

RUSH UNIVERSITY MEDICAL CENTER

RELATIONSHIPS WITH VENDORS AND REFERRAL SOURCE GUIDELINES

Purpose and Scope

Consistent with the Rush University Medical Center (“RUMC”) Conflict of Interest and Commitment Policy (“COI Policy”), these Relationships with Vendors and Referral Source Guidelines (“Guidelines”) require that business transactions and relationships between RUMC Persons and Vendors and Referral Recipients be at arms-length and free from offers or solicitation of gifts and favors, or other inducements that may have the potential to improperly influence, or appear to improperly influence, clinical, purchasing, prescribing or research decisions by RUMC Persons. RUMC also prohibits RUMC Persons from accepting or paying any amount, in cash or in kind, in exchange for or to induce the purchasing, prescribing or ordering of any item or service covered under a federal health care program.

Supervisors are responsible for communicating these Guidelines to RUMC Persons, for providing training that will give RUMC Persons in their departments a firm understanding of the Guidelines, and for taking steps to effectively monitor and enforce compliance with these Guidelines. Violations of these Guidelines are subject to disciplinary action in accordance with applicable RUMC disciplinary policies.

Any questions about these Guidelines should be addressed to the RUMC Corporate Compliance Office.

Who is Covered by these Guidelines?

These Guidelines shall apply to all RUMC directors and officers, all other full-time or part-time RUMC employees, members of the RUMC Medical Staff, Faculty, and independent contractors retained by RUMC from time to time (“RUMC Persons” or “Persons”).¹

Definitions

Business Courtesy: A meal, entertainment or other hospitality or favor for which fair market value is not paid by the recipient.

Gift: A gift includes receipt of any good, service, courtesy (including a Business Courtesy) or other item of value without paying money or giving something of comparable or equal value in return, either before or after receipt. Gifts include, by way of example, the following: cash, checks, gift certificates, securities, property, favors, prizes, services, referrals, food, attendance at plays, concerts, sporting events, golf outings or any other entertainment events or hospitality.

¹ While certain Sections of these Guidelines involve arrangements or activities that are more likely to apply to only certain types of RUMC Persons (e.g., physicians, purchasing department personnel), all RUMC Persons should be familiar with the terms of the Guidelines to support a systemwide understanding of, and compliance with, its requirements.

Referral Recipient: Any individual or entity that obtains health care business or referrals from RUMC, or potentially could obtain health care business or referrals from RUMC, including, for example, hospitals, nursing homes, ambulatory surgical centers, imaging facilities, health care suppliers, non-medical suppliers and any family member, officer, director, employee, agent or representatives of individuals or agents.

Referral Source: Any person or entity that is a source of patient referrals to RUMC, such as community physicians who refer patients to RUMC for specialty services.

Vendor: Any for-profit enterprise that develops, manufactures, sells, or distributes drugs or medical devices or other goods and/or services to the health care industry, including but not limited to, pharmaceutical companies, medical device manufacturers, laboratories, imaging companies, sales organizations, banks, auditing firms, law firms, insurance companies and consulting firms.

RUMC Person or Person: The individuals described above under the heading “Who is Covered by these Guidelines?”

Guidance Regarding Specific Financial Relationships.

The following additional Sections of these Guidelines are intended to implement the purpose set forth above and shall be considered part of these Guidelines:

- Section I Gifts and Business Courtesies
- Section II Meals
- Section III Consulting and Other Compensation Arrangements
- Section IV Third Party Medical Education Programs
- Section V Educational Grants and Donations
- Section VI Training and Education Regarding Use of Medical Devices
- Section VII Funding for Medical Education Programs Accredited by the Accreditation Council for Continuing Medical Education
- Section VIII Purchase Contracts; Discounts and Other Reductions in Price

All interactions with Vendors or Referral Recipients not covered by specific Sections of these Guidelines will be governed by the general policy statement set forth above. In addition, any Gifts or other financial arrangements with entities that provide and bill patients or payors for any of the following services should be discussed with the Office of Legal Affairs: clinical laboratory services; physical and occupational therapy services; radiology and other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Such gifts or financial relationships shall also be established and implemented in accordance with the provisions of other applicable RUMC policies.

