

**UAB MEDICINE
POLICY FOR RELATIONSHIPS WITH INDUSTRY**

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I. BACKGROUND

Relationships between health care providers and industry, particularly pharmaceutical and device manufacturers, continue to come under scrutiny because of both real and perceived conflicts of interest. The perception of conflicts of interest is a result of the previously common practice of physicians receiving gifts, travel, and/or financial support from industry vendors that stood to gain from referrals from the physicians' medical care practices. Although most companies and providers have created policies to prevent conflicts of interest from occurring, the perception continues and has resulted in increased oversight of the relationship between industry and health care providers by the government, the health care community, and the public.

II. PURPOSE

It is important to acknowledge at the outset that UAB Medicine and industry have a relationship that is mutually interdependent. Many UAB investigators receive industry grants to fund clinical trials that enhance the well-being of patients through the development of new therapeutics or interventions. Many activities that provide education and resources to UAB employees and members of our community are also supported by grants from industry. The UAB mission is furthered in these and many other ways by an appropriate and transparent relationship with industry. Toward this end, the guiding principles in this document are focused on managing 'competing interests' while promoting the transparency that is essential to a relationship of trust with our patients and the community we are here to serve.

III. SCOPE

A. Definitions

"UAB Medicine team member" refers to any physician, faculty member, staff member, trainee, or other individual who is employed by or in training with:

- UAB School of Medicine ("SOM"), including the Joint Health Sciences departments;
- UAB Health System;
- University Hospital (including UAB Highlands, Gardendale Freestanding Emergency Department and the Kirklin Clinic and Whitaker Clinics of UAB Hospital);
- University of Alabama Health Services Foundation ("HSF");
- UAB Callahan Eye Hospital;
- Ophthalmology Services Foundation; and
- The Valley Foundation.

The term includes those individuals with either full-time or part-time employee status and those with regular, adjunct, clinical (formerly called voluntary), visiting, or emeritus appointments.

Trainee includes any individual who is (i) receiving formal education from the SOM, including medical residents employed by University Hospital, medical students, graduate students, post-doctoral scholars, visiting scholars, and fellows, or (ii) participating in training activities under the direction or supervision of a UAB team member.

“**Industry**” refers to pharmaceutical, device, equipment, supply, and service manufacturers and providers.

“**UAB Medicine campus**” refers to UAB or HSF-owned or -leased buildings and property, including but not limited to University Hospital, the School of Medicine, The Kirklin Clinic at Acton Road, UAB Health Centers, UAB Medicine Gardendale, Gardendale Freestanding Emergency Department, and Callahan Eye Hospital.

B. Applicability

These guidelines are operable for UAB Medicine team members in any clinical facilities in which they practice and/or work, including, but not limited to UAB Medicine campus facilities, Children’s of Alabama Hospital, Cooper Green, and the VA Hospital, among other facilities.

IV. GIFTS AND MEALS

Gifts, even small gifts, may carry an implied expectation of reciprocity. Gifts are defined as items of value received by a UAB Medicine team member or their spouse or dependent for which the recipient has not provided adequate consideration in return. Examples of gifts under these guidelines would include, but are not limited to: cash or cash equivalents, meals, medication/device samples, promotional items, pens, notepads, entertainment or recreational opportunities, medical or research equipment, text books, software, computer hardware and accessories, and payment and/or travel expenses for attending a meeting where the recipient is not providing a service at the meeting.

A. Gifts from Industry to Individual UAB Medicine Team Members

1. General Rule

The acceptance of gifts by individual UAB Medicine team members from industry is prohibited. The prohibition on industry gifts applies regardless of the gift's nature, purpose, or value. Food and meals are considered personal gifts, and as such, are not permitted. If invited to a meal by an industry representative, UAB Medicine team members must pay for their own food and drink.

Note that UAB Medicine team members that are “public employees” under the Alabama state ethics law are subject to stringent restrictions regarding accepting gifts, including

accepting meals. Any UAB Medicine team member that needs assistance in determining whether they are public employees or what state ethics laws apply to them should contact the UAB Medicine Office of Counsel.

2. Exceptions to General Rule

Food and meals. Food of moderate value may be provided at educational events, either at a UAB Medicine site or off-campus, if the program is certified for continuing education credit by an organization that has been accredited by a national accrediting body (e.g., Accreditation Council for Continuing Medical Education, American Dental Association, Council for Optometric Professional Education, or other similar organization). The cost of provided food and drink should not exceed \$50 per person. A cash gift by industry to provide food at an educational event must be in compliance with Subsection C below, *Gifts from Industry for Specific Educational or Professional Activities*.

Compensation and reimbursement related to services. Fair market value compensation and associated travel and meals for a specific service rendered are not considered gifts because these are payments for a service. A common example is consulting fees associated with an approved external activity. UAB Medicine team members are expected to maintain adequate records to document the services they provide and associated payments they receive. See Section VII below, *Participation in Industry Sponsored Programs Off-Campus*, for additional guidance on this topic.

Competitive grants. Competitive grants made to UAB Medicine are not considered gifts.

Informational materials. Informational materials that have been produced under Accreditation Council for Continuing Medical Education (ACCME) guidelines or published under a peer review process are not considered gifts.

