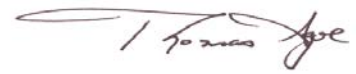


Lifespan System-wide Policy **Subject:** Interactions With Industry Representatives (From Pharmaceutical, Medical Device and Medical Supply Industries) **File under:** CCPM-46

Issuing Department: Corporate Compliance **Latest Review Date:** **Latest revision date:** November 2015
November 2014
June 2014
October 2013
October 2010

Original Policy Date: June 2010 **Page** 1 of 17 **Approved by:**



(Vice President)



(Executive)

I. Purpose:

Lifespan has derived significant benefits from its collaborations with the pharmaceutical, medical device and medical supply industries¹ in the areas of research, education and patient care. Lifespan continues to embrace these relationships because they often translate into improved health care. However, they must occur in a transparent, non-biased environment where conflicts are disclosed and appropriately managed, costs are fair and patient safety protected. Furthermore, these interactions must conform to the highest ethical principles and comply with supporting practices designed to maintain and enhance Lifespan’s reputation with the public and the credibility of its medical staff with its patients.

This policy defines those ethical principles and supporting practices governing employee and medical staff interactions with pharmaceutical, medical device and medical supply industry representatives (Industry Representatives). Nationally, the appropriateness of these relationships have received considerable negative publicity; thus, many integrated

¹ This policy applies to bio medical, pharmaceutical, medical device companies and other companies making products used to diagnose or treat patients or provide medical care, including palliative care (Industry).

healthcare systems, hospitals and medical schools are placing greater restrictions on Industry Representative contact with professional staff². This policy is designed to (1) provide guidance to Lifespan employees, medical staff and Industry Representatives who call on Lifespan, and (2) ensure Lifespan practices reflect those of peer institutions. It supplements existing Lifespan policies governing conflicts of interest and relationships with Industry Representatives³. In all situations where this policy is more restrictive than existing policies, this policy shall control.

II. Eligibility:

The ethical guidelines and supporting practices below apply to all Lifespan employees and medical staff while acting in an official Lifespan capacity or who are conducting Lifespan’s business of patient care, teaching and/or research, involving Lifespan property (whether owned or leased), patients, employees and/or trainees (Lifespan Business). Lifespan’s medical staff is composed of physicians and allied health professionals who Lifespan directly employs, or who provide services to Lifespan under contract (for example serving as Medical Directors), and those physicians and other providers who admit and/or treat patients at Lifespan facilities (Medical Staff). **This policy applies to all activities that Lifespan employees and Medical Staff perform under the auspices of, or on the behalf of, Lifespan, or when using a Lifespan title, or using the name of Lifespan or any of its affiliated hospitals.**

Lifespan is not attempting to dictate to its non-employed Medical Staff members how they should interact with Industry Representatives when conducting their private non-Lifespan business. However, Lifespan strongly encourages adoption of similar ethical guidelines and supporting practices.

Attestation by each Medical Staff member that s/he will comply with this policy when engaged in Lifespan Business or when on Lifespan property must be obtained during the credentialing process. In addition, annually Industry Representatives must attest to compliance with this Policy.

While Lifespan is primarily composed of hospital affiliates, it also encompasses numerous other entities such a physician practices, outpatient clinics, research facilities, laboratories (Lifespan Facilities). Management of these entities should review this policy and conform to the extent practical.

² Examples of professional staff include, but are not limited to, medical staff, Lifespan employed management officials at the director level or above, nurses, respiratory therapists, pharmacists, nurse practitioners, and physician assistants (Professional Staff).

³ See Materials Management Policy MM-107 “Sales Representatives,” and Materials Management Policy MM-150 “Institutional Purchasing: Conflict of Interest Guidelines.”

III. Ethical Guidelines:

Section IV of this Policy sets forth specific guidelines to govern the management of commonly occurring high risk situations. If a particular scenario involving interaction with an Industry Representative is not addressed in Section IV, it may still be problematic and due care should be exercised.

Lifespan believes that the supporting practices listed in this Section III provide general guidance useful in mitigating many risks arising from Industry Representative interactions, whether or not such interactions are explored in detail in Section IV. These principles also represent best practices for Industry interactions involving Lifespan employees and Medical Staff that occur away from Lifespan properties and during non-Lifespan work hours. Lifespan reminds all employees and Medical Staff to take responsibility for their own actions.

