



ROWAN UNIVERSITY

School of Osteopathic Medicine

Title: Industry Relations with Physicians and Continuing Medical Education

Subject: Health Services

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Applies: School of Osteopathic Medicine

Issuing Authority: Dean, School of Osteopathic Medicine

Responsible Officer: Dean, School of Osteopathic Medicine

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INITIATED BY: RowanSOM Administration

APPROVED BY:

Thomas A. Cavalieri, DO, Dean

Approved by: Rowan University School of Osteopathic Medicine Executive Council

PURPOSE: To establish guidelines for interactions between Industry and faculty, staff and students of the Rowan University School of Osteopathic Medicine (RowanSOM).

POLICY: RowanSOM is committed to providing humanistic education in the art and science of medicine within an environment in which excellence in patient care, innovative teaching, research, and service to our community are valued. These goals require that faculty, students, trainees and staff of RowanSOM interact with representatives of pharmaceutical, biotechnology, medical device, and hospital equipment supply industry (hereinafter “Industry”), in a manner that advances the use of the best available evidence so that medical advancements and new technologies become broadly and appropriately used. While the interaction with Industry can be beneficial, Industry influence can also result in unacceptable conflicts of interest that may lead to increased costs of healthcare, compromised patient safety, negative socialization of students and trainees, bias of research results, and diminished confidence and respect among patients, the general public and regulatory officials. Because provision of financial support or gifts may exert an impact on recipients’ behavior, RowanSOM has adopted the following policy to govern the interactions between Industry and RowanSOM personnel. This policy has been designed to reflect the best available literature on conflict of interest and is intended to provide guiding principles that members of the RowanSOM community as well as representatives of Industry can use to assure that their interactions result in optimal benefit to clinical care, education, research, and maintenance of the public trust.

SCOPE: This policy applies to all faculty, staff, and students of RowanSOM, to all healthcare professionals and staff employed and/or contracted by RowanSOM, and to all facilities owned or controlled by the RowanSOM. In all cases where this policy is more restrictive than other RowanSOM conflict of interest policies, this policy shall take precedence. This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry, including those individuals whose purpose is to provide information to clinicians about company products, even though such personnel are not classified in their company as “sales or marketing.”

STATEMENT OF THE POLICY: It is the policy of RowanSOM that clinical decision-making, education, and research activities are free from influence created by improper financial relationships with, or gifts provided by Industry. These general principles should guide interactions and relationships between RowanSOM personnel and Industry representatives. The following limitations and guidelines are directed to certain specific interactions. For situations not specifically addressed, RowanSOM personnel should consult in advance with their deans, departmental chairs and/or their administrators to obtain further guidance and clarification.

SPECIFIC ACTIVITIES:

1. Support of Continuing Education in the Health Sciences:

Industry support of continuing education (“CE”) in the health sciences can provide benefit to patients by ensuring that the most current, evidence-based medical information is made available to healthcare practitioners. In order to ensure that potential for bias is minimized, all CE events in which RowanSOM participates as a sponsor or co-sponsor must comply with the ACCME Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for attendance at the event. As a CE Provider accredited by the American Osteopathic Association (AOA), RowanSOM sponsors CE events and from time to time conducts educational events in conjunction with affiliated Hospitals or other partners. All agreements for Industry support must be negotiated through and executed by the RowanSOM Director of Continuing Medical Education (CME) and must comply with all policies for such agreements. Industry funding for such programming should be used to improve the quality of the education and should not be used to support hospitality, such as meals, social activities, etc., except at a modest level.

Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings or retreats (either on or off campus). RowanSOM facilities may not be rented by or used for Industry funded and/or directed programs, unless there is a CE agreement for Industry support that complies with the policies of the Office of the Director of CME.

At RowanSOM co-sponsored Continuing Education programs, if there is an area utilized and designated for vendor displays, that area will be separate from the location assigned for the educational presentations. Any materials utilized by the industry vendors will be subject to the guidelines established in Section 3. Promotional materials shall be limited to those which do not include product brand names and logos. Additionally, no gifts or enticements such as food or snacks will be permitted at these displays.

