UnityPoint Health

Title: Vendor Management 2.AD.04

Effective Date: 07/18

POLICY: Iowa Health System, d/b/a UnityPoint Health ("UPH") shall provide clear and consistent guidelines governing all vendor representative activities while conducting business within UnityPoint Acute Care/Infusion Center facilities. These guidelines and processes are intended to meet the needs and expectations of UnityPoint Health employees, health care providers and patients. This policy is necessary for the protection of patients, physician and staff efficiency and integrity, to avoid disruption of care and to ensure patient privacy and confidentiality

All vendor and service representatives supporting UnityPoint Health facilities must register their company and themselves on an annual basis through UnityPoint Health's Reptrax program.

SCOPE: UPH Acute Care Facilities and Infusion Centers.

BACKGROUND: The objectives of this policy are: (1) to support the evidence based selection of supplies, equipment, and pharmaceuticals; (2) to promote patient safety by assuring adequate information is provided to UnityPoint Health employees; (3) to facilitate centralized contracting, purchasing, and distribution for all UnityPoint Health organizations; (4) to support UnityPoint Health's cost containment activities; (5) to avoid interference with patient care activities and create an environment that maintains patient confidentiality and safety; and (6) to assure that the Materials Management Information System contains accurate supplier and product information.

IMPLEMENTATION:

1. Representatives Definition.

   1.1 This policy governs the activities of all representatives of companies currently or potentially conducting business with UnityPoint Health facilities that market or supply drugs, medical/surgical supplies, equipment, nutritional products, technology, and maintenance and repair services.

   1.2 Delivery personnel that do NOT have access to procedural areas are exempt from Reptrax requirements, but are expected to limit their visit to areas of the facility they service, and follow all facility policies while on the premises (e.g., pharmaceutical delivery – Pharmacy, med-surg distribution – Purchasing, food delivery – Food & Nutrition, construction – Facilities Management).

1.3 Construction/contracted vendors who will be onsite long term (3 months or longer) are required to provide documentation that they have received their annual influenza vaccination to the appropriate department, but are not required to check into Reptrax every day, provided they have been issued an ID badge from the facility.

2. Representative Registration.

2.1 All representatives selling/marketing products or services used in direct patient care and service representatives must register their company and themselves on an annual basis through UnityPoint Health's Reptrax program. Representatives who do not register annually will not be allowed to conduct business at UnityPoint Health facilities.

2.2 Initial Registration

2.2.1 Representatives must initially register their company and themselves by accessing UnityPoint Health Reptrax system via https://www.sec3ure.com/login.

2.2.2 At registration, representatives will be required to provide information about their company, themselves, and their products as well as reviewing and documenting agreement with various UnityPoint Health policies.

2.2.3 Fees will be assessed and collected at the time of initial registration. Fees are assessed annually for each company based on UnityPoint Health's established risk criteria. Each company may register an unlimited number of representatives (under the same tax ID) for the annual fee paid by the company.

2.3 All representatives (per 1.1) shall check in and obtain a badge at the Reptrax kiosk within the facility being visited prior to conducting business.

2.3.1 Representatives that are providing direct support to surgical/cardiac catheterization labs cases may proceed directly to the procedural area after obtaining their badge.

2.3.2 Representatives that are providing education/support for a product/pharmaceutical that is on contract/on-formulary may schedule appointments with the appropriate department personnel. Representatives may not use these opportunities to "up-sell" products inconsistent with the contract initiative strategy.

2.3.3 Representatives that are promoting a new product/pharmaceutical shall have prearranged appointments which have been approved one week in advance prior to calling on clinical and operational personnel in procedural/patient care departments by the:

2.3.3.1 Medical/surgical supplies - System Director of Value Analysis, appropriate Contract Sourcing Manager or their designee;

2.3.3.2 Laboratory products – Lab Services Director or their designee

2.3.3.3 Pharmaceuticals – Director of Pharmacy Contracting or their designee

2.3.4 A badge shall print upon successful check-in. The badge must be visible and be worn at all times while in the facility. Representatives who arrive at any department without a badge will be subject to meeting cancellation or sent back to check in before being seen in the department. Any violations should be reported by regional staff to the Director of Clinical Quality Value Analysis.

