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|  Aurora Health Care SYSTEM ADMINISTRATIVE AND CLINICAL MANUAL | NO: | 208 |
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1. PURPOSE

It is the expectation of all Aurora Health Care caregivers that we conduct our business in a manner that minimizes and appropriately manages any potential conflicts of interest. This policy is intended to provide parameters for appropriate decision-making regarding interactions with pharmaceutical, medical device, biotechnology or other health care-related entities (collectively referred to as “Industry”) and Aurora caregivers.

2. SCOPE

This policy applies to Aurora Health Care, Inc. and any entity or facility owned and controlled by Aurora Health Care.

3. DEFINITIONS

“**ACCME**” refers to the Accreditation Council for Continuing Medical Education.

“**Industry**” and “**Industry Representative**” refers to any manufacturer, distributor, marketer or other vendor of pharmaceutical, medical device, medical supply, and medical testing companies, and their employees, representatives and agents.

“**Industry-Sponsored Events**” include, but are not limited to, dinner programs, lunch and learn programs, roundtables, professional networking events, educational conferences, and professional meetings, among others.

4. POLICY

4.1 Consulting and Speaking Arrangements. Individual Aurora caregivers who are invited to speak or provide legitimate consulting services can accept payment and/or expense reimbursement from Industry whether in the form of honoraria or compensation for time or expenses in the following circumstances:

- a. Presentations or consulting engagements must have scientific or academic merit in furtherance of Aurora’s purpose as a charitable organization;
- b. Participation in speaker’s bureaus or other marketing activities sponsored by Industry is prohibited unless academic investigators are presenting results of their research to peers and there is opportunity for critical discussion;
- c. Presentation of “canned” or prepared materials supplied by Industry is not permitted;
- d. Payment for services (whether for speaking or consulting) must be consistent with fair market value and must be directly related to specific, legitimate services provided and work actually performed;

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- e. Only reasonable and necessary expenses directly related to the provision of services may be submitted for reimbursement by Industry;
- f. Compensation for any services provided by an Aurora caregiver must be set in advance and set out in a written agreement detailing the terms of the arrangement, services to be provided, expenses to be reimbursed, and the compensation to be paid. The agreement must be approved in advance by either the Compliance Department or Legal Department.
- g. Caregivers must consult their respective site or organization policies regarding approval of outside activities and payments for such activities. In general, payments for services provided within the scope of one's employment with Aurora are to be made to Aurora.

4.2 Attendance at Industry-Sponsored Events. Aurora caregivers may attend Industry-Sponsored Events at their own discretion. In determining whether attendance at an event is appropriate, caregivers are expected to use their professional judgment and discretion to determine whether the event has legitimate educational or scientific value. If a caregiver is attending an Industry-Sponsored Event, the following apply:

- a. The event must either: (a) be offered by a professional society or academic institution, (b) comply with the ACCME standards, or (c) involve training on the safe and effective use of a medical product or discusses non-promotional clinical educational information.
- b. Financial support from Industry must be disclosed at the event.
- c. The agenda and content presented at the event are not determined by Industry unless FDA-related requirements are being shared or training on the safe and effective use of a medical product or other non-promotional clinical education is being provided.
- d. Aurora caregivers may not receive any remuneration or gifts in exchange for attendance. This prohibition includes the cost of meals and reimbursement for any expenses to attend the event, including but not limited to meals, travel, and accommodations, except as permitted by [GIFTS AND BUSINESS COURTESIES](#)
- e. Caregivers are not required to pay a registration fee to attend the event if the event is free for all participants. Caregivers may not, however, allow Industry or an Industry Representative to pay for their registration for an event if registration is charged to other, non-Aurora participants.
- f. If a caregiver is only attending (i.e., not presenting or speaking at) an Industry-Sponsored Event, either Aurora or the individual caregiver must pay all of his or her own expenses. If a caregiver is presenting or speaking at an Industry-Sponsored Event, their expenses may be reimbursed by Industry in accordance with Section 4.1 above.

