

Policy Title	Conflict of Interest (COI) Consulting and Vendor Sponsored Activities Policy	Policy ID	2845
Keywords	conflict, of, interest, coi, royalties, ownership, ghostwriting, promotional, acquisitions, purchasing, contracts, advisory, board, speakers, bureau, influence, travel, independent, contractor, continuing, education, ce, honorarium, honoraria, consult, consulting, commitment, ACHC, URAC, DRX1-3A		

I. Purpose of Policy

This policy directs Dartmouth Hitchcock employees and/or covered individuals when providing consulting services and/or vendor sponsored activities for direct or indirect compensation.

This policy exists in conjunction with related policies (see links below):

- Conflict of Interest (COI) in General and Business Affairs Policy
- Conflict of Interest Policy (COI) - Personal Gifts including Meals, Travel, and Education

II. Policy Scope

This policy applies to all employees, staff, other covered individuals and trustees of Dartmouth Hitchcock (to the extent the trustees are not otherwise covered by a different policy). Key employees, trustees, officers and other individuals who hold responsible leadership positions at Dartmouth Hitchcock and their affiliate relationships may be subject to additional reporting duties as defined by regulatory agencies' requirements. This policy also applies to direct or indirect remuneration received by an immediate family member of a Dartmouth Hitchcock employee or covered individual.

III. Definitions

Conflict of Interest: A conflict of interest may occur when an employee, other covered individual or immediate family member of either (hereafter identified as “persons”) has, or to a reasonable independent observer appears to have, a financial or business interest in an outside entity doing business with Dartmouth Hitchcock or intending to do business with Dartmouth Hitchcock, the result of which could influence the person's judgment, compromise the person's ability to carry out his/her responsibilities, or weaken public trust in Dartmouth Hitchcock. Conflicts of interest may arise in all aspects of healthcare activities including clinical care, research, education and business matters.

Continuing Education (CE) includes educational activities certified by accreditation councils (for example, the Accreditation Council for Continuing Medical Education) that are intended to keep physicians, nurses and health care professionals and staff current on healthcare technology and information¹. CE activities, presentations, and all associated material in print or any other media must be educational. Activity content must be independent of commercial influence and activity planning and execution must be in compliance with the Standards for Commercial Support, or similar policies, of the accrediting councils.

Dartmouth Hitchcock's CE activities' accreditation is centralized in the Center for Continuing Education in the Health Sciences which adheres to the policies of the following agencies: *Accreditation Council

for Continuing Medical Education (ACCME); *American Medical Association (AMA); American Nurses Credentialing Center (ANCC); and National Association of Social Workers (NASW).

*From the accreditation list within Section §403.904 of the Open Payment (Physician Sunshine) Act 2013. Other accreditation councils, e.g. Accreditation Council for Pharmacy Education (ACPE), may be added in the future.

Direct or Indirect Payment is a payment made to a Dartmouth Hitchcock employee, staff or other covered individual(s) or to another party on behalf of any of the above persons.

Employees: For the purposes of this policy, “employees” includes all privileged physicians, non-physician practitioners, associate providers, nurses, administrators, technicians, ancillary staff, administrative and support staff, individual independent contractors, and all other individuals, including persons whose services have been purchased or contracted to or by external parties, who receive compensation directly or indirectly from Dartmouth Hitchcock.

Ghostwriting: For the purposes of the policy, “ghostwriting” is defined as a faculty member listed as the author of a document that has been written by others who are not listed as authors, and to which document the faculty member has not directly contributed sufficiently to justify authorship.

Honorarium A payment, from a tax-exempt or governmental organization, made to a person for services provided in a volunteer capacity for which fees are not traditionally required or where there is no official charge for services rendered (e.g. invited speaker at a professional society meeting). A payment for similar services by a profit-making entity is not considered an honorarium.

Immediate Family Member includes spouse, partner, children, siblings, step-siblings, parents, step-parents, grandparents, step-grandparents or any person living in the same household.

