

**CONFLICT OF INTEREST
POLICY AND DISCLOSURE PROCESS**

Henry Ford Health System is a leading comprehensive integrated health system located in Detroit, Michigan with facilities throughout the Detroit Metropolitan area:

- **5 Hospitals**
- **600 plus member Henry Ford Medical Group**
- **24 Medical Centers**
- **Community Care Services Division including: ambulatory pharmacies, dialysis centers, hospice, dme, skilled nursing facilities, home health, eye care centers**
- **Health Alliance Plan (HAP) Health Plan**
- **17,000 total employees, approximately 2,000 of these having potential for significant conflict of interest**

Code of Conduct: “... employees must refrain from *outside activities* or *personal interests* that *result in* or *appear to result in* a conflict of interest and must maintain the highest standards of business ethics.”

Individual Conflict of Interest is defined as a situation in which:

- An individual's outside activities or personal interests influence or appear to **influence his/her ability to make objective decisions** for his/her primary employer.
- Official position and/or influence at the primary employer is used to gain an **improper advantage**, economic or non-economic, for the individual or for family members, vendors, patients, customers or associates
- External commitments burden or interfere with the individual's primary obligations and **commitments** to his/her primary employer.

Institutional Conflict of Interest arises when the mission of an organization may be compromised because of an external financial or business relationship held at the institutional level that may bring financial gain to the institution, any of its units, or individuals employed by the institution.

Concern about conflict of interest arises from our need to:

Achieve a High Standard of Corporate Responsibility: Assure ourselves and the public that our trustees, employees and all others acting on behalf of our organization are free from conflicts as they perform their duties and make important decisions on behalf of our organization.

Achieve our Mission: Conduct biased by personal interests may not be in support of the organizational mission, vision and values; it may only be in support of personal mission. Such bias can affect patient care and the financial well-being of an organization and if not evaluated and/or managed, it may result in choices or actions that are incongruent with the organization's mission, vision and values.

In a 2005 Survey of ~ 1,500 physician executives by the American College of Physician Executives (ACPE), the percentage of physician leaders either “very concerned” or “moderately concerned” about these practices are as follows:

- Physicians influenced by medical device companies to perform certain procedures 79%
- Physicians influenced by pharmaceutical companies to prescribe certain drugs..... 76%
- Board members with conflicts of interest 66%
- Non-physician executive leaders with conflicts of interest 66%
- Physicians being paid to make promotional pitches for vendors 63%
- Physicians accepting gifts from vendors 60%
- Board members accepting gifts from vendors 56%
- Non-physician executive leaders accepting gifts from vendors 56%

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Jerome P. Kassirer, in his 2005 book: *On the Take – How Medicine’s Complicity with Big Business Can Endanger Your Health*:

“Away from the eyes of the public, the pharmaceutical industry captures the loyalty of physicians with gifts and lavish meals, pays them as consultants (even though they may do little or no consulting), funds their research, and pays for the expenses of their continuing education.... Trinkets bloom into meals at fine restaurants; meals grow into speaking fees; speaking fees morph into ongoing consultations and memberships on drug company advisory boards-positions that command up to six figures per year.”

Dana J. Lowenstein, in “A Social Science Perspective on Gifts to Physicians from Industry,” *JAMA*, 2003, states:

“...the impulse to reciprocate for even small gifts is a powerful influence on people’s behavior. Individuals receiving gifts are often unable to remain objective; they reweigh information and choices in light of the gift.”

Compliance with the Law

The Federal Anti-Kickback Statute: criminal prohibition against payments (in any form, direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care program Business

The Stark Laws. seeks to prohibit referrals by physicians of Medicare or Medicaid patients to facilities in which the physician has an ownership interest or from which the physician receives compensation.

General Guidance Provided to Employees:

All decisions made by you on behalf of the organization must be free from personal bias. As you carry out your daily responsibilities, you should always guard against placing yourself in situations that have potential to influence the objectivity required by your role. For example:

- If you stand to gain from the sale of a product, you must take yourself completely out of the role of decision maker or influencer regarding that product.
- If you are on the Board of another organization, you must abstain from discussion and vote on matters impacting our organization.
- If you purchase or influence the purchase of a product or service, you must not accept significant gifts or excessive entertainment from that vendor.
- When in doubt, seek guidance and approval from management or the Compliance Office in advance and disclose the interest or activity using the conflict of interest disclosure process.

