



August 5, 2014

To all vendors and Vendor Representatives,

Saint Thomas Health in conjunction with Ascension has developed a revised Vendor Policy and Procedures. Vendor Credentialing Service (VCS) is still the chosen relationship through which you will complete the credentialing process, although some of the Health Care Industry Representative (HCIR) classifications have been updated along with several key policy points. This program is still geared toward creating a systematic approach to credentialing our suppliers while providing a platform that facilitates vendor access policy adherence across all of our Health Ministries.

With very few exceptions, HCIRs must be fully credentialed through VCS, “green-lighted” in the system, and have an approved appointment through VCS’s Direct Appointment Request Tool (DART) prior to coming on-site. Those not in compliance with these three points will be denied access to all Saint Thomas Health facilities.

As was the case with the last version, signing of the Policy and Procedures is a required credential in order to be eligible to come on-site. The document has now been uploaded and its terms effective immediately. Refusal to agree to any of the terms therein will result in those representatives being denied access from all Saint Thomas Health facilities.

We place the utmost priority on the safety of our patients and staff, and see the VCS system as a very effective tool in the safeguarding process. Although VCS provides a number of supportive educational services beyond the scope of our policies, please understand that Saint Thomas Health and Ascension do not receive any benefits from the purchase of those services.

For representatives not yet a member of VCS, you can go directly to the VCS website to sign up at [www.vcsdatabase.com](http://www.vcsdatabase.com). You can also call (281) 863-9500 for direct assistance from a VCS representative.

For representatives who are registered through VCS but whose credentials are out of compliance (“red-lighted”), you will have until ***Thursday, September 4, 2014*** to become compliant. Any vendor “red-lighted” at that time will not be eligible to be on-site at any Saint Thomas Health facility until properly credentialed.

Thank you for your continued partnership,

Sincerely,

Jonathan Douglas  
Vice President, Chief Resource Officer

## Highlights/Points of Emphasis

### Purpose:

There are several key points and/or changes that we would like to highlight at this time. This list of items is merely a subset of points from the full Policy and Procedures for which we would like to stress compliance at this time. All HCIRs are solely responsible for reading and understanding all points within the document. Not all changes to the policy are covered in this summary.

### VCS Kiosk Locations: (two at each of the main three campuses)

Saint Thomas West:	Materials Management Office Surgical Services Desk (2 <sup>nd</sup> floor)
Saint Thomas Midtown:	Main Store Room, Materials Management Continuing Education Area (4 <sup>th</sup> floor Operating Room)
Saint Thomas Rutherford:	Main Store Room, Materials Management Hallway outside of Environmental Services

### Highlights/Changes:

- All credentials are not eligible for declination for any reason unless you have written documentation from a physician citing a medical reason for not completing it. At that point, accommodations will be made by facility staff pending the approval of the local VCS Administrator. **This includes but is not limited to the influenza vaccination.**
- DART must be utilized in order to come on-site unless otherwise specified by a member of The Resource Group. If the department you wish to visit does not appear in the choices available through DART, contact the local office of The Resource Group for further instruction.
- It is the sole responsibility of the HCIR to understand what is/isn't on contract products/services. Off-contract products and/or services must have the approval of the Chief Resource Officer before they can be brought into the facility. **This approval should be petitioned for a minimum of 48 hours in advance of coming on-site.**
- All HCIRs must both sign in and out at a VCS kiosk when coming and going from the facility. There is a mandatory 15 minute period between when you sign in and when you are eligible to sign out. Please understand that this cannot be petitioned for change. Failure to sign in or out will be considered non-compliance
- Profile information must be complete and accurate. Incomplete and/or incorrect profile information will be viewed as an act of non-compliance.
- HCIRs are not to post or leave any promotional materials within the facility unless specifically requested by an internal associate. Under that circumstance, promotional materials are to be left only with the requesting associate.
- **HCIRs are not to bring ANY food or gifts on-site with the intent of distribution to associates of Saint Thomas Health.**
- **Anyone found tampering with a VCS Kiosk is subject to an immediate and permanent ban from all Ascension facilities.**



## Vendor Access Policy and Procedures

Effective: September 1, 2014

### **PURPOSE**

Saint Thomas Health's (STHe) policy is to establish and maintain relations with suppliers based on mutual confidence, respect and ethical business conduct. Although, vendors are recognized as a valuable source of information and support to staff members of the hospital, they must provide services according to accepted rules of conduct in such a manner as to provide the greatest benefit to the system's hospitals.

