

Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools



COI Toolkit on Gifts, Meals, and Entertainment

I. Introduction

The pharmaceutical and device industries provide gifts to physicians and other prescribers in order to influence treatment decisions, medical education, and research. These gifts can take many forms—stethoscopes, meals, entertainment, travel funds, and textbooks. Numerous studies have demonstrated that such gifts, both large and small, create feelings of obligation and self-serving bias¹ and have negative effects on patient care.^{2 3 4} Former sales representatives for drug companies have also documented that they were trained to use gifts and meals to engender in the targeted physician a sense of obligation to reciprocate by prescribing more of the company's products.⁵

In 2006, a task force of prominent medical leaders recommended that academic medical centers (AMCs) should take the lead in addressing this problem by banning all pharmaceutical and device industry gifts of any value, free meals, payment for time for travel to or time at meetings, and payment for participation in online CME.⁶ Two years later, the Association of American Medical Colleges (AAMC) issued a report recommending that AMCs prohibit any industry gifts because their acceptance by physicians and other faculty, students, trainees, and staff is unprofessional and unacceptable, as it undermines the trust of patients and the general public in the objectivity of the physician's decision making.⁷ The AAMC emphasized that any gift, regardless of the dollar amount, created a sense of obligation that influenced the gift recipient's actions. In 2009, the Institute of Medicine (IOM), in an exhaustive review of the evidence on conflicts of interest in medicine, recommended that physicians, wherever their site of clinical practice, should not "accept items of material value from pharmaceutical, medical device, and biotechnology companies except...for payment at fair market value for a legitimate service." IOM also called on health care providers to establish policies prohibiting gifts.⁸

Academic medical centers have now made significant progress in setting policies to prohibit faculty and staff from accepting gifts from pharmaceutical and medical device companies. The American Medical Student Association (AMSA), which collects policies from 158 medical schools for its annual scorecard, found that in 2011–12, 59 percent of medical schools had a robust policy prohibiting gifts, compared to just 28 percent in 2009.⁹ To date there is no comprehensive assessment of gifts policies at teaching hospitals, but AMSA will release its first scorecard for those institutions in the spring of 2014.

Gifts, Meals, and Entertainment

"Gifts and meals are used by pharmaceutical companies to transform a medical decision from a scientific basis to one that's based on personal relationships, and that's not in the patients' best interests."

*— Ross McKinney, Jr., MD,
Director, Trent Center for
Bioethics, Humanities and History
of Medicine, Duke University*

Industry gift-giving arrangements also violate federal law if (1) they have a potential to interfere with, or skew, clinical decision-making; (2) they increase the costs to federal health care programs, beneficiaries, or enrollees; and (3) they increase the risk of overuse or inappropriate use.¹⁰ Both manufacturers and the recipients of such gifts have been prosecuted.¹¹ The threat that the federal government would consider gifts to be illegal kickbacks, as well as gifts legislation in the states, also induced the pharmaceutical industry to update its voluntary PhRMA Code in 2002 and 2009, which can be adopted by companies to curtail the most egregious gifting practices.¹²

Most policies at AMC's apply to employed faculty and staff but not to voluntary clinical faculty in the community. This is true, despite the IOM recommendations to prohibit acceptance of gifts by all physicians and health care providers. The AAMC also recommends that academic medical centers:

- make clear to their faculty, students, and staff that the interactions with industry that are prohibited within academic medical centers are also prohibited off-site.
- communicate to off-site training facilities the expectation that those venues adhere to the standards of the academic center regarding interactions with industry.¹³

AMCs can play a leading role in changing the culture of medicine to one where accepting gifts from industry is no longer the norm. A recent survey showed that progress has been made on this front with the percentage of practicing physicians who report receiving gifts from industry dropping from 83 percent in 2004 to 70.8 percent in 2009, but further improvement is clearly needed.¹⁴ AMC's can catalyze change in the practicing community by extending a gift ban to physicians who hold clinical faculty appointments and who may serve as key opinion leaders among their colleagues in practice.

The implementation of the public transparency ("Sunshine") provisions of the Affordable Care Act will make information on gifts and payments from industry to all individual physicians available to the public in 2014.¹⁵ The ensuing public scrutiny of the appropriateness of these relationships may motivate AMC's to bring voluntary faculty under their policies since industry payments to these faculty will be public and could affect the reputation of the associated AMC.

