

HOWARD UNIVERSITY POLICY

Policy Number: 100-001
Policy Title: RELATIONSHIPS WITH INDUSTRY- HEALTH SCIENCES
Responsible Officer: Provost and Chief Academic Officer
Responsible Offices: Office of the Provost and Chief Academic Officer
Effective Date: July 27, 2011
May 29, 2012 - Conforming Revisions

I. POLICY STATEMENT

Principled relationships between academic health centers (AHC) and industry can promote patient care, biomedical research, information transfer, and education. For purposes of this policy, “Industry” includes, but is not limited to pharmaceutical, device, equipment, biotechnology, service, software, supplies, biomedical investment, and for-profit educational companies, and foundations sponsored by companies such as drug and device companies.

It is the policy of Howard University Health Sciences (HUHS) to manage, reduce, or eliminate any conflicts of interest that are identified. Howard University Health Sciences must strive to avoid even the appearance that clinical care and business decisions are influenced by outside commercial interests, or by benefits expected or received from industry. Such influences by industry are unacceptable and unlawful, and as such shall be strictly governed by Howard University Health Sciences in the best interests of our patients and the preservation of the integrity of the institution.

II. RATIONALE

Research has shown that gifts, no matter how small, may influence behavior in favor of the donor. For purposes of this policy, “Gifts” are considered anything of value provided by or on behalf of industry, including but not limited to charitable donations, food, beverages, tickets to sporting events, entertainment, hospitality, pads, pens, stethoscopes, journals, textbooks, pharmaceutical or device samples, or travel related expenses. Health care providers who receive gifts therefore may unintentionally or subconsciously consider factors that are extraneous to or in conflict with patient care considerations.

Legislators and medical organizations, including the Association of American Medical Colleges, have called upon AHCs to develop and implement guidelines and policies on the relationship between the AHC and industry.

To this end, this policy is developed to benefit the patients and employees at Howard University Health Sciences. The purpose of this policy is to minimize, if not eliminate, conflicts of interest or bias in the delivery of health care or purchasing. The policy is intended to promote an environment that supports professionalism and one that is free from influence by industry. It is also intended to promote high quality, evidence-based learning, research, and patient care.

III. ENTITIES AFFECTED BY THIS POLICY

This policy applies to all members in the Health Sciences Units who are full-time and part-time administrators, faculty, staff, and residents, herein after referred to as employees. This policy applies to contractors and grantees that perform work for Health Sciences. It also applies to other University entities as listed here:

- Accounts Payable Department
- College of Dentistry
- College of Medicine
- College of Nursing and Allied Health
- College of Pharmacy
- Counseling Service
- Development and Alumni Relations
- Faculty Practice Plan
- Health Sciences Library
- Howard University Hospital
- Office of Human Resources
- Strategic Sourcing and Asset Management (SSAM)
- Student Health Center

IV. DEFINITIONS

GIFTS – “Gifts” are considered anything of value provided by or on behalf of industry, including but not limited to food, beverages, tickets to sporting events, entertainment, hospitality, pads, pens, stethoscopes, journals, textbooks, pharmaceutical or device samples, or travel related expenses.

CHARITABLE DONATIONS - “Charitable Donations” include, but are not limited to cash, non-cash gifts (real property, tangible personal property, securities, other gifts of restricted and alternative assets), and event sponsorships.

CONFLICT OF INTEREST - A situation in which financial or other considerations have the potential to compromise or bias professional judgment and objectivity.

INDUSTRY – “Industry” includes, but is not limited to pharmaceutical, device, equipment, biotechnology, service, software, supplies, biomedical investment, and for-profit educational companies, and foundations sponsored by companies such as drug and device companies.

AFFILIATED PERSONS – means an immediate family member, (including stepmother, stepfather, stepson, stepdaughter), close personal acquaintances, and others who live within such person’s household; a family member of an individual and includes only his or her spouse, ancestors, brothers and sisters (whether whole or half-blood), children (whether natural or adopted), grandchildren, great-grandchildren, and spouses of brothers, sisters, children, grandchildren, and great-grandchildren. A close personal

acquaintance will be deemed to exist when a business or social relationship between individuals is such that a neutral observer could reasonably conclude that a transaction in which both such individuals participate may either: (1) be affected in whole or in part by factors extraneous to the merits; or (2) have the appearance of being influenced by such extraneous factors.

SIGNIFICANT FINANCIAL INTEREST – means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include (i) salary, royalties or other remuneration from Howard University, (ii) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities; (iii) income from service on advisory committees or review panels for public or nonprofit entities; (iv) an equity interest that when aggregated for the professional or key personnel and his or her Affiliated Persons meets both of the following tests: (a) does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; AND (b) does not represent more than a five percent ownership interest in any single entity; (v) salary, royalties or other payments that, when aggregated for the staff, management or faculty or their Affiliated Persons over the next twelve months, are not expected to exceed \$5,000.

