Policy VI – Conflicts of Interest in the Practice of Medicine

Purpose

To assure professional and commercial integrity in all matters, Cleveland Clinic United States (CCUS) maintains a program that identifies and addresses conflicts of interest in the practice of medicine.

Policy Statement

Having Relationships with Non-Cleveland Clinic (CC) Entities While Also Practicing Medicine

This policy applies to CCUS Professional Staff, residents and fellows who provide healthcare to CCUS patients (Healthcare Providers) [See also the Conflicts of Interest in Research Policy]. A Healthcare Provider may deliver outside lectures or engage in consulting or other external activities related to their Institutional Responsibilities for which he or she receives Honoraria and/or Consulting Compensation from a Non-CC Entity, as long as the Healthcare Provider complies with applicable CCUS policies. Under the policies, when the compensation—which may be direct or indirect, financial or otherwise—is received by an Immediate Family Member or an entity controlled by the Healthcare Provider or Immediate Family Member, it is treated as compensation to the Healthcare Provider. CCUS Healthcare Providers may also engage in activities related to the commercialization of intellectual property, as long as the Healthcare Provider complies with this and other policies related to conflicts of interest and commercialization of intellectual property. [See also the CCF Intellectual Property and Commercialization Policy] The intent of this policy is to ensure that the Healthcare Provider’s primary concern is promoting the best interests of their patients.

The Innovation Management and Conflict of Interest (IM&COI) Program will review all potential Conflicts of Interest in Clinical Practice and may require certain actions, such as disclosure to patients, limits on the relationship with the Non-CC Entity or adoption of a Conflict Management Plan, to ensure, to the extent possible, that the clinical activity is free from bias that may result from the Financial Interest. In its evaluation of Conflicts of Interest in Clinical
Practice, the IM&COI Program will strive not to interfere with the practice of medicine. Any required actions will not limit the clinical activities that CCUS Healthcare Providers believe to be in the best interests of their patients; rather, the IM&COI Program will make efforts to manage the relationship or Financial Interest in the Non-CC Entity.

Definitions

Cleveland Clinic United States locations- Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lakewood, Lutheran, Marymount, Medina, South Pointe, Children’s Hospital for Rehabilitation, Cleveland Clinic Florida, Cleveland Clinic Hospital (Weston), and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, Urgent Care Centers and Ambulatory Surgical Centers reporting to these facilities.

Policy Implementation

Receipt of Gifts by Healthcare Providers from Non-CC Entities

In general, CCUS Healthcare Providers and their Immediate Family Members may not accept gifts from Non-CC Entities. Gifts include any transfer of value (financial or otherwise) provided by a Non-CC Entity to a CCUS Healthcare Provider that is not for services rendered or is not for goods received or that is in excess of fair market value and includes, but is not limited to, compensation for attendance at a conference, goods, cash, gift cards, meals*, travel and event tickets. Accepting items of minimal value, such as flashlights, pens and notepads, is discouraged but not prohibited.

*Exception for Meals: It is permissible to accept meals that are off-site of CCUS facilities paid for by Non-CC Entities if these meals are modest, infrequent from a single provider and served during or in conjunction with medical education, healthcare information exchange, biomedical research discussions, or discussions of data relevant to clinical practice. [Subject to Policy VII on Conflicts of Interest in Education]

The Institution will only accept philanthropic gifts from Non-CC Entities if made through the Philanthropy Institute in accordance with its policies.
[See also Policy VII Conflicts of Interest in Education for other limitations regarding gifts]

Distribution of Non-CC Entity-Derived Materials Containing Information Directed at Patients as Part of Clinical Practice or Patient Education

Educational materials directed at patients that are developed by Non-CC Entities for use in patient care may only be made available following approval by a Professional Staff physician. If the Professional Staff physician has financial interests of any kind related to the company in question, he/she may not participate in the determination. In that case, the Institute Chair in collaboration with the Department Chair in that Institute must decide whether the materials should be made available. The decision will be based on the best interests of patients and the limitation of inappropriate Non-Cleveland Clinic (CC) Entity influence. Educational items with Non-CC Entity logos are discouraged.
Having Financial Interests in a Non-CC Entity (stock, stock options, rights to royalties or other commercialization revenues, receiving consulting, speaking or other fees) While Using the Entity’s Product in Treating Patients