B. Unrestricted Gifts or Educational Grants from Industry to UAB Medicine

Through unrestricted gifts, industry supports the education, research, and patient care missions of UAB Medicine. Cash gifts must be received and managed by the UAB Development Office in accordance with [UAB's Fundraising and Gift Acceptance Policy](#) and procedures. In-kind gifts (e.g., equipment, software) to the institution may be accepted if they are provided in accordance with applicable policies and research administration, development, and hospital requirements and are reviewed by UAB Medicine Office of Counsel. There may be no quid pro quo, nor any limitations or conditions placed on gifts that are inconsistent with UAB Medicine policies and applicable regulations. An unrestricted gift from industry should not originate as part of a vendor's sales and marketing efforts but instead should be part of the vendor's charitable giving or community benefit programs.

Gifts from industry will be allocated for department use by the UAB Development Office and may be used by recipient departments to support faculty and staff education, research, and/or patient education. Distribution of the funds will be at the discretion of the department chair, who will disseminate the criteria for requesting funds to the department and will maintain documentation regarding gifts received from industry in the previous 12 months and specific information as to how the funds were used. Departments may publicly acknowledge the unrestricted support of specific companies as long as the acknowledgement is not tied to a particular activity or program.

C. Gifts from Industry for Specific Educational or Professional Activities

All events that receive industry support and are hosted by UAB Medicine must be certified for continuing education credit by a nationally accredited organization. This includes not only educational events, but also other professional activities such as faculty or staff meetings, regardless of whether these events occur in a UAB Medicine site or off-campus. Funds from industry must be administered by departments or divisions and not by individual faculty. When a company supports a particular lecture or educational event with an unrestricted educational grant in accordance with this policy, the support must be disclosed and acknowledged in connection with the event in accordance with accrediting body standards.

D. Industry Funded Scholarships

Scholarships from industry or not-for-profit organizations substantially supported by industry must be given to a department or division through the UAB Development Office or Office of Sponsored Programs, as applicable. There may be no expressed or implied quid pro quo for the funds. The evaluation and selection of recipients of such funds is the sole responsibility of the School of Medicine, with no involvement by the donor organization or company. When such conditions are met, the financial support and donor may be acknowledged in appropriate settings.

V. INDUSTRY EXHIBITORSHIPS AND VENDOR FAIRS

Exhibitorships are arrangements made with industry supporters that allow certain promotional activities alongside educational events certified for continuing medical education credit. In order not to jeopardize certification of the educational event itself, exhibitorships must follow very specific requirements set forth by the accrediting body, including being separate and apart from the educational space, no influence over the development of the educational content, etc. If a department wishes to allow exhibitors in association with an event that is certified for credit, it must work closely with the Division of CME or other unit certifying for continuing education in advance of the event.

Other promotional activities or event sponsorships that are NOT associated with a CME event, like for example a stand-alone type of vendor fair or corporate “sponsorships” of different events, may be allowed in certain circumstances with written memoranda of understanding or agreements with industry. This

allows the department to set out clearly what the fees associated with acquiring a table, obtaining space in the vendor area, getting promotion, etc. are or what each exhibitor will get for its payment of the different gold, silver, bronze levels. Documentation must also address some basic terms and conditions for participation, including: a) participation is not a condition of current or future business; b) business relationships are evaluated separately and apart from any involvement as an exhibitor; c) the sponsor has no influence over educational content presented to attendees (if any); and d) that the sponsorship/exhibitorship fee(s) charged are reasonable in exchange for the exhibit space/opportunities for interaction offered. All exhibitorships NOT associated with a CME event must be coordinated through Hospital Supply Chain in advance of the event.

VI. PHARMACEUTICAL SAMPLES

Free pharmaceutical samples may not be accepted by individual UAB Medicine team members. The practice of accepting free pharmaceutical samples has the potential to inappropriately influence clinical care of patients. For example, samples may encourage a physician to prescribe a new, expensive brand-name medication when older, less expensive generic medications may have the same or greater proven efficacy and safety.

When samples are necessary for patient education (e.g., instructing patients in the use of inhalers), they may be accepted, provided they do not display the name of the company.

VII. ACCESS TO CLINICAL AND NON-CLINICAL AREAS BY INDUSTRY SALES AND MARKETING REPRESENTATIVES

UAB Medicine is firmly committed to protecting the privacy of our patients. Individuals who are not involved in the care of the patient will not be allowed to be present without the patient's consent while the patient is being examined or otherwise treated. The presence of device vendor representatives in a clinical area such as an operating room or procedure room to assist with device implantation, testing, or settings will be listed as part of the treatment team in the operating room log maintained in the patient's medical record.

Sales and marketing representatives are not permitted in any clinical areas except to provide in-service training on devices and other equipment already purchased, or to provide demonstrations that may be of benefit to patients and where no purchase is required. Appointments are required in the OR.

Sales and marketing representatives are permitted in non-clinical areas by appointment*, with some restrictions. All sales and marketing representatives are required to be credentialed and registered with UAB Medicine. Representatives must sign in at the designated kiosks/computers located throughout the facilities. A badge/ID will be provided to each representative and must be worn while on-site. (*Note – Appointments are not required throughout the facility – this is department dependent.)