V. POLICY PROCEDURES

1) GIFTS

- Gifts of any value, no matter how small, have an implied expectation of some return in favor to the donor. The return favor may be conscious or subconscious, thereby resulting in biased clinical decisions.
- To avoid the risk of bias in decision-making, HUHS employees shall not accept gifts regardless of value (with exceptions shown below) from industry, e.g. pharmaceutical companies, medical device companies, or any other suppliers of products or providers of services to Howard University.
- Departments that receive gifts shall submit a report of such gifts to the Dean of the College in which the department is located and to the Office of the Senior Vice President for Health Sciences or his/her designee.
- All offices and clinical areas should be free of any materials that bear the name of a particular product or company (e.g. pens, papers, notepads, and tote bags) unless the item is an integral part of a product or service that has been previously purchased or contracted by Howard University Health Sciences.

Charitable Donations

- For the purpose of this policy, “Charitable Donations” include, but are not limited to cash, non-cash gifts (real property, tangible personal property, securities, other gifts of restricted and alternative assets), and event sponsorships.

- Charitable contributions provided by industry in connection with fundraising done by or on behalf of HUHS shall be subject to University gift acceptance & administration policies.
- HUHS can accept charitable donations from industry with the following stipulations:
 - The gift must be unrestricted (per Accreditation Council for Continuing Medical Education Standards).
 - The gifts must be used to support education, research or patient care at Howard University.
 - There must be no expectation from the donor of reciprocity, but the college or Health Sciences division or department may publicly acknowledge the donor.
 - The gift must be deposited centrally to the Office of the Senior Vice President for Health Sciences or his/her designee.
 - Expenditure of the gift shall be at the sole discretion of the college or Health Sciences division or department.

2) PHARMACEUTICAL SAMPLES

Except as listed in the circumstances outlined in the next paragraph, Howard University Health Sciences staff including College of Medicine, College of Dentistry, College of Pharmacy, Nursing and Allied Health faculty, staff, students, Faculty Practice Plan and Howard University Hospital may not accept pharmaceutical samples. In lieu of samples, the staff may distribute vouchers to patients for medications through a voucher program overseen by either the Howard University Hospital Pharmacy or the Howard University School of Pharmacy.

Howard University Health Sciences staff including College of Medicine, College of Dentistry, College of Pharmacy, Nursing and Allied Health faculty, staff, students, Faculty Practice Plan and Howard University Hospital staff may accept medications from pharmaceutical industry representatives on behalf of Howard University Health Sciences if approval has been granted by the Health Sciences Provider Compliance Committee. Approval to accept pharmaceutical samples may be granted on a case-by-case basis where a department chair demonstrates to the satisfaction of the Provider Compliance Committee that the health of patients served by the department would be compromised if samples are not made available through the department.

The Howard University Health Sciences School of Pharmacy Practice Dispensing Laboratory may accept pharmaceutical samples from industry to use for instructional purposes.

Upon approval by the Provider Compliance Committee, samples may be accepted from industry by HUHS for distribution to patients under the following conditions:

- Accepted by the designated representative of one or more of the colleges, departments authorized by the chair to accept pharmaceutical samples, and not by individuals.

- Stored, managed and distributed according to guidelines established by the Provider Compliance Committee.
- The unit or department must maintain a catalog for each sample that shows at a minimum:
 - Name of the product
 - Lot number
 - Quantity Provided
 - Expiration date
 - Name employee who received the samples
 - Date sample was received by HUHS
 - Names and contact information of patient(s) who received the samples; and amount of medication, dose, and dosing schedule
 - Notation made in the patient medical record indicating the name of the samples, lot number, dose, and date of expiration of the medication.
- Department administration of the sample program will be audited annually by the Pharmacy Sample Subcommittee of the Provider Compliance Committee or other appropriate entities of the University after consultations with the Senior Vice President for Health Sciences.

3) SITE ACCESS FOR PHARMACEUTICAL AND DEVICE MANUFACTURER SALES AND MARKETING REPRESENTATIVES

Access to any site within the HUHS complex by sales and marketing representatives shall be limited to non-patient care areas, unless the purpose is to:

- Train staff or in-service on equipment already purchased by the HUHS unit.
- Repair equipment.
- Maintain equipment.
- All industry representatives must be credentialed through the Howard University Hospital vendor management program administered by the Director of the Department of Materials Management for access to Howard University Health Sciences sites. Promotional material may not be displayed or left on site at HUHS.
- Site access by sales and marketing representatives of industry shall be only by invitation or permission of department heads or his/her designee.
- Representatives from industry who wish to present educational information on products may be invited to do so in structured group settings that provide the opportunity for interaction and critical evaluation. There must be at least two faculty members present, if the presentation shall be to students or residents.
- Attendance at conferences by representatives from industry shall be by permission of the department that sponsors the conference.