The purpose of this policy is to set forth guidelines for relationships with Health Care Industry Representatives (HCIR). STHe and its parent Ascension Health desire to provide a safe and effective environment for patients, associates, physicians and other allied health professionals, while complying with all applicable laws and regulations. This Vendor Access Policy is designed to:

- Maintain a single business standard for vendor management.
- Ensure that decisions regarding the use or purchase of pharmaceutical products, medical supplies, and equipment are made based on the best available scientific knowledge.
- Ensure that neither medical education nor patient care is unduly biased by the activities of Health Care Industry Representatives (HCIR).
- Maintain security access points, vendor registration, and credentialing to protect our patients, staff, and buildings.
- Ensure patient confidentiality, compliance with regulatory standards, and a collaborative approach to promote safe and effective product use throughout the hospital.
- Facilitate appropriate HCIR interaction with health care personnel and dissemination of information without causing a disruption in the care of patients or interfering in the work performance of hospital staff.

- Ensure products are marketed through the proper channels that are consistent with policies and guidelines established by STHe.
- Not allow vendors into any Saint Thomas Health facility unless they have been requested by a physician to assist in a surgical or invasive case or they have been requested to service equipment. In most cases, the HCIR will still need an approved appointment through DART prior to entering the facility (see Key Points and Rules point “a” under the Policy section of this document for further details).
- Ensure all HCIRs badge-in at a VCS kiosk between the hours of 6:00 AM and 7:00 PM, Monday through Friday, and with Security after 7:00 PM, Monday through Friday and during weekends.
- Validate that all HCIRs are fully credentialed through VCS prior to coming on site. Upon successfully signing in at a kiosk, the HCIR will be provided a sticker-badge to wear at all times while in a Saint Thomas Health facility. All HCIRs failing to properly badge in will be asked to leave the premises immediately. Saint Thomas Health specific hospital badges are no longer considered valid for use by HCIRs. All such badges will be collected and destroyed.

Information pertaining to the STHe Policies and Procedures for vendors is provided on the STHe web site: [www.sths.com](http://www.sths.com), under the Vendor tab.

## **DEFINITIONS**

Ascension Health: This term refers to Ascension Health as a multi-hospital health system, each of our Health Ministries and/or individual locations dependent on the context of its use.

Associate(s): Includes practicing health care professionals and employees working at Ascension Health facilities.

The Resource Group: This term refers to the division of Ascension Health Alliance responsible for all supply chain functions, supply contracting, service contracting, and vendor credentialing within Ascension’s local Health Ministries as well as in Ascension’s System Office in St. Louis, Missouri.

Vendor Credentialing Service (VCS): VCS is the Ascension Health contracted vendor management/vendor credentialing system. VCS is responsible for directing the HCIR through the credentialing process and maintaining the web portal used by vendors. Drafting of vendor policies as well as the enforcement of said policies is the responsibility of the local office of The Resource Group.

Health Care Industry Representative (HCIR): This term refers to a sales or service professional who represents a company or companies to Ascension Health associate(s) including physicians, nurses, buyers, purchasing agents, executives and other associates who may be general users or influencers of the company’s product. HCIRs represent manufacturers, distributors, service companies, and other organizations. HCIRs generate sales, manage contracts, provide quotes,

demonstrate products, make repairs, consult, and perform other duties generally associated with representing their company.

For the purposes of this policy, the classifications of HCIRs are defined:

**Classification 1: Non-clinical, Credentialed, Health Care Industry Representatives:**

*VCS Level 1 (red badge):* Access to general hospital areas, but not patient care or procedure areas. Examples: Pharmaceutical representatives and managers, general medical sales representatives, laboratory representatives, distributor representatives and service technicians.

*VCS Level 7 (white badge):* Pharmaceutical representatives who access doctor offices but do not access hospitals. Pharmaceutical representatives who access hospitals must be credentialed as a VCS Level 1 vendor.

**Classification 2: Clinical, Credentialed, Health Care Industry Representatives:**

*VCS Level 2 (blue badge):* Access to general hospital areas, patient care areas, and procedural areas. Examples: Medical device representatives, technicians and company consultants. The required credentials permit presence in live procedures.

*VCS Level 3 (green badge):* Access to general hospital areas and patient care areas. Vendor does not have access to procedure areas or live procedures.