- *Act with honesty and integrity, thereby protecting your reputation and Lifespan's good name.*
- *Industry interactions should be conducted so as to avoid or minimize conflicts of interest.*
- *When conflicts of interest do exist, they must be recognized, disclosed and either eliminated or effectively managed.*
- *Lifespan business, research and patient care decisions should not be influenced by the possibility of personal financial gain.*
- *External activities should not compromise an employee or Medical Staff's ability to perform all Lifespan activities expected of him or her.*
- *An individual should not conduct external business activities under circumstances in which a reasonable person could infer that Lifespan business, research or patient care activities could have been distorted by the desire or expectation of direct or indirect personal economic gain.*
- *All federal and state laws must be followed; anti-kickback laws bar the payment or receipt of remuneration⁴ for directly purchasing, leasing, ordering or recommending the purchase, lease or ordering of any goods, facilities, or services, reimbursed by Medicare or Medicaid.*

⁴ Remuneration is defined as anything of value, such as gifts, free travel, sponsored research and below fair market commercial rates.

- *Persons associated with Lifespan should not circulate announcements or become involved with recruiting patients, employees, physicians or others on behalf of Industry Representatives for participation in research endeavors, unless performed pursuant to an IRB approved protocol.*
- *The e-mail addresses or contact information of Lifespan employees or Medical Staff should not be provided to Industry Representatives.*

IV. Supporting Practices:

4.1 Registration:

Lifespan employee and Medical Staff contact with Industry Representatives is appropriate when scientifically valid information is exchanged, patient care is enhanced and training intended to advance health care and scientific investigation is rendered. Nevertheless, these benefits need to be balanced against Lifespan's requirements to maintain effective procurement, research and education processes; protect patient confidentiality; maintain employee work schedules; and provide healthcare services. As such, no Industry Representative should be on Lifespan property conducting business without an invitation from a Lifespan Professional Staff member. **Visits should be infrequent and their duration limited.** Industry Representatives must use the registration (REPTRax) system to record who issued the invitation, the purpose of the visit, date and duration of the visit, and other information requested as part of the registration process. Failure to register will result in the loss of privileges for the representative. Lifespan employees and Medical Staff meeting with an Industry Representative must confirm that the Industry Representative has registered and received a valid badge through REPTRax prior to commencing the meeting. The registration rules are summarized in greater detail below.

4.1.1 First Time Visitors:

All Medical Industry Representatives, prior to their first visit to a Lifespan Facility, must first report to the Lifespan Supply Chain Operations (Purchasing Office) located in the Item Building on 139 Point Street, Providence, RI, to be briefed on REPTRax and Lifespan policies/procedures. At this initial meeting, they will receive a copy of Lifespan's rules governing their behavior when visiting Lifespan properties. First-time appointments should be scheduled by calling Purchasing at 401-444-5041.

All Pharmaceutical Industry Representatives, prior to their first visit to a Lifespan facility, must first report to the Lifespan Pharmacy to be briefed on REPTRax and Lifespan policies/procedures. At this initial meeting they will receive a copy of Lifespan's rules governing their behavior when

visiting Lifespan properties. First-time appointments should be scheduled with the Rhode Island Pharmacy Manager at 401-444-5447.

4.1.2 Repeat Visits:

Upon arrival, Industry Representatives will proceed directly to a REPTRax kiosk to register. One or more REPTRax kiosks exist at the main offices of Lifespan Corporation and at each Lifespan hospital affiliate. Kiosk locations will be identified at initial registration or by Information Desk staff located in each hospital lobby. Upon registration, the REPTRax system will issue to each Industry Representative an official badge, which must be worn and visible at all times while on Lifespan property. Company-supplied identification badges should also be worn while on Lifespan property.

The time Industry Representatives may spend on Lifespan property is limited. Industry Representatives are expected to register no more than 30 minutes prior to a scheduled appointment and leave Lifespan property no more than 30 minutes after the conclusion of their appointment.

- Failure to register, log out, wear official representative badges and otherwise conform to this policy, will result in the loss of visitation privileges. **(See VII—Infractions and Disciplinary Actions)**

Representatives must sign out at a REPTRax kiosk at the end of their visit. Loitering in Lifespan cafeterias, restaurants, and other public or private areas of Lifespan property prior to or after scheduled visits is strictly prohibited. Lifespan senior management, Medical Staff leadership and Corporate Compliance will periodically review REPTRax information reports to ensure strict adherence to these registration rules and procedures.