4) CONTINUING MEDICAL, DENTAL, PHARMACY, NURSING AND ALLIED HEALTH EDUCATION

- All continuing education programs at Howard University or off-site and bearing Howard University identification, for credit or not for credit, must meet the standards of the applicable continuing education accrediting body, such as the Accreditation Council for Continuing Medical Education (“ACCME”), the American Dental Association (ADA) Continuing Education Recognition Program (CERP), the Accreditation Council for Pharmacy Education (ACPE), the American Nurses Association (ANA) or the appropriate allied health continuing education program.
- All requests for industry support and receipt of funds for continuing education activity must be submitted to, coordinated and overseen by the Office of Continuing Medical Education, Continuing Dental Education, Continuing Pharmacy Education, Continuing Nursing Education Offices or Continuing Allied Health Education offices.
- The applicable continuing education office shall conduct audits annually to ensure compliance with professional standards with particular emphasis on content validation and meals.
- Industry support for education programs may be accepted from ACCME, ADA, ANA-CERP, ACPE, or allied health continuing education accredited providers, exclusively.
- For purposes of continuing education, the HUHS faculty member must be able to demonstrate to the applicable continuing education office that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider.
- The ACCME defines “relevant financial relationships” as any financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

5) PARTICIPATION IN INDUSTRY-SPONSORED PROGRAMS: SPEAKERS’ BUREAUS, CONSULTING ARRANGEMENTS

- HUHS faculty members or staff may speak at programs sponsored by industry only under the following conditions:
 - The presentation(s) must not be subject to editing by industry.
 - Industry must not dictate what the faculty or staff member says in his/her presentation.
 - Faculty members or staff who accept honoraria must:
 - Disclose all honoraria to HUHS.
 - Make the presentation during periods of approved leave (vacation/annual) that includes travel time, OR
 - Make the presentation during periods of approved administrative leave that includes travel time and turn all honoraria over to the respective HUHS unit.

- Honoraria may not exceed the fair market value of the services provided.
- Except for academic investigators presenting results of their industry-sponsored studies to peers where there is opportunity for critical exchange, faculty and staff are strongly discouraged from participating in industry-sponsored speakers bureaus. Full transparency and disclosure is required when participating in industry-sponsored programs.
- Howard University Health Sciences professionals and staff may not accept payment for attendance (as distinguished from honoraria) or personal gifts at meetings from industry.

6) INDUSTRY-SPONSORED SCHOLARSHIPS FOR TRAINING /OTHER EDUCATIONAL EVENTS

HUHS professionals and staff are prohibited from offering or providing anything in exchange for industry sponsorship of scholarship or educational events. This section applies to industry-sponsored scholarships for training as distinguished from financial assistance for Howard University tuition, fees, and other appropriate costs of education as administered by the Development and Alumni Relations Office and the Office of Financial Aid of the respective college.

Industry may provide funds to support the education of trainees at HUHS or funds to support other educational events, at the discretion of HUHS, provided that all of the following conditions are met:

- Industry-Sponsored Scholarships
 - Donations for scholarships from industry shall be delivered to and managed by the Office of the Senior Vice President for Health Sciences or his/her designee.
 - Industry support for scholarships and fellowships must comply with all University gift and scholarship requirements and policies for such funds, including the execution of an approved budget and written gift agreement.
 - Scholarship funds must be maintained in an appropriate restricted account and managed at the school or department, as determined by the Senior Vice President for the Health Sciences with consultation on accounting matters with the University's Chief Financial Officer.
 - Selection of recipients of scholarships or fellowships will be completely within the sole discretion of the school in which the student or trainee is enrolled or, in the case of graduate medical education, the Dean for graduate medical education. Written documentation of the selection process of industry scholarships will be maintained.
 - The donor may be publicly acknowledged.
- Other Educational Events
 - Educational funds from industry shall be delivered to and managed by the applicable continuing education office.

- Industry support for other educational events must be accompanied by an appropriate written funding agreement and may be accepted only into an established HUHS discretionary fund. This fund shall be maintained under the direction of the dean or department (as specified in the funding agreement) for the relevant school.
- Industry may not earmark contributions to fund specific recipients or to support specific expenses.
- The selection of the participants shall be at the sole discretion of the HUHS or one of its units, and documentation of the selection process must be maintained by the unit.
- Departments or divisions may requisition monies from the appropriate fund to pay for reasonable travel and tuition expenses for residents, students, or other trainees to attend conferences or training that have legitimate educational merit (see section VIII below) and other expenses deemed appropriate under the University's travel policy.
- Approval of particular requests shall be at the discretion of the Senior Vice President for HUHS or assigned designee.

