

Policy Number: **UW I-03**

Approved by: Management Forum & Leadership Council

Issue Date: 02/01/2010

Applies to: Upstate Medical University

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

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## **Relations by the Upstate Community with Commercial Entities (Formerly known as the Relations with Industry Policy)**

<i>Review Date:</i>	<i>Change Description:</i>
02/04/2016	Formerly CAMP A-24. Moved to University-Wide Policy Manual on 03/26/2015.
<i>Revised Date:</i>	<i>Change Description:</i>
02/04/2016	Revisions to reflect change in 6W.

### **Policy:**

#### **A. Policy Statement**

Upstate’s mission is to improve the health of the communities we serve through clinical care, biomedical research and education. Clinicians have a duty to recommend specific drugs and devices based on the patient’s best interests; researchers should be dedicated to furthering scientific understanding in ways that can be translated into applications that benefit society; and educators should be committed to a process that produces clinicians and scientists in fulfillment of Upstate’s mission.

In order to achieve these ends, members of the Upstate community often interact and/or partner with private commercial entities. This policy establishes expectations for behavior by members of the Upstate community in relations with such entities (individually referred to as a “Commercial Entity” and defined below). It is intended to guide these interactions so that institutional and individual integrity are maintained while we care for patients, engage in research and teach clinicians, scientists, and students.

This policy is intended to apply broadly, and at all times and to all interactions at Upstate, including its hospitals, clinics, offices of affiliates and medical services groups (“MSG’s”) and other clinical practices, and any other locations that may be added to Upstate, and also applies to Covered Individuals at all times and in all contexts including while they are attending professional meetings and other off-campus events.

#### **B. Scope of Policy**

This policy is one of three policies that deal with interactions by member of the Upstate community with commercial entities and it should be read in conjunction with:

- Policy [UW C-12](#) “*Identification and Management of Conflicts of Interest and Commitment by Members of the Upstate Community Involved in Entrepreneurship or with Companies (ECOI Policy)*” which pertains to members of the Upstate community when they are engaged in outside commercial activities; and
- Policy [UW R-03](#), “*Identification and Management of Conflicts of Interest by Members of the Upstate Community Involved in Sponsored Research (RCOI Policy)*” which

pertains to members of the Upstate community when they are engaged in sponsored research.

Members of the Upstate community should also be guided by the provisions of New York Public Officers Law Sections 73, 73-a and 74, applicable federal regulations and conflicts of interest policies promulgated by the State University of New York and the Research Foundation for SUNY. Upstate’s *Managing Potential Conflicts of Interest: A Handbook for the Upstate Community* is an additional resource to answer questions regarding frequently encountered conflicts of interest issues.

**C. Definitions**

***Covered Individual*** includes all members of the Upstate community, including, but not limited to students, faculty members, employees (including residents, fellows, others in training), employees of the various MSG’s, employees of the Research Foundation for SUNY who work at Upstate, and employees of entities affiliated with Upstate. 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.

***Commercial Entity*** includes for-profit organizations, vendors, lobbyists, employee unions, textbook publishers, commercial enterprises that contract with or wish to contract with Upstate and pharmaceutical, medical device and equipment companies and biotechnology industries. For purposes of this policy, Commercial Entity shall also include any person or entity considered an “Interested Source” as that term is defined in Section 73 of New York Public Officers Law.

***Gift*** means anything having more than nominal value, and includes payments and reimbursements, office items, medical equipment and devices, textbooks, money, services, favors, discounts, conference fees, meals, lodging, travel, entertainment, or other hospitality provided by a Commercial Entity at any time or location. Title 19 NYCRR Part 933.4 identifies those items that are not gifts under state law. This policy adopts this provision for purposes of identifying items from a Commercial Entity that are not gifts and thus, not subject to the provisions of this policy.

**D. Specific Topics**

**1. Access and contact by Commercial Entities**

(a) Access by a Commercial Entity representative to Upstate’s clinical premises may occur only by invitation of a physician, department chair, or an appropriate hospital department head. Commercial Entity representatives 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. Pharmaceutical representatives are allowed only in non-patient care areas. Device manufacturer representatives are permitted in patient care areas only when approved by the relevant department.

(b) Contact by Commercial Entity representatives with residents, fellows, students, and others in training should occur only for educational purposes under

the supervision of a faculty member, with faculty-supervised critical analysis of the information provided.

(c) Notwithstanding the provisions of Paragraph 3 below, a Commercial Entity may not provide, serve or distribute food, beverages, promotional items or anything having a monetary value while on the premises of Upstate Medical University except with specific written permission from the Office of University Compliance and Ethics.

2. **Institutional decisions regarding purchasing by individuals with financial interests in industry**

(a) Covered Individuals with any financial interest in a Commercial Entity, or whose family member (spouse, partner, child) has such an interest, and Covered Individuals who serve or intend to serve in an advisory or management role for a Covered Entity must disclose the interest as required by Upstate Policy No. UW C-12 (*"Identification and Management of Conflicts of Interest and Commitment by Members of the Upstate Community Involved in Entrepreneurship or with Companies"*) and withdraw from involvement in purchasing decisions relevant to the conflicting interests.

(b) Covered Individuals who request that a drug, device, or product be adopted by Upstate must disclose any interests they have in the product to those making the purchasing decision.

(c) If the expertise of a Covered Individual who meets the criteria of paragraph (a) above is necessary in order to evaluate a product in which the Covered Individual has an interest, the interest must be disclosed in writing to those who have the responsibility for making the decision. Only written testimony from that Covered Individual will be accepted in deciding whether to adopt the drug, device, or product.