4.1.3 Access is Limited:

Drop in visits are not permitted. Industry Representatives are **not** permitted to conduct business in any Lifespan outpatient clinic, emergency room, urgent care area or program or inpatient area unless prior approval is obtained from either Purchasing, Pharmacy officials or a Professional Staff member responsible for that location. In the rare cases where Industry Representatives are allowed access to these areas, it should be for a specific purpose at the invitation of a Professional Staff member; for example, for a credentialed medical device representative to provide product training.

- All Lifespan pharmaceutical, medical supply and device purchasing decisions are the primary responsibility of Pharmacy and Purchasing officials, who will solicit input from significant user and various supporting committees. **(See Section V – Procurement Responsibility/Conflict of Interest Management)**
- Industry Representatives or Professional Staff who want to introduce a new product to Lifespan must first present it either to Lifespan Purchasing or Pharmacy officials. **A Lifespan Product Request Form must be completed for all new product requests. This form is available via the Lifespan Intranet at http://intra.lifespan.org/matmgt/New%20Product%20Request%20Form%202013_rev_12052013.pdf**
- No pharmaceutical or medical device may be trialed for purchase without prior approval of the Pharmacy & Therapeutic (P&T) Committee or Purchasing Department.
- Preceptor arrangements whereby Industry Representatives train in a Lifespan Facility or participate in clinical rounds are not permitted as they present an unacceptable HIPAA Privacy Act risk.
- Invitations to Industry Representatives will normally be made for such purposes as to obtain in-service training for research or clinical equipment already purchased; to evaluate the potential purchase of equipment, devices or related items; or to resolve product or contractual issues.
- Medical device Industry Representatives, who provide Lifespan Professional Staff with assistance in the use of devices in patient care areas must be credentialed through REPTRax and their companies must have a Business Associate Agreement on file with Lifespan.

4.1.4 How to see Hospital Officials/Clinicians:

- Industry Representatives must receive an invitation from a Lifespan Professional Staff member to conduct business on Lifespan property. The Industry Representative must record in REPTRax who issued the invitation. Marketing efforts designed to secure such invitations are discouraged.
- Acceptable areas for discussion of products or services are the Pharmacy, Purchasing, Professional Staff administrative offices and may take place only *by invitation* of a Professional Staff member. Such discussions are expressly prohibited from taking place in any public or clinical or patient care areas of Lifespan Facilities.
- Lifespan employees and Medical Staff meeting with an Industry Representative must confirm that the Industry Representative has registered and received a valid badge through REPTRax prior to commencing the meeting.

4.1.5 Lifespan Employees Serving as Vendor Representatives

In an effort to avoid and minimize conflicts of interest, full time, part time, and per diem Lifespan employees, who also work for manufacturers, distributors, sellers, retailers and any other vendors of Covered Products are prohibited from working at, or calling upon any Lifespan facilities as vendor employees. Both roles must be entirely separate⁵. This does not prohibit individuals from working or calling upon non-Lifespan entities.

“Covered Product” means all or any of the following: (i) implantable medical devices (including external fixation devices) and/or related instrumentation; (ii) pharmaceuticals; and (iii) biologics.

Please also refer to HR Policy 3.9 **“Outside Employment and Reimbursement by Outside Persons or Entities”** before accepting employment with a vendor.

4.2 Gifts:

To avoid the risk of conscious or subconscious bias in decision making, Lifespan employees and Medical Staff (or their family members) may not accept gifts⁶, from Industry Representatives.

4.2.1 Distribution of promotional material (e.g., pads, pens, other giveaways) anywhere on Lifespan property is not permitted; no nominal value exception exists. Such gifts introduce a commercial, market presence that is inappropriate to a not-for-profit healthcare system.

- Gifts of diagnostic equipment, such as stethoscopes are no longer permitted.
- Gifts of complimentary texts, handbooks, treatment compendia and other similar items are not permitted.
- Gifts of cash or cash equivalents (such as a gift certificate) are not permitted.

4.2.2 Gifts in the form of free or subsidized tickets to sporting events, concert performances, plays and other forms of entertainment not related to patient care are not permitted.

⁵ This prohibition does not apply to Lifespan Home Medical employees working at Lifespan facilities.

