Subject

This Administrative Policy sets forth guidelines for relationships with Vendor Representatives. Ascension desires to provide a safe and effective environment for patients, Associates, physicians and other allied health professionals, while complying with regulatory guidelines.

Post-Acute Representatives are also addressed in this policy.

This Administrative Policy is intended:

- To establish a structured system among Ascension Participants for education, training, and introduction of products, procedures, techniques, technology, and equipment to our Associates and physicians.
- To define conditions and requirements Vendor Representatives must abide by to provide training, knowledge transfer, expertise, products and/or services within facilities owned by Ascension Participants.

Definitions

1. “Ascension” means Ascension Health Alliance and all organizations directly or indirectly controlled by Ascension.

2. “Ascension Participant” means an Ascension-owned or Ascension-controlled site of care, currently excluding Ascension Living sites, which, through a Participation Agreement with The Resource Group, has access to The Resource Group’s contract portfolio.

3. “Associate” means an employee of an Ascension Participant who provides services in exchange for compensation and receives a W-2 from Ascension.

4. “Sample” means products, including pharmaceuticals, provided at no cost to the facility or patient and not procured and/or paid for through the standard procurement and ordering process. Product Samples requested by Ascension through the standard product evaluation process are not considered “Samples” for the purposes of this policy.


6. “Vendor Credentialing System” means The Resource Group contracted system to manage Vendor Representative registration, appointments and credentialing.

7. “Vendor Representative” means a sales or service professional that represents a company or companies to The Resource Group and/or Ascension Participants including: physicians, nurses, buyers, purchasing agents, executives and other Associates that may be general users or influencers of the company’s product. Vendor Representatives represent manufacturers,
distributors, service companies, and other organizations. Vendor Representatives generate sales, manage contracts, provide quotes, demonstrate products, make repairs, and perform many other duties generally associated with representing their company. Contractors, delivery service representatives, general or skilled laborers performing facility maintenance and construction, installers installing equipment in non-patient care areas, facility-employed project consultants, clinical trial researchers, or any third-party representative providing care or services directly to patients on behalf of the Ascension Participant are not considered Vendor Representatives for the purposes of this policy. See Appendix B for a list of out of scope representatives.

8. “Post-Acute Representative” means a representative of a post-acute provider or durable medical equipment company that assists directly with patient discharge and/or patient transition to a post-acute facility. Examples include but are not limited to assisted living facilities, skilled nursing facilities, rehabilitation facilities, hospice companies, and durable medical equipment companies.

9. “Vendor” means any entity that sells or attempts to sell products or services to Ascension.

Administrative Policy

1. Criteria to Enter.

1.1 Training Requirements/Credentialing

1.1.1 No Vendor Representatives shall be given access to property of an Ascension Participant without the successful completion of the Ascension’s vendor credentialing program and strict continued compliance to Ascension rules, standards, policies, and procedures. At a minimum, these requirements include:

- Background check
- Immunizations (negative TB test, hepatitis B, influenza vaccine, MMR)
- HIPAA training
- Insurance

1.1.2 Vendor Representative access to patient-specific information in any clinical setting shall be managed in accordance with the HIPAA Privacy Rule.

1.1.3 The Vendor is responsible for timely notification to Vendor Credentialing System in the event an Vendor Representative is terminated, voluntarily leaves the company, or transfers within the company and/or if the competency changes for any reason.

1.2 Vendor Credential Levels

- Level 1 – All Access
  - Access: Full access to facility including patient care and procedure areas
  - Granted to: Vendor Representatives assisting with clinical procedures and direct patient care
- **Examples**: Orthopedic, spine, trauma procedures

  - **Level 2 – Patient Care Access**
    - **Access**: Enables access to engage with Ascension Associates in patient care areas or areas where access to Protected Health Information is available. This does not provide access to any procedure areas.
    - **Granted to**: Vendor Representatives performing product, equipment or general maintenance, or education/in servicing where patients or protected health information is present.
    - **Examples**: Pacemaker calibration, maintenance on equipment that stores protected health information

  - **Level 3 – Administrative/Provider Access**
    - **Access**: Enables access to all general and administrative areas of a facility and ambulatory offices and pharmacy. This does not provide access to patient care or procedure areas.
    - **Granted to**: Vendor Representatives performing product, equipment, or general maintenance, or education/in servicing where patients or protected health information is not present.
    - **Examples**: New technology demonstrations, clinical education

Review Appendix A for additional examples.