I. Gifts and Other Business Courtesies

- A. Gifts from Vendors or Referral Recipients.** As a general rule, RUMC Persons shall not accept or use Gifts (including Business Courtesies) from Vendors or Referral Recipients, except for permitted Business Courtesies discussed below. Any Gift or Business Courtesy given to an immediate family member of an RUMC Person is prohibited.
- B. Gifts and Business Courtesies from Pharmaceutical, Medical Device, and Biotechnology Companies.** Gifts and Business Courtesies from pharmaceutical, medical device and biotechnology companies are prohibited under all circumstances (See Section II(A)(1) of the COI Policy). Refer to Section II (Meals) for additional information.
- C. Permitted Business Courtesies.** There may be times when it is permissible to accept a Business Courtesy or other invitation offered by a current or potential Vendor. However, the purpose must never be to induce or influence a business transaction. As a general rule, the cost must be reasonable (not to exceed \$100 per RUMC Person). If the occasion appears extravagant or if the invitation could be perceived as intended to influence a business decision involving RUMC, attendance at such an occasion is prohibited. To be acceptable, the occasion should conform to the following guidelines:
1. The cost and location must be reasonable and not extravagant.
 2. Paid expenses for any travel costs or overnight lodging for the RUMC Person or his/her family are prohibited.
 3. The invitation is for an ordinary business meal or gathering during which the host is present and business is conducted.
- D. Gifts to RUMC Referral Sources.** RUMC Persons are prohibited from making any gift to a RUMC Referral Source. A RUMC Person may not use his/her own funds to pay for gifts for the purpose of influencing referrals.

II. Meals

A. Meals Furnished by Vendors or Referral Recipients.

1. Vendors and Referral Recipients are not permitted to provide food to RUMC Persons on-site at RUMC facilities. Except as provided below, if RUMC Persons attend a meal (off-site of RUMC facilities) to discuss business-related or education-related matters with Vendors or Referral Recipients, then RUMC Persons must pay for his or her own meal. Under no circumstances may RUMC Persons accept or provide money, entertainment or other Business Courtesy in exchange for attending the meal. In addition, RUMC Persons may not allow a Vendor or Referral Recipient to pay for meals for the RUMC Person's spouse, other immediate family member or other guests who do not have a bona fide professional interest in attending the meal.
2. Food may be accepted from Vendors or Referral Recipients only in the following limited circumstances:
 - a. The meal is related to a permitted Business Courtesy pursuant to Section I(C) of these Guidelines (Permitted Business Courtesies).
 - b. Off-Site Educational Presentations and Meetings: RUMC Persons may attend meals and receptions provided by a Vendor in connection with an educational conference, training or meeting if the Vendor sponsoring the educational presentation or meeting is a signatory to the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Healthcare Professionals. The PhRMA Code requires that meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.
 - c. Medical Device Training Sessions: RUMC Persons may attend modest meals and receptions when attending Vendor-sponsored training and education regarding the use of medical devices.
 - d. Consulting Services: RUMC Persons may attend modest meals and receptions in connection with RUMC Persons performance of legitimate contractual services.

B. Meals and Business Courtesies Furnished to Referral Sources.

1. RUMC Persons may only provide meals to Referral Sources if doing so is part of a bona fide business purpose (e.g., as part of an information presentation to educate community physicians about RUMC capabilities). However, the meals must be modest in value, occur at venues appropriate

for the exchange of information, and be approved by the Corporate Compliance Office in advance of the meeting.