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4.3 Industry Support for Research and Education-Related Activities. Aurora believes in collaboration with Industry in the furtherance of legitimate scientific and academic inquiry. To that end, it is permissible to accept Industry support for certain research and educational related activities under the following conditions:

- a. All Industry support for research-related activities must be processed through the Aurora Clinical Research Department. Sponsored clinical trials must also be approved by the Aurora Institutional Review Board in accordance with its policies and procedures.
- b. Grants, awards and donations from Industry in support of research or education may be made to the Aurora Foundation provided that prior approval of the arrangement has been obtained from the Compliance Department and the VP for Research and Academic Relations or designee for research-related activities or the VP for Academic Affairs for education-related activities.
- c. Aurora caregivers are expected to author their own scholarship. Industry support for “ghostwritten” works is not permitted. Actual authorship must be attributed in all publications and scholarly works.
- d. Solicitation for Industry support of research or educational events or other activities must be done in connection with the Aurora Foundation. Such solicitation must clearly indicate that Industry support is not a factor in vendor selection. Solicitation of Industry support may not involve individuals with vendor or product recommendation roles within Aurora.
- e. While it is acceptable for a donor to designate a particular purpose of a donation (e.g., in support of cardiac research, or to support educational scholarships), donations in support of research or education will only be accepted if Aurora has control over the use of the funds (e.g., selection of scholarship recipients, content of educational event, selection of research projects).
- f. Training for new products purchased by Aurora Health Care may be paid for by the vendor if it is covered in the vendor contract with Aurora Health Care. Any additional training costs would be paid for by the caregiver or Aurora, as applicable.

4.4 Royalties, Patents and Intellectual Property. Intellectual property developed within the scope of a caregiver’s employment with Aurora or using Aurora resources is governed by [INTELLECTUAL PROPERTY](#). If a caregiver is involved in a project that does not involve Aurora resources and is conducted outside the scope of the caregiver’s employment with Aurora, any agreement between the caregiver and Industry for any royalty, patents or other forms of intellectual property rights must be structured in a manner that complies with the following:

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- a. Any payments made for commercial products developed must not include any sales that take place at any Aurora facility or by any Aurora entity. The caregivers receiving the royalty or other such payment are responsible for notifying the source of the payment of this policy.
- b. A caregiver with any intellectual property rights or financial arrangements related to a commercial product developed by a caregiver must be disclosed in writing to any patient who is presented with the option of receiving the commercial product as part of their care at Aurora.
- c. The total value of all payments received from the commercial product must be disclosed to Aurora annually.
- d. Any agreement for a grant of a royalty, patent or other intellectual property rights may be entered into only when the caregiver has made, or is expected to make, a contribution that is scientifically novel, innovative and significant.

4.5 Industry Samples. Aurora does not accept or dispense drug samples at any of its facility except as permitted by applicable site policy and documented Compliance approval. Trial equipment or other items for consideration for purchase may be reviewed in accordance with the policies and procedures established by System Logistics.

4.6 Patient Education Materials. Industry representatives may not directly place any promotional or educational materials in any patient care area or other public location of any Aurora facility. Aurora caregivers may accept and distribute high-quality patient education materials produced by Industry provided that the following requirements are met:

- a. The materials are reviewed and approved in advance by the AHC Patient Education Department.
- b. Product-specific materials may be distributed to patients only if it has previously been determined that the patient needs to use the product.

4.7 Disclosures. Caregivers who have any relationship with Industry (whether or not such relationship is specifically addressed by this policy) must disclose the relationship as part of their annual conflicts of interest disclosure. Please refer to [CONFLICTS OF INTEREST-CAREGIVERS](#) .

4.8 Enforcement. Leaders are responsible for helping enforce this policy. Any violation must be reported to the Compliance Department for appropriate resolution. Violations of this policy may result in disciplinary action, up to and including termination of employment.

4.9 Exceptions. Exceptions to this policy may be granted only by the SVP - Chief Compliance Officer. Caregivers seeking an exception to this policy must submit the request in writing to the Compliance Department.

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CROSS REFERENCES:

[GIFTS AND BUSINESS COURTESIES](#)
[CONFLICTS OF INTEREST-CAREGIVERS](#)
[SIGNATURE AUTHORITY AND CONTRACTING](#)
[INTELLECTUAL PROPERTY](#)
[VENDOR](#)

REFERENCES:

Advanced Medical Technology Association (AdvaMed), *Code of Ethics on Interactions with Health Care Professionals* (July 2009), available at: <https://www.advamed.org/resource-center/advamed-code-ethics-interactions-health-care-professionals>

Pharmaceutical Research and Manufacturers of America (PhRMA), *Code of Interactions with Health Care Professionals* (Jan. 2009), available at: <http://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals>

Pharmaceutical Research and Manufacturers of America (PhRMA), *Code of Interactions with Health Care Professionals* (Jan. 2009), available at: <http://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals>

Anti-Kickback Statute, 42 U.S.C. § 1320a-7a and 42 C.F.R. § 1001.951 *et seq.*

Stark Law, 42 U.S.C. § 1395nn and 42 C.F.R § 411.350 *et seq.*

Partners Healthcare, *Partners Commission on Interactions with Industry* (April 2009), available at: http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf

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