While appointments may be made at the discretion of any faculty member, the overall activity of sales and marketing representatives is subject to the oversight of division chiefs, department chairs, medical staff leadership, and other designated officials of UAB Medicine.

Industry sales representatives have the same access to the official educational offerings of UAB Medicine as other members of the general public.

VIII. PARTICIPATION IN INDUSTRY-SPONSORED PROGRAMS OFF-CAMPUS

UAB Medicine team members and trainees should evaluate very carefully their own participation in meetings and conferences that are fully or partially sponsored or run by industry off-campus because of the high potential for perceived or actual conflicts of interest.

A. Speaking for Industry

With advance approval in accordance with the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy, a UAB Medicine team member may speak at an industry-sponsored program only if he/she retains full control and authority over material in the presentation and discussion and does not allow such materials or communications to be subject to prior approval by any commercial interest other than approval for the use of proprietary information. Activities with any of the following characteristics may NOT be undertaken by UAB Medicine team members at any location, whether on-site or off-site:

- Industry has the contractual right to dictate what the UAB Medicine team member says;
- Industry (not the UAB Medicine team member) creates the slide set (or other presentation materials) or has the final approval of all content and edits;
- The UAB Medicine team member receives compensation from the company and acts as industry's employee or spokesperson for the purposes of dissemination of industry-generated presentation materials or promotion of company products;
- The primary purpose of the event is marketing, and industry controls the publicity related to the event; and/or
- The payment received exceeds fair market value for the service provided.

Under this framework, activities traditionally known as "speakers' bureaus" are prohibited. However, it is the circumstances surrounding the speaking engagement – not just what the organizer calls it – that determines whether the activity is allowed under this policy. "Non-branded" or "unbranded" talks may also fall into the prohibited category. These restrictions apply to all UAB Medicine team members at all times, not just when using their academic titles or affiliations.

At any presentation for which the UAB Medicine team member has received industry payment or support, the UAB Medicine team member must fully disclose the name of the company and the nature of the support.

B. Attendance at Industry Sponsored Promotional Events Off-campus

UAB Medicine team members are strongly discouraged from attending promotional speaking events sponsored by Industry. If UAB Medicine team members attend, they must pay for their own expenses, such as food, drink, travel, entertainment, etc.

Because the informational content may not have undergone a process for independent validation (similar to that performed for CME certification), UAB Medicine team members may wish to consider the following prior to attending meetings and conferences sponsored in part or in whole by Industry:

- Has financial support provided by industry been fully disclosed by the meeting planner?
- Is the lecturer solely responsible for the content of the lecture? Is the lecturer expected to provide a fair, balanced, and (where possible) evidence-based assessment of therapeutic options and facilitate balanced discussion of the topic? Has the lecturer prepared his or her slides and other educational materials and not delegated this to industry supporters?
- Is the meeting organizer required by an industry supporter to accept advice or services concerning speakers, content, or meeting organization as a condition of the supporter's contribution of funds or services?

These considerations do not apply to meetings of professional societies that may receive partial industry financial support, or other meetings governed by continuing education certification standards, where outside organizations not associated with industry are responsible for ensuring that presentations are free of commercial influence.

C. Consulting for Industry

A UAB Medicine team member must be thoughtful about engaging in external consulting activity for industry that is related in any way to their research or clinical activity. Even the most principled compensated consulting activities related to research or clinical activity might constitute a conflict of interest and might impose restrictions on a UAB Medicine team member to engage in related areas of research and/or involve students and trainees in areas of conflicted research.

Consistent with the [UAB Enterprise Conflict of Interest and Conflict of Commitment Policy](#), consulting arrangements are subject to prior approval by the chair of the department at all times, including summers and/or other non-academic sessions, and must be documented with a written

contract between the individual UAB Medicine team member and industry. The current official means of obtaining and documenting approval for consulting is through the [UAB Request for External Activity Approval form](#), where the nature and scope of the consulting services and amount of time and remuneration must be included for evaluation by the department and, if applicable, the UAB Conflict of Interest Review Board. UAB Medicine team members will be required to eliminate any conflicts of interest in research or clinical practice that cannot be managed effectively and therefore would compromise or prevent them from carrying out their UAB Medicine obligations.

Examples of private, external consulting with industry that must be approved include, but are not limited to: serving on scientific advisory boards to review research on novel products, developing educational materials advising industry about the structure of clinical trials, and advising industry about the design, appropriate clinical use, or internal research on its products or the direction of its research and development.