⁶ The guidelines relating to gifts, meals, consulting, pharmaceutical samples and other similar items apply to Lifespan employees and Medical Staff members engaged in Lifespan Business and their family members who are defined as any close relation by blood or marriage and/or any person residing with the Lifespan employee or Medical Staff member.

- 4.2.3 Consulting arrangements without commensurate associated duties are considered gifts and are not permitted.
- 4.2.4 Pharmaceutical samples given to Lifespan employees and Medical Staff for personal use are considered gifts and may not be accepted.
- 4.2.5 Acceptance of items bearing Industry logos, provided as part of a legitimate off-site educational program, such as professional society meetings, including name tags, tote bags, writing tablets, pens, and other similar items, where the items are of nominal value, are incidental to attendance, and are **not subsequently** used in connection with Lifespan Business, is permitted.

4.3 **Meals:**

The provision of meals is a common technique used by Industry Representatives to meet and market to healthcare professionals. This technique has been abused and is never appropriate on Lifespan properties.

- 4.3.1 Direct Industry sponsorship of meals on Lifespan property is considered a gift and is not permitted.
- 4.3.2 Industry sponsorship of meals off site, for instance at local restaurants, is considered a gift and is not permitted. When invited to a small group meal by an Industry Representative, if Lifespan employees and/or Medical Staff members choose to attend, they must pay for their own food.
 - Takeout meals or meals to be eaten without an Industry Representative present (such as “dine and dash” programs) are not permitted.
- 4.3.3 Industry Representatives may provide unrestricted support for medical education to Continuing Medical Education offices, hospital departments/divisions or to physician foundations/groups. This unrestricted educational support may be used to support modest meals at education sessions. (See 4.4 below)
- 4.3.4 Industry sponsorship of or supplied food may be accepted in connection with providing legitimate consulting or advisory services, in connection with professional society meeting events open to all meeting attendees, or if directly related to ongoing sponsored research projects.

4.4 **Educational Programs and Presentations:**

Unrestricted Industry educational grants are allowable but should be awarded only to the Continuing Medical Education offices, hospital departments/divisions or

physician foundations/groups. They may not be awarded to an individual. Restricted Industry educational grants can only be accepted with the advance approval of the affiliate Chief Medical Officer. No quid pro quo should be implied or expressed in connection with soliciting or receiving educational grants. Lifespan's specific rules regarding educational programs and presentations are listed below.

4.4.1 To ensure transparency, periodically, the Continuing Medical Education offices, the hospital departments/divisions, and the physician foundations/groups may be asked to provide the Lifespan Compliance Office with a listing of all Industry educational grants received to support Lifespan training and educational activities (including any event in which residents or fellows are present) -- by vendor, amount, and documenting how and when used.

- Pharmaceutical and medical device companies must publicly disclose payments, via the CMS Open Payments database made to individual healthcare professionals, physician groups and teaching hospitals. Lifespan Corporate Compliance will routinely obtain and analyze this information to ensure transparency and policy compliance.
- The purpose, terms and conditions associated with the educational grant must be documented in writing and maintained for five years.

4.4.2 Industry sponsorship of educational programs offering CME credits on Lifespan property (including teleconferences and Webinars) are permitted only under the following circumstances:

- The program meets relevant requirements for approved continuing education credit and is consistent with the requirements of the Accreditation Council for Continuing Medical Education (ACCME) or other applicable professional continuing education organization.
- The applicable clinical director, for example, for the hospital department or division, is immediately responsible for ensuring that the program meets the ACCME Standards for Commercial Support (or other similarly applicable standards required by other health professions).
- Funds to sponsor the educational program are given to either the Continuing Medical Education offices, hospital departments/divisions, or to physician foundations/groups. **Payment may not be made to individual physicians** (including residents or fellows) or other healthcare providers or Professional Staff members.
- Responsibility for the educational program's content resides with Lifespan officials, **sponsorship must be fully disclosed**, Industry Representatives can attend but should not engage in marketing

activities and the provision of food/refreshment by Industry Representatives is prohibited (see 4.3).

- No promotional material should be displayed or distributed in the same room immediately before, during, or after the educational program and no presentation or verbal descriptions of product or devices are permitted.
- Vendor initiated product fairs, exhibits, and displays are prohibited.
⇒ Industry promotional items may not be displayed in any Lifespan facility.