1.3 Sign-In/Sign-Out

1.3.1 A Vendor Credentialing System registration kiosk will be located at the facility main entrance, in The Resource Group Department (which may be at a different location than the facility) and/or in the Operating Room.

  - Vendor Representatives must register at the Ascension Participant’s designated Vendor Credentialing System access point to receive their time/date sensitive identification for the visit.
  - If visiting a non-acute, ambulatory location with no kiosk, Vendor Representatives are required to check-in at the front desk and utilize mobile application technology to display mobile badge that verifies Vendor Representative is credentialed and checked in.

1.3.2 Vendor Representatives must check-out at the conclusion of each visit.

1.4 Dress Code and Badge Requirements

1.4.1 Vendor Representatives are required to wear at all times a clearly visible time stamped badge, printed through the Vendor Credentialing System kiosk, while visiting the facility of an Ascension Participant.

  - Badge information must include
    - Credentialing Level
    - Vendor Name
    - Vendor Representative Name
Valid Dates
Reason for visit
- If visiting a non-acute, ambulatory location with no kiosk, Vendor Representatives are required to utilize mobile application technology to display mobile badge that verifies Vendor Representative is credentialed and checked in.

1.4.2 Vendor Representatives must comply with facility Surgical Department and Infection Prevention policies regarding scrubs and surgical attire.
  - Hospital-designated surgical attire must be worn in designated restricted and semi-restricted areas of the hospital.
    - Additionally, in designated areas, Vendor Representatives must wear an identifying bouffant cap provided by facility, as well as any other personal protective equipment (PPE), such as shoe covers, masks/beard covers, etc.
  - Vendor Representatives may be restricted as to where they can wear their assigned surgical attire upon leaving the restricted or semi-restricted areas.
  - Under no circumstances should hospital-designated surgical attire be worn off of the property.

1.5 Parking

1.5.1 Vendor Representatives must review and abide by Ascension Participant’s parking policies for any visit.

1.5.2 Vendor Representatives are not permitted to park in designated patient, Associate, or physician parking or against loading docks.

2. Approved Circumstances for Entry.

2.1 Vendor Representatives are not permitted in patient care areas, nursing units, emergency room, outpatient clinics or other patient treatment areas where patient care is provided unless specifically requested by the hospital medical, clinical, or administrative staff.

2.2 Medical Procedure/Direct Patient Assistance

2.2.1 Vendor Representatives are not permitted to access any operating room or procedural suite unless invited by a physician to assist with the use of an approved product in an approved procedure. Approved procedures can be found HERE.

2.2.2 While the Vendor Representative may be present at the point of care, if so designated, they are not to open any sterile product unless the Vendor
Representative has received specific permission from the physician and the local facility permits this practice.
  o  When opening sterile product, the day / month of expiration must be communicated.
  o  Vendor Representatives will not retrieve patient tissue or blood from the blood bank at any time.

2.2.3 Vendor Representatives may enter at a physician’s request to provide direct patient assistance with products or equipment that require advanced expertise. A list of approved products meeting that criteria can be found on The Resource Group’s website [HERE](#).