*VCS Level 6:* Agency nurses, technicians, and any contracted representatives who access patient care areas and have patient contact. Competency documentation is required.

**Classification 3: Non-Credentialed Representatives:**

*VCS Level 4 (yellow badge):* Administration and delivery representatives and GPO representatives who access general hospital areas. Non-vendors.

*VCS Level 5 (black badge):* Maintenance, design and construction workers who access general hospital grounds.

*VCS Level 8:* Representatives who have access to Protected Health Information (PHI). A Business Associate Agreement (BAA) is required. Examples: IT, Legal, financial consultants, interpreters, etc. If accessing remotely, only need to sign policies.

**Classification 4: Care Management Vendor Representatives:**

These individuals act as liaisons between the facility and the various providers of post-acute services. Examples include skilled nursing facilities, home health care, hospice, durable medical equipment, assisted living facilities, etc. This policy applies to all HCIRs (not owned and/or operated by STHE and its affiliates) who assist with discharge planning or provide post-acute services to our patients.

*VCS Level 2 (blue badge):* Access to general hospital areas, patient care areas, and procedural areas. Examples: Medical device representatives, technicians and company consultants. The required credentials permit presence in live procedures.

*VCS Level 3 (green badge):* Access to general hospital areas and patient care areas. Vendor does not have access to procedure areas or live procedures.

Though classification level dependent, credential requirements will include, but are not limited to confirmation of current documentation or acknowledgement of:

Our Vendor Policies	Hepatitis B Vaccination
Product and Service Training	Influenza Vaccination
OR Protocol – Aseptic Technique	Tuberculosis Test
Bloodborne Pathogen Training	Proof of Liability Insurance
HIPAA Training	Company Information
General Expectations & Safety	HHS, OIG, EPLS Check
Varicella (Chicken Pox)	Criminal & Sex Offender Check
MMR Vaccination	

Submission of any/all of these documents is not sufficient for entry into the facility. All such documentation and credentials must then be approved by VCS prior to the HCIR coming on site. Declinations will not be accepted for any credential except where written cause from a personal physician cites just cause.

## **POLICY**

Access to STH facilities by HCIRs is a privilege provided to allow mutually beneficial interactions. As invited guests, HCIRs are expected to strictly adhere to this policy as well as guidelines outlined by the Food and Drug Administration (FDA), the American Medical Association (AMA), the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Tennessee State Health Department. Violation of these policies and procedures may result in disciplinary action up to and including termination of privileges of the HCIR and the company he or she represents.

### Key Points and Rules

- a. Credentialed vendors are required to utilize the VCS sponsored Direct Appointment Request Tool (DART) to request potential meetings within Ascension Health and all other VCS customers across the country. Making the request through DART does not guarantee that access will be granted. The internal associate representing the respective department will make that determination. That decision is final. If the department you wish to visit is not visible in DART, contact the local office of The Resource Group for assistance.
- b. It is the responsibility of each commercial enterprise to ensure that the names of their registered representatives are accurate.
- c. It is the responsibility of each HCIR to register with VCS and be credentialed at the appropriate determined VCS Level for access to Ascension Health facilities and personnel. A VCS representative will make this determination.
- d. HCIRs must receive confirmation of approval for appointments through VCS and badge in at a kiosk from 6:00 AM to 7:00 PM on weekdays and through security after 7:00 PM or on the weekends. Access during week after 7:00 PM or on the weekends should only come at the request of a duly authorized internal associate.
- e. HCIRs will not be provided free or unlimited access to any floor, area, suite or operating room within Ascension Health. Access to STHe or Ascension Health personnel not from The Resource Group will only be permitted by scheduling an appointment through DART.
- f. HCIRs are to only bring fully-contracted items that are also approved for used locally by a member of The Resource Group. Non-contracted items may be petitioned for use but must be requested at least 48 hours in advance of the case for which they are to be used. Permission for use will be granted on a case-by-case basis.
- g. HCIRs must bring any instrument and/or implant to the sterile processing department for wrapping and sterilizing 48 hours in advance of procedure. Flash sterilization is prohibited except in the event of an emergency.
- h. Any HCIR seeking access to an STHe facility for the purpose of performing maintenance services must have an approved appointment through DART with a relevant internal associate.
- i. HCIRs are not permitted access to any operating room or surgical suite within STHe without written request from a physician. Such request must specify and demonstrate a critical clinical need for the presence of the representative.

