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Approved by: **President**

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Applies to: **Upstate Medical University-Hospital & Campus**

Value(s): *(Drive Innovation & Discovery, Respect
People, Value Integrity, Serve Community)*

Page(s): **1 of 7**

Policy on the Relations with Industry in Patient Care and Education

Review Date:	Change Description:
10/04/2014	<i>Formerly CAMP A-24. Moved to University-Wide Policy Manual on 03/26/2015.</i>
Revised Date:	Change Description:
10/04/2014	Section 2 replaced by new Research Conflict of Interest Policy (CAMP A-32). Sections 3 and 4 eliminated.

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Introduction

Purpose of Policy

The mission of SUNY Upstate Medical University is to improve the health of the communities we serve through education, biomedical research and health care. Clinicians have a primary responsibility to work for patients’ welfare. Researchers are dedicated to furthering scientific biomedical understanding in ways that can be translated into products and techniques that benefit society. To achieve these ends, SUNY Upstate’s faculty, staff and students interact and, at times, partner with the pharmaceutical, medical device and other companies and organizations, such as federal, state and local governments, foundations and individuals.

This policy establishes expectations for behavior in relations with the pharmaceutical, medical device, biotechnology, and other companies (hereafter referred to as Industry¹), and other organizations in accordance with the expressed values of SUNY Upstate Medical University. It is intended to guide interactions with Industry and other organizations so that institutional and professional integrity is maintained while we care for patients; teach clinicians, scientists, and students; and carry out biomedical research.

Covered Individuals

This policy applies throughout SUNY Upstate to all employees (including faculty, staff, residents, fellows, others in training), students, employees of the Research Foundation of the State University of New York, employees of MedBest, and members of the SUNY Upstate Council, who shall be known as covered individuals, unless otherwise noted.

This policy incorporates and, at times augments existing laws, including the New York State Public Officers Law; state, SUNY, and campus policies; and negotiated agreements. Nothing in this policy shall take precedence over existing laws, policies, and negotiated agreements with any union of employees. Individual departments and units shall review their policies and revise them if necessary to ensure that they are consistent with this policy.

Oversight and Implementation

The President of SUNY Upstate Medical University is responsible for overseeing the implementation of this policy.

Section 1. Relations with Industry¹ in Patient Care and Education

A. Introduction and Purpose

Academic health centers and their clinicians have fundamental responsibilities to save lives, ameliorate disease, and relieve suffering. The pharmaceutical, medical device, and

¹ Unless otherwise noted in this report, “Industry” is meant to refer collectively to the pharmaceutical, medical device and equipment, and biotechnology industries.

biotechnology industries have developed and brought to market drugs, devices, and other products that help achieve these ends. Clinicians have the ethical duty to recommend and prescribe specific drugs and devices based on the patient's best interests, and not out of personal gain. The following guidelines are intended to:

1. help ensure that clinicians select products based primarily on the patient's welfare, and
2. minimize the influence of Industry on clinical decision-making through gifts, personal or institutional financial interests in Industry, or uncritiqued marketing presentations or materials.

B. Scope of Policy

This section focuses on the clinical realm and education of health care professionals and applies to all covered individuals, as defined in the Preamble, at all times, both on and off-duty, and to all interactions at SUNY Upstate, including its hospital, clinics, MSG practices, and any other locations that may be added to Upstate's space inventory. An exemption for part-time, paid faculty may be granted by the department chair with the concurrence of the dean, provided that the part-time faculty's clinical, teaching, and research commitments and obligations to Upstate are not compromised and remain fulfilled. A department chair may choose to extend this policy to the department's voluntary faculty and must inform the voluntary faculty in writing if he or she does so.

In addition to complying with this policy, covered individuals must comply, where applicable, with the legal requirements as expressed in the New York Public Officers Law, other relevant State and Federal laws and regulations, and the Research Foundation of the State University of New York policies and procedures.

C. Specific Topics Requiring Scrutiny

1. **Detailing by Industry Representatives²**
 - a. Access to premises of Upstate by Industry representatives may occur only by appointment or invitation of the physician. Pharmaceutical representatives are allowed only in non-patient care areas and nonpublic areas, except when it is necessary for them to traverse a public area (e.g., lobby or hallway) to reach an approved destination. Device manufacturer representatives are permitted in patient care areas only when they are appropriately credentialed by the relevant Upstate department. They may be present during patient care only to provide in-service training or assistance on devices and equipment, and then only with prior disclosure to and consent by the patient. Departments that allow the presence of medical device representatives must develop written guidelines for clarifying the credentialing of such representatives.

² Adapted from the AAMC's report, *Industry Funding of Medical Education* (2008).