UAB Medicine team members who propose to serve as consultants to industry should keep in mind not only the highest ethical and professional standards in conducting these external activities, but also pertinent UAB policies that support the following principles:

- Prior approval of the activity is required through a [UAB Request for External Activity Approval form](#).
- UAB Medicine has ownership rights in intellectual property generated by its employees in the scope of their employment, and UAB Medicine's rights cannot be assigned to other entities without prior written approval obtained through the proper UAB Medicine channels.
- UAB Medicine team members must avoid use of UAB Medicine resources in their personal external professional relationships, including, but not limited to, facilities, personnel, letterhead, equipment, funds, supplies, services, and communication networks. While incidental personal use of resources may not raise concern, it should never limit or interfere with UAB business.
- UAB Medicine team members may not use UAB Medicine's name, logo, or marks in their approved personal external professional relationships for industry and other entities.
- UAB Medicine team members who have personal external financial relationships with industry and other entities that also transact business or compete with UAB (such as companies that are vendors to UAB) must disclose them when relevant. Such relationships may prevent the UAB Medicine team member's participation in UAB Medicine business decisions concerning those entities.
- Payment by industry to UAB Medicine team members for professional services rendered may not exceed fair market value. Relevant ranges for fair market value are generally described in terms of hourly rates consistent with national salary survey data for legitimate work performed and depend on the individual's expertise and leadership in the relevant medical specialty (e.g., specialized training, professional certifications, appointment, research

experience and funding history, invited presentations, publication history, and other leadership or recognition in the community).

- Many of the principles listed here also apply if the UAB Medicine team member's immediate family member or domestic partner has a financial interest in industry or other entities that are related to the UAB Medicine team member's institutional responsibilities.

UAB Medicine team members must disclose all relevant payments from and interests in industry in related presentations and publications and in lectures to students and trainees.

D. Ghost-writing and Ghost-authoring

UAB Medicine team members are responsible for publications listing them as authors. They may not permit their professional publications or presentations of any kind, oral or written, regardless of medium, to be ghost-written by any party. Authorship on the part of UAB Medicine team members and trainees should be offered and accepted in accordance with the standards set forth in the [UAB Authorship Policy](#). UAB Medicine team members and trainees may not participate in ghost-writing or ghost-authoring of professional presentations of any kind, oral or written, regardless of medium.

Similar to speakers' bureau activities, UAB Medicine team members may use slides from industry with proper attribution and acknowledgement to demonstrate particular concepts, but they may not adopt or offer under their name presentations or publications that have been prepared and provided by industry.

IX. TRAVEL

UAB Medicine team members may accept travel funds from industry in the following circumstances:

- for legitimate reimbursement for travel, accommodations, and meals associated with their providing contractual services, such as approved consulting activity or to provide educational services
- to view capital equipment in situ if the equipment has been contracted for and purchased by a UAB Medicine entity;
- to attend professional society meetings or other accredited continuing education conferences when travel grants have been proposed through the Office of Sponsored Programs and managed through Grants Accounting;
- to participate in meetings directly related to ongoing sponsored UAB Medicine research or clinical trials, in which case budget and/or accounting arrangements must be made through the Office of Sponsored Programs; or
- to attend a program or conference which is certified for continuing education credit but supported by industry booths as long as the funds for travel are distributed by the society or conference itself and not received directly from industry.

Unrestricted gifts to the institution (as specified in these guidelines in Section IV. B.) may be used in part to support travel for UAB Medicine personnel attending professional meetings; however, the decision to use gift funds for travel expenses must be made at the sole discretion of the division director or department chair. Students and trainees may accept travel funds from scientific societies, whether or not industry is the source of funds, provided the society controls the selection of the recipient of travel support.

X. CONFLICTS OF INTEREST AND PUBLIC DISCLOSURE

UAB Medicine team members having any personal financial interest or fiduciary role, or whose spouses or dependents have such interests or roles, in companies that might substantially benefit from the decisions made within the scope of their UAB Medicine duties must:

- Fully disclose all industry relationships or other potential conflicts of interest to the department chair or other supervising manager as applicable;
- Refrain from influencing or making any decision that would be to the benefit or detriment of the company with which there is a conflict of interest; and
- Refrain from influencing committees analyzing, contributing to, or making decisions that would be to the benefit or detriment of the company with which there is a conflict of interest.

UAB Medicine team members with supervisory responsibilities for students, residents, trainees, or staff should ensure that conflicts or potential conflicts of interest do not affect or appear to affect his or her supervision of the students, resident, trainee, or staff member.

UAB Medicine team members must disclose all relevant payments from and interests in industry in presentations, publications, and lectures to students and trainees. For scholarly publications or journal submissions in particular, UAB Medicine team members must disclose their related financial interests in accordance with the [UAB Authorship Policy](#) and management plans authorized by the UAB Conflict of Interest Review Board.

XI. ENFORCEMENT

Confirmed violations of these guidelines will result in consequences from UAB Medicine commensurate with the offense. Less severe consequences will be imposed when the violations are found to be unintentional, minor, and/or inadvertent and are not part of a pattern of disregard for the spirit of the guidelines. Severe consequences will be imposed when the violation is found to be deliberate and/or major.

Depending on the nature of the violation and whether the individual is faculty, staff, student, or trainee, various departments may be involved in the inquiry or investigation. These might include but are not limited to the UAB Medicine Compliance Office, University Compliance Office, Human Resources, Department Leadership, CIRB, Institutional Review Board, or UAB Medicine Office of Counsel.

