

Regional One Health Vendor/Sales Representative Relations Policy

Policy

This policy applies to all vendor and manufacturer/sales representatives (Hereinafter Vendor Representatives) providing patient care related products and services to Regional One Health (ROH).

Purpose

To maintain a professional business relationship with Vendor Representatives, suppliers and contractors through established guidelines to ensure high quality care, to preserve patient safety, protect patient rights and privacy, dignity and confidentiality related to the presence of medical supply vendors and their sales representatives requiring access to patient care areas.

To establish guidelines to ensure that patient care related supply vendors and their sales representatives adhere to the established policies and procedures of ROH. Each Vendor Representative must abide by the laws, regulations and guidelines set forth by the State of Tennessee, Federal Government, The Joint Commission (TJC), Association of Perioperative Registered Nurses (AORN), Health Insurance Portability and Accountability Act(HIPAA) privacy rule, ROH Corporate Compliance guidelines and other regulatory standards of practice.

To establish guidelines for the introduction of new patient care related technology, equipment, supplies and services to ROH.

Process

Functions Affected

Any facility or entity that operates under the governance of Shelby County Health Care Corporation d/b/a Regional One Health (ROH) including, but not limited to, the hospital, outpatient center, clinics, and all departments, groups and divisions involved in direct patient care.

Definitions

Vendors Representatives- Include individuals(s) who market products and/or services(s) to ROH related to any supply item, purchased service, equipment, instrument, pharmaceutical or medical device used at ROH.

New Medical Technology, Equipment or Supplies - Defined as any new invasive procedure, technique, supply, tissue and tissue products 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 ROH; 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 - Defined as any and all medications, drugs and IV solutions.

Vendors/Sales Representatives

Vendor Representatives provide a valuable service to ROH and are to be treated with respect. Vendor Representatives can also be disruptive and may have goals that are different from and even opposed to those of the organization. Therefore, it is important to control their access to and time with members of ROH. This policy does not include Auditors conducting reviews for insurance providers, payors, accounting or government agencies.

All Vendor Representatives are required to make an initial appointment with the Materials Management (MM) Department where they will complete registration requirements, (see **Related Documents** below for Exhibit I - *Vendor Data Sheet*) and be informed about the policies of ROH.

Special Notice for Vendors Representatives of Procedural Based Services Areas (i.e., Operating Rooms, Cath Labs, Radiology Departments, etc.):

Vendor Representatives calling on Procedural Based Service Areas are required to submit to the Materials Management (MM) Department documentation of completed protocol/training specific to that area of operation along with representation of the necessary health records in compliance with ROH's Infection Control requirements listed in the Compliance section of this policy under the heading of Contractor Warranties and Agreement. Registration documents are required and will remain on file in the MM Department.

Vendor Representatives are required to adhere to the policies and/or procedures specific to that operational area in addition to this policy and must maintain the specific protocol/training requirements. Any vendor representative in the unit for the first time must meet with the Nurse Manager or designee for completion of unit orientation.

Visitation

Upon completion of the registration requirements, Vendor Representatives may make appointments directly with hospital personnel; however, each visit will start at the MM office to sign in with the receptionist or at one of the convenient RepTrax Kiosk's to obtain visitor's badge. Upon authorization, the MM receptionist or RepTrax Kiosk will issue a picture ID badge to the Vendor Representative to be worn at all times while on the campus of ROH. The badge will contain a photo of the Vendor Representative and will specify the company name, representative name, date and the approved department/functional areas authorized to visit. The receptionist will contact the department/s to verify the appointment areas. Badges are valid for **one** day only. Vendor Representatives will only have authorization to visit the approved departments/functional areas. Vendors without valid Vendor Identification Passes will not be permitted into any department. Vendors may not display badges or identification from other area health care facilities.