Risk Areas to be Addressed by a Disclosure Statement:

1. Employee or a family member has a personal ***significant financial interest*** in a vendor and employee also *interacts* with the vendor in his/her employee role.
2. Employee or a family member has a ***compensated arrangement*** with an outside organization:
 - token arrangements
 - excessive compensation
 - excessive commitment (conflict of commitment).
3. Employee has a ***personal or family relationship*** with someone who owns or is employed by a vendor when the employee or the relationship or both stand to gain personally.
4. Employee accepts ***items or services of value*** from a vendor and also *interacts* with the vendor in his/her employee role.

5. Employee holds a ***board membership*** of an outside organization and actively participates in decisions potentially impacting the employer.
6. Employee or family member enacts ***transactions with the employer*** and the employee has control or influence over decisions related to the transaction.
7. Employee is involved in making decisions that directly affect the hiring process or other employment-related decisions pertaining to a family member (**nepotism**).
8. Employee obtains ***intellectual property rights*** by making, conceiving, developing, contributing to, improving or deriving a device or process as a result of the employee's contractual, employment, appointment or other relationship with the employer.

9. Researcher, involved in *sponsored research*:

- personal financial interest in sponsoring organization
- consulting or speaking arrangement
- education support funds
- gratuities or special favors related to research duties
- payment above the accepted norm
- results held confidential, unpublished, or significantly delayed
- access to information
- equipment purchases
- negotiation of contracts

Why a disclosure process?

Many situations and issues involving ethical or moral judgment do not readily reveal the right course of action with certainty.

Individuals should not rely solely on their own judgment but shall seek prior approval and/or shall disclose certain matters to those responsible for administering conflict of interest policy.

The organization seeks to identify and resolve conflict of interest or the appearance of conflict of interest before it becomes a problem.

Disclosure Process Overview

- At the time of appointment/hire/contracting and annually thereafter, trustees, employees in “selected positions” shall file a disclosure statement.
- As new conflicts arise, employees should complete a Disclosure Statement
- The requirement should be consistent for all trustees, employees and others acting on behalf of the organization.
- The process should be easy to use and facilitate full disclosure by all requested employees.
- Disclosure questions must include all relevant conflict risk areas.
- The review process should be formalized through a panel of reviewers with escalation if required.

Positions Requiring Disclosure Upon Hire and Annually Thereafter

- Members of the Boards of Trustees
- Senior Executives and their direct reports
- Employed Medical Chairs, Medical Directors and Staff Physicians
- All employees involved in the review of conflict of interest
- Employees having authority for recommending or enacting purchases
- Key Researchers
- Individuals with the authority to authorize payment to outside parties
- All employees not listed above in the position of “Manager” or higher
- Any other employees determined to have outside interests that could be in conflict with organizational interests.
- Any agents, volunteers or contractors acting on behalf of the organization whose role has conflict of interest potential.

1. Information for all individuals in positions requiring disclosure gathered

- Employees: "manager" or higher
- Direct reports to Sr. Executives
- All employees of Philanthropy, Audit, Legal, Compliance, Purchasing
- All other employees who purchase goods or services
- Key Researchers
- Non-employees (agents, volunteers, contractors) who act on behalf of the organization
- Other employees having potential for conflict of interest

2. Disclosure Form Completion Requested

E-mail notice sent to selected employees instructing them to access web-based policy statement and disclosure form and complete questions within specified deadline

3. Disclosures Acquired, Screened, Reviewed and Filed

Automated follow up notices sent as necessary at intervals until disclosure submitted. If necessary, escalation to manager

As soon as submitted, completed disclosure information is transmitted from web site to Compliance. All new disclosures reviewed regularly; those without substantive disclosures filed.

For substantive disclosures, Chief Compliance Officer reviews, investigates, then appointed panel reviews until resolved or escalated to CEO

Trustees

- Subcommittee appointed by the Board of Trustees
- If unresolved, review by Executive Committee of the Board. Decisions of the Executive Committee considered final.

Employees

- “Conflict of Interest Review Panel:” chaired by the Chief Compliance Officer or designee and staffed by representatives of Legal, Human Resources, Purchasing and any additional member(s) deemed necessary.
- If unresolved, review by Chief Executive Officer, whose decision is final. Should the issue under consideration involve the Chief Executive Officer, the matter is reviewed by the Audit and Compliance Committee of the Board of Trustees.

A. Generally Acceptable

- Do not compromise, have the potential to compromise or give the appearance of compromising mission.
- Generally minimal in their personal financial impact

B. Requires Examination and Possible Action

- May compromise, have the potential to compromise or give the appearance of compromising mission.
- May be acceptable with disclosure, and, where appropriate, review and approval, and management.