2.3.5 After concluding their appointment, the representative will return to the kiosk/mobile app, check out using the Reptrax system and destroy their badge.

2.4 Any representative, delivery personnel, or construction staff conducting business within a UnityPoint facility that is exempt from registering within Reptrax must provide written documentation on an annual basis that they have received an annual influenza vaccination and are negative for Tuberculosis on or before November 1st of each year to the department that they are supporting. Representatives who fail to comply will be barred entrance into any UnityPoint Health facility until they become compliant.

2.5 Representatives will comply with the requirements as outlined within Reptrax (Vaccinations, Certification, Training, Background checks) consistent with the role/access to be granted within UnityPoint facilities. (See Reptrax Requirement Credentials Table)

3. Representative Guidelines in Patient Care Area.

3.1 Representatives are not allowed to directly contact nursing, pharmacy or support staff to ascertain health care provider or patient information. This includes use of email, telephone or in-person requests. Patient information

that is required to process Purchase Orders or continue patient follow-up/monitoring will be provided by UnityPoint Health staff.

3.2 Representative access to direct patient care locations (e.g., the operating room and suites, cardiac catheterization labs, etc) are only permitted when accompanied by a physician, PA, RN-NP or patient care service director/leader and shall be limited to the specific procedure being performed by the physician requesting their presence in the procedure unless performing a responsibility approved by regional directors (e.g. Water Management).

3.3 Representatives shall follow all procedures noted under Section B, and be in good-standing with UnityPoint Health or they may not enter any procedural care area.

3.4 Prior to accompanying the physician or approved clinical escort, all representatives must first check in with the appropriate department director (operating room, cardiac catheterization lab) and are to leave the department upon the completion of the scheduled case. Representatives must wait at the procedural care area front desk (e.g. operating room/cardiac catheterization lab) until being approved to proceed into the procedural care area.

3.5 If there are several cases that the representative will be involved with during the same day, the representative may remain in the patient care area only if they are actively involved in setting up for the additional case(s). The representative shall retreat to a public waiting area when not actively involved in a case. Representatives are NOT allowed to "loiter" in the physician/clinical lounge areas at any time. Representatives caught in the physician/clinical lounges without being invited by a physician may be subject to immediate suspension of privileges.

3.6 Representatives are not allowed to offer clinical assistance of any degree to the patient or the physician during any given procedure. They are not to operate equipment nor attach a patient to any medical device. This is the sole responsibility of UnityPoint Health clinical staff. Any product opened by a representative and NOT used during the procedure will not be paid for. Representatives requiring credentialing as part of their position must not perform any duties that are inconsistent with their credentialing/clinical practice.

3.7 Representatives should not enter any procedural/patient care area while the patient is awake. Exception granted for procedures involving conscious sedation where a representative is expected to be present during the case/procedure (e.g. cardiac catheterization lab).

3.8 Representatives are NOT to detail or present marketing or sales materials related to products within UnityPoint Health facilities unless they have been approved to do so through the System Value Analysis/Pharmacy portal where new product requests have been submitted and approved.

3.9 Representatives are not to promote their product for expanded use until the request has been approved by the Value Analysis Committee, Clinical Service Group (CSG) or System P&T Committee (pharmaceuticals). Representatives cannot bring product/pharmaceutical into any procedural care area at the request of the MD/office RN without prior approval of the appropriate Value Analysis Committee, Clinical Service Line Director, or System P&T Committee.

3.10 Representatives may not access hospital on-site supply closets/rooms, including consignment inventory space provided by their company, without a UnityPoint Health representative present.

3.11 All Representatives entering any procedural care area must wear specified approved colored scrubs and a representative bouffant cap according to regional guidelines and comply with all other Regional or Facility-specific policies and procedures.

4. Representative Presentations.

4.1 Representatives may present topic or product related programs to UnityPoint Health staff, students and physicians when the programs have been cleared through the appropriate Value Analysis Committee, Clinical Service Group (CSG) representatives or System Services Director of Pharmacy.

4.2 Representatives may not incorporate the UnityPoint Health logo or branding into program information without the express written consent from UnityPoint Health.

4.3 The only time representatives will be allowed to conduct product educational sessions will be at the request of UnityPoint Health P&T Committee or VAT's.

