compliance.

B. Vendor representatives must wear their approved Symplr badge.

C. Vendor representatives found in any area without proper authorization and identification will be asked to leave at once. Failure to leave may result in an escort off the premises and permanent revocation of access privileges. All incidents shall be reported to the VP Materials Managment, Security and Corporate Compliance.

D. If a prior appointment has been scheduled and approved by authorized personnel, vendor representatives may be present in patient care areas only if escorted by ECMCC management or designated staff.

E. Exceptions from the sign-in process may be granted for certain vendor representatives. Reasons include, but are not limited to: 1, 2 and 3 below and require an ECMCC identification badge.

1. ECMCC-retained attorneys

2. Administrative level consultants
3. Maintenance or other contracted personnel

f. **Appointments**

A. Appointments made with attending medical staff must be scheduled through the physician's private office, and the meeting should take place in the physician's private office unless other arrangements are made with the Department Directors

B. ECMCC Surgical Services Management will meet with vendors BY APPOINTMENT ONLY. NO cold calls or drop in visits are acceptable.

g. **Vendor Representative Presence in Operating Rooms or Invasive Procedure Rooms.** (NOTE: It is the responsibility of the physician to obtain patient consent to the presence of medical observers or vendor representatives. This form is a permanent part of the medical record.) See Consent Form #ADM.LGL 001

A. Vendor representative's presence in the operating room or invasive procedure rooms are subject to the following:

1. Visits are limited to procedures by physician request and approved by the site Department Manager/designee.
2. The vendor representative may act as a resource ONLY regarding the representative's product and MAY NOT scrub in or participate in patient care.
3. The vendor representative may NOT handle ECMCC stock products.
4. The vendor representative must leave the facility upon completion of the scheduled procedure(s) or earlier if requested. NO LOITERING.
5. Documentation of a representative's presence during the procedure, with exact in and out time, must be included in the permanent medical record.
6. Access to Operating Rooms is strictly limited to one representative per room unless authorized by surgeon and Director of Surgery Department.

h. **Surgical Attire**

A. All vendors who will be present in the OR must follow the hospital policy regarding appropriate surgical attire #IC-056 (Dress Code Surgical Services).

i. **New Products and Product Samples**

A. All offers of samples and requests to provide samples of supplies shall be referred to the VP Materials Managment for processing. Devices or products furnished by the vendor representative shall have current (as applicable) FDA approval, be within the expiration date of the manufacturer and shall be in a clean, sterile (as applicable) and unopened condition at the time it is brought into the hospital. Sample medications shall be handled in accordance with Formulary Policy FRM-4 and may not be provided to inpatient areas.

B. Any new product (supply, equipment, implant, etc.) offered for use in any department must first be approved by the Department Director, VP Materials Managment and then presented to the Value Analysis Committee for processing. If a product has not

been previously approved, and does not have an ECMCC purchase order (PO) assigned, the product will not be processed for payment and will be considered a gift to ECMCC.

1. A copy of the 510K (FDA Approval) form to ensure safety and effectiveness may be requested.
2. A copy of the GPO contract number and information must be submitted or be on a signed ECMC contract.

C. All supplies, equipment and materials must have a purchase order prior to acceptance by the Receiving department.

D. Vendor representatives may only discuss the attributes and specifications of the product(s) with clinical staff. Any request to deliver or ship any product to ECMCC shall be directed through the Purchasing Department with the appropriate PO.

E. Any product supplied by the vendor on the day of the surgical procedure must have prior approval for use and be on a signed ECMC contract. If the product does not have prior approval or an ECMCC purchase order (PO) assigned, the product will not be processed for payment, and will be considered a gift to ECMCC.

F. Supplies must be from the vendor who will guarantee the product. In addition, the vendor must follow Federal regulations on the sale of products.

j. **Instrumentation Delivery Protocol**

A. Vendor representatives who request to deliver an instrument set must:

1. Provide an ECMC Trays & Implants Information sheet to ECMCC staff and review the instruments prior to leaving the set. Both the representative and two ECMCC staff members will sign the information sheet.
2. Upon return of the set, the representative and both the ECMCC staff members will review the set to verify the set is complete. All will sign the reviewed information sheet as complete.

B. ECMCC requires 48 hours to process instrumentation.

C. All instrumentation must be delivered to Prep and Pack for processing.

k. **Vendor representatives who request to borrow an instrument set must**:

A. Get approval from OR charge RN, or designee

B. Review the information sheet with Prep and Pack Prep staff to verify the components of that set prior to its leaving ECMCC. Both will sign the information sheet as complete. Scan into the tracking system the ECMC Trays & Implants Information sheet.