- c. **Travel funded by Industry to be trained on equipment already purchased by or approved for use at Upstate is not considered a gift and is permitted. Provision for such travel should be included in the contract or memorialized in some other manner. Travel funded by Industry to evaluate equipment not yet purchased by Upstate is allowed if the equipment to be purchased is included in the open bid process. For sole-source vendors, the purchasing entity (e.g., University Hospital, medical service group) should pay for the travel.**

4. Free drug samples⁵

- a. **Drug samples may be dispensed only to patients being cared for at the practice site. They may not be used by employees, students, volunteers, family members or anyone else who is not a patient at the practice site.**

Samples may be dispensed only to patients meeting one of the following conditions:

- **medically indigent**
 - **no prescription coverage and extraordinarily expensive agents are required**
 - **access to pharmacy services is temporarily unavailable (e.g., the pharmacy is closed)**
 - **a short trial (1 week or less) of the medication is necessary to determine whether it has the desired effect or the medication needs to be changed before taking the prescription to the pharmacy, thus avoiding unnecessary costs**
- c. **Drug samples must be managed centrally within the practice site. Samples must be dispensed consistent with standards of pharmaceutical practice, which include, but are not limited to, correct labeling (including patient name, date, medication name and dosage, instructions for use, prescribing clinician), a log tracking the medication and documenting that the patient has received appropriate medical counseling, and secure storage. The Pharmacy Department will conduct routine on-site inspections and annual review of written procedures.**

5. Industry-sponsored speakers' bureaus⁶

- a. **Industry-sponsored speakers' bureaus are defined as follows. Industry hires faculty speakers to deliver promotional talks, using Industry-prepared and approved presentations. These talks are confined to FDA-approved product safety and efficacy discussions and approved disease-state education. By the**

⁵ Adapted from the Associated Medical Schools of New York State's *Common Policy for Interacting with Pharmaceutical Company Representatives* (2008) [hereafter referred to as "AMSNYS Common Policy"], AAMC's *Industry Funding of Medical Education*, and University Hospital policy CM D-06 and University Hospital policy M-12.

⁶ Adapted from AMSNYS Common Policy

nature of their content and origin of their authorship, such talks do not qualify for CME certification.

- b. **Participation in Industry-sponsored speakers' bureaus by covered individuals is prohibited. (Covered individuals may provide certified CME talks.) Covered individuals or Upstate departments may not sponsor or promote Industry-sponsored speakers' bureau talks, and Industry-sponsored speakers' bureau talks are prohibited on University premises.**
6. **Continuing education⁷**
- a. **The following applies to all continuing education (CE), whether it is continuing medical education (CME) or CE in other disciplines. SUNY Upstate units (e.g., departments, colleges, University Hospital) may accept funds from Industry for CE, but Industry may not specify the content or the speakers. Industry may request the overall topic, such as a condition or disease state (e.g., epilepsy, hypertension, lung cancer). All agreements for Industry support must be negotiated through and executed by the Office of CME (CME Office).**
 - b. **In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing, all CE events hosted or sponsored by SUNY Upstate must comply with Accreditation Council for Continuing Medical Education standards (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for the event. CE programs must be open on equal terms to all interested practitioners and may not be limited to attendees selected by Industry.**
 - c. **Industry funding for such programming should be used to improve the quality of the education, not to support meals or social activities. Industry funding may be used to support the costs of internal department meetings, if the subject and content of these meetings is determined solely by the department, in consultation with the CME Office. The CME Office will audit CE programs to ensure that departments comply with these policies.**
 - d. **Training programs designed solely for sales or marketing, presented by personnel supported by Industry, are prohibited.**
 - e. **Upstate facilities may not be rented by or used for Industry-funded or directed programs, unless there is a CE agreement for Industry support that complies with these policies.**
 - f. **Industry support for CE in the form of donated funds shall be recognized in a manner that does not promote a particular product.**

⁷ Adapted from *Accreditation Council for Continuing Medical Education Standards for Commercial Support of Educational Programs* (2007) and University of Pittsburgh policy/

D. Implementation**1. Responsibility for Implementation**

The President of SUNY Upstate Medical University is responsible for overseeing the implementation of this policy.

2. Declaration, Disclosure, and Referral**a. Disclosure of financial interests in Industry**

All covered individuals must disclose any financial arrangements with Industry that exceed \$1,000 from any single company annually.

b. Disclosure of relationships with Industry to students

Covered individuals in a teaching capacity should inform their students and other learners of their relationships with Industry. This may be done at the beginning of a course or session or other appropriate time. In situations that are transient or inconvenient (e.g., patient rounds), the teacher should use his/her discretion in informing students, being guided by the relevance of the relationship with Industry to the situation at hand.

Section 2. Review and Evaluation of the Policy on the Identification and Management of Conflicts of Interest and Commitment

This policy shall be reviewed and evaluated periodically by the University to determine if it is working as intended and whether any modifications are needed. This review and evaluation as well as any changes in the Policy will be made available to the University community.

Originating Department: Office of the President

Contributing Department(s): Research Administration

Office of the Dean

Department of Bioethics and Humanity

References: None