The MM office is open from 7:30 am to 4:30 pm Monday - Friday. During these hours, all Vendor Representatives must stop at the MM receptionist desk to sign the visitors log and obtain a badge if not registered with RepTrax. MM will contact the department to verify the appointment. Upon authorization, MM will issue a badge to the Vendor Representative to be worn at all times while on the campus of ROH. Vendor Representatives visiting after normal hours should report directly to the security office located on the 1st floor of the Chandler Building to obtain a visitor's badge. Visitor badges are only good for the date of issue and may not be used on another date.

Exceptions: Vendor Representatives wishing to visit the Outpatient Pharmacy or Primary Care Clinics should check in with the receptionist at the visiting location. If a prior appointment has been made, the MM, Outpatient Pharmacy, or Primary Care Clinic receptionist will contact the appropriate individual to determine if they are available and wish to see the Vendor Representative. Pharmaceutical Vendor Representatives delivering samples must register with the MM or Outpatient Pharmacy receptionist to obtain a visitors badge. Upon the approval of authorized Pharmacy personnel, Pharmaceutical Vendor Representatives will see the physician to obtain his signature, and be allowed to bring samples to the Pharmacy, where the representative will log them into the log book. Pharmaceutical Vendor Representative will follow ROH Sample Drug Policy. Pharmaceutical Vendor Representatives visiting the Primary Care Clinics should register with the receptionist at the visiting location. Pharmaceutical Representatives' displays will be scheduled through the Pharmacy Department. Formulary/Non-formulary status of detailed drugs must be clearly visible at scheduled exhibits.

All computer and communication related equipment and/or computer systems to include software and demos of software must be reviewed by the Chief Information Officer (CIO) prior to vendor contact with any department or individual throughout the organization.

In no case will the Vendor Representative be allowed to visit departments of ROH without the approval of an authorized person in that department. Any guests of an approved Vendor Representative must be accompanied by that approved Vendor Representative while on the campus of ROH.

Vendor Representatives are informed in their initial visit that the MM department is solely responsible to commit ROH to all purchases with the exception of food items and pharmaceuticals. No one in the organization will present themselves in a way that would imply otherwise.

Vendor Representatives are not permitted to visit or approach physicians in clinical/ patient care areas. If physicians maintain administrative offices within ROH, Vendor Representatives may visit by appointment only. Vendor representatives are still required to sign in with the MM, Outpatient Center or Primary Care Clinic receptionist. Vendor representatives are **not** permitted in Physician Lounges **except** for pre-scheduled in-service education.

Vendor Representatives must park their private/company vehicles in the appropriate visitors parking areas. Vendor Representatives making deliveries to ROH may unload at the ROH loading dock only and promptly remove their vehicle to the visitors parking areas. Vehicles parked in unauthorized areas will be towed at the expense of the driver (this includes physician or Administrators parking lots).

Hospital personnel will inform any Vendor Representative observed visiting an area of ROH without a badge of the existence of the policy and direct them to the MM Purchasing office located in the basement of the Jefferson Building. Hospital personnel will also notify the MM receptionist to expect the Vendor Representative and explain the location the Vendor Representative was found and the activity that he/she was performing. The badge is not transferable and does not authorize person to person or department to department visits. Each department visit or appointment must be announced by MM.

Introduction of New Products

Vendor Representatives who wish to introduce items or services to ROH must contact the Value Analysis Coordinator in MM Department located at 877 Jefferson Avenue, Memphis, TN 38103, via telephone at (901) 545-8000. If the product or equipment is approved by the Food and Drug Administration (FDA), is not in violation of an existing contract, and appear to have merit; the Value Analysis Coordinator or appropriate Value Analysis Committee will facilitate visits with the applicable department's personnel.

Products, equipment or devices to be evaluated must be approved by the appropriate Clinical Value Analysis Team (CVAT) the Perioperative Services Value Analysis Team (PVAT), the Outpatient Services Value Analysis Team (OVAT), the Radiology Services Value Analysis Team (RVAT) and/or the appropriate Committee and a "no charge" purchase order will be provided. All trials and evaluations will be provided at no cost to ROH. No trial or evaluation may be initiated without approval from the appropriate Value Analysis Committee and a "no charge" purchase order has been issued.