2.2.4 Exceptions may be made for emergent circumstances that will affect patient care as determined by physician.

2.3 In-Servicing/Education

2.3.1 Vendor Representatives are permitted to perform in-servicing and product education/training if approved by The Resource Group in coordination with Clinical Professional Development.
  o  Education/training refers to providing clinical instruction on how to appropriately and properly use the product, medication, or service.
  o  Providing product or medication information is not considered education/training. Providing medication information deemed necessary for appropriate, indicated use must include approval from the National Pharmacy Education Team.
  o  Vendor Representatives will schedule an in-service at least 30 days in advance with The Resource Group.
  o  All in-services will be conducted in The Resource Group Department or designated education area.

2.4 Product, Equipment and Facility Maintenance

2.4.1 Vendor Representatives are permitted to perform product, equipment and facility maintenance if approved by The Resource Group or The Resource Group’s designee (e.g., information technology, clinical engineering or facilities personnel).

2.4.2 Any Vendor Representative seeking access to an Ascension Participant facility for the purpose of performing maintenance services must schedule service at least thirty (30) days in advance, with The Resource Group Lead or The Resource Group’s designee (e.g., information technology, clinical engineering or facilities personnel).
2.5 Inventory Counting

2.5.1 Vendor Representatives are permitted to enter facilities to count consignment inventory only upon request by The Resource Group.

3. Vendor Access to Areas, Patients, and Patient Information.

3.1 Access to Facility

3.1.1 Vendor Representatives are not permitted on patient care areas, nursing units, in the emergency room, in outpatient clinics or other patient treatment areas where patient care is provided unless specifically requested by the hospital medical, clinical, or administrative staff to support an approved patient procedure or assist a patient.

3.1.2 Vendor Representatives are not permitted in physician lounges unless expressly invited by a physician. At any point while present in a physician lounge, a physician, administrator, or other Ascension Associate may request that Vendor Representative leave the physician lounge.

3.2 Access to Patients and Patient Information

3.2.1 Vendor Representatives will not be permitted to observe or have direct contact with patients unless clinically necessary.

- The formulation of treatment plans for patients requires a confidential, candid exchange and assessment of confidential patient and treatment information among health care professionals, without the potential appearance of outside influence, especially from Vendors.
- Examples of contacts prohibited by this policy include making rounds on the inpatient units (including the intensive care units), being present when examinations are conducted in the outpatient setting and observing surgical and non-surgical procedures.

3.2.2 All Vendor Representatives present while patients are receiving care, whether during a procedure or other circumstance, should adhere to the following protocol:

- Introduction to patient upon entering, including company and product/service represented.
- Explanation of role in patient’s care.
- Professional, courteous, and respectful behavior that promotes patient-centered delivery of care.
3.2.3 Vendor Representatives are only permitted to access the minimum amount of protected health information required to provide care, as permitted by HIPAA guidelines.

4. Incoming Products and Equipment.

4.1 Vendor Products and/or services not expressly included within a contract executed between The Resource Group, Ascension, or a designated GPO, and the Vendor or product for which no purchase order was issued in advance (collectively referred to herein as "off-contract products") may not be introduced or provided to the members of the medical staff or Associates of Ascension for use.

   o Unless otherwise stated within a national contract with The Resource Group, any off-contract products that are provided to and used by Associates in violation of Ascension policy shall be deemed Vendor-donated product. Vendor shall not invoice for, nor receive any reimbursement for such off-contract product from Ascension.
   
   o The Resource Group recognizes that there may be instances where patient care dictates use of an off-contract product. In such rare circumstances, the physician requesting use of the off-contract product, with assistance from the Vendor Representative, may apply for an exception to the off-contract product policy.
   
   ▪ Please be aware that the exception process is time consuming and may take up to one hundred and eighty (180) days to resolve.

4.2 Vendor Representatives are strictly prohibited from providing demonstration model or loaner equipment to an Ascension Participant without having submitted a proposal for such equipment to The Resource Group Lead and having received a zero-dollar purchase order for such equipment prior to its arrival on the premises.

   o All equipment brought in for demonstration/evaluation must have a safety check completed by biomedical engineering or clinical staff before the equipment can be used at Ascension Health.

