



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 10.27, **Health Care Vendor Interactions**

PURPOSE: The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to maintain the integrity of Texas Tech University Health Sciences Center's (TTUHSC) educational and research programs, and clinical decision making by providing guidance on acceptable interactions between TTUHSC faculty, staff, students and trainees and Health Care Vendors (as defined below) to optimize the benefits of such interactions and foster compliance with applicable federal and state laws, while minimizing the risk of actual or perceived conflicts of interest.

REVIEW: This HSC OP is effective April 1, 2009. It will be reviewed on May 1 annually (ANN) by the TTUHSC Institutional Compliance Working Committee, with recommendations for revisions forwarded to the President by July 1.

GENERAL BACKGROUND:

Interactions between health care providers and Health Care Vendors occur in various and unique ways, especially in the academic setting and when properly managed and monitored can benefit public health and education. However, those interactions must be conducted in such a manner as to maintain the public trust.

As a health care provider and state agency, TTUHSC, its faculty, other employees and students, are subject to federal and state laws, Texas Tech University System Regents Rules (Regents Rules) and institutional policies that govern our interactions with Health Care Vendors.

The Federal Anti-Kickback statute makes it a crime to knowingly and wilfully solicit, receive, offer or pay, overtly or covertly, directly or indirectly anything of value in cash or in kind in exchange for the referral of patients, items or services payable by a federal health care program. A gift can be improper if it is made to someone in a position to generate referrals (i.e., prescribe drugs or durable medical equipment) or if the payment represents more than fair market value.

Texas Government Code, Section 572, Subchapter A, Section 572.001 prohibits any state officer or employee having a direct or indirect interest, financial or otherwise, from engaging in a business transaction or professional activity that is in substantial conflict with that individual's duties in the public interest.

See also Texas Tech University System Regents Rule 03.01, Personnel Ethics Policy and TTUHSC OPs 10.08, Ethics Policy, 70.15, Other Employment, and 70.18, Multiple Employment, may also apply to interactions between Health Care Vendors and TTUHSC faculty, other employees and students.

The American Association of Medical Colleges' (AAMC) "Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council" provides further guidance on policies to manage, and where necessary, prohibit academic-industry interactions that can inherently create conflicts of interests and undermine standards of professionalism.

DEFINITIONS:

Compensation or gift includes any benefit or remuneration, including, but not limited to, cash, checks, coupons, securities, discounts, pre-bates subsidies, real property, personal property, referrals, goods, prizes, services, promotional items, tickets, or anything else that has value to the person receiving it.

Health Care Vendor is any individual or company that sells or markets health care services or items to TTUHSC and/or its patients, including, but not limited to pharmaceutical companies or their representatives, device (or DME) manufacturers or their representatives, and equipment and/or service providers, or their representatives. It does not include vendors of items not related to the provision of health care items or services, such as research test tubes, office supplies, etc.

Educational Conference or Meeting as defined by the AMA Council on Ethical and Judicial Affairs¹ is any activity held in an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the focus of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support of conflict of interest should be made as part of the conference or meeting.

POLICY/PROCEDURE:

1. General.

To the extent that certain interactions with Health Care Vendors are prohibited in this policy, they are also prohibited when conducted outside the confines of the TTUHSC campuses, sites and/or facilities² as set forth below.

2. Compensation or Gifts from Health Care Vendors.

- a. Textbooks and education items that promote objective and scientific knowledge beneficial to teaching and/or patient care may be accepted on behalf of TTUHSC if approved by the department chair/director, provided such acceptance is allowed by state law and/or TTUHSC's policies. Promotional gifts (such as pens, pads, etc.) featuring product names shall not be accepted.
- b. No **personal** gift, including free drug samples, shall be sought or accepted from any Health Care Vendor. See Section 6 for further information on accepting free drug samples.
- c. No one shall seek or accept compensation or gifts from Health Care Vendors for prescribing, or changing a patient's prescription, using a specific device or equipment, or for the referral of patients to a provider of health care services or items.
- d. Faculty, other employees, students and departments shall not seek or accept compensation or gifts from Health Care Vendors for listening to sales presentations or talks about their products (i.e., detailing) by the Health Care Vendor.
- e. Compensation or gifts from Health Care Vendors given as a grant for studies of products when the studies require little or no actual scientific pursuit shall not be sought or accepted. An example of an unacceptable "research grant" is one that only requires minimal record keeping.
- f. No compensation or gift shall be sought or accepted from a Health Care Vendor by an individual who has or may have a substantive role in the selection of that Health Care Vendor to provide items or services under contract to TTUHSC.
- g. No compensation or gift shall be accepted in exchange for conducting marketing tasks during the course of providing health care, research and/or development services. For

¹ See AMA Opinion 8.061

² See Regents Rule 03.01

example, no one shall accept compensation or gifts from a Health Care Vendor to complete an evaluation form after using a health care item or product.