II. Arguments For and Against Gifts Policies

Some argue that gift-giving is a common practice in business. But medicine is more than just a business; physicians are in a position of trust with their patients and are expected to put patients' best interests ahead of their own narrow financial self-interest. The ethics of professionalism dictate that physicians avoid situations where their

"That we in the academic medical community have not yet established and enforced ethically sound, transparent, universal policies around the receiving of industry gifts is inexcusable. The evidence of harm to the public and to the education of future doctors is absolutely clear."

— Michael S. Wilkes, MD, MPH, PhD, Professor, Internal Medicine, UC Davis Medical Center

clinical judgments may be influenced, or even appear to be influenced, by secondary considerations that may be in conflict with the patient's best interests.

Huddle¹⁶ argues that while studies show that pharmaceutical marketing results in influence, the case has not been made that actual harm has come to patients because of that influence. But many disagree. For instance, studies and court cases have documented very serious consequences of such influence—the inappropriate and harmful prescribing of drugs such as Neurontin and Vioxx, which resulted in serious side effects, and even deaths, for tens of thousands of patients.^{17 18} And other studies have shown that industry inducements are associated with prescribing patterns inconsistent with evidence-based guidelines; reduced generic prescribing; increased drug costs; and biased requests for additions to hospital formularies.¹⁹

We don't need field trials to prove that gifts from professional sports teams to referees, or from defendants or plaintiffs to judges, will cause harm. Gift-giving in these situations is universally considered unethical.²⁰ So should it be with physicians.

III. Arguments For and Against Extending Prohibitions to Voluntary Faculty

With respect to voluntary clinical faculty specifically, some would say institutional policies should not apply because voluntary faculty are not employees of the medical school or AMC and hence are not subject to employee rules. Yet, bestowing a faculty appointment is not constrained by the employment relationship of the physician to the medical school. Rather, the faculty appointment recognizes admirable personal and professional qualities in the recipient that are deemed valuable and desirable to the medical school, especially as that faculty member can serve as a teacher, role model, and mentor to trainees. Voluntary clinical faculty appointments can be withdrawn if a faculty member fails to meet those professional standards.

Others insist that extending policies to hundreds or even thousands of voluntary clinical faculty cannot be adequately monitored or enforced. This ignores the potent benefit that accrues by articulating institutional values even if enforcement is limited. Proclaiming those values shapes the culture of the institution and eliminates a dual standard—one for full-time faculty and another for voluntary faculty.

Medical schools—especially new ones—express concerns that imposing policies on conflict of interest on voluntary faculty might make the job of recruiting faculty more difficult. No empirical data is available to judge whether this is true or not. On the other hand, physicians might welcome standards that push them to extricate themselves from troubling industry interactions, such as the industry-catered free lunches each week that some doctors have continued mostly to please their staff.

“Our policy does apply to courtesy faculty. In fact, we’ve terminated the appointments of several courtesy faculty who continue to engage in promotional speaking.”

— Gary Wimslett Jr., JD, Director,
Conflict, University of Florida
School of Medicine

IV. Policy Considerations

Medical schools and teaching hospitals should not allow faculty, clinical staff or trainees to accept gifts, regardless of monetary value, on- or off-site. Meals and snacks provided by industry should not be allowed at any clinical site associated with the AMC.

Some institutions continue to make an exception for meals funded by industry for ACCME-accredited CME programs, but we would recommend against this exception.

These policies should extend to all faculty, including voluntary clinical faculty in the community who engage in both patient care and medical education. This would be most consistent with the fundamental reasons for prohibiting gifts to faculty, which are (1) to assure that physicians are making clinical decisions only on the basis of what is best for their patients; (2) to maintain the trust of patients and the public; (3) to uphold the highest standards of professionalism; and (4) to model that behavior to trainees.

IMPLEMENTATION ISSUES:

Like other conflict-of-interest policies, implementation of gift and meal restrictions requires initial and ongoing education of faculty, staff and trainees, as well as affected vendors. Ending industry-funded meals may be especially contentious, since it has been such a widespread practice. Some leaders recommend that the departments provide lunches at noon conferences, especially for house staff,²¹ to mitigate their expenses and reduce opposition to a ban on industry meals. Some AMC leaders have noted that banning meals has had the related benefit of reducing the incentive for staff to meet with industry sales representatives.