4.3 Vendor Representatives must bring any instrument and/or implant to the sterile processing department for wrapping and sterilizing 24 hours in advance of procedure unless there are emergent circumstances that may affect patient care.

   o Flash sterilization is prohibited except in the event of an emergency.

4.4 All Non-FDA approved Investigational Devices (Class A or B) must have IRB approval and a FDA IDE/HDE number and a Material (SAP) number.

4.5 Drugs for Clinical Investigation: All drug products used for clinical investigation, whether commercially available or investigational must be procured and distributed through the Department of Pharmacy’s Investigational Drug Service (IDS). Drugs used in this manner may require an IRB-approved protocol.
5. **Inventory Management.**

5.1 Unless performed at the request of The Resource Group during a supervised consignment management visit as permitted through The Resource Group’s contract or otherwise approved by The Resource Group, Vendor Representatives will not remove or restock hospital-owned inventory, consigned inventory, or equipment at any time.

5.2 Vendor Representatives may perform consignment inventory counts at The Resource Group’s request. The expectation is that consignment reconciliations occur at minimum twice per year.

   o Reference the Consigned Inventory Management Procedure available in Vendor Credentialing System for additional detail.

6. **Additional Vendor Behavior Parameters.**

6.1 Marketing, Advertising, and Sales Activities

   6.1.1 Selling and promotional activities are prohibited.

   o Prohibited activities include, but are not limited to: delivering sales presentations, unapproved product trials, and promotion of off-contract products.

   o Vendor Representatives are not permitted to promote medications or supplies, in a manner that is contrary to Ascension System, Ministry Market or local ministry policies, guidelines, or formulary, as approved by the relevant hospital or system level committees.

   6.1.2 Vendor Representatives are not permitted to take still or video pictures within the hospital unless there is a clinical reason and without prior authorization from the Ascension legal department.

   6.1.3 Vendor Representatives are prohibited from distributing items displaying company advertisements and logos, without prior permission from appropriate clinical staff and approval from The Resource Group Lead.

   o Logos displayed on clothing or personal items such as bags and briefcases are permitted.

   6.1.4 The Resource Group initiates business with Vendors by seeking bids or proposals from potential sources and awards contracts based on a variety of criteria.

   o Vendor Representatives are prohibited from soliciting Associates for pricing information or documents from meetings or other discussions.
6.2 Gifts and Food. Vendors are not permitted to provide food, gifts, or any items of monetary value to Associates while visiting any Ascension Participant location.
   - Donations to foundations are not governed by this policy.
   - Product donations directly from Vendors for use on mission trips or other charitable purposes are not permitted. These should be coordinated through approved Medical Surplus Recovery Organizations (MSROs).

6.3 Samples, Vouchers, and Coupons. Ascension permits distribution of free samples, vouchers, and coupons in the following categories:
   - Pharmaceuticals
   - Infant formula
   - Pediatric and adult supplements/nutritional

6.3.1 When dropping off approved samples, Vendor Representatives may not access the facility beyond the front desk of the site or department.
   - Samples Request – Vendor Representative will not access physicians. A facility/department associate may deliver the paperwork/tablet to the physician for signature while the Vendor Representative waits at the front desk.
   - Samples Drop off – Vendor Representative will not access physicians. A facility/department associate designated by the physician may sign to confirm receipt.

6.3.2 With regard to other product samples, distribution is not permitted.

6.4 General Behavior. Vendors are required to exhibit professional, courteous, respectful, ethical, and appropriate behavior while in Ascension Participant locations.

6.4.1 Counter detailing activities are considered inappropriate and are prohibited.

7. Enforcement and Non-Compliance.

7.1 Enforcement

7.1.1 All Ascension Associates are permitted to approach and request Vendor Representatives take corrective action to remain compliant to the Vendor Access Policy, or report non-compliance to The Resource Group Lead, at any time while Vendor Representative is in an Ascension Facility. Reasons for non-compliance include:
   - Vendor Representative badge is not visible or present
   - Vendor Representative badge is expired
   - Vendor Representative is violating dress code requirements
7.1.2 For all violations, the Resource Group Lead will notify the Ascension Participant’s Chief Resource Officer and the System Office of Vendor Representative non-compliance to policy.