C. Generally Not Acceptable

- Generally not permissible: involves significant potential conflicts or presents obvious opportunities to favor personal interests.
- May be approved with substantial management or monitoring plans.

Establishing Criteria

- Guiding Principle
- Definitions
 - Conflict of interest, compensated arrangement, employee, excessive, family member, fair market value, vendor, items of value, business entertainment, gift, etc.
 - Dictionary definitions
 - Context definitions
- Categories
- Limits
 - What is occasional? Excessive? Extravagant? Genuine? Etc.

Compensated Arrangement Disclosure:

I was asked to speak at a vendor sponsored conference. The Vendor paid my travel, hotel room and all my meal expenses. I received an honorarium for the presentation.

Additional Information Required for Review:

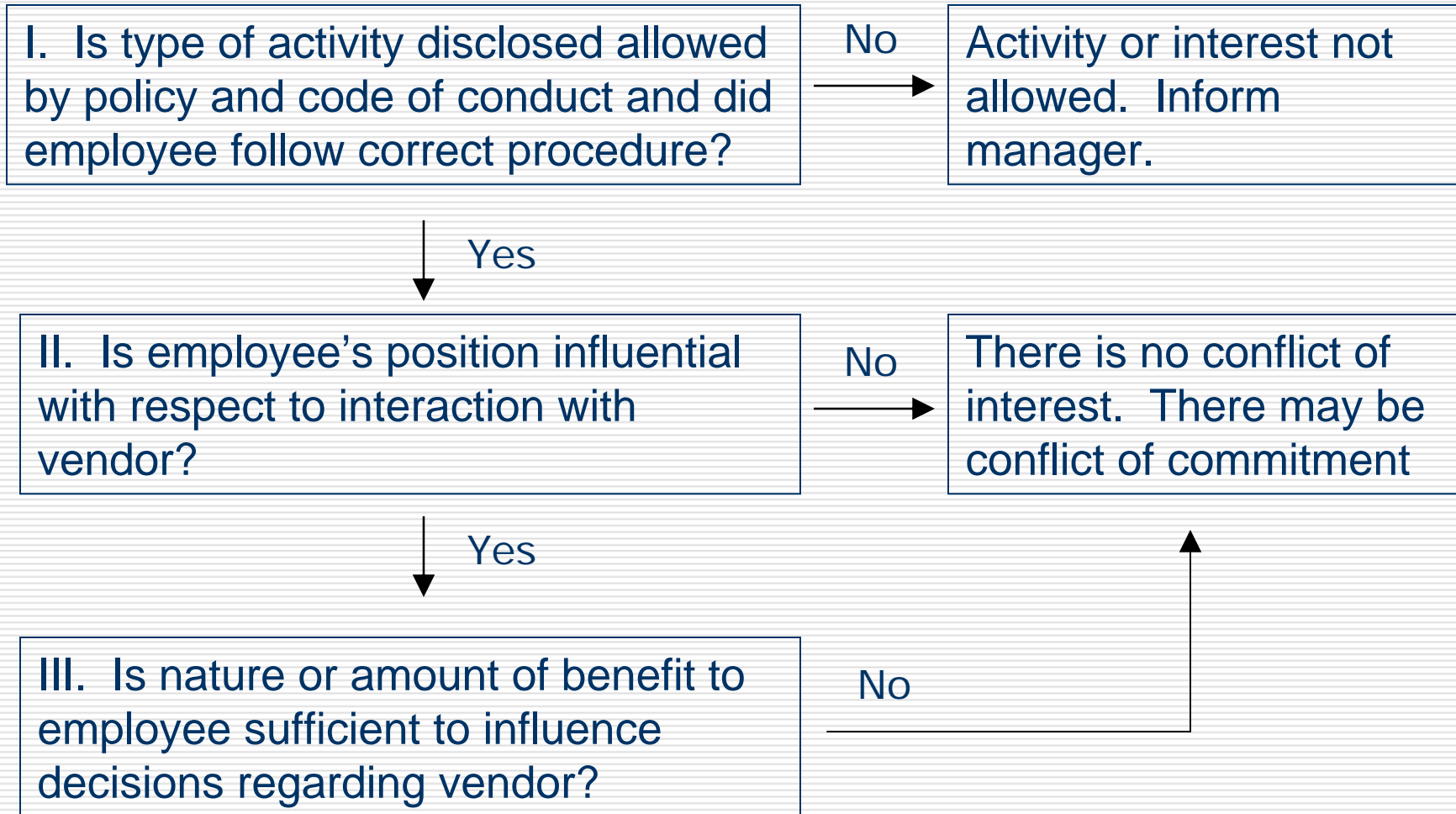
- Vendor name and products/services provided
- Employee's role in organization and interaction with vendor in this role
- Nature of the services performed
- Location where services performed
- Frequency of services
- Type and amount of compensation, including expense reimbursement
- Written agreement for this arrangement/activity
- Use of company resources, if any.