Examples of consequences include, but are not limited to:

- Education of the UAB Medicine team member about the guidelines and its principles;
- Written reprimand, placed in the UAB Medicine team member’s personnel file or record;
- Payback of remuneration received by the individual to industry or other external entity;
- Further training in aspects of conflict of interest and commitment;
- Revocation of clinical privileges;
- Removal from administrative positions;
- Fines and/or salary reductions or denial of merit pay; and
- Suspension, non-renewal of the faculty appointment, or termination.

XII. OTHER APPLICABLE LAWS AND POLICIES

These guidelines support standards of behavior expected of all UAB community members outlined in the [UAB Enterprise Code of Conduct](#). UAB Medicine team members should also be familiar with the [UAB Enterprise Conflict of Interest and Conflict of Commitment Policy](#).

A. Alabama Ethics Law

UAB Medicine employees who are considered “public employees” should be aware that the Alabama Ethics Law may further restrict interactions and relationships with Industry, regardless of whether those interactions occur on or off-campus. For additional information, see <http://www.uab.edu/compliance/areas-of-focus/alabama-ethics-law>.

B. Open Payments Law

UAB Medicine physicians, optometrists, dentists, and certain other clinical care providers should also be aware that applicable manufacturers must report transfers of value over \$10 they make to these types of healthcare providers to the Centers for Medicare and Medicaid on an annual basis and that this information is then made publicly available. For more information, see <https://www.uab.edu/compliance/areas-of-focus/federal-open-payments-law>.

C. Anti-kickback Statute

UAB Medicine team members’ relationships with industry – whether in terms of meals, gifts, external activities, travel support, or grants – must comply with the federal Anti-Kickback

requirements. The Anti-Kickback Statute prohibits providers from soliciting or receiving remuneration in return for referrals of items or services covered by Medicare, Medicaid, and other federally funded programs. The Anti-Kickback Statute is intended to ensure that providers' clinical judgments are based on the best interests of their patients, not on improper financial incentives. If even one purpose of an arrangement is to improperly induce referrals, both parties may be criminally prosecuted, with potential penalties including imprisonment and fines.

UAB Medicine team members should make sure direct and indirect benefits they receive are consistent with the Anti-Kickback Statute or fall squarely into one of its safe harbor exceptions. For example, vendors may not furnish free goods to a UAB clinic in return for an agreement to purchase other products from the vendor, and physician consulting agreements conducted as external activities should be arranged in writing and paid for at fair market value based on appropriate documentation of the time and services provided. For more information, contact UAB Medicine Office of Counsel.

D. Expert Witness Activities

Subject to [the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy](#) and [HR Policy 128 External Employment and Other External Activities](#), UAB team members may provide expert witness services to outside organizations. However, expert witness services involve a heightened risk for the UAB Enterprise as well as for other UAB Medicine team members because such activities may infringe upon the UAB Medicine team member's duties to the UAB Enterprise and may conflict with or compromise the interests of the UAB Enterprise. Due to this heightened risk, expert witness services provided by UAB Medicine team members related to cases filed in Alabama are subject to greater scrutiny. UAB Medicine team members must abide by the following to engage in external expert witness activities:

1. Prior to accepting any expert witness services arrangement, UAB Medicine team members must obtain advance approval for such activity pursuant to UAB's online process (Request for External Activity Approval). The scope of work and expected compensation for the proposed activity must be described in writing by the law firm. UAB's Office of Counsel will be consulted prior to department and school review of expert witness activity requests.
2. The expert witness services are personal activities conducted outside the scope of a UAB Medicine team member's employment. Accordingly, the UAB Enterprise will not be responsible for any proceeding or cause of action brought against the UAB Medicine team member arising out of the external activity.
3. UAB Medicine team members are prohibited from using any UAB Enterprise facilities, staff, information, or other resources for any activities related to expert witness services. While incidental personal use of resources like computers or telephones may not raise

concern, it should never limit or interfere with the UAB business use of resources. UAB Office of Counsel will not represent or provide legal advice to UAB Medicine team members regarding their external activities, including expert witness services.

EXHIBIT B

FREQUENTLY ASKED QUESTIONS

APPLICABILITY OF GUIDELINES FOR RELATIONSHIPS WITH INDUSTRY

Question: I am a resident working at the clinic in Selma, Alabama. Do the guidelines apply to me?

Answer: Yes. As an employee of the UAB School of Medicine, you meet the definition of a UAB Medicine team member subject to the guidelines.

GIFTS TO INDIVIDUALS FROM INDUSTRY

Question: At my professional society meetings, registrants are given the conference program material in a tote bag with the name of the society and the name of a pharmaceutical company that I assume paid for the tote bags. May I accept the bag?

Answer: The guidelines do not prohibit you from accepting the bag, even with the company logo. However, the practice of company support for professional societies in exchange for marketing opportunities (such as printing the company name and logo on conference material) is coming under scrutiny. Many professional societies have or are considering eliminating this practice.

Question: Every year, there is a week devoted to recognizing a particular group of allied health professionals in the hospital, and it is coming up soon. As director of these staff members, I have been asked by outside vendors and others whose services we recommend to patients whether they can provide food and small gifts to our staff members. Is this ok?

