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Effective	Upon Approval	Applicability	Erie County Medical Center
Last Revised	11/2024	References	CORP-007
Next Review	1 year after approval		

Interactions Between ECMCC and Industry

I. Policy Purpose, Statement of Policy, and Policy Goals

The purpose of this policy is to provide parameters for appropriate decision-making regarding the acceptance or provision of business gratuities, gifts, activities and courtesies and other interactions between affected Individuals and Industry. Any questions as to whether a particular collaboration, interaction, relationship, gift, or social occasion would be appropriate in a specific circumstance should be directed to the Compliance Office.

It is the policy of ECMCC that interactions with Industry should be conducted to avoid or minimize conflicts of interest. When conflicts of interest arise, they must be addressed appropriately as described in the Procedure section below. Interactions with industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, equipment, and supplies on-site, on-site training for newly purchased devices, educational support of medical students and trainees, and continuing education.

Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of ECMCC. However, these interactions must be ethical and cannot create conflicts of interest or improper relationships that could endanger patient safety, data integrity, the integrity of our training programs, or the reputation of either staff members or the institution. In some situations, a conflict of interest or improper relationship could violate certain federal, state, or anti-kickback laws. These laws impose severe civil and/or criminal penalties upon institutions and affected individuals who request or receive anything of value (such as gifts, meals, trips or payments) in exchange for a clinical or business referral. The goal of the policy, which consists of both rules and guidance, is to foster a culture

in which ECMCC employees, senior administrators, managers, contractors, governing body, students, and trainees exercise independent judgment in all their activities and practice evidence-based, cost-effective medical care.

Federal and State laws and the regulations promulgated there under (commonly referred to as the anti-kickback, Stark, and civil monetary penalty statutes and regulations) prohibit the acceptance of any item of value (remuneration) made directly or indirectly, in cash or in kind, that may induce or appear to induce the purchase, recommendation to purchase or referral of any kind of health care goods, services, or items reimbursed by a federal or state healthcare program such as Medicare and Medicaid.

Consequently, the acceptance of any gifts or business courtesies from any third parties with whom ECMCC conducts business or who are seeking to do business with ECMCC may implicate Federal and State prohibitions.

In addition, ECMCC adopted a Conflicts of Interest policy with additional disclosure provisions to mitigate potential or actual conflicts of interest. Please be sure to consult this policy with regard to potential conflicts of interest.

II. