

PR 4

Office of the President
March 2, 2004

Members, Board of Trustees:

ADOPTION AND DELEGATION OF AUTHORITY TO IMPLEMENT CLINICAL ENTERPRISE CODE OF CONDUCT ADDENDUM

Recommendation: that the Board of Trustees adopt the attached Clinical Enterprise Code of Conduct Addendum and delegate to the University Provost and the Executive Vice President for Health Affairs the authority to implement and further amend as required by law the Code of Conduct Addendum – Clinical Enterprise Compliance Policy as an addendum to the University Code of Conduct.

Background: The University of Kentucky Clinical Enterprise (Clinical Enterprise) is subject to a number of restrictions pertaining to the acceptance of gifts and relationships with industry that are more stringent than the regular University Policy concerning the same. The restrictions are found in the Federal Anti-Kickback Law, 42 USC Section 1320a; Stark I and II, 42 USC Section 1395nn and 42 USC Section 1396b(s) and in various announcements of Federal and State regulatory authorities. These restrictions and their interpreting regulations change, from time to time. Violation of these restrictions can lead to serious criminal and civil penalties.

In order to be regulatory compliant, the Clinical Enterprise should have a policy that is more stringent than that which would be applicable to other segments of the University. In addition, in order to accommodate regulatory changes, said policy must be able to be revised, frequently, as needed. The Clinical Enterprise Compliance Office, in conjunction with the University Office of Legal Counsel, has developed a policy (the Policy) as an Addendum to the University Code of Conduct. The Policy is attached hereto as Exhibit A. The Policy has been presented to the Clinical Enterprise Compliance Committee and been approved by the same. In order to implement the Policy and to have the flexibility to amend the Policy, rapidly, to correspond to additional regulatory guidance, it is recommended that the Board of Trustees delegate to the Executive Vice President for Health Affairs and the Provost, the two University officials having direct oversight of the Clinical Enterprise, the authority to implement the Clinical Enterprise Code of Conduct Addendum and revise the same, from time to time, as needed.

Action taken: Approved Disapproved Other Amended – text to come

**University of Kentucky
Code of Conduct Addendum - Clinical Enterprise Compliance Policy**

Purpose

The federal anti-kickback law is intended to protect patients and the federal health care programs from fraud and abuse by curtailing the influence of money on health care decisions. The law generally states that anyone who receives anything of value that may influence the purchase of items or services billed to Medicare or Medicaid can be subject to fines, prison terms, and/or exclusion from federal health care programs. Federal laws known as “Stark I” and Stark “II” prohibit physicians and other medical providers from referring business to an entity with which they (or an immediate family member) have a financial relationship or from giving or receiving anything of value in exchange for a referral. Additionally, the Kentucky Board of Medical Licensure, the American Medical Association and the U.S. Department of Health and Human Services Office of Inspector General caution medical providers against receiving gifts and other items of value from industry that can implicate federal anti-kickback or Stark laws. Even gifts that may not implicate federal or state laws must also be carefully scrutinized for conflicts of interest or the potential to unduly influence purchasing decisions.

For these reasons activities that are common practices in other industries and other areas within the University of Kentucky may not be appropriate in healthcare settings.

Code of Conduct

Those acting on behalf of the University of Kentucky Clinical Enterprise (Clinical Enterprise) must endeavor to conduct business in a manner that facilitates the delivery of quality and efficient health care and to act in accordance with recognized legal and ethical standards aimed at preventing conduct that may inappropriately influence their judgment. This Code of Conduct reflects the law, regulations, and official published guidelines that are in effect at the time of its adoption. It is a dynamic document that will be reviewed and updated on an annual basis. In the event of a conflict between this policy and subsequent more restrictive regulations or law, the more restrictive regulation or law will control.

This Code of Conduct Addendum is intended to supplement the University of Kentucky Ethical Principles and Code of Conduct by providing guidelines that will assist Clinical Enterprise faculty, staff and students in the review and determination of appropriate gifts and benefits from vendors. Unless specifically addressed by this Addendum the University of Kentucky Ethical Principles and Code of Conduct is applicable. Clinical Enterprise faculty, staff and students are strongly urged to consult with their supervisors to review and evaluate specific situations. While this code of conduct provides guidance, and in some instances interpretation, additional guidance is found in other official University and Clinical Enterprise policies and documents, such as Governing Regulations, Administrative Regulations, Human Resources Policy and Procedure Manual, Hospital and Clinic Policies, Medical Staff Bylaws, College of Dentistry Policy Manual, Corporate Compliance Policies and Procedures, Behavioral Standards in Patient Care, and state and federal law. Neither this Code of Conduct Addendum nor the University of Kentucky Ethical Principles and Code of Conduct apply to any benefit or other value provided to UK faculty or staff from funds collected by Kentucky Medical Services Foundation, Inc.