Covered individuals: For the purposes of this policy, Dartmouth Hitchcock covered individuals are defined as persons who are not an employee of Dartmouth Hitchcock and are not active in the core Human Resource database with a compensation rate or benefit status, and therefore are unable to be paid but are relevant to Dartmouth Hitchcock and could be perceived to represent Dartmouth Hitchcock. Examples of covered individuals include: Trustees (except where covered by other policies), certain Dartmouth College faculty, staff and students, including Geisel School of Medicine faculty, staff and students while actively working at a Dartmouth Hitchcock location, travelers and/or volunteers assigned to any Dartmouth Hitchcock location when those individuals are actively representing or could reasonably be perceived to be representing Dartmouth Hitchcock. For clarity of the above statement, individuals are excluded from this policy when **NOT** actively working at a Dartmouth Hitchcock location or otherwise representing Dartmouth Hitchcock.

Outside Entity: The term “outside entity” includes, but is not limited to, pharmaceutical, medical device, medical supply/equipment companies and other health-related entities that conduct or are seeking to conduct business with Dartmouth Hitchcock. In addition, an Outside Entity is any entity providing or wishing to provide non-healthcare or non-medical services, such as financial services, legal services, consulting services, independent contracting services, food services, external auditing services or other services to Dartmouth Hitchcock. An “entity” includes proprietary (commercial interests) organizations, not-for profit organizations, governmental agencies or professional societies.²

Remuneration: Any form of monetary compensation or equivalent including honoraria, travel, entertainment, accommodations, and other benefits that may be extended in connection with the individual's relationship with an outside entity.

Speakers Bureau: A group of professionals hired by a non-tax-exempt outside entity, such as a pharmaceutical company or medical device manufacturer, for the stated purpose of peer education but which also provides marketing services for the company's products. Speakers Bureau activity is defined by the following criteria:

- The employee or physician contracts or accepts an offer from the outside entity to speak on its behalf, and
- There is a direct relationship between the employee or physician and the outside entity, and
- The employee or physician receives remuneration for speaking provided directly or indirectly from the outside entity, and
- The employee or physician functions as an agent of the non-tax-exempt entity.

Vendor: A vendor is considered any manufacturer, distributor, company or representative thereof, who solicits, markets, or distributes medications, products, equipment or services. Any remuneration received from a vendor by a physician is reportable by the vendor in accordance with the Open Payments (Physician Sunshine) Act 2013.

IV. Policy Statement

Dartmouth Hitchcock employees, immediate family members and covered individuals may be asked to provide professional services to outside entities or individuals and receive remuneration for these professional services. Those individuals may engage in consulting services and vendor sponsored activities for which they receive remuneration from a source other than Dartmouth Hitchcock, as long as the employee or covered individual complies with the Dartmouth Hitchcock Conflict of Interest Policies (all three) and Code of Ethical Conduct and discloses the relationship. Examples of consulting relationships include paid engagements and other direct or indirect exchanges of value for service on an advisory board, as a member of workgroup and/or for lectures that do not constitute a Speakers Bureau.

A. Disclosure

Any type of professional consulting services or vendor sponsored activities for which an employee or covered individual receives remuneration from a third party must be disclosed. The requirement of disclosure does **NOT** necessarily mean that the activity is prohibited or constitutes a conflict of interest.

It is permissible to accept honoraria, travel or expense reimbursement for educational activities provided to not-for-profit hospitals, medical centers, research institutes and professional societies whose mission is education, research or charitable. However, the honorarium, travel or expense must be disclosed.

B. Requirements For Relationships With Outside Entities

Dartmouth Hitchcock employees and other covered individuals who provide consulting or speaking services for outside entities must ensure that these relationships promote Dartmouth Hitchcock's mission and do not constitute a conflict of interest or conflict of commitment. Participation in outside entities' interests, if conducted in excess, could lead to a conflict of commitment if the outside entities' interest takes precedence over the employee's work responsibilities at Dartmouth Hitchcock. The Dartmouth Hitchcock employee's supervisor determines the acceptable amount of time an employee spends pursuing outside entities' interests during Dartmouth Hitchcock work time.