Answer: Whether these companies and organizations are vendors doing business with UAB Medicine or the recipient of referrals by UAB Medicine team members, they benefit commercially from the work of your staff. Food and gifts may consciously or unconsciously influence the decisions made by our team members. As stated in the guidelines, the offers of food and gifts may not be accepted.

Question: May a UAB Medicine faculty member accept a stethoscope from a vendor?

Answer: No. The stethoscope would be considered a personal gift. UAB Medicine team members may not accept gifts, even if they are related to clinical practice.

FOOD

Question: A company that manufactures important devices in my field wants to host a dinner for fellows from five select institutions at our next professional society meeting. The dinner will be at a well-known, expensive restaurant. Can my fellows attend?

Answer: The company is organizing the dinner to obtain goodwill and loyalty from specialists who will soon be in practice. The dinner is a gift and should not be accepted.

Question: A pharmaceutical company is supporting a visiting professor who will lecture at grand rounds in my department. Can the company supply food for this event? It's scheduled at 8 am, and I would like to serve breakfast. What are my options?

Answer: Food of moderate value may be provided at educational events, either at a UAB Medicine site or off-campus, if the program is certified for continuing education credit by an organization that has been accredited by a national accrediting body (e.g., Accreditation Council for Continuing Medical Education, American Dental Association, Council for Optometric Professional Education, etc.) like the UAB Division of Continuing Medical Education or it otherwise meets the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support.

Question: A device manufacturer sales representative wants to provide pizza for the staff of a clinic office. Can the clinic office accept the pizza?

Answer: No. Industry may not furnish meals to UAB Medicine team members unless in conjunction with an educational event meeting professional continuing education accrediting standards.

Question: May industry support medical resident journal clubs convened once a month at local restaurants where there are educational presentations made by the residents?

Answer: Food of moderate value may be provided at educational events, either at a UAB Medicine site or off-campus, if the program is certified for continuing education credit by an organization that has been accredited by a national accrediting body (e.g., Accreditation Council for Continuing Medical Education, American Dental Association, Council for Optometric Professional Education, etc.) like the UAB Division of Continuing Medical Education or it otherwise meets the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support. If the journal clubs are not certified for credit or otherwise equivalent to events that are, meals may not be accepted.

Question: A medical equipment manufacturer invites several UAB Medicine team members to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the baseball game. May the UAB Medicine team members attend?

Answer: The UAB Medicine team members should think carefully about the value of the educational activity in overall relation to the perceived conflicts of interest arising from associated social activities. If the UAB Medicine team members attend, they must pay for all expenses associated with their attendance, such as the meal and sporting event ticket.

Question: A vendor who does business with a UAB Medicine department wants to provide financial support for the department's holiday party or other departmental social events. Is this allowable?

Answer: No, because these gifts are solely personal or social in nature.

Question: As a nurse-manager, I supervise several nurses on an inpatient unit. We routinely use equipment from a particular large medical supply company. Although I serve on a committee that makes purchasing recommendations, I am one of about fifteen members. Each year at Christmas, the company sales rep sends a fruit basket to my nursing unit. Can we accept the basket?

Answer: While the fruit is no doubt appreciated, it is a gift from an industry representative and therefore should not be accepted. You should notify your department administrator who should politely remind the sales representative that the guidelines do not allow acceptance of gifts. In the meantime, it's recommended that you deliver food items to a food bank or soup kitchen.

UNRESTRICTED GIFTS

Question: I conduct basic science research and clinical research, and I have a clinical practice. One of the drug manufacturers in my specialty field would like to make a gift to my discretionary account. I plan to use the funds to do some exploratory studies in the lab and, if the results are promising, use the preliminary data to apply for an NIH grant to continue the basic research. May I accept the gift?

Answer: The guidelines require that unrestricted gifts be directed to the institution's Development Office and deposited in a departmental or divisional account. The concern is that, while the recipient may use the gift funds for independent research, the act of making the gift might create a sense of reciprocity; it might lead you, the individual recipient, to view the company's products more favorably. You should introduce the company representative to your department's or division's development officer and allow them to execute the gift. The director should set up a mechanism for faculty to request unrestricted support from a pool of money – the funds from this company and others. The division or department can acknowledge the company's support, along with unrestricted support from other sources.

Question: The hospital recently purchased a new piece of equipment that is used for performing a particular out-patient procedure in our clinic; the procedure is faster and potentially safer using this equipment. The product is new and has been installed at only a few other practices in the region. The manufacturer would like to print and mail several thousand post-cards advertising that our clinic uses the new equipment for this procedure. We would provide the company a list of patients and referring physicians we would like to receive the announcement. Is this acceptable?

Answer: The manufacturer is offering to provide your UAB Medicine clinic a gift in the form of printing and mailing of advertising material, with the dual purpose of marketing your clinical services and their equipment. Unlike an unrestricted monetary gift that your department can use at its discretion for education, research or patient care, or patient education material about a particular disease or disorder that cannot be readily obtained elsewhere, the purpose of this offer is to promote the vendor's product – and incidentally clinical services at UAB Medicine. Accepting a gift from a vendor may raise questions or the appearance of a *quid pro quo*. In addition, UAB Medicine services should be marketed and promoted in accordance with UAB Medicine marketing standards and should not be supported financially or in-kind by vendors. Finally, providing patient names to a third party without the patients' permission may violate HIPAA regulations. So this offer cannot be accepted.