3. **Meals from a Commercial Entity**

While Covered Individuals may not accept a gift from a Commercial Entity, Covered Individuals may accept meals from Commercial Entity representatives under the following circumstances:

(a) at an education program when the Covered Individual is receiving continuing education credits, or at a non-credit education program when the Covered Individual has received appropriate approval to attend the program, or when the Covered Individual is a presenter at a program that fits one of the two criteria for participation;

(b) at a research investigator meeting when the source of the meals is the research sponsor and meeting attendance is included in the research grant or approved budget;

(c) during travel permitted under Paragraph 5 below when the source of the meals is the vendor.

4. **Educational materials**

While Covered Individuals may not accept a gift from a Commercial Entity, Covered Individuals may accept educational materials from Commercial Entity representatives under the following circumstances:

Educational materials for patients or students (including residents and fellows) developed and provided by a Commercial Entity are not considered a gift and may be accepted if the materials are the best available source and are for the purpose of education. They may not be accepted if they are primarily for the purpose of selling a product. Also, informational materials are permitted for products for which manufacturers' information and instructions are required.

5. **Travel**

While Covered Individuals may not accept a gift from a Commercial Entity, Covered Individuals may accept travel payments from Commercial Entity representatives under the following circumstances:

Travel funded by a Commercial Entity 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 and should be in accordance with state travel rules. Travel funded by a vendor 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.

6. **Free drug samples**

Drug samples may be dispensed only in accordance with Upstate's Pharmaceutical Sample Policy (CM D-06). Those persons offered drug samples should direct the offeror to Upstate's Pharmacy Department and otherwise should not accept drug samples.

7. **Commercial Entity-sponsored talks, lectures and speaking engagements including speakers bureaus**

Covered Individuals should be aware that their delivery of, or participation in, Commercial Entity-sponsored talks, lectures and speaking engagements may implicate restrictions contained in law and/or other applicable policies. For example, New York Public Officers Law Section 73 prohibits the acceptance of a payment from, among others, a person or entity that has contracts with, or seeks to have contracts with Upstate. New York Public Officers Law Section 74 prohibits state employees from having an interest in, or engaging in any activity which is in substantial conflict with his/her state job. Similarly, SUNY and RFSUNY conflict of interest policies prohibit the participation in any activity that impairs or would reasonably appear to impair the ability to perform one's

duties with independence and objectivity. Covered Individuals should be aware of these and other applicable provisions and take reasonable steps to ensure compliance with all laws and policies before engaging in any industry-sponsored activity.

(a) Participation in Commercial Entity-sponsored speakers bureaus by Covered Individuals is prohibited, either as a speaker or as an attendee. Speakers bureaus are defined as follows: a Commercial Entity hires speakers to deliver promotional talks, using Commercial Entity-prepared and approved presentations. Covered Individuals and Upstate departments may not sponsor or promote Commercial Entity-sponsored speakers bureau talks, and Commercial Entity-sponsored speakers bureau talks are prohibited on Upstate premises.

(b) Notwithstanding the foregoing, Covered Individuals may provide and participate in certified continuing education programs (defined below).

### 8. Continuing education

(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 unrestricted grants of funds from a Commercial Entity for CE, but the Commercial Entity may not specify the content or the speakers. A Commercial Entity may request the overall topic, such as a condition or disease state (e.g., epilepsy, hypertension, lung cancer). Commercial Entity funding for such programming should be used to improve the quality of the education. All agreements for Commercial Entity support must be negotiated through and executed by the 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 Upstate must comply with Accreditation Council for Continuing Medical Education (ACCME) 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) In accordance with ACCME policy and guidelines, modest meals and snacks may be paid for out of the unrestricted grants of funds from Industry if the meals or snacks are incidental to the educational activity.

(d) Training programs designed solely for sales or marketing, presented by personnel supported by a Commercial Entity, are prohibited.

(e) Upstate facilities may not be used for Commercial Entity-funded or directed programs, unless there is a CE agreement for Commercial Entity support that complies with these policies.

(f) Commercial Entity support for CE in the form of donated funds shall be recognized in a manner that does not promote a particular product.

(g) Staffed exhibits and promotional materials may not be displayed or distributed in the educational space immediately before, during, or after a CE activity. The educational space includes the room or venue of the actual activity as well as the space through which the activity is accessed, such as a hallway or anteroom. Staffed exhibits and promotional materials may be displayed in another room or venue through which the participants in the CE activity are not obligated to pass to attend the activity.

(h) The CME Office will audit CE programs to ensure that departments comply with these policies.

9. Disclosure of relationships with industry to students

Covered Individuals who teach should inform their students and other learners of their relationships with Commercial Entities. 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 Commercial Entities to the situation at hand.

E. **Implementation**

The operational responsibility for the implementation of this policy is delegated to the Office of University Compliance and Ethics. Members of the Upstate community shall be required to submit, at least annually, a completed disclosure form prescribed by and obtained from the Office of University Compliance and Ethics. Said disclosure may include the identification of all outside activities (i.e., non-Upstate activities) and all involvement with companies, including Commercial Entities and entities that constitute an “Interested Source” as that term is defined in New York Public Officers Law.

**Education/Related Documents:**

**Form Name(s) and Number(s):**

**Originating Department:** Office of the President  
**Contributing Department(s):** Research Administration  
Office of the Dean  
Ethics Officers  
Office of General Counsel

**Evidence-Based References:**