2. Industry Sponsored Meetings or Industry Support for Participation in Off-campus Meetings:

RowanSOM faculty, personnel, students or RowanSOM providers or staff may participate in or attend Industry-sponsored meetings or other off-campus meetings where Industry support is provided, only if:

- a. The activity is designed to promote evidence-based clinical care and/or advance scientific research
- b. The financial support of Industry is prominently disclosed
- c. Industry does not pay attendees’ travel and expenses except as specified below in f., g. and h.
- d. Attendees do not receive gifts or other compensation for attendance
- e. Meals provided are modest (value comparable to Standard Meal Allowance as specified by IRS)
- f. If participating as a speaker, all lecture content is determined by the speaker and reflects a balanced assessment of the current science and treatment options, and the speaker makes clear that the views expressed are the views of the speaker and not of RowanSOM

- g. If participating in connection with a research study or project
- h. Compensation is reasonable and limited to reimbursement of reasonable travel expenses, and a modest honorarium not to exceed \$2,500 per event unless otherwise authorized.

3. Gifts and Provision of Meals:

RowanSOM personnel shall not accept or use personal gifts (including food) from representatives of Industry, *regardless of the nature or dollar value of the gift*. Although personal gifts of nominal value may not violate professional standards or anti-kickback laws, such gifts do not improve the quality of patient care, and research has shown they may subtly influence clinical decisions, and add unnecessary costs to the healthcare system. Gifts from Industry that incorporate a product or company logo (e.g., pens, notepads or office items such as scales or tissues) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system.

Meals or other hospitality funded directly by Industry may not be offered in any facility owned and operated RowanSOM. RowanSOM personnel may not accept meals or other hospitality funded by industry, whether on-campus or off-campus, or accept complimentary tickets to sporting or other events or other hospitality from Industry. Modest meals provided incidental to attendance at an off-campus event that complies with the provisions of subsection 2, above, may be accepted.

All full-time and part-time RowanSOM faculty, as well as RowanSOM medical students will act in accordance with RowanSOM policy at all times, including during time spent in the community with RowanSOM clinical faculty.

Industry wishing to make charitable contributions to RowanSOM may contact the Development Office. Such contributions shall be subject to any applicable policies maintained by RowanSOM.

4. Consulting Relationships:

Rowan University School of Osteopathic Medicine recognizes the obligation to make the special knowledge and intellectual competence of its faculty members available to government, business, labor, and civic organizations, as well as the potential value to the faculty member and RowanSOM. However, consulting arrangements that simply pay RowanSOM personnel a guaranteed amount without any associated duties (such as participation on scientific advisory boards that do not regularly meet) shall be considered gifts and are consequently prohibited.

In order to avoid gifts disguised as consulting contracts, where RowanSOM personnel have been engaged by Industry to provide consulting services, the consulting contract must provide specific tasks and deliverables, with payment commensurate with the tasks assigned. All such arrangements between individuals or units and outside commercial interests must be reviewed and approved by the Dean or his designee, prior to initiation in accordance with appropriate RowanSOM policies. Consulting relationships with Industry may be entered into only with the prior permission of the vice dean, departmental chair or administrator. For employees of RowanSOM who are not faculty, prior written approval of the appropriate supervisor within RowanSOM is required for any outside consulting. Rowan University School of Osteopathic Medicine reserves the right to require faculty and employees to request changes in the terms of their consulting agreements to bring those consulting agreements into compliance with RowanSOM policies.

5. Frequent Speaker Arrangements (Speakers Bureaus):

While one of the most common ways for RowanSOM to disseminate new knowledge is through lectures, "speakers bureaus" sponsored by Industry may serve as little more than an extension of the marketing department of the companies that support the programming. Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to determine whether

the event meets the criteria set forth in Section 2 of this policy, relating to Industry Sponsored Meetings. RowanSOM personnel may not participate in, or receive compensation for, talks given through a speaker's bureau or similar frequent speaker arrangements if any of the following are true:

- a. Events do not meet the criteria of Section 2;
- b. Content of the lectures given is provided by Industry or is subject to *any* form of prior approval by either representatives of Industry or event planners contracted by Industry
- c. Content of the presentation is not based on the best available scientific evidence
- d. Company selects the individuals who may attend or provides any honorarium or gifts to the attendees.
- e. Under no circumstances may RowanSOM personnel be listed as co-authors on papers ghostwritten by Industry representatives. In addition, RowanSOM personnel should always be responsible for the content of any papers or talks that they give, including the content of slides.

Speaking relationships with company or company event planners are subject to review and approval of the participant's administrator, department chair, or dean as delineated in Section 4, Consulting Relationships.