- j. HCIRs must schedule in-services at least 30 days in advance with The Resource Group. All in-services will be conducted in offices of The Resource Group or designated education areas.
- k. All associates attending in-services will be provided CEUs by the HCIR's education department and the appropriate accrediting organization.
- l. Any distribution of samples and literature shall be coordinated and arranged through a member of The Resource Group. Such materials should be relevant only to items that are on contract and approved for use locally. These materials must be given directly to the approved associates and not left out, hung, or otherwise displayed in any areas of the facility.
- m. HCIRs are strictly prohibited from providing demonstration model or loaner equipment to STHe without having submitted a proposal for such equipment to a member of The Resource Group and having received a zero-dollar purchase order for such equipment prior to its arrival on the premises. Legal must also approve the terms and conditions of such equipment before it is brought on-site. At that point, equipment brought in for demonstration/evaluation must have a safety check completed by biomedical engineering before the equipment can be used at Ascension Health.
- n. Products or services not expressly included within a contract executed between the vendor and Ascension Health, STHe, or a designated GPO, 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 STHe for use. Any off contract products that are provided to and used by associates in violation of this policy shall be deemed vendor donated product. Vendor shall not invoice for, nor receive any reimbursement for such off contract product from Ascension Health.
  - 1. Ascension Health recognizes that there may be instances where patient care dictates use of an off contract product. In such rare circumstances, the Health Ministry physician requesting use of the off contract product may apply for an exception to the off contract product policy. This request should originate directly from the requesting physician. Such requests cannot be submitted by the HCIR.
  - 2. Willingly providing off-contract items as donations to the facilities is expressly prohibited and viewed unfavorably. This should not be considered an opportunity to bring in off-contract items.
- o. STHe initiates business with vendors by seeking bids or proposals from potential sources and awards contracts based on a variety of criteria. Copies of bids, quotations, special offers, etc. must only be submitted to The Resource Group either at the System Office level or at STHe, regardless of the original requestor.

- p. Vendors shall submit all product recall notices to a member of The Resource Group and to the attention of the appropriate hospital department designee within three days of notice.
- q. HCIRs are not permitted to take still or video pictures within the hospital without prior authorization from STHe's legal department.
- r. Gifts and/or gratuities of any kind are prohibited except where compliant with the Business Courtesies from Vendors section of this document.

#### Prior to Arrival

- a. It is the responsibility of the HCIR to verify all of his/her credentials are either green or yellow prior to attempting to come on-site at any STHe facility.
- b. HCIRs must log in to VCS and request an appointment through DART prior to each requested appointment unless explicitly told otherwise by the local VCS Administrator. All vendor appointment requests will be reviewed by an appointed representative of the respective department. All submitted appointments must then be approved before the HCIR can come on-site. If the HCIR does not receive an email confirming the appointment was granted, he/she is not permitted on-site. Information required of vendor for successful appointment request will include but not be limited to:
  - 1. Date of HCIR visit
  - 2. Purpose of the visit
  - 3. HCIR destination at the facility
  - 4. Time of entry to the facility
  - 5. Time of exit from the facility
- c. No HCIR shall be given access to STHe without the successful completion of the vendor credentialing program and strict continued compliance to Ascension Health rules, standards, policies, and procedures.

#### Upon Arrival

- a. HCIRs must comply with STHe parking policies.
- b. VCS kiosks are located in each facility and should be utilized to "badge in" immediately upon entering the premises. There is one kiosk located in the local office of The Resource Group at each facility as well as a second unit strategically located elsewhere in the hospital.

- c. HCIRs must register at one of the VCS access points to receive their time/date sensitive identification for the appointment. This printed sticker badge must be worn **at all times** while on-site.

#### While at the STHe Facility

- a. Vendors are not permitted on nursing units, in the emergency room, in outpatient clinics or other patient treatment areas except by invitation of a member of the attending Medical Staff, Chief Nursing Officer or her designate or by invitation of a department manager. Representatives are not permitted in the physicians' lounges or house staff offices at any time.
- b. Access to STPS sites and clinics by HCIRs is not allowed unless the site is approved for access by the COO of STPS.
- c. HCIRs are not allowed to enter areas beyond their pre-determined level of access. Upon registration with VCS, a VCS representative will help gauge what level that should be.
- d. HCIRs may be present but shall not wait in common hospital areas (such as building lobby areas, eating areas, parking areas, public telephone areas, OR, etc.) for the purpose of initiating unsolicited contact with health care professionals and detailing their products to these individuals.
- d. HCIRs are required to wear at all times the time stamped badge while on an STHe campus.
- e. Vendors may visit Medical Staff members only by appointment or at scheduled exhibits. Detailing (provision of samples, marketing of products) must be cleared by a member of The Resource Group and consistent with decisions or opinions of the Medical Staff.
- f. HCIRs may not use facility telephones or paging systems.