All CCUS Healthcare Providers who have a Financial Interest in a Non-CC Entity making drugs or devices being used by or at the direction of the Healthcare Provider to diagnose or treat patients, whether the use is on-label or off-label, must receive approval from the IM&COI Program unless the total of the annual fees for services, annual royalties, and the approximate market value of the holdings over the prior 12 months are below $20,000 from a single Non-CC Entity and the stock holdings are less than five percent of the Non-CC Entity (excluding stock held in a diversified mutual fund). The IM&COI Program may require elimination or a reduction of the Financial Interest or devise a Conflict Management Plan to ensure, to the extent possible, that clinical practice is free from bias that may result from the Financial Interest. Certain types of relationships will be publicly disclosed via CCUS webpages, brochures or other means generally accessible to CCUS patients.

[For relationships with Non-CC Entities related to the use of experimental devices and drugs, see the conflict of interest policies that pertain to research, i.e., Conflict of Interest Policies III and IV.]

Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-CC Entities

The potential of a Significant Financial Interest (“SFI”) to create a Conflict of Interest, or in research, either a Conflict of Interest or PHS-Reportable Financial Conflict of Interest, is not eliminated by donating Honoraria or Consulting Compensation or Royalties and Other Revenues from Commercialization received from Non-CC Entities to a charity designated by the individual with the SFI. The only exception to this provision is where the individual with the SFI donates the Honoraria or Consulting Compensation, or Royalties and Other Revenues from Commercialization to the Cleveland Clinic Innovators’ Charitable Fund.

No Royalty Payments or other Commercialization Revenues for use at Cleveland Clinic Enterprise (CCE) of Products Commercialized by CCUS or developed by CCUS Employees

See Policy III Conflicts of Interest in Research for restrictions on the receipt of royalty revenues from products used, sold or purchased by CCE. There is no restriction on the receipt of royalty payments by CCUS or its Healthcare Providers for the purchase and use of products at locations other than CCE.

Patient Referrals to a Physician, Entity or Practice with which there is a Potentially Conflicting Relationship with the Referring Healthcare Provider

A conflict of interest between the recipient of a referral and the referring Healthcare Provider occurs when the referring Healthcare Provider or member of his or her Immediate Family could benefit financially from the referral. If the referring physician is personally compensated by a
Non-CC Entity or the referring physician or member of their Immediate Family owns any part of a company to which he/she is referring a patient, approval must be obtained from the IM&COI Program and the Law Department. In all cases, prior to referral, approval must be obtained from the referring Healthcare Provider’s Department Chair and his/her Institute Chair must be notified. He/she must also disclose the relationship to the patient being referred and any reasonable alternatives should be made clear.

The restrictions herein do not apply when a Healthcare Provider is referring a patient to a sub-unit of CCUS (e.g. a physician is referring a patient to radiology, but not to a specific radiologist and the physician’s spouse works in CCUS radiology). It is emphasized that all referrals of patients be made based on the best interest of the patient.

**Distribution of Prescription or Over-the-Counter Samples to Patients**

CCUS has a policy containing specific restrictions regarding drug samples. [See Department of Pharmacy Policy 10-002: “Pharmaceutical Representative Guidelines”]

**Site Access to CCUS by Pharmaceutical, Diagnostic and Medical Device Non-CC Entity Representatives**

CCUS has a policy pertaining to site access by Pharmaceutical Representatives. This policy hereby extends the limitations contained in the Department of Pharmacy Policy to include all Non-CC Entity representatives. [See Department of Pharmacy Policy, Pharmaceutical Representative Guidelines, and the Conflict of Interest Procedure for Vendors].

The IM&COI Program may grant exceptions where the Non-CC Entity representative visit is of direct benefit to a patient currently being treated.

**Ghostwriting**

CCUS Staff, residents and fellows are prohibited from allowing their professional presentations, oral or written, to be ghost-written by other(s). Ghostwriting encompasses instances in which a person who qualifies for authorship is not acknowledged or listed as an author on a publication and instances in which a person who does not qualify for authorship is named as an author on a publication. All persons designated as authors should qualify for authorship. [Qualifications for authorship should be in accordance with the Guidelines for Manuscripts and Books and Commercial Publication, included in the Major Policies for the Professional Staff (Yellow Book)]

**Oversight and Responsibility**

The Office of Professional Staff Affairs is responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements.

It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.