ROH standard *Product Evaluation Form* (see **Related Documents** below for Exhibit II - *Product Evaluation Form*) will be utilized for trials unless language specificity would benefit the evaluation process. If required the appropriate ROH Value Analysis Team will assume responsibility for the language additions. Forms will be returned to and collected by the Value Analysis Coordinator or designee. The Vendor Representative for the product or service will be notified of the results of the product evaluation in a timely manner by the Value Analysis Coordinator.

Materials cannot be shipped or hand carried into ROH without an authorized purchase order and delivery document or packing slip. Any violation in this procedure will result in non-payment of the resulting invoice. Any product or equipment brought in without prior purchase order authorization will be seized and will be held for vendor pick up.

Equipment may not be evaluated, placed on a trial basis, or demonstrated clinically unless it is:

- On the pre-approved capital budget, and
- Has been administratively authorized for contingency funding approval.
- Has been inspected by Biomed or Engineering Departments, as applicable.
- Has prior authorization from the Purchasing Department.

Equipment approved for evaluation or loan must be documented on a purchase order or memorandum of agreement. ROH will not be liable for theft, damage, etc. if this requirement is not followed. A “Hold Harmless Agreement” is required for products or equipment left at ROH for evaluation.

Vendor Representatives Visit to the Operating Room (OR) and Other Specialty/Procedural Departments:

Vendor Representatives will be properly and professionally attired. Vendor Representatives in procedural areas are **required** to wear ROH supplied scrub suits in restricted areas and a **red** bouffant cap also supplied by ROH. The scrubs or other PPE may **not** be worn outside of the procedure areas.

The number of vendors in an area will be limited at the discretion of physicians and management. The vendor representative may act as a resource regarding the representative’s product **only** and may **not** scrub or participate in patient care. The vendor representative may not handle any ROH stock products.

Prior to entering the operating room (OR) and/or Specialty Department, the Vendor Representative will have a letter on file via RepTrax with the MM Department stating that competencies in the principle of asepsis, infection control practices, blood borne pathogens, fire and safety protocols and patient rights and confidentiality have been documented. The Vendor Representative will be in-serviced on these areas by his/her employer. Each competency must be validated annually by his/her employer. Failure to validate competencies will result in restriction from visiting the OR or specialty departments.

Vendor Representatives will serve as a consultant only. He/she is not permitted to scrub in or touch the patient unless specified in the vendor contract.

New product introduction in procedure areas must meet the following criteria prior to use:

- Has been made available for trial at the vendors expense
- Offered for clinical review by all physicians in a particular service with a goal of best practice utilization.
- Products meet all FDA requirements for efficiency and safety
- Has been reviewed by the appropriate department and purchasing for cost analysis and impact
- Has been appropriately reviewed for potential cost reimbursement
- All new products and services will comply with the Value Analysis Policy and Procedures

Emergency, After Hours and Weekend Loans

Vendor representatives who request to deliver an instrument set must:

- Provide a count sheet to sterile processing, and count the instruments with a hospital representative prior to leaving the set.
- Both the representative and Sterile Processing Technician will sign the count sheet.
- Upon return of the set, the Representative and the Sterile Processing Technician will inventory the set to verify the set is complete. Both will sign the reviewed count sheet.

Vendor representatives who request to borrow an instrument set must:

- Obtain approval from the OR Patient Care Coordinator (PCC)/Charge Nurse after consultation with Central Processing & Distribution (CPD) Staff
- Review the count sheet with CPD Tech to verify the components of that set prior to its leaving the facility
- Upon return of the set, the Representative and CPD Tech will inventory the set to verify the set is complete. Both will sign the reviewed count sheet.
- CPD staff will track all borrowed sets and equipment by keeping a log

Important Note: All trays, implants and items requiring sterilization must be received in CPD by 6:00 pm prior to the day of planned surgery in order to allow sufficient time for processing and sterilization. Items received later than 6pm prior to the day of surgery will still be processed according to established practice, but may not be available at desired start time. Only in emergent circumstances and at the direction of the attending physician will items be autoclaved in the OR sterilizers.