#### Before Leaving

HCIRs *must* log out at a VCS access point at the conclusion of each scheduled appointment. Failure to do so will result in sanctions being levied. Please note that there is a 15 minute waiting period after badging in before an HCIR can badge out. We apologize for any inconvenience this may cause, but this policy is not up for change.

#### Care Management Procedures

- a. Post-acute HCIRs shall be restricted from STHe facilities except when they are invited by a member of the hospital staff via phone or eDischarge to make a request for services on behalf of a particular patient. If a request for services is made directly to a provider

by a physician, patient, or family member, the provider must notify the care management department of the request prior to making an onsite visit.

- b. All printed materials must be mailed to the Care Management Department.
- c. HCIRs are expected to follow the STHe Code of Conduct for Vendors. The Code of Conduct may be obtained from the Saint Thomas website.
- d. Vendor Representatives will comply with HIPAA guidelines and patient confidentiality. HIPAA violations will be reported according to regulations set forth by governing bodies.
- e. No food items will be allowed on-site as per the Business Courtesies section of this document.
- f. Care Management HCIRs may not give gifts of any kind or value to any STHe associate.
- g. In-services related to post-acute services must be scheduled through Care Management at each facility and must be approved by the facility CFO.

#### Marketing Activities

HCIRs may promote their products and disseminate information only within the following parameters:

- a. HCIRs shall confine their promotional activities within STHe facilities to attending medical staff, nurse practitioners, pharmacy management staff, management staff in areas where the commercial enterprise's supplies and equipment could be used, and employees of The Resource Group.
- b. HCIRs will respect and abide by the decisions of the relevant Medical Executive Committees and their subcommittees, such as the Pharmacy and Therapeutics Committee. HCIRs are not permitted to promote medications, supplies or equipment contrary to STHe Policies or Guidelines as approved by the relevant hospital committees. Before visiting members of the medical staff to promote medications, HCIRs must meet with the Director of Pharmacy to inform/provide them with any of the information they will be using to promote their product(s). Such an appointment should be made through DART. Any information/materials deemed inappropriate or biased by the facility pharmacy may not be provided to individuals in the Hospital. Examples of policies/guidelines HCIRs are expected to follow include:
  - 1. Promotion of restricted products only to those attending physicians who are authorized to prescribe them

2. Promotion of products within guidelines where STHe recommends specific dosing, the agents are restricted at STHe for specific indications, clinical parameters that must be met prior to use of the agent at STHe, etc.
  3. Promotion of non-formulary and/or non-preferred items is denied
- c. The following are *acceptable* forms of information for dissemination by HCIRs within the Hospital if the drug is a Formulary item and the materials are approved for distribution by pharmacy and the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Food and Drug Administration.
1. Reprints of primary literature from peer-reviewed journals
  2. Promotional materials that are deemed unbiased and are approved for distribution by the facility point of contact
- d. The following are *unacceptable* forms of information for dissemination by HCIRs at the Hospital:
1. Abstracts related to potential benefits of a drug marketed by the commercial enterprise
  2. Any information deemed as inappropriate or biased by the facility point of contact
  3. Information related to the unapproved use of medications as determined by the Food and Drug Administration (this information may only be obtained if a hospital employee or a member of the medical staff requests this information through the Medical or Scientific Affairs Division of the commercial enterprise)
  4. Any comparative cost analysis related to the product being promoted
- e. HCIRs may not post any notices in STHe facilities that promote their products or a program they are sponsoring. Program notices must be posted by the Hospital representative responsible for that program in concordance with hospital policies for posting notices. Promotional materials may only be given during an appointment and may not be left in hospital areas, including public areas.
- f. Violations of applicable laws governing the promotion and marketing of drug products will be reported by STHe to the Division of Drug Marketing, Advertising and Communications (DDMAC) of the Food and Drug Administration.

