



SAINT LOUIS UNIVERSITY

POLICY ON MEDICAL CENTER CONFLICTS OF INTEREST IN PATIENT CARE AND SERVICE

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Responsible University Officials: Deans, Assistant Vice President Medical Affairs, Vice President Medical Affairs, Medical Center

1.0 INTRODUCTION

1.1 Conflicts of Values may exist between the professional ethics of health care professionals and the business ethics of the health care products industry. Such conflicts may arise in connection with promotional activities, through financial support for a broad array of educational programs, industry-sponsored research, and social events. These activities may influence medical decision-making and have biasing effects which impact patient care.

1.2 Faculty, fellows, residents, students, other trainees, and staff develop and demonstrate professional values in the learning environment created by the Medical Center and its affiliated healthcare facilities. Activities condoned in this learning environment therefore have a direct bearing on the “learned” professionalism of all health professions trainees.

1.3 Health professions organizations and regulatory agencies have increased their scrutiny of both industry and physicians. Health care products companies are expected to report nearly all money, gifts, and travel that they offer physicians and institutions and post this information on publicly searchable websites.

1.4 This policy sets forth standards consistent with the University’s commitment to continually strive for the highest standards of professionalism while actively seeking engagement with the industries impacting the health care system. This policy is intended to supplement the University’s Conflicts Policies which include the Conflict of Interest in Research Policy.

2.0 PURPOSE

2.1 The purpose of this policy is to define specific Conflicts of Values between the professionalism and patient centeredness of the health professions and the business ethos of the health care products companies, and the biases which are created by interactions with representatives of those companies.

2.2 The policy further describes the necessity for the reporting, tracking, and monitoring of certain interactions between Medical Center personnel and these companies; and proscribes or

limits certain activities which may impact decisions relating to patients, community service, and health professions education and research to protect the learning environment and guard against conflicts of interest in patient care and service

2.3 These policies are not meant to discourage the development of business relationships intended to foster clinical or basic investigation and education that might be supported by health care products companies. It is recognized that Medical Center faculty will be involved in relationship building with such companies to support a variety of research and educational programs. Sections III.G.6 & 7 of the Faculty Manual pertain to these interactions.

3.0 PERSONNEL AFFECTED

3.1 Health professions faculty (especially physicians) and clinical and investigative support staff. This includes all categories of faculty, and staff (e.g. part time, full time, adjunct, etc.).

3.2 Health professions trainees at the undergraduate, graduate, and post graduate level; including graduate medical education trainees (e.g. residents and fellows).

3.3 Support staff for clinical, educational, and research programs of the Medical Center

3.3 Medical Center Administration

3.4 Health care products companies and their representatives seeking to do business or having any constructive interactions with any academic unit of the Medical Center, individual faculty, staff, administrative support personnel, and trainees at all levels.

4.0 DEFINITIONS

4.1 Health Care Products Company (or Companies). A company, or a group or class of companies, including their respective representatives, which investigate, develop, produce, market, and sell treatments, goods or services used in the care of patients, groups of patients, and community health programs.

4.2 Conflict of Values. Any interaction with health care products companies which calls into question the patient centeredness of actions for patients and health professions trainees, or creates the perception of bias. These interactions include, but are not limited to, circumstances which could create both Conflicts of Interest and Conflicts of Commitment

4.3 The Learning Environment. The educational, investigative, and clinical settings in which health professions trainees learn, and observe interactions with patients, and might encounter representatives of the health care products companies.

4.4 Industry Support. Any and all gifts, promotional materials (including samples), food, and monetary or other resource support for travel, education, presentation, investigation, consulting, or representation provided or funded by health care products companies. Additional examples of Industry Support will be appended to this policy as necessary and listed as an Exhibit.

4.5 Conflict of Commitment. A Conflict of Commitment occurs when the time devoted to extramural activities interferes with a person's obligations and commitments to the University.

4.6 Conflict of Interest. For purposes of this policy, a "Conflict of Interest" shall have the same meaning as the term defined as in the Conflicts Policy, In the context of this policy it is explicit that the University has a compelling interest in the creation of a learning environment free of conflict of values and the perception of influence and introduced bias from health care products companies.

5.0 POLICY

Any support received from a health care products company ("Company") by an individual faculty member, trainee, staff, or division, department, or academic unit of the Medical Center ("Recipient") creates a dual responsibility on the part of that Company as well as the Recipient to disclose and log the interactions. The Medical Center administration has the responsibility to monitor those interactions through a quality assurance process which will include developing and implementing practical procedures for monitoring, setting thresholds for required reporting, sharing data and educational programs with the academic units, and reporting the outcomes of this monitoring, analysis, and education to the University.