4.4.3 Industry sponsorship of educational programs ***not*** offering CME credits are permitted only under the following circumstances:

- Pre-approval is obtained from the Continuing Medical Education offices, or from hospital departmental/divisional leadership, or physician foundations/groups. The program meets the requirements of the ACCME Standards for Commercial Support (or other similarly applicable standards required by other health professions).
- Funds to sponsor the educational program are given to the Continuing Education Offices, hospital departments/divisions, or physician foundations/groups. **Payment may not be made to individual physicians or other healthcare providers.**
- Responsibility for the educational program's content resides with Lifespan officials, **sponsorship must be fully disclosed**, Industry Representatives can attend but should not engage in marketing activities and the provision of food/refreshment by Industry Representatives is prohibited. (See 4.3)
- No promotional material should be displayed or distributed in the same room immediately before, during, or after the educational program and no presentation or verbal descriptions of product or devices are permitted.

4.5 **Industry Sponsored Meetings:**

Lifespan employees and Medical Staff members may attend off-site (i.e. not on Lifespan property and not implicating Lifespan Business) Industry sponsored meetings if the meetings are designed to promote evidence based clinical care and/or advanced scientific research, Industry financial support is prominently disclosed and they pay for their own meals.

- Industry may not pay for attendee travel and lodging.
- Industry may not compensate attendees to attend or to participate in interactive sessions.

- 4.5.1 Lifespan employees and Medical Staff members are strongly discouraged from attending Industry sponsored promotional speaking events, i.e., designed to discuss a company's product. If they attend, they must pay for their own meals.
- 4.5.2 Announcements should not be circulated on or using Lifespan property regarding Industry sponsored promotional speaking events, nor should Lifespan employees or Medical Staff member email addresses be provided to Industry Representatives.

4.6 **Scholarships/Other Financial Assistance:**

Industry scholarships, travel grants and other financial assistance to permit medical students, residents, fellows, or other healthcare providers to attend **educational conferences** are appropriate as long as payment is made to Lifespan Continuing Medical Education offices, hospital departments/divisions or physician foundations/groups.

- **Educational conferences** are defined as the major annual educational, scientific or policy-making meeting or national, regional or specialty medical or other professional association meeting.
- 4.6.1 The evaluation and selection of scholarship or travel grant recipients is the sole responsibility of Lifespan senior management and Medical Staff leadership with no involvement by Industry Representatives.
 - 4.6.2 To ensure transparency, periodically, the Continuing Medical Education offices, the hospital departments/divisions, and the physician foundations/groups (to the extent Lifespan Business is implicated) may be asked to provide the Lifespan Compliance Office with a listing of Industry provided scholarships/other financial assistance -- by vendor, amount, and documenting how and when used.
 - The purpose, terms and conditions associated with the scholarship/financial assistance must be documented in writing and maintained for five years.
 - 4.6.3 Payment, direct or indirect by an Industry Representative to a Lifespan employee or Medical Staff member to attend an educational conference, dinner, presentation, access a Website or engage in a similar activity, is not permitted unless the individual is a bona fide program faculty member or consultant.

4.7 Consulting/Training Arrangements:

- 4.7.1** Consulting arrangements are permitted if a legitimate need has been identified in advance of providing the services from the Lifespan employee, a signed written contract outlining the service is created, and bona fide expertise/service is provided at fair market value rates.
- Lifespan employees should review HR policy 3.9 entitled “**Outside Employment and Reimbursement by Outside Persons or Entities**” before entering into such consulting arrangements.
 - Lifespan employees and employed physicians and non-employed physicians serving in Lifespan leadership positions such as medical director, Chief of Service or on a Lifespan committee, should obtain approval from their respective Lifespan senior management member or Chief/Chair before entering into consulting arrangements with Industry Representatives.
- 4.7.2** Token consulting/advisory arrangements are not permitted. If a Lifespan employee or Professional Staff member provides genuine services to the Industry Representative, reasonable compensation for time and travel expenses can be given.
- 4.7.3** In-service training provided to Lifespan employees and Professional Staff relating to pharmaceuticals, supplies, equipment and systems is permitted if part of a Lifespan contract.