6. Ghostwriting:

Under no circumstances may RowanSOM personnel be listed as co-authors on papers ghostwritten by Industry representatives. In addition, RowanSOM personnel should always be responsible for the content of any papers or talks that they give, including the content of slides.

7. Industry Support for Scholarships or Fellowships and other Educational Funds to Students and Trainees:

Rowan University School of Osteopathic Medicine may accept industry support for scholarships and discretionary funds to support trainee or student travel or non-research funding provided that the following criteria are met:

- a. Industry support for scholarships and fellowships must comply with all RowanSOM requirements for such funds, including a written pledge agreement through the Development Office. It will be maintained in an appropriate restricted account, managed at the school as determined by the Dean. RowanSOM will select the recipients of such funds with no involvement by the donor industry. Written documentation of the selection process will be maintained.
- b. Industry support for other student or trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by a written agreement and will only be accepted into a common pool of discretionary funds, which will be maintained under the direction of the Dean. Industry cannot designate contributions to fund specific recipients or specific expenses. Departments may apply to use monies from this pool to pay for reasonable travel and tuition expenses students, or other trainees to attend conferences or training that have legitimate educational merit. Recipients will be selected by the department based on merit and/or financial need. Proper documentation must accompany the request.
- c. Final approval and possible exceptions shall be at the discretion of the Dean.

8. Samples:

Utilization of drug or device samples at RowanSOM run clinics will be judicious and cost-effective. Utilization of drug samples will be at the discretion of the appropriate medical care provider solely for the purpose of patient care (e.g., allowing patients to begin early treatment; testing a therapeutic option prior to filling a prescription; offering an alternative for individuals having difficulty affording their medicines). Utilization of equipment or device samples will be deemed appropriate when healthcare

practitioners are developing a familiarity with new materials. Samples of any kind are not intended for personal use by faculty, staff or students. The sale or trade of any industry related sample is strictly prohibited.

Wherever possible, a central distribution and documentation site for medication samples should be established in each medical office that maintains storage of such samples. Samples should be logged in through a designated and secure sample storage process. Logs should include the name of the medication, lot number, expiration date, date of receipt, quantity received, and the name of the individual receiving the samples, including those received on behalf of a group practice. Logs will be maintained in the healthcare facility for a specified time as designated per policy. All samples will be labeled and dispensed in accordance with federal and state laws. A Sample Medication Form will be used to document dispensing information, patient counseling and auxiliary notes. Utilization of vouchers is preferable to actual physical drug samples. The preferred method of obtaining pharmaceuticals for indigent patients would be through specific corporate plans which provide such product directly to the patient.

9. Site Access for Industry Representatives:

All Industry professionals wishing to gain access to RowanSOM designated sites will be required to check into the facility through a centralized, appointed individual. Purposes which are appropriate for site visits include the exchange of scientific information, dissemination of materials/information regarding new therapeutic options, and training or discussions which can lead to the advancement of healthcare. Name badges are required for all industry personnel when visiting a RowanSOM site. Industry representatives are prohibited from roaming areas frequented by faculty or students. They may provide informational material, such as product literature or journal articles, only at the request of a faculty or staff member.

Prior to gaining access, the individual must have a scheduled appointment with appropriate RowanSOM personnel. There may be designated times for Industry representatives to convene in a specific location as pre-determined by department heads in order for questions to be answered or for information to be distributed regarding new equipment or therapeutic options. Any marketing activities will be limited as per sections 1 and 3 of this policy. Upon an initial visit to a RowanSOM site, industry representatives will be provided a vendor policy sheet which will outline procedures that they must follow while visiting the facility.

10. Policy Enforcement:

RowanSOM faculty and staff will disclose all ties to industry on an annual basis using the RowanSOM Conflict of Interest disclosure form. This information will be included on the faculty information pages on the RowanSOM website.

Faculty and Staff: Any violations of this policy should be reported to the Chief Compliance Officer or the Ethics Liaison Officer/Deputy Ethics Liaison Officer for the Stratford Campus, who will notify the appropriate supervisory personnel, department chair, deans, Conflict of Interest committee or other body of potential violations to this policy or to other relevant policies. Possible consequences of policy violation include but are not limited to: counseling, training, requiring repayment of monies acquired in violation of policies, fines or termination.

Industry personnel: Any violations of this policy may be subject to any of the following disciplinary actions: Warnings issued to corporation and supervisory personnel (written &/or verbal); access to RowanSOM revoked for offending representative and other company personnel; lengthy restriction by all personnel from any access to the property for varying lengths of time.