1. Consulting Services

The employee must obtain pre-approval by the Section Chief, Department Chair, or supervisor for the following:

- Direct or indirect remuneration for providing advice or services to information technology, financial or investment firms.
- Direct or indirect remuneration from pharmaceutical or biotechnology outside entity for consulting services.

2. Speaking at Educational Events

a. Speakers Bureau

- Speaking engagements at symposia or national meetings sponsored by an outside entity to present research findings or opinions do not constitute a speakers bureau if the activity/event has been awarded accredited continuing education except as provided below.
- Dartmouth Hitchcock does not permit anyone covered by this policy to participate in speakers bureaus sponsored by pharmaceutical companies, device manufacturers, or other companies or businesses. This prohibition excludes serving as faculty member or speaker at an ACCME approved medical center continuing education program.
- Engagements to speak as a marketing agent of the vendor are not allowed. This prohibition applies even when the company does not control the content of the presentation or influence it, and whether the activity has been awarded certified CME credit, Continuing Nursing Education (CNE) contact hours, or other relevant continuing professional education credit.

b. Accredited Continuing Education Activities

- Speaking or teaching at an accredited continuing educational activity sponsored by an outside entity is acceptable as long as the following conditions are met:³
 1. The CE activity meets the accreditation or certification requirements and standards of the accreditation council associated with the activity. Examples may include, but are not limited to, the following: Accreditation Council for Continuing Medical Education (ACCME); American Academy of Family Physicians (AAFP); American Dental Association's Continuing Education Recognition Program (ADA CERP), the American Medical Association (AMA); Physician's Recognition Award and Credit System; American Osteopathic Association (AOA); American Nurses Credentialing

Center (ANCC); Accreditation Council for Pharmacy Education (ACPE); or National Association of Social Workers (NASW).

2. The manufacturer does not select the physician or provide the third party vendor with identifiable individuals to be considered as speakers.
3. The manufacturer does not directly or indirectly pay the employee or covered individual.

- Speaking or teaching at an accredited Continuing Education activity sponsored by Dartmouth Hitchcock (or Geisel) is encouraged. All Dartmouth Hitchcock sponsored and accredited Continuing Education activities must be approved by the CE Directors in the CE Offices in the Dartmouth Hitchcock Center for Continuing Education in the Health Sciences (CCEHS). Dartmouth Hitchcock accredited CE Activities meet the Dartmouth Hitchcock requirements and the standards of the accredited bodies.
- Unrestricted grants from a professional society for the purpose of having a professional provide education are allowed except when funds are earmarked by a vendor for a designated individual.

c. Speaking at Non-Accredited Educational Activities

Dartmouth Hitchcock employees and other covered individuals may give presentations at non-accredited educational activities when the program presentation is solely for educational purposes and not for marketing or promotion of a product or service from an outside, non-tax-exempt entity. Any funding received from a vendor to support the speaker must be made as an unrestricted grant to the educational event organizer. The sponsor shall have no influence over the content of the educational program or over the choice of speakers.

3. Remuneration for Other Consulting Vendor Sponsored Activities/Services

- Any type of remuneration (including indirect) received for professional services, including advisory boards, committees and working groups must be disclosed.
- Remuneration for legal services such as an expert witness in a legal matter must be disclosed.
- Remuneration from non-Dartmouth Hitchcock sources cannot be accepted to generate related health care business except when explicitly representing Dartmouth Hitchcock interests as a designated Dartmouth Hitchcock representative.

4. Ghostwriting

Employees and covered individuals shall not have their name and Dartmouth Hitchcock affiliation listed as an author of a manuscript, presentation, or other publication, oral or written, regardless of medium, that is created by an outside entity where the employee or covered individual does not meet the criteria of meaningful authorship.