Note: Any product that is brought into the facility and used by a physician without notification of the Department Manager or Director will **not** be issued a purchase order and the vendor will **not** be paid.

Other Guidelines

ROH expects Vendor Representatives to respect and abide by:

- ROH *Code of Conduct* (see **Related Documents** below for link to Exhibit III)
- ROH's *Infection Control and Prevention Standards for Contractors* (see **Exhibit IV** below)
- ROH's standards governing financial relationships with referral sources (see **Exhibit V** below)
- ROH's Medicare Warranties provision (see **Exhibit VI** below)
- ROH's Privacy and Information Security Sheet for Vendors, Contractors and Consultants of ROH (see **Related Documents** below for link to Exhibit VII and link to the *Appropriate Use of Information Systems* policy)

- *Confidentiality Agreement* (see **Related Documents** below for link to Exhibit VIII)

ROH also stipulates that companies with contracts or agreements with ROH and any of its affiliates adhere to the provisions of ROH Standards of Conduct and policies and procedures that address Vendor Representatives interaction with ROH colleagues and facilities.

Attached is additional compliance related material applicable to this policy. Please sign to verify receipt as outlined:

- The Deficit Reduction Act (see **Exhibit IX** below)
- Federal False Claims Act (see **Exhibit X** below)
- The role of laws in preventing and detecting fraud, waste, and abuse in Federal healthcare programs (see **Exhibit X** below)
- "Whistleblower" protections under the Federal False Claims Act and under state law (see **Exhibit XI** below)
- ROH's policies and procedures for detecting and preventing fraud, waste and abuse (see **Exhibit XII** below)
- ROH's *Standard Purchase Order* terms (see **Related Documents** below for link to Exhibit XIII)

Any exceptions to this policy must be approved in writing by Director of Materials Management at ROH.

Policy Violations

Unauthorized Vendor Representatives or policy violations should be reported to

Materials Management at 877 Jefferson Avenue, Memphis, TN 38103 or via telephone (901) 545-8000.

MM will request the Vendor Representative's name and/or company and the nature of the violation.

Failure to comply with the established policies and procedures will result in appropriate action, including the loss of access to ROH facilities by Vendor Representative, products and/or services to ROH as appropriated.

Materials Management will determine if violations of this policy constitutes an offense or subsequent breach of procedures. Disciplinary action will take place based on the severity of the offenses committed.

Exhibit IV

Infection Control: For any vendor representative who may pose an infection control risk to patients at ROH, CONTRACTOR agrees to comply with ROH's Infection Control requirements as follows:

- Varicella (Chickenpox) - 2 doses of vaccine or documented immune status

- Measles, Mumps and Rubella (MMR) immunization (or documented immune status)
- Influenza immunization annually
- Recent Tuberculin Skin Test (i.e., within one year)
- Hepatitis B (not mandatory but indicated if around blood and body fluids)
- Basic infection control education

Note: Contractor will provide evidence of the above upon request of Regional One Health.

Exhibit V

Financial Relationships With Referral Sources

Relationships with Prohibited Referral Sources: It is expressly agreed that any contract or other financial relationship entered into between CONTRACTOR and ROH will be in full compliance with applicable state, local and federal law, including the Medicare/Medicaid anti-kickback/Fraud and Abuse provisions and the Stark Law. Accordingly, CONTRACTOR has an affirmative obligation to notify ROH of any compensation relationship that it has with any prohibited referral source as that terms is interpreted under the Stark and Anti-Kickback laws.

Exhibit VI

Medicare Warranties Provision

Medicare Warranties: It is the policy of ROH and its subsidiaries and affiliates not to contract or have business relationships with individuals or entities that have been excluded from federal health care programs. CONTRACTOR hereby agrees that if it is excluded from participation in federal healthcare programs, it will immediately notify ROH in writing of such exclusion. CONTRACTOR agrees that it has an affirmative obligation to verify whether any of its employees or subcontractors have been excluded from federal healthcare programs. CONTRACTOR agrees that if ROH learns that CONTRACTOR or any employees or subcontractors of CONTRACTOR have been excluded from participation in federal healthcare programs, ROH may immediately terminate, without penalty, any contracts or other business arrangements it has with CONTRACTOR upon written notice to CONTRACTOR.