- h. Prescription pads from Health Care Vendors shall not be accepted.
- i. No compensation or gift from a Health Care Vendor raffle, lottery or contest shall be accepted.

3. Travel, Lodging, Meals and Conference Fees Provided by Health Care Vendors.

- a. Faculty, other employees, students and departments shall not seek or accept, from Health Care Vendors any compensation to travel to and/or attend sporting or entertainment events, all expense paid trips to vacation resorts, or similar activities.
- b. Faculty and other employees may accept reasonable honoraria and reimbursement for travel, lodging, meals and conference fees for their attendance at educational conferences or meetings, including those related to research activity, only if the person presents, serves as a panel discussion participant, panel moderator, or otherwise actively participates in the conference or meeting. Participation in the event must be more than merely perfunctory and the presenter must determine his/her own lecture content, prepare his/her own materials and present a balanced assessment of the topic being presented. The terms of the arrangement must be set forth in writing and all compensation must represent fair market value. Acceptance of honoraria must be consistent with state law and TTUHSC policies. Faculty and other employees who are only attendees at conferences cannot accept either honoraria or reimbursement for travel, lodging or meal expenses. Token consulting or advisory arrangements cannot be used to justify receipt of honoraria or reimbursement for travel, lodging, meals and/or conference fees.
- c. Faculty and other employees may accept Health Care Vendor reimbursement for travel, lodging, and meals to attend meetings to act as a “bona-fide” consultant or participate in panels regarding development of new research protocols, to discuss research results or to participate in a conference to understand requirements for future research activities.
- d. No compensation or gift shall be personally sought or accepted by an individual or on behalf of an individual from a Health Care Vendor for attendance at any conferences or meetings where the individual is not lecturing, presenting or otherwise actively participating in the conference or meeting. This policy does not prohibit attendance at conferences or meetings, but only prohibits accepting compensation or benefits from Health Care Vendors solely to attend a conference or meeting, whether or not it is an educational conference or meeting.
- e. Faculty and other employees may accept compensation for food, lodging and travel expenses from a Health Care Vendor if the purpose of the travel is to view, evaluate, or assess a piece of equipment or other product under consideration for possible purchase by TTUHSC or any of its Schools in accordance with Regent’s Rule 03.01.4, which requires that the TTUHSC faculty or employee is a “guest” as defined in the Rule.

4. Health Care Vendor Representative Access to TTUHSC Campuses, Sites and/or Facilities.

- a. TTUHSC has entered into an agreement with Vendormate, Inc. (“Vendormate”) to provide registration, screening and credentialing of Health Care Vendors subject to this policy. Each Health Care Vendor seeking access to TTUHSC facilities, clinics, faculty or residents shall register with Vendormate before their representatives are allowed onto a TTUHSC campus, site, or facility. As part of this registration process, the Health Care Vendor shall receive information on this policy and other relevant policies based on the Health Care Vendor’s registration tier/level.

- b. TTUHSC shall publish instructions for Health Care Vendors on the appropriate vendor tier/level for registration through Vendormate. Health Care Vendors with access to patients in accordance with this policy shall be designated at the highest registration tier through the Vendormate service.
- c. In coordination with the TTUHSC Institutional Compliance Officer, Vendormate may provide additional Vendor Program awareness/education to TTUHSC leadership and employees.
- d. Each TTUHSC campus shall provide at least one central location for Health Care Vendors to register and receive an access badge to TTUHSC facilities.
- e. TTUHSC shall communicate with known Health Care Vendors regarding mandatory registration using the Vendormate service and provide written notification that the Health Care Vendor will not be allowed access to TTUHSC facilities or clinics until it registers using the Vendormate service at <http://ttuhsc.vendormate.com>
- f. Health Care Vendors are required to check-in and receive a Health Care Vendor ID badge each time they enter onto a TTUHSC facility, clinic, office and/or department. A Health Care Vendor who fails or refuses to check-in and/or clearly display their ID badge will be asked to leave or directed to the check-in area.
- g. Health Care Vendors shall only have access to TTUHSC campuses and facilities during normal business hours or during scheduled on-site educational conferences or meetings.
- h. Health Care Vendors shall not have access if the purpose is to interact with students and/or residents or fellows about their products without a TTUHSC faculty member present.
- i. To maintain patient confidentiality under HIPAA, Health Care Vendors are limited to administrative areas such as physicians' administrative offices, department offices, conference rooms, public areas and other non-patient care areas. In those cases where it is not possible to directly access administrative areas, the Health Care Vendor shall be escorted through patient areas to access the administrative areas. Health Care Vendors are only allowed in patient care areas for:
 - 1. required training on new equipment or devices that have been purchased by TTUHSC, setting up such equipment, or similar activities associated with the contract as approved by TTUHSC;
 - 2. evaluation of new uses for equipment, devices, or related items.In these cases, the Health Care Vendor shall execute an appropriate Business Associate agreement.
- j. Health Care Vendors shall not attend any conferences or meetings at TTUHSC facilities where patient specific information (i.e., the information is not de-identified) or quality assurance activities are being discussed.
- k. In limited circumstances related to delivery of patient care (i.e., use of new equipment), a Health Care Vendor may be present during treatment, only if the patient has been informed and provided written consent to their presence, and a HIPAA Business Associate agreement has been signed, and then only to provide in-service training or assistance on devices and/or equipment. The Health Care Vendor shall not provide patient care at TTUHSC campuses, sites and/or facilities.