4.8 Speakers Bureau Participation:

Speakers’ Bureau is defined as any situation in which a Lifespan employee or Professional Staff member provide services as a speaker for industry and the arrangement has any of the following characteristics:

- *the company has the contractual right to dictate or control the content of the presentation or talk;*
 - *the company creates the slides or presentation material and has final approval over content and edits;*
 - *the employee or staff member is expected to act as the company’s agent or spokesperson for the purpose of disseminating company or product information.*
- 4.8.1** It takes considerable time and effort to determine if speakers’ bureau participation is part of an Industry marketing effort versus a legitimate

academic endeavor. Consequently, Lifespan employees and employed medical staff are prohibited from speakers' bureau participation.

4.8.2 Lifespan does not wish to expend its time and expertise reviewing speakers' bureau presentations for non-employed physicians who serve Lifespan as independent contractors. As such, if these individuals wish to participate in speakers' bureaus, they may not use their Lifespan title, their affiliation with, or name or logo of, Lifespan or its affiliates.

4.8.3 Periodically, Lifespan's Compliance Office will review Industry, federal and state websites, such as CMS Open Payments database, which document payments from Industry for speaker bureau participation, meals, gifts, scholarships and other similar items to ensure organizational transparency and policy compliance.

4.9 Industry Support of Clinical Fellowships:

Industry sponsored support for clinical fellowship positions are allowable but should be awarded only to the Graduate Medical Education (GME) office, not to hospital departments/divisions or physician foundations/groups.

4.9.1 Written criteria developed by GME must guide the solicitation, receipt and selection of the individual for this award. Industry Representatives will not participate in the selection.

- The purpose, terms, and conditions associated with each award must be documented in writing and maintained for five years.

4.10 Ghostwriting:

Lifespan employees and Professional Staff are responsible for publications that list them as authors. They may not permit their professional publications or presentations of any kind, oral or written, to be ghost written by any party, including Industry Representatives

4.10.1 Professional Staff are always responsible for the content of any presentations they give, including the content of the slides and handouts.

4.11 Pharmaceutical Samples:

The provision of free drug samples is a marketing practice designed to promote the use of these products and to influence physician ordering behavior. However, some patients receive a benefit via the receipt of these samples.

- 4.11.1** Formulary approved drug samples may be provided at the request of a physician for use in the ambulatory clinics, the emergency departments, and employed physician offices. Prior to an area initially soliciting samples, written permission from the Lifespan affiliate's Pharmacy Department must be obtained. (This provision does not apply to private physician's offices even if located on Lifespan property.)
- 4.11.2** Non-formulary drug samples may be provided to ambulatory clinics only if the clinical director has requested specific non-formulary drug samples for clinical evaluation or compassionate use and the Lifespan or hospital P&T Committee has approved the non-formulary drug samples prior to use,
- 4.11.3** Samples, both formulary and non-formulary, are prohibited in all inpatient areas.
- 4.11.4** Free samples given directly to Professional Staff are considered gifts and may not be accepted.

4.12 Pharmaceutical Representatives Non-permissible Activities:

- 4.12.1** Certain actions by a Pharmacy Industry Representative are strictly prohibited and will result in immediate corrective action.
- Misrepresenting, directly or indirectly, the current formulary status of drugs or promotion of non-formulary drugs or promotion of nonindicated uses of drugs in conflict with hospital policy, guidelines or restrictions or published materials setting forth indicated uses are prohibited.
 - Distribution, directly or indirectly, of unsupported superiority claims, false or misleading statements, omission of information (newly acquired or well known) about a serious risk of drug interactions, or distribution of reprints handed out that "cherry-pick" a study from all available publications on the subject are prohibited.
 - Provision, directly or indirectly, of comparative cost information on competitive products to clinicians unless cost data is previously verified and authorized by Pharmacy is prohibited.
 - Attendance at Lifespan Registry Boards, Tumor Boards, Morbidity & Mortality Conferences and similar types of meetings is prohibited.
 - Initiation, or partial or total completion, or offering to do so, of a Lifespan Request for Formulary Addition form is prohibited.
 - Obtaining or attempting to obtain P&T Committee meeting information, including dates, reviewer information, or discussions is prohibited.

V. Procurement Responsibility/Conflict of Interest Management:

All Lifespan pharmaceutical, medical supply and device purchasing decisions are the primary responsibility of Supply Chain Operations (Purchasing) and Pharmacy officials with input from significant individual physician users and supporting committees such as the Surgical Executive, Value Analysis, and Pharmacy & Therapeutics.