4.4 Prior to setting up any product educational or CEU presentations, representatives must arrange the presentation with both Director of the Service Line/department or designee AND the Department of Supply Chain/Department of Pharmacy Services within that facility.

4.5 Catering of food by representatives must be in conformance with UnityPoint Health Policies - 1.CE.02 – Code of Conduct and 1.CE.14 Gifts and Business Courtesies.

5. Product Standardization/Evaluation.

5.1 Physicians, UnityPoint Health personnel, Value Analysis Chairs or patient care committees are the only ones who may request that new products/pharmaceuticals or equipment be considered by a designated Value Analysis Committee/System P&T Committee.

5.1.1 Representatives may not directly submit product evaluation or standardization requests.

5.1.2 All new product/pharmaceutical requests shall be reviewed consistent with the policy on new supplies/new drugs as established thru the Value Analysis Committees and/or System P&T Committee. No products shall be brought in or marketed without prior approval.

5.2 Any product/pharmaceutical that has not gone through the appropriate/designated process noted under Section One will be denied payment. This includes any "new technology" for which contract pricing has not been negotiated and approved prior to the use of the product.

5.2.1 All contract negotiations must be approved by the UnityPoint Supply Chain Strategic Sourcing Contracting team.

5.2.2 No contract may be executed without appropriate administrative and legal review.

5.2.3 Any new technology solution that connects to the UPH network must have a completed security review that demonstrates the technology solution meets or exceeds UPH minimum security requirements. Refer to policy 1.IT.07, Information Systems Security.

5.2.4 Finalized contracts may not be signed by anyone other than the appropriate system-level administrative/purchasing representative or approval from the same. (e.g. Regions participating in the 340B pharmacy program)

5.3 Penalties for non-compliance include:

5.3.1 First Offense – Warning

5.3.2 Second Offense – Representative privileges will be revoked for one month with notification to their manager.

5.3.3 Third Offense – Representative privileges will be revoked for 3 months with a discussion with the representatives' manager for potential permanent replacement.

5.4 Under no circumstances are products/pharmaceuticals to be used on patients prior to going through the appropriate approval processes or without proper in-servicing of the Medical Staff and other health care providers. Failure to comply with any of the above may jeopardize the representative's ability to conduct future business with UnityPoint Health.

5.5 Trial of Product within the organization

5.5.1 Trial of products/evaluations shall be at NO COST to the organization and patient and shall be documented by a No Charge Purchase Order unless an exemption is granted by the Director of Value Analysis. (The product under evaluation shall be at NO COST – routine disposable products and/or instrumentation normally used during the procedure are exempted from the NO COST requirement.)

5.5.2 An adequate supply of trial products shall be available for all interested parties to use and shall be determined by the Value Analysis Committees or System Strategy Sourcing representative to ensure an adequate number of cases/patients are trialing the product to determine acceptability.

5.5.3 Evaluation period of the trial shall be coordinated with the System Value Analysis Director, Director of the Clinical Service Group Leader (CSG) and the representative.

5.5.4 Product Evaluation Forms must be submitted to the system level Value Analysis Director or Regional Supply Chain representative at the completion of the trial and will be used as a basis to determine if the product will be brought into the organization

6. <u>Sterile Processing Guidelines</u>

6.1 Manufacturer's written validated instructions for the handling and reprocessing of instrumentation and other equipment must be submitted to the Sterile Processing Department (SPD) prior to the purchase and/or use of the instrumentation and/or equipment.

6.1.1 Validated instructions are required to determine whether the facility has the capacity to appropriately clean and reprocess the instrumentation and/or equipment, including loan instrumentation.

6.1.2 Loaner instruments/trays for surgical cases must arrive and be checked in, per hospital policy, a minimum of 24 hours prior to the scheduled surgery. 48 hours, would be preferred.

6.1.3 Loaner instruments/trays should be picked up within 3 days of the completion of the procedure. Trays left behind longer than 3 days will be sent back to the manufacturer Cash on Delivery (COD).

