



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 52.16, **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, residents, 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 will be reviewed on May 1 of each odd numbered year (ONY) by the TTUHSC Institutional Compliance Working Committee, with recommendations for revisions forwarded to the President by July 1.

DEFINITIONS:

Gift means a tangible item received directly from a Health Care Vendor. Gifts include any benefit or remuneration, including, but not limited to, cash, checks, coupons, securities, discounts, pre-bates, rebates, subsidies, real property, personal property, referrals, goods, prizes, services, promotional items, tickets, or anything else that has value to the person receiving it. It does not include items such as product brochures, fact sheets, article reprints, and bibliographies. This list is provided as examples only and is not intended to be comprehensive.

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 and their representatives, device or durable medical equipment (DME) manufacturers and their representatives, and equipment and/or service providers, and 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 topic(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 at the beginning of the conference or meeting.

Financial Interest includes, but is not limited to equity ownership, compensated positions on advisory boards, paid consultancy or other forms of compensated relationship. It does not include indirect ownership, through mutual funds or other investment vehicles in publically traded companies.

¹ See AMA Opinion 8.061

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 advance drug discovery, technology development and improving public health while maintaining the public trust.

As a health care provider and state agency, TTUHSC, its faculty, residents, staff, and students, are subject to federal and state laws, [Texas Tech University System \(TTUS\) Regents' Rules \(Regents' Rules\)](#) and institutional policies that govern our interactions with Health Care Vendors.

The American Association of Medical Colleges' (AAMC) Task Force report² 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.

POLICY/PROCEDURE:

1. General.

TTUHSC clinical and academic activities are carried out at multiple campuses and affiliated entities. In all cases where this policy is more restrictive than a TTUS or TTUHSC conflict of interest policy, this policy shall control. When faculty members, residents or students are in affiliated entities (i.e., hospitals), they should abide by this policy or the affiliated entity's policy, whichever is more strict with respect to a particular action in question.

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 facilities and affiliated entities.³

2. Conflicts of Interest and Disclosure

- a. [Texas Government Code, Section 572, Subchapter A, Section 572.001](#) prohibits any state officer or employee from, having a direct or indirect interest, financial or otherwise, engaging in a business transaction or professional activity, that is in substantial conflict with that individual's duties in the public interest. See also [TTUS Regents' Rule 03.01, Personnel Ethics Policy](#), [TTUHSC OPs 52.06, Standards of Conduct and Ethics Guide, 73.09, Financial Conflicts of Interest in Research](#), and [70.18, Dual Reporting and Multiple Employment](#), which may also apply to interactions between Health Care Vendors and TTUHSC faculty, residents, and staff.
- b. Any faculty employee who recommends or approves the purchase of a Health Care Vendor's product for TTUHSC or its affiliated hospitals shall not have a consulting relationship with or serve on the Advisory Board of that Health Care Vendor for the 12 month period prior to and after the recommendation or approval of the purchase. See also [Regents' Rule 03.01, Personnel Ethics Policy](#).
- c. As required by [73.09, Financial Conflicts of Interest in Research](#), individuals involved in research activities are required to make an annual report of their financial interests as defined in that policy.

²Industry Funding of Medical Education, Report of an AAMC Task Force, June 2008
http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd_id=232

³ See Regents Rule 03.01

3. **Compensation or Gifts from Health Care Vendors.**

The Federal Anti-Kickback statute makes it a crime to knowingly and willfully 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.

- a. No personal Gifts, shall be sought or accepted by TTUHSC faculty, residents, staff or students from Health Care Vendors.
- b. Faculty, residents, staff, and students shall **not** seek or accept compensation or gifts from Health Care Vendors for prescribing, or changing a patient's prescription, using or purchasing a specific device or equipment, or for the referral of patients to a provider of health care services or items (i.e., hospital, hospice, nursing facility, etc.).
- d. Faculty, residents, staff, students, Schools and Departments shall **not** seek or accept compensation or gifts, including meals, 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 research or studies of products when the research or 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 any TTUHSC faculty, resident or staff who has or may have a substantive role in the selection of that Health Care Vendor to provide items or services (including DME) under contract to TTUHSC or its affiliated hospitals. See Paragraph 8 for further restrictions.
- 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 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.

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

- a. Faculty, residents, staff, students and/or Departments shall not seek or accept from Health Care Vendors any compensation or reimbursement for travel to and/or attendance at, sporting or entertainment events, all expense paid trips to vacation resorts, or similar entertainment activities.
- b. Conferences.
 - i. Faculty, residents and staff 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 individual presents his/her own educational materials, 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 (including slides and handouts), and present a

balanced assessment of the topic being presented. The terms of the arrangement must be in writing and all compensation must represent fair market value. Acceptance of honoraria must be consistent with Texas laws and TTUHSC policies.

- ii. Faculty, residents and staff who are only attendees at conferences cannot accept either honoraria or reimbursement for travel, lodging or meal expenses directly or indirectly from any Health Care Vendor. Token consulting or advisory arrangements cannot be used to justify receipt of honoraria or reimbursement for travel, lodging, meals and/or conference fees.
- iii. Faculty, residents and staff 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 in which the person is involved.
- iv. No compensation or gift shall be personally sought or accepted by faculty, residents or staff on behalf of such 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 or research conference or meeting. This policy does not prohibit acceptance of modest meals (comparable to the meal allowance specified by the United States Internal Revenue Service) included as part of the conference fee paid by the individual and/or TTUHSC or by the Health Care Vendor as allowed under this policy.

c. Meals for TTUHSC Educational Events.