SITE ACCESS FOR PHARMACEUTICAL INDUSTRY REPRESENTATIVES

Question: A scientist I know at a large pharmaceutical company will be in Birmingham on the day of my department's next grand rounds. The topic is closely related to her areas of expertise. May I invite her?

Answer: If she signed in according to UAB Medicine site access rules or grand rounds are open to the public, she may attend the grand rounds. However, industry representatives may not attend UAB Medicine meetings or rounds where patient-specific information is discussed; they may not attend lab meetings or other meetings where proprietary data are discussed; they may not be in patient care areas; and they may not distribute company literature at hospital meetings.

Question: I direct resident training in the clinic where I practice. The FDA recently approved a new drug for a disease we treat and the drug is based on a novel chemical compound. The clinical trials have been published, but the residents are not familiar with the chemistry behind this new drug class. I would like to invite a representative of the company to speak with the residents and possibly to deliver grand rounds. Is this permissible?

Answer: It is appropriate to support education about new drugs. However, a sales representative for the company should not be invited. Only a company scientist should be invited to speak about the new drug. As the inviting faculty physician, you will need to supervise company representatives directly and be continuously present during the entire event to ensure there is opportunity for interaction and critical discussion. If your grand rounds are certified for CME credit, you are encouraged to contact the certifying organization to ensure the speaker has satisfied all conflict of interest criteria imposed for certification.

SITE ACCESS FOR DEVICE INDUSTRY REPRESENTATIVES

Question: Many of my patients are fitted in our clinic for specialized braces. The fit of the brace must be inspected by company professionals in the clinic, so the company representative comes to the clinic by appointment. Is this ok?

Answer: Fitting the brace in the clinic is a necessary component of on-site care for these patients. This is permitted, provided the conditions for site access by device representatives are met.

PATIENT EDUCATION/PROMOTIONAL MATERIAL

Question: I'm the administrator of an outpatient clinic. Can we accept and distribute material provided by industry that has educational value for patients?

Answer: The guidelines prohibit exhibiting or displaying industry promotional material at any UAB Medicine site, except at UAB Medicine CME events as permitted under ACCME standards. Some material is clearly promotional and therefore cannot be exhibited or provided to patients. However, in some cases material provided by industry includes valuable educational content that is not readily available otherwise. The attending physicians at each clinic must determine whether a particular brochure or item has more educational than promotional value and make a decision regarding whether to accept it and provide it to patients. Industry representatives offering educational material to UAB Medicine clinics must deliver the material to the clinic and request review by the attending physicians. The representatives may not display the material themselves.

INDUSTRY-SPONSORED PROGRAMS

Question: As a nurse manager, I must earn a certain number of continuing education (CE) credits each year. Many of the CE events sponsored by the American Nurses Credentialing Center (a subsidiary

of the American Nurses Association) are supported financially by healthcare companies. If I attend an ANCC event that is supported financially by a company, can I accept the meals that are part of the program?

Answer: ANCC, ACCME (Accreditation Council on Continuing Medical Education), and most continuing education accrediting bodies in the health professions have standards for commercial support of their continuing education events. Provided the event is accredited by a group that has such standards and that the standards provide for independent development of educational content and transparency of commercial support, UAB Medicine team members may accept meals that are part of the accredited CE program.

Question: A company has asked me to present a webinar on a topic in my area of expertise and they will post the program on their website. The company is requiring that they review and approve the content of my webinar in advance and they've told me the purpose is to ensure there is no product promotion and that my statements are adequately sourced. Although the program is administered by the company's marketing division, I'm told the goal is educational. Can I participate?

Answer: The company appears to have good reasons for requiring prior review and approval of your content, but there is no assurance that they won't require revisions to your material. And while their review may not result in the addition of material that overtly favors the company's drug or device, it may shape your content so as to influence opinions about optimal treatments, such as those involving their products. Under the guidelines on industry-sponsored programs, you must be able to control the intellectual content of your program.

Question: I have been invited by an academic institution on the west coast to deliver grand rounds. I believe the program may have industry support, although I don't know which companies are involved. My hosts have invited me to dinner the evening before the talk at a restaurant where I'll have a chance to talk with several faculty in my field. If the dinner also is being underwritten by industry, may I attend the dinner?

Answer: You were invited by another academic institution, not by industry. Even if industry is supporting the program, it's the institution that has invited you and is organizing the academic program and dinner. As long as there is no industry control over your talk, you may give grand rounds and attend the dinner.

Question: For several years, I have been a consultant to a pharmaceutical company. The company just received FDA marketing approval for a drug in my field of expertise. They have asked that I train physicians who have agreed to serve on their speakers bureau for this drug. I know that JHM and SOM policies prohibit me from serving on a promotional speaker's bureau. May I train the speakers? Does it matter whether I use the company's slides or my own slides in the training webinar?