C. Vendor Representative will provide a copy of the inventoried count sheet to the Pack and Prep staff.

D. The set must be decontaminated and clean before it is returned to ECMCC.

E. Upon return of the set, representative will meet with the Sterile Processing staff, review the information sheet and verify all the appropriated components are clean and in the set.

l. **Agreements and Contracts**

A. The VP Materials Management will review all contracts with legal, submit for signatures to the CEO (Chief Executive Officer) or CFO (Chief Financial Officer) who are the only positions that have authority to sign contracts for ECMCC.

B. Any agreement not authorized by the CEO or CFO is invalid.

C. Contracts and agreements must follow ECMCC's procurement and RFP processes.

m. **Demonstrations and/or Evaluations**

A. All requests for demonstrations, testing and/or evaluations of supplies and equipment must be approved by the Director of Purchasing.

B. It is the responsibility of the vendor or representative presenting a pharmaceutical display or in-service to notify the audience when the product being presented is non-Formulary or of a restricted status at ECMCC.

C. Once approved, appropriate action will be taken.

n. **Product and/or Equipment Removal**

A. Medical equipment, instrumentation and supply products may not be removed from the ECMCC system premises without the notification and written approval of the Director of Purchasing.

o. **Inappropriate Vendor Actions**

A. The following are examples of inappropriate actions by vendor representatives and are NOT ACCEPTABLE:

1. Going to any department without following Sign-In Procedures
2. Not wearing Symplr Badge.
3. Appearing in any department without a pre-arranged appointment.
4. Pre-arranged appointments in excess of four (4) hours per week.
5. Examining and/or removing a patient's medical record and/or PHI in any format. (unless for regulatory purposes)
6. Entering occupied patient rooms without express permission of the nursing management of the area involved and the patient.
7. Soliciting business from patients or non-management ECMCC staff.
8. Performing any clinical function without the appropriate credentials.
9. Use of ECMCC phones to conduct non-ECMCC business.
10. Removal of any equipment or products without prior approval by the Department Director.
11. Provision of gifts not in accordance with ECMCC's Code of Conduct, Corporate Compliance Program, Business Ethics policy and the NYS Code of Business Ethics.
12. Failure to provide quotations to Supply Chain Management before providing them to physicians, nursing, etc.

13. Promoting products that are known to be non-Formulary or of a restricted status in a manner that misrepresents that product's status within ECMCC.
14. Taking unauthorized photos.
15. Offering remuneration to an ECMCC employee.
16. Accessing the OR break/lunch room.

p. **Consequences of Policy Violation by a Vendor**

A. The following steps may be taken in the event of violation of this policy by a vendor and/or vendor representative. In all cases, the vendor, vendor representative and GPO, will be notified of the violation. The severity of any infraction may necessitate the skipping of certain steps:

1. Issue a written warning to the vendor and vendor representative.
2. Six months (or a timeframe determined by the Compliance Officer and OR Manager) ban of vendor representative from ECMCC property for vendor activities.
3. Permanent ban of vendor representative from ECMCC property for vendor activities and possible termination of vendor contract.
4. Non-payment for any supplies/materials/equipment delivered.

B. The VP Materials Management, or designee, in conjunction with the Compliance Officer are responsible for enforcement of these steps.

Reference:

NYS/Federal/JCAHO:HIPAA Privacy Rule;
American College of Surgeons ST-33;
JCAHO IM.2.10 Standards and Recommendation Practices and Guidelines
2002 AORN Health Insurance Portability and Accountability Act (HIPAA)
ECMCC Code of Conduct and Business Ethics policy ECMCC Corporate Purchasing Policy
NYS Medicaid Update April 10, 2010 Vol 26 #6
OIG Special Advisory Bulletin 5/8/2013

ECMCC has developed these policies and procedures in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team in making clinical decisions about patient care. These policies and procedures should not be construed as dictating exclusive courses of treatment and/or procedures. No health care team member should view these documents and their bibliographic references as a final authority on patient care. Variations from these policies and procedures may be warranted in actual practice based upon individual patient characteristics and clinical judgment in unique care circumstances.

Approval Signatures

Step Description	Approver	Date
	Andy Davis: Administration Chief Operating Officer	12/2023
Owner	Diane Artieri: Purchasing VP	12/2023

Applicability

Erie County Medical Center