Voluntary faculty:

Institutions should strive to make restrictions on gifts or meals as easy as possible for voluntary faculty to accept. The AMC should solicit input from voluntary faculty prior to extending these policies to their affiliates. Ample time should be given for practices to adjust to the new policy.

Voluntary faculty should be provided with examples of medical practices that are already in compliance with the policies, along with testimonials from those physicians describing how they went about implementing the changes in their practices. An example is described by Evans and colleagues.²²

AMCs could also minimize voluntary faculty interactions with sales representatives, and the meals and gifts they bring, by providing information from AMC clinical pharmacists about new and existing drugs—for instance, through e-bulletins.

ENFORCEMENT:

Education of faculty, staff and trainees on the policies should be provided, including information on disciplinary action for violation of the policies and on reporting mechanisms for violations both inside the institution and at other locations. As at University of Florida COM (below),

disciplinary action could include limiting outside activities or research, demotion or termination.

Institutions can hold industry accountable, as well, by requiring vendor training and written agreements with consequences for violations.

V. Model Policies

UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE (EXCERPTS)

Introduction. COM personnel must pay particular attention to potential conflicts of interest in connection with Industry in order to protect the integrity of professional judgments and to preserve public trust in physicians, researchers, and academic medical institutions.

Gifts. COM personnel may not accept gifts from Industry regardless of the monetary value of the gift unless such a gift is specifically allowed under this policy. A “gift” is anything accepted by COM personnel, or by another person on behalf of the COM personnel, when equal or greater payment is not given within 90 days of receipt. Gifts include, without limitation, food or beverages, transportation, lodging, parking, membership dues, admission fees, flowers, personal services, preferential rates or terms on a debt, loans, goods or services, forgiveness of a debt, and the use of real property. Any prohibition against gifts does not extend to gifts from a relative.

“COM personnel” means any employee or appointee of the University of Florida (whether full-time, part-time or courtesy), including but not limited to Academic Personnel (AP), Technical, Executive, Administrative and Managerial Support (TEAMS), University Support Personnel System (USPS), and Other Personnel Services (OPS) employees, who has a COM appointment. Academic Personnel are defined in University of Florida Regulation 7.003 and include without limitation faculty members, residents, fellows, graduate assistants and post-doctoral associates.

Penalties and Enforcement. COM personnel who fail to abide by the provisions of this Conflict of Interest Policy are subject to appropriate disciplinary action in accordance with University regulations. Examples of sanctions are: disallowance or limiting outside activities, changes in assignment, limitation on research activity, reduction in pay, demotion, written reprimand, suspension without pay, and termination for cause.

UNIVERSITY OF CALIFORNIA HEALTH CARE VENDOR RELATIONS POLICY (2008)

I. Summary

...This Policy establishes minimum standards for campus implementation of Health Care Vendor relationship policies. Campuses may implement stricter policies.

II. Purpose

The Political Reform Act, which governs University of California employees, aims to remove bias from their decisions. The University of California Policy and Guidelines Regarding Acceptance of Gifts and Gratuities by Employees under California's Political Reform Act (January 2001) adds the following statement:

In addition to compliance with the requirements of law, University officers and employees must avoid the appearance of favoritism in all of their dealings on behalf of the University. All University officers and employees are expected to act with integrity and good judgment and to recognize that the acceptance of personal gifts from those doing business or seeking to do business with the University, even when lawful, may give rise to legitimate concerns about favoritism depending on the circumstances.

Recent research shows that certain health care vendor activities allowed under the Political Reform Act, such as the provision of gifts of nominal value, may affect provider behavior and give the appearance of favoritism. This policy supplements the provisions of the Political Reform Act and University Business and Finance Bulletin G-39 (the Conflict of Interest Policy) in order to reduce the influence of health care vendors on the decisions made by University of California health care professionals. Additionally, while offers of free or discounted goods, gifts, benefits, donations, honoraria, travel expenses or grants for teaching or research programs frequently serve an important and socially beneficial function, they may, in some circumstances, violate the federal Anti-Kickback Statute and similar California state law. Guidance on compliance with this law is provided hereinafter.

III. Applicability

This policy applies to those members of the UC community who work, train, or are students at health care locations or in health professional schools (e.g., medicine, dentistry, nursing, pharmacy, optometry, veterinary medicine).

Except as specifically noted, this policy applies both to on and off-campus activities.

