

**Hackensack University Medical Center
Administrative Policy Manual**

Conflicts of Interest: Clinical

Policy # 541-1

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Purpose: The medical profession is increasingly perceived, from without and within, as a commercial enterprise. What sets healthcare apart from other commercial enterprises, however, is the fiduciary relationship between physicians and their patients, the notion that those in positions of power and expertise have an obligation to put the interests of those who rely on them before their own interests. Hackensack University Medical Center, in policy and practice, strongly supports the fiduciary relationship and behaviors that promote it. Accordingly, the following policy sets forth the Medical Center's position on the management of conflicts of interest in the clinical and research settings.

Policy: There is a rebuttable presumption that conflicts of interest in the clinical setting have the ability to impact quality of care and patient safety. In light of this, Hackensack University Medical Center requires that interactions with industry within the medical center conform to certain guidelines intended to avoid potential conflicts. Also defined in this policy are the requirements for covered individuals to disclose potential conflicts to their patients and periodically disclose potential conflicts as a condition of appointment and reappointment to the medical staff.

Administration: The Executive Vice President and Chief Medical Officer and the Vice President, Chief Compliance Officer are responsible for the administration and subsequent revisions to this policy.

Definitions Conflicts of Interest refers to the relationship between those with public or fiduciary responsibilities and those in positions of reliance, specifically when the clash between their interests advantages the party in power and disadvantages the dependent party. Despite its generally negative connotation, conflicts of interest describes a nearly universal circumstance in which an individual with responsibility to others, including professional responsibilities, might be consciously or unconsciously influenced by financial or personal factors that involve self-interest. Conflicting interests become problematic when self-interest is acted upon in ways that compromise or bias professional judgment and objectivity.

Conflict of Interest: A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest (source-Institute of Medicine)

Covered Person: All individuals providing clinical care at Hackensack University Medical Center, including all members appointed to Medical and Dental Staffs, including Adjunct and Affiliate Medical Staff.

Healthcare-Related Industry (Industry): Refers to pharmaceutical industry, medical device industry, and any and all entities marketing, selling, or distributing healthcare goods or services consumed by, or used on, patients and/or research subjects within the medical center.

Disclosable Conflicts: A relationship or any gift, payment or transfer of other value, without regard to amount, between a Covered Person and Healthcare-Related Industry.

Campus: Includes all HackensackUMC inpatient and outpatient hospital facilities and all affiliated practice locations, including remote sites.

Forms of Payment: May include cash or cash equivalents, in-kind items or services, stock, stock options, any other ownership interest, dividend, profit, or other return on investment.

Nature of Payment: Includes any consulting fees, compensation for services other than consulting, honoraria, entertainment, food, travel, support of education or research, royalty or license, ownership or future ownership or investment interest, grants or compensation for service as faculty or speaker. Any payments typically reported on IRS forms 1099 or W-2 would be considered reportable under this policy. Relationships not resulting in payment or transfer of other value, including but not limited to, advisory board appointments or non-compensated directorships should also be disclosed as required by this policy as a matter of course.

Procedure Under the terms of this policy, covered persons are not responsible for determining whether conflicting interests can or will influence their decision making. They are responsible only for abiding by the following requirements:

- Disclosure to Patients and/or Research Subjects – Covered Individuals are encouraged to disclose to their patients and/or research subjects any disclosable conflicts (as defined in this policy) that are relevant to their patients' care or the conduct of research on human subjects. If a patient or subject voices concerns that cannot be satisfactorily resolved, the covered individual should offer to assist in the transfer of the patient's care

to another qualified individual or the withdrawal of the subject from the research. For the specific requirements related to the management of research related conflicts of interest see Administrative Policy 541.

- Periodic Disclosure – At the time of initial appointment or reappointment, Covered Individuals must include a list of all disclosable conflicts as part of the appointment/reappointment application. Failure to provide a signed disclosure will result in the application being deemed incomplete. This disclosure must be revised any time a new conflict arises or if there is a change in the details of a previously disclosed conflict.

Interactions with Industry including but not limited to the following:

- Meals – Except as noted below, industry-supplied food and meals are considered personal gifts and will not be permitted and may not be accepted on campus, in connection with activity conducted under the auspices of or using the medical center name or in the context of any professional activity. Unrestricted financial gifts to the institution may be used in part to provide food for HackensackUMC personnel; however, the decision to use gift funds to provide food will be made at the sole discretion of the CMO, department chair or division director. As with any unrestricted gift, departments may publicly acknowledge the unrestricted support of specific companies as long as the acknowledgement is not tied to a particular activity or program.
- Gifts – Gifts or gratuities of any amount are prohibited. Gifts include, but are not limited to, payments in cash or cash equivalents (e.g., gift certificates), entertainment or meals provided in the absence of an informational presentation, or promotional materials of nominal value.
- Event Sponsorship – All industry-sponsored continuing medical education programs at medical center sites or using the medical center name or resources must comply with ACCME standards (whether or not CME credit is offered). For continuing education programs not offering AMA PRA Category 1 CME credit, prior approval of the general terms of the program by the CMO or Chief Academic Officer will be required to ensure that the activity is of legitimate educational value and is consistent with medical center standards. When a company supports a particular lecture or educational event, the support must be disclosed and acknowledged.

The Office of Continuing Medical Education (OCME) is the sole provider of programs offering continuing medical education credit under the Hackensack University Medical Center name. All requests for industry support and receipt of funds for continuing medical education activity must be managed centrally by the OCME. The OCME will audit its courses to ensure compliance with ACCME standards, including those with respect to content validation and meals. For approved activities, the company's support must be disclosed in connection with the event.

Healthcare-Related Industry displays or other written promotional materials are not permitted anywhere on campus site except in formal exhibit areas during symposia or other educational programs, in accredited CME areas and approved by the Department Chair, Office of the CMO or Compliance Department.

Notification to Patients

The Medical Center will provide notice, via consent documents, the website or other appropriate means, to patients, staff and licensed independent practitioners regarding its policies on clinical Conflicts of Interest. The Medical Center will also maintain a list disclosed conflicts and resources regarding management of conflicts. The policies, list of disclosed conflicts and patient resources will be made readily available to patients, staff and licensed independent practitioners.

Any questions regarding implementation of the requirements of this policy should be directed to the Vice President, Chief Compliance Officer.