Answer: The proposed activity directly supports a type of speaking that is prohibited under UAB Medicine guidelines. While you would not be directly promoting the company's new drug, by training speakers you would be enhancing the company's promotional capacity, and your expertise and UAB Medicine affiliation would add to the credibility of the activity in the view of the trainees. This activity is not allowed, whether or not you use your own slides, because in effect it is a promotional activity on behalf of the company.

DISCLOSURE

Question: My spouse works for a pharmaceutical company. Do I have to disclose his/her income and stock options under the guidelines?

Answer: It depends. The guidelines require that you disclose these financial interests to the UAB Conflict of Interest Review Board if you are engaged in research. If you are an investigator as defined by the UAB Enterprise Conflict of Interest and Conflict of Commitment Policy and your spouse's employment relates to your institutional responsibilities, you must complete a Disclosure of Financial Interests form. If you are involved in a purchasing committee or otherwise involved in procuring goods or services on behalf of UAB, you may also need to be transparent about your spouse's employment through that process.

Question: I know that when I lecture to medical students, I need to include a disclosure slide in my PowerPoint presentations or a page in the printed material I distribute listing my relationships with companies if the relationships are related to the topic of the lecture. What is the time period for disclosure?

Answer: You should generally disclose all relevant industry relationships in effect within one year of the lecture. However, if you are subject to a conflict of interest management plan issued by your department chair or the Conflict of Interest Review Board, you must follow its specific instructions for disclosure periods.

Question: What should I disclose in my presentation's disclosure slide?

Answer: You should disclose all relationships related to your institutional responsibilities, including personal payments (e.g., consulting, advisory board service, speaking), fiduciary roles (e.g., board of director service), and ownership interests (e.g., stocks, equity, royalties, etc.). You should also disclose the source of funding that was the basis of your presentation. Always err on the side of transparency. While it is not necessary to disclose other sponsored research or grant support, you may want to consider doing so.

Question: May I enter into a consulting agreement with a medical device manufacturer to advise on general medical and business issues and provide guidance on product development and research programs for the manufacturer's products and for which I am compensated?

Answer: Yes, with the approval of your chair and dean through a Request for External Activity Approval. The services must be legitimate, reasonable, and necessary, there must be a written agreement describing the services in some detail, and the compensation must be fair market value. These agreements should be negotiated with the manufacturer's research division and not through their marketing or sales division. As they are personal agreements between the faculty member and the manufacturer directly, they are not negotiated, reviewed, or signed by UAB.

Question: May I recommend that UAB Medicine contract with a medical supply company if I have a consulting agreement with that company?

Answer: UAB Medicine team members participating on the P&T Committee or other product purchasing/evaluation committees or assuming product/services evaluation and recommendation functions must disclose all of their relationships with vendors or potential vendors to individuals leading the evaluation/purchasing process so that the leaders of the process may decide on appropriate steps to

take to ensure objective decision making by UAB AMC. Depending on the nature of the relationship, committee leaders may decide recusal from the decision is appropriate.

TRAVEL

Question: May a pharmaceutical company pay directly or reimburse a trainee for travel expenses to attend a meeting that is being certified for CME credit?

Answer: No, payment or reimbursement of travel expenses to a trainee or other UAB Medicine team member to merely attend a CME activity would be considered a personal gift and would be prohibited by the guidelines. However, applications for travel grants made to UAB from industry may be submitted through the Office of Sponsored Programs.

Question: A trainee would like to attend a meeting that is being certified for CME credit and would like to apply to the professional association sponsoring the conference for a scholarship to cover registration, travel, lodging, and meals. The materials make it clear that there is commercial support associated with the meeting. Can the trainee use the scholarship funds to attend?

Answer: Yes, if the process for awarding financial support for the trainee's meeting attendance is controlled by the professional association sponsoring the conference, and the conference is being certified for CME, the trainee can use the scholarship funds to attend. ACCME Standards for Commercial Support do not allow CME providers to use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-speaker or non-author participants of a CME activity. Therefore, if the CME certification process is working appropriately, the funds being used to support travel would be from sources other than industry.

Question: A faculty member would like to attend an industry-sponsored meeting, and a pharmaceutical company would like to make a gift to UAB Medicine to help cover the cost of the faculty member's attendance. Can the faculty member be reimbursed for travel costs with funds from the company's gift?

Answer: No, the company is directing the funds to be used for a particular purpose that would otherwise be prohibited as a personal gift. This has the appearance of a sham or work-around to avoid the general principle that industry cannot pay for UAB Medicine team member travel unless it is associated with reasonable, legitimate, and necessary professional services being rendered by the UAB Medicine team member to industry. However, this is not to say that legitimate, unrestricted gifts from industry to the institution placed in a general departmental account could not be used at the department chair's discretion to support the department's education mission.

Question: We purchased a new assay machine for our pathology lab and it's essential that a member of the lab attend one of the vendor's training sessions. The vendor pays all expenses, including travel, for clients to attend these sessions. Can we send one of our fellows?

Answer: Yes, provided the expenses are reasonable and the contract for purchase of the products or equipment provides for employee training at the expense of the vendor, team members may attend training classes paid for by the vendor; otherwise, vendor payment for training on their products or equipment should not be accepted.

For additional questions, please contact the UAB Medicine Compliance department at 205.731.9863.