5. **Provision of Meals by Health Care Vendors at TTUHSC campuses, sites, and facilities.**
 - a. Meals for TTUHSC approved and accredited continuing education programs shall only be provided through the applicable continuing education office.
 - b. Meals provided for non-accredited educational meetings must be modest and coordinated with/by TTUHSC departments and only at the request/approval of the designated faculty representative in the department. Any materials to be presented by the Health Care Vendor at such activities must be reviewed and approved by the faculty designated. The Health Care Vendor shall not be allowed to discuss their product.
 - c. Meals may not be provided to anyone except for the educational activities stated in 5a and 5b above. Meals shall not be provided to non-provider employees.

6. **Drug, Equipment and Medical Device Samples.**
 - a. No drug, equipment or medical device samples shall be accepted for personal use of faculty or other employees or their family members. Samples of drugs, equipment or medical devices shall only be accepted if they are used for patient care or student educational purposes.
 - b. No drug, equipment or medical device sample shall be billed to any patient or third-party payer, including, but not limited to, government payers or private insurers. Free drug, equipment or medical device samples shall never be sold.
 - c. Sample drugs shall be stored in a secure and locked location within the Department or Division or in a central campus location. Expired sample drugs shall be disposed of in accordance with state and federal law.
 - d. Sample drugs, equipment and medical devices shall be tracked when given to a patient in a log, indicating the date of it was given to the patient, the patient's name or medical record number, and the lot number of the sample drug(s), or identifying number of the equipment or medical device(s) given to the patient. The lot number of sample drugs shall be noted in the patient's medical record at the time it is given to the patient.

7. **Funding of Continuing Education Programs at TTUHSC by Health Care Vendors.**
 - a. No faculty, other employee or department shall accept or receive any subsidy from a Health Care Vendor to support the cost of continuing education provided at or through TTUHSC. All funding from Health Care Vendors in support of continuing education programs at or through TTUHSC shall be in accordance with applicable accrediting agencies and shall only be made to the appropriate continuing education office at TTUHSC.
 - b. For continuing education activities not using the accreditation of internal TTUHSC continuing education departments, review and approval or funding mechanisms and channels must be reviewed and approved by the appropriate school's continuing education department or appropriate individual designated by the Dean of each School, for compliance with accepted accreditation practices.

8. **Faculty Consulting Honoraria from Health Care Vendors.**
 - a. Consulting honoraria shall only be accepted in accordance with Regents Rule 03.05; HSC OP 70.15 and any applicable plan by-laws regarding income-generating activities. (See also TTUHSC CME policy regarding honoraria for TTUHSC CME activities) All arrangements must be in writing and represent fair market value for actual work performed by the faculty member or employee.

- b. Payment or compensation from Health Care Vendors for token consulting or advisory arrangements shall not be accepted.
- c. Faculty and other employees shall not accept honoraria or any other type of payment for presenting at events where the content and/or materials (in whole or in part) have been prepared by or on behalf of a Health Care Vendor.

9. **Health Care Vendor Gifts for Scholarships.**

Scholarships or subsidies from Health Care Vendors to permit students, residents and fellows to attend carefully selected educational conferences or meetings (i.e., major educational, scientific or policy-making meetings of national, regional, or specialty medical, nursing, pharmacy or allied health associations) may be permissible as long as:

- the funds are provided to the School, Department, Program or Division and not directly to the student, resident or fellow;
- Nothing is given in return for the scholarships or subsidies;
- the selection of students, residents or fellows who receive the funds is made by the Dean or Department;
- the educational conference or meeting does not solely address the Health Care Vendor's products; and
- it is otherwise consistent with any continuing education requirements.

10. **Ghostwriting.**

Faculty, other employees, residents and students shall not have their professional presentations or publications ghostwritten by any party, including, but not limited to, individuals employed or contracted by Health Care Vendors. Ghostwriting occurs when written material is officially credited to someone other than the original writer(s) of the material. Writing collaboration where all authors are appropriately recognized based on the extent of their contribution is not ghostwriting.

11. **Response to Health Care Vendor Non-Compliance.**

Health Care Vendors or their representatives who repeatedly fail or refuse to comply with this policy, after written notice, shall be banned from TTUHSC facilities until further notice.

12. **Right to Change Policy.**

TTUHSC reserves the right to interpret, change, modify, amend or rescind any policy in whole or in part at any time without the consent of workforce, but may seek input, where appropriate.