

**Lifespan System-wide Policy**

**Subject:** Clinical Conflict of Interest: Physician Disclosure and Patient Consent of Vendor Business Relationships

**File under:** CCPM-76

**Issuing Department:**  
Corporate Compliance

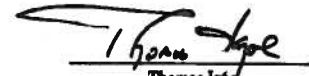
**Latest Review Date:**

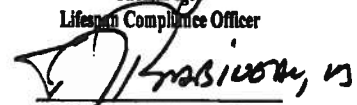
**Latest Revision Date:**

**Original Policy Date:**  
December 2013

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**Approved By:**

  
Thomas Igo  
Lifespan Compliance Officer

  
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Lifespan President & CEO

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**I. Purpose:**

At Lifespan the safety and well-being of our patients is paramount, as is our commitment to providing quality patient care consistent with the highest principles of integrity and ethical standards. This policy ensures that, prior to an invasive procedure, the Primary Surgeon fully discloses to the patient any Business Relationships with Commercial Companies that produce, manufacture, distribute, or otherwise provide medical devices, supplies, pharmaceuticals, or other medical care related products that may be used during the procedure (all capitalized terms are defined in Section 3.4, below)<sup>1</sup>. Lifespan recognizes that Business Relationships are often beneficial to the provision of health care, but we are committed to ensuring that they occur only in a transparent environment. As such, this policy ensures that the conflicts that arise from such Business Relationships are known to our patients and that they have the opportunity to question the Primary Surgeon prior to a procedure.

**II. Eligibility:**

This policy applies to all Lifespan medical staff who are conducting Lifespan's business of patient care as the Primary Surgeons during an invasive cardiac, general internal medicine, or surgical/diagnostic procedure. Lifespan's medical staff is principally composed of physicians who Lifespan either directly employ or those non employed physicians who admit and/or treat patients at Lifespan facilities (Medical Staff).

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<sup>1</sup> Payments relating to products and services not reimbursable by Federal health care programs are excluded from the scope of this policy.

### III. Policy:

Lifespan recognizes that collaborative Business Relationships between our medical staff and industry are vital to advancing and improving patient care and treatment. Physician services provided in the course of a Business Relationship can include, but are not limited to, consulting, faculty services, scientific advisory board membership, training, and product development. When medical staff provide such services, they should receive reasonable compensation from the Commercial Companies. The compensation can take many forms such as cash, stock, stock options, royalties, and partnership shares (See 3.4 for definition). Lifespan and its medical staff acknowledge that these relationships must be carefully scrutinized and managed to avoid conflicts of interest and improper inducements, whether real or perceived. Additionally, patients need to be advised of these relationships where that information may be pertinent to their treatment or informed consent.

#### 3.1. Patient Disclosure:

If a Lifespan physician has a Business Relationship with a Commercial Company that involves payments that total more than \$5,000 annually, individually or in aggregate, the physician must disclose to his/her patients the name of each such Commercial Company. Also, the physician must obtain the patient's written acknowledgment and consent that a medical device, drug, equipment, or other medical supply produced by one or more such Commercial Companies may be used during the procedure. Such disclosure shall be documented in the appropriate patient consent document which will be included in the patient's medical record<sup>2</sup>.

- 3.1.1 The attached model patient consent form **must** be used when obtaining consent. *See Attachment A.*
- 3.1.2 The patient consent form must be signed by both the patient (and the surrogate decision maker if the patient does not have the capacity to make the decision) and the Primary Surgeon prior to the invasive procedure being performed.
- 3.1.3 If a physician chooses to develop an addendum to the consent form for their own unique business relationships or multiple business arrangements, the addendum template must be approved by the Corporate Compliance Department; also the addendum **must** be used as a supplement to the patient consent form. i.e., the patient and the physicians must sign Attachment A.

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<sup>2</sup> Research and clinical trial payments are excluded from the scope of this policy; see Research Conflict of Interest Policy, CCPM #43.

**3.1.4** It is the primary responsibility of the respective Chief/Chair to ensure that Primary Surgeons are properly adhering to guidelines set forth within this policy.

**3.2 Acceptable Payments:**

Physicians who provide services to Commercial Companies should receive reasonable, fair market value compensation for their services. Lifespan physicians who collaborate or otherwise provide services to Commercial Companies shall ensure that compensation is based on the provision of tangible services.