2. Under no circumstances may such meals be paid for by a Vendor unless otherwise permitted under these Guidelines.

- C. **Other Provisions of these Guidelines Relating to Permitted Meals.** As noted above, additional guidance relating to meals also may be found in the following Sections of these Guidelines: Gifts and Other Business Courtesies (relating to meals provided as part of a permitted business courtesy); Consulting and Other Compensation Arrangements (relating to meals provided as part of or incident to a physician's compensated services to a Vendor or Referral Recipient); Third Party Medical Education Programs (relating to meals and receptions provided by Vendor or Referral Recipient to program attendees, where permitted by the program sponsor); Educational Grants and Donations (relating to funding of meals provided in connection with programs conducted by RUMC); and Training and Education Regarding Use of Medical Devices (where meals, travel and lodging are provided in connection with training provided by a manufacturer in order to facilitate safe and effective use of certain medical technology).

III. Consulting and Other Compensation Arrangements

This Section applies to all consulting and compensation arrangements between RUMC Persons and Vendors or Referral Recipients, including all consulting, medical director, product development, advisory committee, teaching and speaking, or other services that RUMC Persons provide to Vendors or Referral Recipients (collectively, referred to as “consulting arrangements”). All such arrangements shall be memorialized in writing, reflect fair market value compensation for legitimate purposes, and involve only reasonable, necessary and documented services.

- A. **Prohibited Arrangements.** A Person may not enter into a contract that involves the provision of services or other terms that would restrict or interfere with the Person’s RUMC-related duties. Also, under no circumstances should a Person enter into a contract that is, or appears to be, motivated by any improper purpose, such as to induce the individual to change or maintain his or her purchasing or prescribing habits or his or her decision-making or judgment in research or clinical matters. Each Person is responsible for determining that a proposed consulting arrangement complies with these Guidelines.
- B. **Mandatory Written Contract.** RUMC Persons may be engaged by Vendors or Referral Recipients to perform such services only pursuant to a written contract signed by both parties that details the Person’s duties, provides for no more than reasonable fair market compensation for necessary services that are actually rendered, and requires ongoing documentation of the actual provision of services.
- C. **Contract Guidelines.** Each consulting arrangement must meet the following guidelines:
 - 1. The consulting arrangement must be documented by a written contract, signed by the appropriate parties. RUMC, rather than the individual Member, is the appropriate contracting party for certain arrangements, such as facility medical director agreements, as well as arrangements involving a Person’s clinical, administrative or consulting services if such Person is an RUMC employee. Departments are not separate legal entities, and therefore are not appropriate contracting parties. Any questions about the appropriate contracting party should be addressed to the Office of Legal Affairs.
 - 2. The contract must specify the services to be provided, and the services must be legitimate, commercially reasonable services needed by the contracting party.
 - 3. The payment amount or formula must be set in advance and must reflect fair market value for the services to be provided. When compensation is based on a royalty or similar arrangement, the payment amount should not take into account sales or use of products by RUMC or any Persons, nor

should it include other payment methodologies that will inappropriately influence clinical decision-making.

4. The contract must specify a means for the RUMC Vendor to document on an ongoing basis the actual provision of the services and require documentation as a condition of payment.

D. Other Requirements and Restrictions.

1. Use of RUMC facilities or staff, by either the RUMC Person or the third party in connection with a consulting arrangement is prohibited.
2. The arrangement cannot involve or permit the use of RUMC's confidential or proprietary information. The contract must prohibit the use of the RUMC name by any third party, except with RUMC's written consent.
3. Meals, travel and other Business Courtesies provided in connection with performance of the services must be modest and incidental to the services being performed (e.g., a meal in connection with an all day meeting is acceptable; a three hour meeting followed by golf or other entertainment is not).

E. Notice/Approval Process for Consulting Arrangements.

1. Contracts for consulting arrangements that are executed by RUMC are subject to review and approval by the Office of Legal Affairs and the appropriate RUMC signatory.
2. RUMC Persons must report any permissible individually executed consulting contracts in accordance with RUMC's Conflict of Interest and Commitment Policy.

F. Other Provisions of these Guidelines, and other Policies, Applicable to Consulting and Compensation Arrangements. These Guidelines do not apply to service as an expert witness for an entity that is not a Vendor or Referral Recipient. Service as an expert witness is permitted only if the compensation is reasonable, paid time off is taken for the time spent on the engagement, and the Person additionally receives written confirmation from the Office of Risk Management that no Conflict of Interest exists with RUMC. Questions about such arrangements should be addressed to the Office of Risk Management.