Some interactions are inherently biasing, or cannot be made acceptably free of actual or perceived Conflict of Values. These interactions may inherently compromise the integrity of the learning environment, and cannot be allowed. Further specifications of non-allowable interactions, and limits or acceptable methodologies for allowable interactions include:

5.1 Personal Compensation from Industry. Personal compensation includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) and may be arranged between the University personnel and the health care products company without University involvement. Personnel are expected to abide by University policies regarding Conflict of Commitment and the University Faculty Manual in accepting such relationships, as well as the expectation that they will disclose such relationships to Medical Center Administration as required in **7.2. Reporting Requirements for University Personnel.**

5.2 Gifts from Industry.

- Gifts of any value from health care products companies can unduly influence physicians' prescribing patterns. Accordingly, no gift of any value can be accepted.
- Proposed educational materials and donations should fall under and abide by stipulations of **5.4. Educational Grants from Industry.**

5.3 Food Provided by Industry. Food is a type of gift and thus represents the same challenges to health professionals. Food is perceived as enabling lunch or dinner meetings, and as a motivational tool for encouraging trainee attendance at valuable education sessions.

- Accepting food directly from or through the direct support of a health care products company is prohibited.
- Accepting food or food support in educational settings may be allowable with the following stipulations. All food or food support must be reported, and:
 - Food or food funding must be donated as an unrestricted educational grant:
 - Anonymously from multiple sources, so that no single company is associated with a particular educational session, or

- To a central food fund, control of which is up to the discretion of the School or other academic units within the Medical Center.
- Donors of food or funding may be recognized periodically as a group, to maintain individual anonymity but still receive recognition for donations.
- At Non-Saint Louis University national meetings, CME meetings accredited by the ACCME, and other national or international meetings with public records, food provided by health care products companies may be accepted only when the registration forms submitted by the faculty, trainees, and staff document this support. Under these circumstances, receipt of food will be considered reported by registration processing.
- Provision of anonymously donated food or food related support at a Saint Louis University School of Medicine sponsored event or an event organized at least in part for School of Medicine faculty, trainees, and staff must be requested and approved at least four (4) weeks in advance of the intended use. Food cannot be provided at events with a single industrial sponsor because the source of the donation would be inferred by association.

5.4 Educational Grants from Industry.

- There is a need for educational funding from the health care industry. Accepting educational grants is acceptable if:
 - These grants are unrestricted, or restricted to the educational purpose specified by the school or the Medical Center.
 - The funds go directly to the school, or the department (with oversight by the school). The funds may go directly to a division only with oversight and prior approval by the department and the school.
 - They are of legitimate educational merit (and would meet external scrutiny by a non specialist).
 - Individual faculty members, trainees, or staffs are not direct recipients of these funds.
 - Indirect beneficiaries (or their training programs) of grant funding or educational support through this mechanism are not under any expectation of reciprocity.
 - All health care products company educational grants are reported.
 - Individuals must disclose all related conflicts of interest in presentations.

5.5 Funds for Travel to Conferences.

- Accepting this support is allowed only if:
 - They follow all provisions of **5.4. Educational Grants from Industry** and the funds support only conference presenters.
 - Support for conference attendees is prohibited unless the conference is part of a training, general education or faculty development program approved in advance by the program, department, and the school.

5.6 Medication Samples and Supplies. There is a well documented alteration of prescribing patterns due to pharmaceutical sample use for patients, and by individual faculty, students, residents, fellows, trainees, and staff use of sample medications. Medication samples or supplies may significantly benefit some patients in the short term who might otherwise be unable to afford these items, or not be able to obtain the medications for other reasons.

- Accepting medication samples or health care products supplies is allowed only if:

- They are distributed to patients directly (or to their caregivers); and
- They are distributed through a voucher system or under the oversight of pharmacist (if these are available).
- Personal use of pharmaceutical samples by faculty, staff, students, residents, fellows, trainees and other University personnel is prohibited.
- Industry representatives must provide regular reports regarding the type and number of samples medications provided and must report all interactions with faculty, trainees, and staff as part of their sampling.

5.7 Industry Sponsored Presentations. Industry sponsored presentations are allowed only through the previously outlined criteria for unrestricted educational grants. Refer to Section **5.4. Educational Grants from Industry.**

5.8 Publications.

- Individuals are prohibited from attaching their names to articles or materials written wholly or in part by health care products company employees (“ghost writing”) unless their own personal contributions warrant authorship.
- Individuals must disclose all related conflicts of interest in scholarly publications.
- In all other situations, the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements should be followed.