### Business Courtesies from Vendors (gifts and entertainment)

- a. HCIRs may not provide gifts or courtesies of any kind to individual STHe associates, including physicians who are employees of STHe. This includes but is not limited to food of any sort.
- b. Items of minimal value, such as pens, notepads and similar “reminder” items with company or product logos may be distributed to associates.

### Educational Programs

STHe may accept unrestricted educational grants, made without stipulation regarding the content of teaching sessions. *All scholarships and educational assistance funding should be directed to the STHe Foundation for appropriate distribution.*

- a. Program funds will be administered by the CME office or hospital department.
- b. Checks for operating expenses such as meals and speakers’ honoraria are to be made payable to the Hospital. **All** expenses and honoraria will then be paid directly by the host body.
- c. Speakers must disclose at educational programs any financial support or conflict of interest they may have related to the materials they are presenting.
- d. If an HCIR is providing financial support for a CME approved program (such as Grand Rounds), the Hospital will allow the HCIR to attend the program provided they do not display advertising or promote their products to the staff attending these programs.
- e. HCIRs are not allowed to attend non-CME approved teaching sessions for students, residents, pharmacy, nursing or laboratory staff.
- f. STHe does not allow HCIRs to meet with students, residents, pharmacy, nursing or laboratory staff on hospital property.
- g. STHe will not provide the names or addresses of students or staff to HCIRs.
- h. STHe employees, who are offered speaking engagements, consultantships, etc., must follow policies as outlined in the university or hospital Conflict of Interest policy.

### Vendor Sponsored Educational and Operational Items that are Donated

Educational/Donated Items: Healthcare professionals may accept items primarily for the benefit of patients if they are not of substantial value (\$500 or less). If a vendor wishes to donate an item that has a value greater than \$500, the donation should be submitted to the Foundation with review by the Compliance Department. For example, an anatomical model for

use in an examination room primarily involves a patient benefit. All free items must go through the Purchasing Department so that items can be properly accounted for. It is not appropriate to give items (specifically chargeable items) to patients. Patients having financial hardship may request assistance through the Foundation or the Charity Care vehicles. Please seek out assistance through either of these options.

#### Vendor Sponsored Third Party Educational or Professional Meetings

Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible as outlined in these guidelines. A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

- a. Supplier funded attendance (registration only) at local workshops, seminars and training sessions that are sponsored by the supplier is permitted.
- b. Supplier funded attendance (registration fee only) at out of town seminars, workshops and training sessions is permitted if:
  1. Supplier vendor is a sponsor of the seminar or education session; and
  2. The training is to improve the use of equipment/services purchased from supplier or vendor; and
  3. The remaining expenses have been approved by the Hospital's appropriate authority
- c. Periodically, hospital professionals may be requested to serve on an advisory board offering input into product performance and development. Participation in such events must merit value to patient care services. The vendor shall be financially responsible for all reasonable accommodations to include lodging, food and travel expenses.
- d. With the purchase of new equipment or services, it may be necessary that the vendor train SThe associates. The expense for training is incorporated into the new equipment or service contract. As part of the contract, the vendor may be financially responsible to provide the total cost of the training to include registration, travel, lodging and meals.

#### Vendor Loans to Associates

At no time may a vendor of SThe extend any loan to an SThe associate. Loaning money to any SThe Associates is considered a conflict of interest.

### Access to SThe Information

HCIRs are not allowed access to verbal or written information about specific patients, quality of care issues, or information that would jeopardize the process for product selection or competitive pricing.

- a. HCIRs will not access patient information, clinical data or billing information. Ascension approved third party vendors may be used to assist in the billing and reimbursement process for particular drugs.
- b. Information discussed or distributed at Medical Executive Committees or Subcommittees (e.g., Pharmacy and Therapeutics Committee, Subcommittee on Critical Care Therapeutics, etc.) may not be provided to or obtained by HCIRs. Information needed by HCIRs to ensure promotion of their products within guidelines or policies approved by the Pharmacy and Therapeutics Committee will be provided by the Drug Information Center or other appropriate information source for supplies and equipment.
- c. Training by HCIRs for new equipment or devices that involves exposure to patients is highly discouraged. When such training by an HCIR is necessary, approval from the Departmental Chair AND patient consent, documented in the patient's chart, are required. The Operating Room has specific policies related to training provided by HCIRs, and these must be followed in that area.
- d. Institution specific data related to prescribing practices, product consumption, or prices may not be provided to HCIR's except by The Resource Group.