G. In addition, while the general principles set forth in these Guidelines apply to research arrangements, any arrangements involving research must also comply with and be processed through the applicable research-related policies and procedures of RUMC. Similarly, while the general principles set forth in this Section apply to medical education programs sponsored by entities accredited by the Accreditation Council for Continuing Medical Education ("ACCME"), funding for such arrangements must comply with the specific criteria set forth in

these Guidelines in Section VII (Funding for Medical Education Programs Accredited by ACCME).

IV. Third Party Medical Education Programs

This Section applies to attendance or participation by Persons in third party conferences, including continuing medical education events, professional society meetings, roundtables and other educational or scientific programs. RUMC permits Persons to attend bona fide third party conferences and to accept associated meals and receptions sponsored by Vendors or Referral Recipients at such conferences so long as they are modest and clearly subordinate to the conference goals of promoting objective scientific and educational activities and discourse.

- A. **Program Faculty.** Subject to compliance with Section III of these Guidelines (Consulting Agreements and other Compensation Arrangements), a Person may serve as a faculty member for a third party educational conference and may accept a reasonable honorarium and reimbursement for his or her own transportation, lodging and meals expenses relating to the conference. Such compensation and reimbursement must be paid by the conference sponsor and not by Vendors or Referral Recipients. In such circumstances, the Person must ensure that no Vendor or Referral Recipient influences the content of the presentation made by the Person, and that there is appropriate disclosure of any financial ties to any Vendors or Referral Recipients, consistent with the rules of the third party sponsor, the body accrediting the program, if any (e.g., ACCME), and RUMC policies.
- B. **Attendees.** If a Person is attending a third party conference only as an attendee and not as a bona fide faculty member of the conference, the individual may not accept reimbursement from any Vendor or Referral Recipient for the program registration fee, transportation, lodging, meals or other expenses of attending the program. Under no circumstances may a Person accept reimbursement for transportation, lodging or meals for the cost of his or her spouse or other guest(s).
- C. **Conference-Related or Approved Meals and Receptions.** A Person may participate in a meal or reception sponsored by a Vendor or Referral Recipient at a third party conference if the event complies with the guidelines of the organization sponsoring the conference. The meal or reception should be modest in value and conducive to discussion among those participating in the event. The amount of time at any such meals or receptions should be clearly subordinate to the amount of time spent at the conference's educational activities.
- D. **Attendance by Healthcare Professionals in Training.** RUMC does not accept financial assistance from Vendors or Referral Recipients to allow medical students, residents, fellows and other healthcare professionals in training to attend educational conferences.
- E. **Other Provisions of these Guidelines and Other Policies, Applicable to Medical Education Programs.** Educational programs provided by RUMC are addressed in Section V of these Guidelines (Educational Grants and Donations). Funding for medical education programs sponsored by sponsors accredited by the ACCME must comply with Section VIII of these Guidelines.

V. Educational Grants and Donations

This Section applies to acceptance of grants and donations from Vendors or Referral Recipients only where such grants and donations directly benefit RUMC patients or serve an educational purpose. RUMC will not accept funding that is offered in connection with the purchase or sale of goods or services. The provision of funding by Vendors or Referral Recipients should never influence clinical decision-making, research, purchasing or prescribing decisions, or the awarding of contracts.