7.2 Non-Compliance. Vendor Representative non-compliance to this policy will result in the following consequences:

7.2.1 First violation by vendor:
- If a Vendor Representative violates this policy, he/she will be permanently banned from all Ascension facilities.

7.2.2 Second violation by vendor:
- For vendors providing products or services in multiple categories, a second violation in a different product or service category will be treated as a first violation. The Resource Group will determine how products/services are categorized.
- If a second Vendor Representative from the same vendor and same product or service category violates this policy at any location, Ascension and The Resource Group reserve the right to take any of the following actions:
  - Apply a bid transformation, up to and including +2% or greater, at the vendor’s next competitive bid (RFP, e-Auction, etc.)
  - Permanently ban all Vendor’s Vendor Representatives from Ascension facilities
  - Terminate vendor agreement upon contract review and evaluation
  - Shift purchase volume with the vendor to alternative vendors upon contract review and evaluation
  - Eliminate or limit future contracting opportunities.

8. Post-Acute Representatives

8.1 Post-Acute Representatives are considered a separate group from Vendor Representatives for the purposes of this policy. Post-Acute Representatives must adhere to section 6 in this policy or the consequences outlined in section 7 will be applied, but are exempt from the other sections.

8.2 In addition, to these requirements, Post-Acute Representatives must be invited by an Associate to enter a Participant site. If required by Participant, upon entry, Post-Acute Representatives must secure a facility visitor badge and/or check-in with case management staff prior to entering patient care areas.
8.2.1 Case management staff may ask Post-Acute Representatives to leave Participant site at any time
Appendix A
Credentialing Level Examples (not exhaustive)

Level 1 – All Access
- Medical implants/devices
  - Orthopedics
  - Spine
  - Trauma
  - Cardiac Rhythm Management
  - Interventional Cardiology
  - Interventional Radiology
  - GI/Endoscopy
  - Aortic Intervention
  - Ophthalmics
  - Breast Reconstruction
  - Neuro-surgery
- Medical sharps disposal
- Equipment repair or installation in procedure areas
  - Medical gas
  - Patient lifts
  - Suction equipment
  - Monitors
  - Lights

Level 2 – Patient Care Access
- Equipment repair or installation in patient care areas
  - Beds
  - Medical gas
  - Suction equipment
  - Patient Exam (blood pressure, etc.)
  - Monitors
  - Lights
  - Medication carts
  - Monitored/locked supply storage containers
- Education/In servicing in patient care areas

Level 3 – Administrative/Provider Access
- New technology demonstrations in general/administrative areas
- Education/In servicing in general areas
- Equipment repairs in general/administrative areas
- Visiting ambulatory or pharmacy staff
Appendix B
Out of Scope Representatives (not exhaustive)

General and Skilled Laborers
• General construction workers
• Painters
• Landscapers
• Window washers

Installation
• Capital/Lab/IT or other equipment installers who will not enter patient care areas

Facility Maintenance
• Elevator maintenance
• HVAC maintenance
• Electrical maintenance

Contractors
• Facilities/construction project managers
• Facilities/construction project engineers
• Facilities/construction project architects

Individuals providing services to patients on behalf of Ascension Participant
• Food/Environmental services staff
• Contracted medical staff
  o Radiology Technicians
  o Hospitalists
• Interpreters/Translators

Consultants
• Executive coaches
• Process improvement consultants
• Accounting consultants

Delivery Representatives
• Courier service representatives
• Equipment delivery service representatives (engaged only in pick up/drop off)

Clinical Trial Representatives
• Site evaluators
• Researchers
• Auditors
• Monitors