For purposes of this addendum, the “Clinical Enterprise” is defined as all healthcare delivery and clinical enterprises, including but not limited to the College of Medicine, College of Dentistry, College of Nursing, College of Pharmacy, College of Health Sciences, University of Kentucky Hospital, Kentucky Clinics, Centers for Rural Health, Sanders Brown Center on Aging, Markey Cancer Center, and the Gill Heart Institute. In order to avoid even the appearance of impropriety or conflict of interest, this Code of Conduct applies to all faculty, staff, and students within the Clinical Enterprise, without regard to an individual’s specific job duties or function. Students of other UK Colleges are not subject to the general UK Code of Conduct, however, students of Colleges included in the Clinical Enterprise are covered by the Clinical Enterprise Code because of their involvement, or potential involvement, in clinical or healthcare activities and because of the training value for such students of compliance with regulations pertaining to the healthcare industry.

Clinical Enterprise faculty, staff and students who fail to comply with this code of conduct can be subject to disciplinary action in accordance with University policy and procedure. Faculty, staff and students failing to act in compliance with this code of conduct will be considered to be acting outside the scope of their employment and could be personally liable should government intervention result.

Gifts and Benefits

“Gifts and Benefits” include, but are not limited to anything of value provided at no charge or at discount such as; loans, cash, gift certificates, services, prizes, art objects, transportation, meals, use of a vehicle or vacation facility, stocks or other securities, participation in stock offerings, home improvements, and tickets to sporting and cultural events. The potential list is endless – these are only intended as examples. Gifts do not include reimbursement for reasonable business expenses paid by faculty practice plans or other University of Kentucky related organizations.

In accepting any gift or benefit, the following guidelines must be observed:

1. Clinical Enterprise faculty, staff and students may not accept gifts or other benefits that take into account the volume or value of referrals, purchases, or other business generated.
2. Clinical Enterprise faculty, staff and students may not accept gifts or other benefits in exchange for prescribing certain products or services, or to induce referrals.
3. Clinical Enterprise faculty, staff and students may not accept gifts or other benefits that could be perceived as an attempt by a vendor to interfere with their independent judgment.
4. Discounted goods and services, or those that eliminate or reduce an expense that would have otherwise been incurred, are also considered gifts under this code of conduct.
5. Appropriate gifts must primarily benefit patients or have genuine educational value. (e.g. textbooks and anatomical models.)
6. When otherwise appropriate, gifts to individuals (or to members of their immediate family) from any one source should have a fair market value of less than \$100.00 per gift. Even appropriate gifts should only be accepted occasionally and the annual aggregate should not exceed \$300.00. Single gifts or benefits to individuals valued above \$100.00 or aggregate annual gifts valued at above \$300.00 must be directed to the Vice President for Development, where they can be acknowledged and accepted on behalf of the University in accordance with University policy.
7. Items of nominal value are appropriate if they are primarily related to business. (e.g. pens, notepads, or similar promotional or advertising items with or without company logo).
8. Items intended for the personal benefit of the recipient are not appropriate. (e.g., golf bags, tickets to sporting or entertainment events, sponsorship of departmental parties or social events).
9. Perishable or consumable gifts given occasionally, such as a holiday gift basket or floral arrangement, may be accepted as long as the value is nominal and the items are shared among the clinical area employees or donated to charity.
10. Cash or cash equivalents are not appropriate. (e.g. checks, gift certificates, and stocks)

11. Gifts intended to be passed on to patients for their use must be limited to \$10 per item (maximum \$50 per year). Federal law prohibits offering or transferring to a Medicare or Medicaid beneficiary anything of value that is likely to influence the patient's selection of a particular provider or supplier.

Sponsorship of Continuing Education Meetings, Professional Meetings, and other Scientific and Education Conferences

Industry organizations may not directly or indirectly subsidize a Clinical Enterprise Member's attendance at a conference or meeting. This prohibition includes conference registration fees, travel, meals, entertainment, accommodations, and the attendee's time for attending the conference. An organization may subsidize a conference or meeting by providing a subsidy directly to the conference sponsor who in turn can reduce the conference fee for all attendees.

Modest meals, such as lunches, refreshments, and receptions that are included in the conference fee and available for all attendees are appropriate. In these cases, the meals or receptions should be modest and conducive to discussion among attendees, and the amount of time at the meals or receptions should be subordinate to the amount of time spent at the education activities of the meeting.

Conference Faculty and Public Service

From time to time, industry representatives ask Faculty, Staff or Students to speak at or otherwise serve as faculty or presenters at conferences or meetings, or to serve as a Board Member for a bona fide trade or charitable organization. In such cases, it is appropriate for those individuals to accept a fee based on the fair market value of the services they have provided, reasonable honoraria, and reimbursement for their reasonable travel, lodging, and meal expenses. For clinical Faculty, such fees and reimbursement for expenses are generally not considered income subject to applicable practice plan agreements; however such income remains subject to University policies and regulations. Reimbursement may not be accepted for expenses of a spouse, family member, or other traveling companion.