7) FOOD

With the exception of food provided in connection with ACCME, ADA, ANA-CERP, ACPE, or the applicable allied health-accredited programming and in compliance with professional association guidelines, industry-supplied food and meals are considered personal gifts and will not be permitted whether on Howard University Health Sciences property or offsite.

8) PROFESSIONAL TRAVEL

Faculty, staff, and trainees shall not directly accept funds from industry for travel to any event, including educational events. Funds donated by industry for professional travel by HUHS staff, management or faculty may be received and distributed exclusively by the Office of the Senior Vice President for Health Sciences or his/her designee. Faculty, staff, and trainees may accept travel funds from industry under the following circumstances:

- The funds are legitimate reimbursement for travel to provide contractual services, such as approved consulting activity; or
- The purpose of the travel is to :
 - View capital equipment in situ if the equipment is being considered for purchase by HUHS or one of its units, or
 - Participate in meetings directly related to ongoing sponsored research, or
 - Attend meetings for educational purposes.

The selection of the faculty, staff, and trainees shall be at the sole discretion of HUHS.

9) GHOSTWRITING

Faculty members, staff, and trainees shall not permit their professional publications or presentations of any kind, oral or written, regardless of medium, to be written by any party from industry.

10) CONFLICT OF INTEREST COMMITTEE

The Conflict of Interest Committee is responsible for making the final decision as to what conditions or restrictions, if any, should be imposed by the Health Sciences to manage, reduce or eliminate the conflict of interest.

The Conflict of Interest Committee shall be a subcommittee of the Health Sciences Provider Compliance Committee with ex officio representation from the Office of the General Counsel.

When the Conflict of Interest Committee determines that an interest or activity poses a conflict of interest, the plan for managing, reducing or eliminating a conflict of interest must include resolution strategies. The plan initially will be formulated by the involved professional or key personnel and must be approved by the Conflict of Interest Committee in consultation with the Office of the General Counsel.

Conditions or restrictions that may be imposed on a professional or key personnel or project to manage or eliminate conflicts of interest may include, but are not limited to, one or more of the following:

- Public disclosure of significant financial interests
- Recusal from participation in decisions that present a conflict with the activity.
- Divestiture of financial interests
- Severance of relationships that create actual or potential conflicts

11) PURCHASING

Faculty members and staff who have a significant financial interest in any particular manufacturer of pharmaceuticals, devices, equipment or any provider of services must disclose such interest to Howard University Health Sciences. Faculty Members and staff must disclose any known significant financial interest of an affiliated person (e.g. family member, household member). When the Conflict of Interest Committee determines that a financial interest poses a conflict of interest, the affected faculty or staff must recuse themselves from any involvement in purchasing decisions relevant to the financial interest. To the extent that an individual's expertise is indispensable to the evaluation of a product or service, that individual's financial ties must be disclosed to those charged with responsibility for making the decision in addition to disclosure to Howard University Health Sciences Conflict of Interest Committee.

12) DISCLOSURE REQUIREMENTS

Howard University Health Sciences requires professionals and key personnel to complete a Conflict of Interest disclosure at the end of each fiscal year and at the occurrence of any activity which modifies the individual's relationship with industry disclosure statements completed under the Health Sciences Conflict of Interest policy will be made available to the Conflict of Interest Committee when requested by the committee.

13) MEDICAL SCHOOL CURRICULUM

The Howard University College Medicine shall educate its student to demonstrate an understanding of personal and institutional conflict-of-interest and to recognize how promotions by industry can influence clinical decision. The College of Medicine shall also inform students on how to manage conflicts-of-interest with industry.

14) OVERSIGHT

The Chief Compliance Officer and the Provider Compliance Committee are responsible for oversight of this policy.

Citations

ACCME Standards for Commercial Support

http://www.med.cornell.edu/education/programs/pdf/accme_stand_comm.pdf

ADA Standards Commercial or Promotional Conflict of Interest

http://www.ada.org/sections/educationAndCareers/pdfs/standard_v.pdf

ACPE Guidelines for Standards for Commercial Support

http://www.acpe-accredit.org/pdf/CE_FAQ_Standards_Comm_Support_2007.pdf

<http://www.acpe-accredit.org/pdf/tf08-5.pdf>

VI. INTERIM POLICIES

There are no interim policies.

VII. SANCTIONS

Violations of this policy will be subject to Howard University Hospital and Howard University disciplinary processes.

VIII. WEBSITE ADDRESS

<http://www.howard.edu/policy>