6.2 Trays must be complete and include an itemized list of the contents of the loaner tray.

6.3 Instructions for use (IFU's) must include:

6.3.1 How to disassemble, if applicable

6.3.2 Cleaning

6.3.2.1 Mechanical (e.g., washer/disinfector, ultrasonic) and/or manual

6.3.2.2 Types of cleaning agents that the equipment can be exposed to (e.g., enzyme solution, detergents)

6.3.3 Packaging

6.3.3.1 Any recommendations regarding delicate instruments

6.3.3.2 If disassembled, parts required to be assembled before sterilization

6.3.4 Sterilization

6.3.4.1 Specific validated sterilization parameters (exposure time, temperature, dry time, sterilant)

6.3.4.2 Specific validated methods – (e.g. steam pre-vacuum, steam gravity, 100% Ethylene oxide, Hydrogen Peroxide including the sterilizer model number Sterrad NX, VPro Max, etc., "I.U.S.S." immediate use steam sterilization).

6.4 Vague statements such as "according to facility procedure" or "usual sterilization method" is not acceptable information.

6.5 Any in-service needed must be carried out in Surgery and SPD.

6.6 Any lost items must be reported to SPD manager the day of surgery.

7. Purchase Orders

7.1 Any item or service supplied to UnityPoint Health must be listed on an authorized UnityPoint purchase order number. No free product samples are to be distributed directly to departments unless product/samples are noted on a NO CHARGE purchase order which has been approved by designated strategic sourcing/UnityPoint VP of Materials Management.

7.2 Purchase orders authorized by Central Procurement will be telephoned, mailed, faxed or hand delivered to the representative.

7.3 Products that have been requested by a physician for use on a patient that are not routinely stocked by the hospital must be approved through the Regional Supply Chain team, Surgical or Catheter Lab management. The request to purchase must be submitted seven days prior to the scheduled case/use on a patient (exceptions to be made for emergency cases).

7.3.1 The request (submitted by the representative) must include the following (form available via the Representative Registration website):

7.3.1.1 Physician's name requesting the product

7.3.1.2 Sign-off by the coordinator

7.3.1.3 Scheduled date of the surgery/use of the product

7.3.1.4 Product details (To be completed on New Product spreadsheet)

7.3.1.4.1 Description of product

7.3.1.4.2 Part #/Catalog #

7.3.1.4.3 Cost of product

7.3.1.5 Other anticipated costs/charges – shipping, handling, loaner fees

7.3.1.6 Other equipment necessary to support the use of the requested product (e.g. instrument sets)

7.3.1.7 Contact information of the representative to confirm approval or denial.

7.3.2 The request form must be submitted to the appropriate manager (Supply Chain, Surgical or Cardiac Catheterization lab). If the product(s) is approved for use, confirmation will be sent to the representative prior to the scheduled case and copies forwarded to the appropriate coordinator/nurse manager and Materials Management staff to inform them of the anticipated use of non-stocked product.

7.3.3 Representatives are not allowed to bring in any additional products other than the item(s) that have been approved for use for the specific case.

7.3.4 Loaner instrumentation required for surgical cases must be appropriately marked and branded as non-UnityPoint Health owned instrumentation and brought into the hospital by no later than 0700 the morning PRIOR to the actual procedure day to allow sufficient time to clean and reprocess the instrumentation prior to the procedure (exceptions to be made for emergency cases).

7.4 Any item received or any service provided without the authorization of Central Procurement or Regional Supply Chain Leader or their designee will be refused or considered as a donation to the hospital. NO PURCHASE ORDERS WILL BE ISSUED RETROSPECTIVELY. Approved Bill Only products are an exception.

8. Equipment

8.1 All equipment, which has contact with a patient, must be reviewed and approved by the UnityPoint Health's BioMedical/Clinical Asset Management Department prior to use. Each time the equipment arrives to be used within the hospital, it is to be rechecked.

8.2 No equipment or instrumentation will be removed from UnityPoint Health facilities unless accompanied by authorized paperwork. This must be completed by a Department Director/Manager.

9. Invoices

9.1 All invoices are to be sent to the Accounts Payable Department (APINVOICES@UnityPoint.org) or Accounts Payable, PO Box 5048, Rock Island, IL. The purchase order number relating to the items must be shown on the invoice. Invoices without purchase order numbers will be considered invalid and returned to the representative/company without payment.

9.2 UnityPoint Health Acute Care facilities are voluntary, non-profit organizations which hold a Certificate of Exempt Status. Items or services purchased directly by UnityPoint Health Hospitals are tax exempt.

/s/ Kevin E. Vermeer

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Kevin E. Vermeer
UPH President