- i. Continuing Education Sponsored Events. Meals for TTUHSC accredited continuing education (CE) programs shall only be provided through the applicable continuing education office.
- ii. Non-Continuing Education Sponsored Events. Meals provided by Health Care Vendors for non-accredited educational meetings shall be modest and must be coordinated with/by TTUHSC Schools or Departments and only at the request and approval of the designated faculty representative in the School or Department. The Health Care Vendor shall not select the speaker and shall not be allowed to discuss its product(s) as part of the content of the educational meeting. Content for such events shall be “peer reviewed” and/or publishable material. Any promotional materials to be made available by the Health Care Vendor at such activities must be reviewed and approved by the designated faculty.

5. **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. Any 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. Health Care Vendors with access to patients (i.e., involved in patient care activities at TTUHSC) 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 where patient care activities are conducted.
- e. Health Care Vendors are required to check-in and receive a Health Care Vendor ID badge each time they enter 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 directed to the check-in area or asked to leave.
- f. 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.
- g. 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.
- h. 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; or
 - 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 [See HSC OP 52.13, HIPAA Business Associate Agreement Policy.](#)
- i. 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.
- j. 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 that has been purchased or is under consideration for purchase by TTUHSC. The Health Care Vendor shall not provide patient care at TTUHSC campuses, sites and/or facilities.

6. Drug, Equipment and Medical Device Samples.

- a. No drug, equipment or medical device samples shall be accepted for personal use of faculty, residents or staff employees or their family members. Samples of drugs,

equipment or medical devices shall only be accepted if they are used for patient care or education, or student educational purposes. Patients shall only be given sample drugs to determine efficacy to treat the patient's condition. Those campuses that have a pharmacy presence should evaluate the transition of sample drugs to a central pharmacy to ensure the availability of brand-name and generic medications to patients.

- 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. See [Ambulatory Clinic Policy 4.02](#).
- 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, resident, staff employee, School and/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, 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. Consulting Honoraria from Health Care Vendors.

- a. Consulting honoraria shall only be accepted in accordance with [Regents' Rule 03.01.4](#); [HSC OP 70.18, Dual Reporting and Multiple Employment](#) and any applicable practice 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, resident or staff employee and approved by the faculty member's immediate supervisor.
- b. Payment or compensation from Health Care Vendors for token consulting or advisory arrangements shall not be accepted.
- c. Faculty, staff, residents and students shall not accept honoraria or any other type of payment for presenting at events where the content and/or materials, including slides (in whole or in part) have been prepared by or on behalf of a Health Care Vendor.

9. Health Care Vendor Support for Scholarships, Fellowships or other Trainees.

- a. 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 and Speakers Bureaus.**

- a. Faculty, staff, residents and students shall not publish articles under their own names that are written in whole or in part by Health Care Vendor employees, contractors or representatives (i.e., "ghost-written"). The International Committee of Medical Journal Editors guidelines should be followed in determining the criteria for being listed as an author on any publication.
- b. Faculty, staff, residents and students may participate in, or receive compensation for, speaking engagements, provided **ALL OF THE** following exist:
 - The event meets the criteria of Section 2 above;
 - The lecture content or presentation materials (including slides and handouts) are prepared by the speaker and is not subject to prior approval by either the Health Care Vendor or its representatives, including, but not limited to event planners contracted by the Health Care Vendor;
 - The lecture content, including slides and handouts, is based on the best available scientific evidence;
 - The Health Care Vendor does not directly or indirectly select the attendees or provide any honorarium to attendees; and
 - The speaking arrangement is not long term (more than 12 months).

11. **Response to Non-Compliance.**

- a. Non-compliance with this policy should be reported to the appropriate Dean or the Institutional Compliance Officer. Alternatively, reports can be made through the TTUS Compliance Hotline at 1-866-294-9352 (toll-free) or the web at www.ethicspoint.com,
- b. Alleged violations of this policy by TTUHSC faculty, residents, staff, or students shall be investigated by the Institutional Compliance Office. Suspected violations involving faculty, residents, or staff shall be referred to the individual's Dean or Department Chair, who shall determine what actions, if any, shall be taken in accordance with TTUHSC policies. Suspected violations involving students shall be reported to the Dean of Students for the School in which the student is enrolled. Violations of this policy may result in one or more of the following, depending on the seriousness of the violation, whether the violation is a first or repeat offense, whether the individual(s) knowingly violated the policy or attempted to hide the violation:
 - Counseling;
 - Additional education/training regarding this policy;
 - Written reprimand;
 - Suspension of future relationships between the individual(s) involved in the violation and Health Care Vendors for a set period of time;
 - Return of any gifts or compensation received in violation of this policy or related TTUS and TTUHSC policies;
 - Termination for cause.

Any disciplinary action taken under this policy shall follow established TTUHSC procedures.

c. Violations of this policy by Health Care Vendors or their representatives shall result in one or more of the following actions by the Institutional Compliance Officer:

- Verbal warning to the representative;
- Written warning to the representative and Health Care Vendor;
- Written notice to the Health Care Vendor that badge access is terminated and its representatives are no longer allowed on TTUHSC campuses, sites or facilities for purposes of selling or marketing their services or items.

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.