- Meaningful authorship is defined as making significant intellectual contribution to the work, including: conception, design, and performance; analysis and interpretation; and manuscript preparation and critical editing for intellectual content.
- For reference, authorship guidelines of the International Committee of Medical Journal Editors (ICMJE) will be used in the determination of meaningful authorship.

- The use of medical writers and editors to assist in grant preparation or manuscript editing or writing is not considered ghostwriting and remains consistent with the Dartmouth Hitchcock Code of Ethical Conduct as long as authorship criteria are met and acknowledgment of all authors is clear, and writers and editors are not employed by an outside entity.

C. Types of Compensation

1. Honorarium

Dartmouth Hitchcock employees and other covered individual are allowed to accept an honorarium from an outside entity or a vendor in certain circumstances as outlined below.

a. Hospitals, academic institutions, and academic publishing

- Dartmouth Hitchcock employees and covered individuals are allowed without additional approval to accept an honorarium external to Dartmouth Hitchcock from other non-vendor, non-industry, and nonprofit sources such as peer academic medical centers, hospitals and other not-for-profit organizations.

b. Other outside entities

- When informed in advance that there will be an honorarium, the employee or covered individual will request review and approval by his/her appropriate supervisor (e.g. Section Chief, Department Chair or Senior Leader). If the supervisor believes the honorarium will represent a Conflict of Interest, a management plan is required prior to the presentation.
- Dartmouth Hitchcock employees and covered individuals must provide documentation for the value of services performed for a professional society or other not-for-profit entity and receive prior approval by their appropriate supervisor (e.g. Section Chief, Department Chair or Senior Leader).
- In all cases the remuneration paid must be consistent with prevailing honorarium for the services provided and must be documented in a written agreement.

2. Royalties and License Payments

Employees and covered individuals shall not receive royalty or license payments if those payments are based on the use of a particular device, implant, pharmaceutical or other medical care-related product or service involving Dartmouth Hitchcock patients.

Employees and covered individuals who receive royalties (from relationships that are unrelated to Dartmouth Hitchcock patient activity) may not participate in any decision making process for purchasing, committees overseeing purchases for Dartmouth Hitchcock or any other equivalent committee when the product for which a royalty is received or a market competitor to such product is under consideration.

3. Attendance at a Medical Education Program Sponsored by Outside Entities

The acceptance of remuneration from a vendor or outside entity (excluding professional societies, governmental agencies, academic medical centers, universities, and research institutes) to defray the cost of attending an educational program or professional meeting is prohibited.

V. References

Department of Health and Human Services, Federal Register Rules and Regulations 42 CFR Parts 402 and 403; Vol. 78, No. 27/Friday February 8, 2013, pp

*Accreditation list from §403.904 of the Open Payment (Physician Sunshine Act) 2013.

VI. Footnotes

¹ Institute of Medicine as a Profession (IMAP),
http://www.imapny.org/conflicts_of_interest/glossary_of_terms (accessed February 19, 2014).

² Department of Health and Human Services, Centers for Medicare & Medicaid Services 42 CFR Parts 402 and 403 Open Payment (Physician Sunshine Act) 2013, 9490.

³ Department of Health and Human Services, Centers for Medicare & Medicaid Services 42 CFR Parts 402 and 403 Open Payment (Physician Sunshine Act) 2013, §403.904 (g) (1) (i).

Responsible Owner:	Organizational Ethics	Contact(s):	Brittany Riordan
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Related Policies & Procedures:	Conflict of Interest (COI) in General and Business Affairs Policy Conflict of Interest Policy (COI) - Personal Gifts including Meals, Travel, and Education Conflicts of Interest (COI) in Research Policy Conflict of Interest (COI) in General and Business Affairs Policy Code of Ethical Conduct-D-H		
Related Job Aids:			