Consulting Arrangements

It is appropriate for consultants who provide bona fide services to accept reasonable compensation for those services and to be offered reimbursement for reasonable expenses incurred as a result of the consulting relationship if the following guidelines are observed:

1. The arrangement is set out in writing.
2. The written agreement covers all of the services to be provided.
3. The compensation is set out in advance.
4. If the agreement is for periodic, sporadic or part-time services, it must identify the schedule of intervals, precise length and exact charge for such intervals.
5. The term of the agreement is for no less than one year.
6. There is legitimate need for the services.
7. The services are actually provided.
8. The compensation is based on the Fair Market Value.
9. The compensation is not determined in a manner that takes into account the volume or value of any referrals or other business generated.
10. All these facts are documented prior to payment.

Compensation given for "consulting" for attending meetings or conferences in a primarily passive capacity is inappropriate. Vendor relationships with physicians or other medical providers where compensation is paid for marketing activities such as speaking, research, preceptor, "shadowing" arrangements or time spent listening to sales reps marketing their products are suspect and payment may

not be accepted as “consulting” fees, even if the physician is required to perform services such as completing minimal paperwork or accessing a website.

Compensation for consulting arrangement should be handled pursuant to applicable practice plan agreements. Consulting agreements must be reviewed by the Clinical Enterprise Legal Office or Corporate Compliance Office prior to acceptance.

Meals - Educational or Scientific Presentations

Meals are appropriate in connection with educational or scientific presentations if the following guidelines are followed: (This does not include sales or marketing presentations)

1. The presentation must be educational and unbiased in content.
2. The presentation must have independent value by an authoritative speaker.
3. The meals must occur only occasionally.
4. The meal must be modest by local standards.
5. The meal must occur in a venue and manner conducive to learning and discussion.
6. Spouse or other guest attendance is not appropriate.
7. Meals in connection with presentations that are strictly for sales or marketing purposes may not be accepted.
8. Take out meals or meals without a company representative being present are not appropriate.
9. Entertainment or recreational events associated with the presentation are not appropriate.

Scholarships

Scholarship funds and other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be appropriate where the selection of the recipients is made by the academic institution.

Conferences that qualify as "carefully selected educational conferences" are in general terms defined by the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

Training and Site Visits

On occasion UK faculty or staff may be required to travel to other locations in order to view or train on new equipment or systems that UK uses, intends to use, or is considering purchasing. Such travel is only considered legitimate if the product, equipment or training cannot reasonably be brought to UK.

The following guidelines should be observed:

1. All site visits must comply with the Commonwealth of Kentucky Model Procurement Code, UK Purchasing rules, and in coordination with the UK Purchasing Division.
2. Generally, if UK is evaluating a product or service, the site visit should be considered an operating expense of the Clinical Enterprise area which is considering the purchase. All costs related to the site visit will be the responsibility of the Clinical Enterprise area that visits a particular location.
3. If UK has purchased or has agreed to purchase an item or service, and a site visit or training is included as part of the purchase agreement, it is appropriate for the vendor to pay for the travel, meals and lodging. However, Entertainment associated with the travel is not appropriate and the travel, lodging, and meals must be reasonable.

Entertainment

Gifts of entertainment have no related business value and should not be accepted. This includes items such as tickets to performances and sporting events, or use of a vacation house. The only exception is events that take place solely to benefit a bona fide charitable organization (e.g. University of Kentucky Children’s Hospital, American Heart Association, American Cancer Association, etc.) such as a golf

scramble or dinner dance. The entertainment must be limited to the activity that is the subject of the event and invitations to such events should be accepted infrequently.

Clarifications and Reporting Violations

For additional interpretation, counsel or advice, regarding this policy, contact the Clinical Enterprise Office of the University Legal Counsel or the Clinical Enterprise Corporate Compliance Office. Reports of suspected misconduct should be made to the University of Kentucky Chandler Medical Center's Corporate Compliance Office according to the Corporate Compliance Program's Operating Policies and Procedures which are available at <http://www.mc.uky.edu/compliance>. Reports must be made within 24 hours of discovery and may be made directly to the Corporate Compliance Officer at 323-6044, by pager at 1-888-898-1872, or anonymously at 1-877-898-6072. All credible reports will be investigated properly and fully within a reasonable time period.

NOTE: Nothing in this code of conduct is intended to place additional limitations on official gifts and endowments made to the University of Kentucky under University Administrative Regulations. Nor is it meant to prevent industry sponsored health fairs aimed at educating the general public or industry support of nationally accredited continuing education programs for health care professionals through educational grants to the University of Kentucky.

References:

42 U.S.C. 1320a-7b(b) Federal Anti-kickback

42 CFR 1001.951 Federal Anti-kickback

42 CFR 1001.952 Federal Anti-kickback

42 U.S.C., sec. 1395nn Stark

42 U.S.C., sec. 1396b(s) Stark

42 CFR 411.350 Stark

DHHS OIG; Special Advisory Bulletin; *Offering Gifts and Other Inducements to Beneficiaries*

2/13/04