IV. Definitions

The terms "Health Care Individual", "Gift" and "Health Care Vendor" have special definitions for the purpose of this policy.

A. UC Community: Regents, faculty and other academic personnel, staff, students, residents, volunteers, contractors, agents, and others associated with the University.

- B. Health Care Individual: A member of the UC Community who works, trains, or is a student at health care locations or in health professional schools.
- C. Gift to a Health Care Individual: Payment to a Health Care Individual or provision to of free or discounted items, medical samples for personal use, food, or travel when the Health Care Individual is not providing a service of similar or greater value to the Health Care Vendor. For example, pens, notepads, free textbooks, free meals, payment for attending a meeting, and samples are all considered Gifts. Honoraria for a specific service rendered (e.g., delivering a speech) are not considered Gifts. [see policy for more details on methods and exclusions]
- D. Health Care Vendor: a company or its representative or the agent of a company that either produces or markets drugs, devices, nutritional products, or other medical products or services.

V. Policy

- A. Gifts and Compensation Provided by Vendors
 - 1. This section applies to University employees and students at all locations, and to all other Health Care Individuals when at University-owned or operated locations.
 - 2. Gifts from Health Care Vendors to a Health Care Individual are prohibited.
 - 3. In circumstances where Health Care Vendors wish to provide a Gift in support of the mission of the University (e.g., food for conferences or payment for educational travel), appropriate alternatives may be available. For example, in lieu of providing free food or payment for educational travel, Health Care Vendors may donate funds to a University unit (e.g., department or division) to support meetings...
 - 4. Free samples, vouchers, supplies, or equipment designated for a Health Care Individual are considered Gifts and are prohibited. Vendors may donate their product to a unit of the University if the administrative head of the unit approves the donation [see full policy for limitations].

**DUKE UNIVERSITY HEALTH SYSTEM POLICY ON GIFTS AND COURTESIES
(05/2000, LAST REVIEWED 09/2011)**

Definitions:

Gift or Courtesy means favor, entertainment, hospitality, food, beverages, transportation, lodging, use of personal property or real estate, or other gratuity item or service.

Medical Staff includes any member of the medical staff who is credentialed to provide health care service at any Duke University Health System (“DUHS”) facility.

Policy:

Background/Purpose

No gifts or courtesies are to be offered or accepted by DUHS employees or members of the medical staff which:

- are inducements for patient referrals;
- improperly influence business relationships or outcomes; or
- increase governmental program costs.

Absolute Prohibition Against Remuneration for Referral of Patients/Business

It is against DUHS policy to offer or receive gifts, courtesies or other remuneration which:

- are inducements for patient referrals;
- improperly influence business relationships or outcomes; or
- increase governmental program costs.

Prohibition of General Gifts and Courtesies

Employees and members of the medical staff of DUHS and its component facilities shall not offer to, or accept gifts or courtesies from actual or potential patients or other consumers of DUHS services, healthcare providers or vendors of goods and services.

Acceptable Gifts and Courtesies Restricted to Reasonable Value

1. It is recognized that health care professionals may, on occasion, be offered gifts and courtesies from patients in appreciation for managing an episode of care. Such unsolicited gifts or courtesies, which are reasonable in value and not related to past or anticipated preferential treatment, may be accepted by health care professionals in rare circumstances. [Limit one per year; no cash or case equivalent]
2. It is recognized that health care professionals may accept a gift of a model of a medical device, supply or other similar product to use for purposes of patient education, explanation of clinical decision-making or informed consent of a procedure or service.
3. It is recognized that health care professionals or staff may accept a perishable gift (e.g., food or flowers) from an individual patient or patient’s family when it is shared with all employees in a department, unit or division.

4. Sample medications may be stocked in outpatient clinics in accordance with applicable DUHS facility's policy and procedure and applicable state and federal laws regarding dispensing, labeling and patient counseling.

Special Circumstances

[See policy for full explanation of exceptions, including fundraising events, representing DUHS in an official capacity, etc.]

Alternatives to Receipt of Gifts

Staff or health care professional, when offered a gift or courtesy, may suggest certain alternatives to a donor such as a donation to DUHS. [see full policy]

Reporting

Any violation of this policy shall be reported in accordance with the DUHS Compliance Reporting (Non-Retaliation/Non-Retribution) Policy.

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<http://tinyurl.com/AmcModelCoiPolicy>

The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.