### Process for Pharmacy Product Review and Selection

All drug information materials for use during the formulary review process must be presented to the director of the Pharmacy Department. Current pricing and catalog information should be directed to Pharmacy Management.

Only attending medical staff can request the addition of a medication to Saint Thomas Health's Hospital Formulary (See Hospital Policies and Procedures Manual: Formulary System Policy).

- a. New products are recommended for hospital or operating room use by the Operating Room Committee, Clinical Support Committee or the Product Evaluation Committee only after successful clinical evaluation and review for suitability, effectiveness, safety, cost and convenience of product.
- b. During pre-implementation of a new product, HCIRs are permitted access to staff in patient care areas for the purpose of providing education specific to product

implementation. These sessions are prescheduled with the management of each area affected by the implementation, and approved by The Resource Group.

### Drug Samples

HCIRs may provide samples to attending physicians for their use in private practice. These samples must be kept in their private practice area and properly stored. All samples for “trials” provided to the hospital must be submitted to pharmacy along with price quotation. Vendors are not permitted to leave samples of products in any patient care area (hospital, emergency room, outpatient clinic, procedure areas, etc.). Department chairs involved and in charge of a clinic or treatment area can submit a written request to the Pharmacy and Therapeutic Agents Committee or Standards Committee for approval of exceptions to this policy. Prescribers may procure samples for direct donation to Dispensary of Hope programs.

Drug samples provided to STPS physicians must be suitable for eventual use by the Dispensary of Hope, and must comply with the Ethical and Religious Directives of the United States Conference of Catholic Bishops.

### Policy on Trial Equipment/Products

Clinical evaluations of new FDA approved products must be approved by the Operating Room Committee, Clinical Support Committee or the Product Evaluation Committee.

- a. A written descriptive statement recommending a product for clinical evaluation must be submitted to the Operating Room Committee Chairperson or the Product Evaluation Committee.
- b. Product supplies left for evaluation must be left with the Procurement & Strategic Sourcing Department or in a location designated by The Resource Group. STHe will not be responsible for supplies, equipment, or material delivered to persons other than those designated.
- c. Equipment that has been approved for clinical evaluation must be inspected by Biomedical Engineering before use.
- d. If the appropriate hospital committee has declined to test or approve the item, the HCIR should not attempt to reintroduce the item until it has been substantially improved or altered in such a manner as to overcome the initial objections of the committee.

### Research and Investigational Products

The STHe Research Department must approve any proposed research study, investigative drug device or procedure. A member of the Medical Staff must submit appropriate protocols for review and approval. Institutional Review Board approval may be required.

## Compliance and Enforcement

**It is the responsibility of every Vendor Company and HCIR to comply with these procedures.**

Associates and members of the medical staff will report infractions of these rules or evidence of misconduct on the part of a vendor directly to the Chief Resource Officer or local VCS Administrator. The Chief Resource Officer (or his/her designee) is responsible for enforcing these policies.

- a. HCIR non-compliance to this policy will result in the following consequences:
  1. First Violation: HCIR will be placed on probation for 30 days during which time they will not be able to conduct business at any Ascension Health facility.
  2. Second violation: HCIR will be suspended from further business with Ascension Health.
  3. Repeated violations by HCIRs from the same company will result in all HCIRs from that company being banned for a period of at least one year from all Ascension Health facilities.
- b. Any infraction brought to the HCIR's attention will also warrant a written report be sent directly to his/her immediate supervisor. The nature of infraction and action taken will be included. Given the significance of the infraction or the establishing of unacceptable practice patterns, Chief Resource Officer reserves the discretionary right to levy appropriate sanctions regardless of the current step in the disciplinary process. Questionable sales practices will be reported to various regulatory agencies for additional follow-up.
- c. Based on the severity of the violation, the Vice President, Chief Resource Officer may determine an immediate suspension is warranted.

HCIR Signature / VCS Acknowledgement of Policy

**The signature below acknowledges that I have read and understand the aforementioned requirements and agree to the terms stated therein.**

SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

PRINT NAME: \_\_\_\_\_ TELEPHONE: \_\_\_\_\_

COMPANY: \_\_\_\_\_

POSITION: \_\_\_\_\_

SUPERVISOR NAME: \_\_\_\_\_ TELEPHON