Exhibit IX

The Deficit Reduction Act of 2005

The Deficit Reduction Act of 2005 (DRA) was signed into law by President Bush on February 8, 2006. The DRA includes healthcare specific provisions, some of which are designed to eliminate Medicaid fraud, waste and abuse. The DRA requires that any entity that receives or makes annual payments under the State plan (Medicaid/TennCare) of at least \$5 Million per year must provide detailed information to its employees and contractors about the Federal False Claims Act (FCA) and any existing State FCA.

Exhibit X

False Claims Act

The federal False Claims Act is a federal statute that prohibits a person from “knowingly” submitting a false, fictitious, or fraudulent claim to obtain payment from the government (including Medicare, Medicaid and other federal and state programs act). Examples of violations include:

1. Billing for services not rendered
2. Misrepresenting as medically necessary non-covered or screening services
3. Falsifying records (including medical records) used to support claims
4. Billing for services or items in excess of those needed by the patient
5. “Up-coding” or using procedure or revenue codes that describe more extensive services than those actually furnished
6. Adding inappropriate or incorrect information on cost reports

Consequences for Failure to Comply with the False Claims Act

Failure to comply with the False Claims Act can result in severe consequences to healthcare providers and suppliers, including Civil penalties:

1. Federal False Claims Act:
 - a. A civil monetary penalty ranging from \$5,500 to \$11,000 per false claim submitted
 - b. Treble damages (three times the amount of damages sustained by the government)
2. Tennessee False Claims Act:
 - a. Liability for the costs of a civil action brought to recover penalties or damages
 - b. Liability for a civil penalty of not less than \$2,500 and no more than \$10,000 for each false claim submitted
3. Other penalties
 - a. Criminal sanctions
 - b. Exclusion from participation in the Federal Health Care programs

Exhibit XI

Qui Tam “Whistleblower” Protections

The False Claim Act contains a “Qui Tam” or “Whistleblower” provision. A Qui Tam action authorizes persons or private parties having direct knowledge of fraud or false claims submitted to the government to file a lawsuit on behalf of the government. The person who brings the Qui Tam action is called the relator. If the relator is successful, he/she can recover from 15 to 30% of the proceeds of the recovery (federal cause) or 25-50% (Tennessee cause). The False Claims Act prohibits retaliation of employees

who file a lawsuit or cooperate in an investigation or provide testimony in connection with a Qui Tam action. Whistleblowers who have experienced retaliatory conduct, may receive relief from the government in the form of employment reinstatement, back pay, and other compensation resulting from retaliatory action.

Exhibit XII

ROH's policies and procedures for detecting and preventing fraud, waste and abuse

ROH has adopted a *Corporate Compliance Program* (see **Related Documents** below for link to policy) designed to detect and prevent fraud, waste and abuse in federal health care programs. ROH has adopted policies to facilitate compliance with applicable laws and regulations including the federal and state False Claims Act. ROH's Compliance Officer may be contacted at (901) 545-6554 to obtain more information about ROH's policies and procedures. Contractors and Agents are urged to contact the Compliance Officer should they encounter any potential violations of the law including the False Claims Act. Alternatively, Contractors and Agents may contact the anonymous hotline at 1-844-260-0009.

1. Sunshine Act
 - Periodically, Materials Management/Purchasing will conduct random-sample reviews of ROH affiliated physicians listed on Center for Medicare and Medicaid Services (CMS) Open Payments system website relative to Physician Payments under the Sunshine Act.
2. Office of Inspector General/General Service Administration (OIG/GSA) Vendor Exclusion List
 - All vendors (Manufactures, Distributors and Sales Representatives) will be validated against the OIG/GSA Vendor Exclusion List as not having be excluded from conducting business with Federal or State funded organizations. Validation to be completed prior to adding a new vendor or sales representative and then at least annually thereafter.