**3.3 Unacceptable Payments:**

It is prohibited that any payments to Lifespan physicians be based on the use of a particular supply, pharmaceutical, equipment, device or other medical care related product when providing patient care. In the case of product royalties, physicians are not allowed to collect royalties based on the use of their product on Lifespan patients.

**3.4 Definitions:**

- A. "Business Relationship" means any relationship in which a Lifespan physician (or his/her immediate family member) has received, or is expected to receive, cash or something of value (including, but not limited to consulting fees, advisory board payments, product evaluation payments, royalties, intellectual property rights, honoraria, ownership interests e.g. stocks, stock options or other ownership interests, excluding stock in a diversified mutual fund not under the control of the physician) from a Commercial Company that produces, manufactures, or distributes a medical device, supply, pharmaceutical or other medical care related product that is recommended to, prescribed for, or used in, hospital patients.
- B. "Commercial Companies" are any entities involved in producing, manufacturing, or distributing a medical care related product such as device, supply, or pharmaceutical.
- C. "Primary Surgeon" in a typical surgery setting is the principal/attending surgeon during a surgical/invasive procedure, not the assistant, fellow, or resident.

This policy supplements existing Lifespan policies governing conflicts of interest and relationships with Industry Representatives<sup>3</sup>.

**IV. 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 Corporate Compliance or General Counsel offices for advice. If any Lifespan Employee or Lifespan Professional Staff 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 the Corporate Compliance Office or Office of General Counsel for instruction as to what action to take.

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<sup>3</sup> See Materials Management Policy MM-107 “Sales Representatives,” Materials Management Policy MM-150 “Institutional Purchasing: Conflict of Interest Guidelines” and Corporate Compliance Policy CCPM-46 “Interactions with Industry (From Pharmaceutical, Medical Device and Medical Supply Industries).”

- Rhode Island Hospital
- The Miriam Hospital
- Newport Hospital



**PATIENT CONSENT FORM – FOR USE WHEN SEEKING PATIENT CONSENT TO USE A MEDICAL DEVICE AND OTHER PRODUCTS PRODUCED BY A COMMERCIAL COMPANY FOR WHICH THE PRIMARY SURGEON HAS A BUSINESS RELATIONSHIP**

Lifespan is committed to providing patient care in accordance with the highest professional and ethical standards. Our organization and medical staff have derived significant benefits from collaboration with the pharmaceutical, medical device and medical supply industries within the areas of research, education, and patient care. However, such collaboration must occur in a transparent, non-biased environment where conflicts are disclosed and appropriately managed, costs are fair and patient safety protected.

Consequently, we are disclosing to you below (**or in the attached document**) that the Primary Surgeon responsible for conducting your surgery Dr. \_\_\_\_\_ has a business relationship with the following pharmaceutical/medical device/medical supply company (s):

- |          |          |
|----------|----------|
| 1. _____ | 4. _____ |
| 2. _____ | 5. _____ |
| 3. _____ | 6. _____ |

**See the attached patient consent document**

The supplies/drugs/equipment/medical devices created by these Companies **may be** used during your procedure. The Primary Surgeon’s business relationship may involve consulting services, product development, research, advisory, or training services.

The selection of the supplies, drugs, equipment or devices to be used in your care, and the care of all of our patients, is based only on what is the best for the patient, not on which company makes the product. Neither Lifespan nor its physicians are in any way compensated by the Commercial Companies for the use of supplies, drugs, equipment, or devices.

Please understand that you may refuse to give your consent (and signature) for the use of the supplies, equipment, or devices created by these Companies. If you are concerned about the use of any supply, drugs, equipment, or device, you should discuss this with your physician to determine whether alternative items can be used or whether you would like to be referred to another surgeon.

Please sign below that you have read and understand this Consent Form (or the attached), it has been explained to you, and questions about it have been answered to your satisfaction.

Date \_\_\_\_\_

\_\_\_\_\_  
Signature of Patient (or Legal Representative)

\_\_\_\_\_  
Print Patient’s Name

\_\_\_\_\_  
Print Name of Legal Representative (if applicable)

\_\_\_\_\_  
Relationship to Patient

**Physician’s Acknowledgment**

The undersigned confirms that patient consent, as described above, has been given by the patient. I have informed the patient that I have a business relationship with a company (s) whose supplies/drugs/equipment/devices may be used during the patient’s procedure. I have provided a description of said use above and have answered the patient’s questions fully. I believe that the patient/legal representative fully understands what I have explained.

\_\_\_\_\_  
Physician Signature/Print Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time