5.9 Interactions with Industry Representatives.

- Industry representatives are allowed to meet with faculty and staff only:
 - By appointment, and
 - In specific, non-patient care areas.
 - Signing for medication samples requires physician-representative interaction, which occurs most often in patient care areas. The faculty may sign for samples; however, marketing or detailing activities during this interaction are explicitly prohibited.
- Trainees may not meet with industry representatives without a faculty member present. Health care products company representatives may not provide information regarding pharmacological or device treatment of diseases unless “counter detailing” is available from a faculty or staff member. This prohibition applies both on campus and during “duty hours” and off campus and on trainees’ own time.

5.10 Formulary or Equipment Recommendations.

- All members of a resource decision-making committee must annually disclose financial, research, or educational Conflicts of Interest.
- Any decision-maker with a direct Conflict of Interest associated with a certain product should excuse him or herself from that decision making process.
- Medical Center faculty, trainees, and staff and all SLUCare providers must adhere to the policies and procedures of their affiliated institutions regarding industry representatives marketing for products not listed on those hospitals’ and health care facilities’ inventories and formularies.

5.11 Curricula on Physician-Industry Interactions. All faculty, students, residents, trainees and staff should receive training as recommended by the pertinent Curriculum Management

Committees, the Graduate Medical Education Committee, pertinent faculty and school committees of the faculty, and the Continuing Medical Education Office.

5.12 Distribution of Promotional Items by Industry Representatives. These activities are prohibited, unless items comply with **5.4. Educational Grants from Industry**. They may not occur away from the workplace or training site. If such promotional materials are made available to trainees, such distribution should be accompanied by counter detailing by a member of the faculty or staff.

5.13 Compensation for Listening to Industry Representatives, Changing a Patient's Therapeutic Plan, or for Providing Lists of Patients to Industry is Prohibited.

5.14 Compensation for Clinical Trials. Compensation for clinical trials is subject to the specific terms of the relevant contract. In general, however:

- Expenses must
 - Cover only direct and indirect costs to the University.
 - Be part of a study budget and proportionate to the value of the clinical trial.
 - Be reported through approved mechanisms
 - Acceptance of “fat” payments or extra funds provided purely as incentive to enroll patients is prohibited.
- **Study-Related Travel/Meetings.** Allowed, but compensation must
 - Cover only business expenses routinely covered by University travel policies.
 - Be required by sponsor for regulatory or educational purposes.
 - Be reported

5.15 Industry Representatives Attending Professional Conferences

- Health care products company representatives are prohibited from attending professional conferences unless the conference is open to the general public.
- If the conference is open to general public, marketing activities by health care products company representatives at these conferences are prohibited.

5.16 Charitable Contributions. Charitable contributions made by health care product companies on behalf of the Medical School faculty member, or in the name of the faculty member, should be considered a gift. Charitable contributions include any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services. Charitable contributions follow all provisions of **5.2 Gifts from Industry**.

5.17 Royalty or License Fees. The receipt of royalties or license fees from a health care products company associated with intellectual property owned, or partially owned, by the Medical School faculty member, should be considered personal compensation and follow all provisions of **5.1 Personal Compensation**.

5.18 Ownership or Investment Interest. Any ownership in a health care products company by the Medical School faculty member, as well as investment interest received by a health care products company, should be disclosed to the Medical School Administration according to the provisions of **7.2 Reporting Requirements for University Personnel**.

6.0 RESPONSIBILITIES

6.1 Faculty. It is the faculty member's responsibility to abide by the prohibitions and stipulations contained in this policy. Faculty must be sufficiently aware of the Conflict of Values that they can provide education and role modeling about the risks and necessity of avoiding the perception of bias in caring for patients, medical decision making, and providing service to patients and communities. The faculty must report certain interactions with health care products companies. Thresholds for reporting will be developed as part of this Policy by the **Committee on Oversight of Health Care Professional Conflicts of Interests. (7.5).**

6.2 Academic Units. The chair or comparable administrator has responsibility for educating faculty, trainees, and staff regarding this policy and assuring timely reporting of interactions. The academic units must participate in the collection, benchmarking, and analysis of interaction data to assess the potential for Conflict of Values; and intervene to enforce policy and improve procedures. They report through their Dean to the **Committee on Oversight of Health Care Professional Conflict of Interests (7.5)**

6.3 Deans. The Deans (or their designated representatives) have responsibility for enforcing policy, supporting timely collection of data, specifying appropriate benchmarks for health care products company interactions, and directing interventions and curricular initiatives as a result of analyses of these interactions. The Deans assure the overall integrity of patient care, service and trainee learning environments. Academic units report to the Vice President, Medical Affairs for the Medical Center through the **Committee on Oversight of Health Care Professional Conflict of Interests (7.5).**