Compensated Arrangement Review Criteria

<p><u>Acceptable</u> Employee is qualified for and <u>occasionally</u> provides a <u>genuine</u> service to an outside organization. Compensation for these services is <u>reasonable honoraria &/or reimbursement for travel, lodging and meal expenses.</u></p>	<p><u>Requires Review</u></p> <ul style="list-style-type: none"> • Employee may not be qualified and/or activity may not be needed • Compensation for any one service may be in excess of fair market value • Employee’s total annual activity for any single company > 5/year and/or a total of \$10,000 • Employee’s total annual activity for all outside companies exceeds 12 and/or \$20,000. 	<p><u>Generally Unacceptable</u></p> <ul style="list-style-type: none"> • Arrangement is clearly a “token” consulting or advisory arrangement • Total annual compensation from any single vendor, including travel/lodging reimbursement, has the potential to influence the employee’s decisions • Level of outside commitment burdens or interferes with primary obligations and commitment • Employee influences, reviews, approves, or administers control over contracts or business relationships with business in which he/she has a compensated arrangement.
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Conflict of Interest Disclosure Process

Review Panel Process



↓ Yes

IV. Employee has a significant conflict. Resolve with employee's direct management.

Direct employee to discontinue outside relationship/activity

Discontinue relationship with outside organization.

Establish management plan to monitor relationship/activity so as to eliminate risk.

Reporting

- To Trustee, Employee**
- To Employee's Manager**
- To Senior Management**
- To the Board of Trustees**

Compensated Arrangement: An arrangement through which an employee receives or has the right or expectation to receive remuneration from an outside individual or organization, e.g.: consultant; expert witness; speaker.

Employee: All trustees, employees; and non-employees who act on behalf of the employer, including volunteers, contractors and subcontractors; and organizations acting or speaking on behalf of the employer.

Excessive: In this context, an item or service provided by a vendor that is not customary and may create an appearance of impropriety; may impose a sense of obligation on the receiver; could result in special or favored treatment or could be considered extravagant, or too frequent considering all of the circumstances.

Fair Market Value: The amount expressed in terms of money, as of a certain date, that may reasonably be expected to exchange between a willing buyer and a willing seller, with equity to both, neither under any compulsion to buy or sell, and both fully aware of all relevant facts.

Family Member: (defined by the organization)

Financial Interest: includes direct or indirect ownership positions; debt or equity interests; and ownership of options or other convertible rights.

Vendor: Company, organization or individual that: conducts or seeks to conduct business with employer; provides research funds to employer; has made donations to employer or from whom employer is actively soliciting donations.

Intellectual Property Rights: Ownership of the rights to intellectual property, being the outputs of creative endeavor capable of being protected by patents, design rights, trade marks, or copyrights.

Items of Value

- **Gift**: Item or service provided to an employee conferring personal benefit for which the employee does not provide goods/services of equal or greater value.
- **Prizes or Awards**: An item or service of value provided to an employee as a result of such events as contests, raffles, or door prizes.
- **Loans**: Provision of cash or an item of value where repayment is required.
- **Business Entertainment**: Invitation to a social activity where the vendor is present and the activity facilitates the business purpose of the relationship.
- **Items Purchased at a Discount**: Item or service purchased from a vendor at a reduced price when not part of an official program agreed to between employer and vendor for all employees.

Sponsorship: Support of an event benefiting either employer or an individual employee.

Travel or Lodging Expense Reimbursement: payment by a vendor to an employee reimbursing travel, lodging and meal expenses incurred.

Product Evaluation Trip: Travel for the purpose of receiving a demonstration of a product/service as a step in the decision making process regarding possible acquisition of that product or service.

Product Education Trip: Travel for the purpose of receiving training for an already acquired product or service, usually agreed to by execution of a purchase or lease contract.

Nepotism: Favoritism shown or patronage granted to relatives.

Personal or Family Relationship with an HFHS Vendor: Relationship between employee or family member and a person who owns or is employed by a vendor.

Researcher: Research principal investigators, grant or contract managers, and other key members of the research team.

Sponsored Research: Research, training, educational, and instructional projects (such as clinical trial agreements, grants, and contracts) involving funds, materials, or other compensation from outside sources

Questions