5.1 Purchasing, Pharmacy and Corporate Compliance officials have developed supporting practices designed to ensure that any individual involved in institutional procurement decisions⁷ disclose significant financial or other conflicts of interest⁸ with Industry. As example:

- All Surgical Executive, Value Analysis and P&T Committee members will periodically, but no less than annually, submit a Lifespan Conflict of Interest (COI) disclosure form. Ad hoc committees established to make major institutional procurement decisions will also complete COI disclosure forms or orally disclose conflicts which will be recorded in meeting minutes.
- Purchasing's Request for Proposal (RFP) process requires all vendors/manufacturers to disclose all business and personal relationships with Lifespan employees and medical staff; this information must be provided before Lifespan will enter into a formal purchasing agreement.
- Corporate Compliance has established a Lifespan Conflict of Interest database, which accumulates all disclosed and identified conflicts arising from association with Industry, including conflicts relating to sponsored research activities.
 - ⇒ The Lifespan Conflict of Interest database will include Industry published listings of payments to Lifespan employees and Medical Staff for speakers bureau participation, consulting, educational grants, etc.
 - ⇒ Purchasing and Pharmacy officials must document and retain evidence of their review of the COI database as part of an institutional procurement decision.
 - ⇒ Only individuals with manageable conflicts will be allowed to participate in the procurement process.

5.2 If a Lifespan employee or Medical Staff member has a financial or other conflict of interest with a vendor/manufacturer, and has the ability to impact Lifespan institutional purchases or formulary decisions related to that vendor's/manufacturer's products or services, the individual must disclose and

⁷Institution procurement decisions relate to entering into a system-wide or hospital arrangement or making available a product as a result of a formal request for proposal process and exceeding the competitive bid threshold of \$75,000; it does not include individual clinician level decisions on product use once an institutional decision to purchase or make available a product has been made.

⁸For the purpose of this policy, "financial and other interests" includes associated interests such as board membership, employment, research support and other financial relationships or situations in which influence over decisions can be exercised.

recuse⁹ him/herself from the final decision and leading the procurement effort. See Purchasing's Policy entitled, **Institutional Purchasing: Conflicts of Interest MM-150**, which describes the conflict of interest recusal process in detail.

- Professional staff expertise is essential to evaluate many products or services; in such cases the professional staff member must report his/her conflict to those individuals responsible for the procurement process. Conflicted professional staff are not precluded from participation, they may provide expert information and participate in discussions. They may not vote on the procurement decision.

VI. Industry Support for Research and Lifespan Fundraising Efforts:

Industry support for Lifespan research activities is encouraged. Lifespan's Office of Research Administration (401-444-5113) has established policies and processes to facilitate Industry support for basic and clinical research, which are structured not to contravene this policy.

Industry support in the form of unrestricted philanthropic gifts is encouraged and may be accepted by the Lifespan Development Foundation (401-444-7540), or through the various Lifespan hospital foundations.

VII. Infractions and Disciplinary Action:

Industry Representative access to Lifespan employees and Professional Staff is a privilege subject to adherence of the requirements and conditions in this policy. Two infractions during a calendar year by an Industry Representative may result in termination of visiting privileges for that Industry Representative involved for a period of 12 months. Repeated termination of privileges of one or more Industry Representatives of the same Industry company or related companies may result in a permanent cessation of privileges for the Industry company (and its affiliated entities) for an indefinite period.

VIII. Procedure:

If a Lifespan Employee or a Lifespan Professional Staff member has a *question concerning the interpretation or applicability* to a particular circumstance of any of the laws or regulations referred to in this Policy, such Lifespan Employee or Lifespan Professional Staff member should first consult with his/her supervisor(s) and if his/her supervisor(s) is unable to answer the question or provide any guidance, or if because of the circumstances it would be inappropriate to discuss the matter with his/her supervisor(s), then such Lifespan Employee or Lifespan Professional Staff member should contact either the Purchasing, Pharmacy, Corporate Compliance or General Counsel offices for advice. If any Lifespan Employee or Lifespan Professional Staff

⁹ Recusal is the act of removing oneself from the decision/judgment because of a conflict of interest.

member is aware of any violation or threatened or potential violation of this Policy, or *suspects* a violation of this Policy has occurred, such Lifespan Employee or Professional Staff member should contact Purchasing, Pharmacy, the Corporate Compliance Office or Office of General Counsel for instruction as to what action to take.