6.4 Vice President, Medical Affairs, Medical Center. The Vice President for Medical Affairs provides oversight to the Medical Center Deans and/or designees regarding this policy and the overall quality management of interactions with health care products companies. The Vice President, Medical Affairs receives regular reports from the **Committee on Oversight of Health Care Professional Conflict of Interests (7.5).** The Vice President, Medical Affairs assures the overall integrity of the Medical Center's educational, clinical, and research programs in reference to this Policy. The Vice President, Medical Affairs is responsible for reporting to the University Board of Trustees through the Clinical Affairs Committee of the Board.

7.0 PROCEDURES

7.1 Reporting Requirements for Health Care Products Companies. Health care products companies must register with the University, and log each interaction with the University and any and all of its administration, faculty, trainees, and staff. Such logs must indicate the date and time of the interaction, its purpose, exchange of resource of any sort, specification of the value of the resource, and the recipient of this resource. Failure to register and to log interactions fully and completely will result in those health care products companies and/or their representatives being barred from interacting with any Saint Louis University academic unit or personnel for a period of three to twelve (12) months. Repeated failure to register and log may result in permanent interdict for such health care products companies and/or their representatives.

7.2 Reporting Requirements for University Personnel. University personnel, including all, faculty, trainees, staff, and administrative personnel must log all interactions with representatives of health care products companies over a threshold value (set by the **Committee on Oversight of Health Care Professional Conflict of Interests (7.5)**). For group activities (such as educational conferences) the log may indicate participation by an attendance list which indicates

the primary point of contact person for the Company representative. Such logs must indicate the date, time, and purpose of the interaction. Failure to log such interactions will constitute a failure of professional and job responsibilities, which will trigger the specific faculty, trainee, or staff policies and procedures for corrective actions.

7.3 Recordkeeping. See documentation software and associated systems, administered as necessary by the Committee on Oversight of Health Care Professional Conflict of Interests; supported as a component of Medical Center Office of Continuing Medical Education (CME) in collaboration with the Office of Research Administration

7.4 Departmental and School Review. At regular intervals, academic and working units of the Medical Center will review aggregated interaction report logs, internally benchmarked across all Medical Center units, and referenced against logs of registered health care products company representatives with associated variance reports. Outliers and significant variances will require further specific review. Interactions or patterns of interactions which are potential violations of this policy, or which create the perception of systematic bias in a working group will be further investigated, and interventions to remediate will be designed and delivered to include education and more frequent regular monitoring.

7.5 Committee on Oversight of Health Care Professional Conflict of Interests. This committee appointed by the Vice President, Medical Affairs, Medical Center shall meet, review data, deliberate, analyze, and provide guidance and recommendations for Medical Center academic units. The Committee will recommend thresholds for reporting; develop procedures for assessing the adequacy of monitoring, reporting, interaction benchmarking, educational programs, interventions, and make recommendations to the Vice President, Medical Affairs.

7.6 Vice President's Review. The Vice President, Medical Affairs (or designate) will review aggregated reports from the Committee and direct and approve the recommendations, as well as direct or approve of the development and delivery of curricular material regarding professional ethics and the appropriate interaction with Health Care Products Companies. The Vice President will coordinate and collaborate with Research Administration and the Compliance Office regarding any necessary individual or unit conflict management plans.

8.0 REFERENCES

8.1 The Accreditation Council for Continuing Medical Education (ACCME) mandates in their **Standards for Commercial Support** that all those “involved in the development and presentation of CME activities must disclose relevant financial relationships with commercial interests and that anyone who refuses to disclose is disqualified from planning or teaching CME activities.” This applies to all extramural health care professionals who participate in CME activities offered by the School of Medicine.

8.2 White Paper: The Report of the Task Force on Relationships between the Healthcare Products Industry and Physicians, December, 2009.

8.3 PhRMA Code

8.4 Industry Funding of Medical Education *Report of an AAMC Task Force*

8.5 Conflict of Interest in Research

8.6 Centers for Medicare and Medicaid Services, 42 CFR Parts 402 and 403: Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests (Sunshine Act)

8.6 Conflict of Commitment Policy

8.7 Interaction with Medical Technology Representatives Procedure for School of Medicine Notification

APPROVAL SIGNATURES

This policy was reviewed by the Office of Legal Counsel, CADD, and the Faculty Senate on September 17, 2014.

This policy has been approved by:

**Philip O. Alderson, M.D.
Dean, School of Medicine
Vice President, Medical Affairs
Saint Louis University Medical Center**