- A. **In General.** All educational grants received from Vendors or Referral Recipients must be documented in a writing, approved by the Office of Legal Affairs, signed by all applicable parties, and must not be made for any improper purpose, such as in exchange for changing (or maintaining) any purchasing, research, prescribing or other clinical decisions or practices. Permitted support includes, but is not limited to: funding for fellowships and funding for educational programs conducted by RUMC and related meals in compliance with Section II of these Guidelines (Meals), funding for textbooks or other educational materials, and funding of outside speakers.
- B. **Solicitation of Support.** To ensure that contributions from Vendors or Referral Recipients do not inappropriately influence RUMC's or a RUMC Member's purchasing, contracting, research, prescribing or other clinical decisions, RUMC and its Persons should not solicit or accept contributions from the marketing or sales department of a Vendor or Referral Recipient.
- C. **Management of Grant Funds.** RUMC will maintain a separate fund for the receipt, management and dispensing of grant monies. The Department conducting the educational activity must independently develop a budget for any such project, and must ensure that donated funds are applied toward the applicable educational program. Any funds remaining after completion of the educational program shall be used for educational purposes, or as otherwise required by the funding agreement. Funds from other sources will not be commingled with grant monies. No donated funds may inure to the benefit of any RUMC Person.
- D. **Program Requirements.** Vendors or Referral Recipients may direct grants to a specific Department and indicate the general topic of the program to be funded. However, Vendors or Referral Recipients are not permitted to specify or pre-approve the program content or speakers. Program speakers must disclose any financial relationships with the Vendor or Referral Recipient providing a grant and any other relevant financial relationships. Any program support by a Vendor or Referral Recipient shall be disclosed to program attendees and any recipients of program materials.
- E. **Grants vs. Marketing/Promotional Activities.** In some cases, funding from Vendors or Referral Recipients could be characterized, in whole or in part, as support of RUMC marketing or promotional activities rather than support of an educational program. Examples of such arrangements include website or other

media references to RUMC or its Persons and support of RUMC outreach to RUMC Referral Sources. Any proposed arrangement that involves marketing of RUMC or Person services, even in an educational context, must be reviewed by RUMC's Marketing Department and Office of Legal Affairs. The appropriate individuals in the Marketing Department and Office of Legal Affairs will determine whether it is appropriate for RUMC's or a RUMC Person's name to be used in connection with the arrangement, whether RUMC may accept such funding consistent with these Guidelines, and whether RUMC should pay a share of funding for the proposed activity or event.

- F. Other Sections of these Guidelines, and other applicable RUMC Policies.** Grants to fund research (including clinical research) must comply with and be processed through the applicable RUMC research policies. Grants to fund medical education programs sponsored by entities accredited by the ACCME must comply with Section VII of these Guidelines (Funding for Medical Education Programs Accredited by ACCME).

VI. Training and Education Regarding Use of Medical Devices

This Section applies to the receipt by RUMC Persons of appropriate training regarding medical devices free from any inappropriate influence, or the appearance of any improper influence, which might interfere with the physician-patient relationship or improperly influence clinical, prescribing, research, or purchasing decisions.

A. Guidelines for attendance at training sessions. RUMC recognizes that the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical technology. RUMC further recognizes that proper training in and awareness of new and innovative medical technology may contribute to better and/or more cost-effective patient care. However, the activities surrounding training provided to physicians and others may raise at least the appearance of impropriety. To ensure that RUMC Persons receive appropriate training free from inappropriate influences over their prescribing or other clinical decision-making, their research decisions, or their purchasing decisions, the following guidelines shall be followed regarding attendance at Vendor-sponsored training sessions:

1. RUMC Persons may attend Vendor-sponsored training and education programs in order to further their knowledge on the subject(s) presented. Such programs must contain objective scientific and educational information that will benefit RUMC patients.
2. Training and education programs must be conducted in settings that are conducive to the effective transmission of knowledge, such as hotel or other commercially available meeting facilities, medical institutions, laboratories or other training facilities. Resort settings are not appropriate settings.
3. RUMC Persons attending training programs should only accept associated hospitality in the form of modest meals and receptions. Any meals and receptions provided in connection with the training program should be subordinate in time and focus to the educational/training purpose(s) of the program.
4. RUMC Persons may not allow a Vendor to pay for meals, hospitality, travel or other expenses for their spouses or other guests who do not have a *bona fide* professional interest in the information being provided at the training program.

B. Other Provisions of these Guidelines, and Other Policies, Applicable to Medical Education Programs. Educational programs provided by RUMC are addressed in Section V of these Guidelines (Educational Grants and Donations). Funding for medical education programs sponsored by sponsors accredited by the ACCME must comply with Section VII of these Guidelines (Funding for Medical Education Programs Accredited by ACCME).

VII. Funding for Medical Education Programs Accredited by ACCME

When RUMC acts as a provider of ACCME-accredited continuing medical education (“CME”), it shall abide by the requirements set forth in the ACCME Standards for Commercial Support (the “Standards”). Compliance with the Standards encourages medical education programs that are free from the improper influence by the entity providing financial support for the CME program.

- A. Disclosure of Financial Interests.** All individuals responsible for controlling or developing the content of an education activity or presenting at a CME event must disclose all relevant financial relationships with any commercial interest to the provider. An individual who refuses to disclose this information will be prohibited from having any control or responsibility over the development, management, presentation, or evaluation of the CME activity.

The following information must be disclosed to CME event attendees prior to the beginning of the educational activity:

1. Name of the individual
 2. Name of the commercial interest
 3. Nature of the relationship the person has with each commercial interest.
 4. If an individual has no relationships, that information must also be provided.
- B. Appropriate Use of Commercial Support.** RUMC, and not the commercial sponsor, will make all decisions regarding the disposition and disbursement of commercial support. RUMC may not agree to accept advice or services concerning teachers, authors or participations or other education matters, including content, from a commercial interest as a condition of contributing funds or services.
- C. Written Agreement Required.** The terms, conditions, and purposes of the commercial support must be documented in a signed, written agreement between RUMC and the commercial supporter.
- D. Fair Market Value.** The amount of honoraria or reimbursement for out-of-pocket expenses for planners, teachers, and authors must be of fair market value, must be set forth in a written contract, and must not take into account any time spent by the individual participating in the CME event as a learner. The Office of Legal Affairs must approve any honoraria or reimbursement paid to planners, teachers, or authors prior to RUMC entering into a contract that includes such provisions.
- E. Educational Value.** Social events or meals cannot compete with or take precedence over the educational events during a CME program.

- F. Restrictions on Funds.** RUMC may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of the CME program.
- G. Commercial Promotion.** RUMC shall follow the ACCME's guidelines with respect to the Appropriate Management of Associated Commercial Promotion, which, among other things, restrict the use of product-specific advertisements.
- H. Documentation.** RUMC must maintain accurate documentation detailing the receipt and expenditure of the commercial support.
- I. Content and Format.** The content and format of a CME activity must promote improvements or quality in healthcare and must not reflect a specific proprietary business interest of a commercial interest. For example, presentations must give a balanced view of therapeutic options, and the use of trade names should be limited when possible.

VIII. Purchase Contracts; Discounts and Other Reductions in Price

This Section applies to contracts for the purchase of goods and services on behalf of RUMC. All such contracts must be negotiated and entered into by authorized RUMC Members, and any discounts, free samples or other reductions in price from Vendors or Referral Recipients must comply with RUMC policies, and satisfy the applicable legal requirements.

- A. Approval by Office of Legal Affairs.** Discounts or other reductions in price that reduce the cost of patient care and are appropriately structured and reported are permissible and beneficial. However, certain arrangements characterized as discounts may be viewed as kickbacks (e.g., providing a free item for a RUMC Member's personal use as part of a package of discounted products sold to RUMC). Because discounting and pricing raise complex legal issues, any discounting or pricing arrangement that involves other than a straightforward discounted price reflected on the seller's invoice must be reviewed by the Office of Legal Affairs.

- B. Additional Guidelines for Discounts and other Reductions in Price.**
 - 1. RUMC may only accept a discount that is made at the time it purchases the goods or services or where the terms of any rebate are fixed and set forth in writing at the time of the initial sale of a good or service.
 - 2. Any invoice, coupon or statement provided by the supplier must accurately reflect the discounted price.
 - 3. RUMC must retain documentation of any discount received from a supplier for items or services billed to federal or state health care programs so that such documentation is readily accessible should it be requested by a federal or state health agency.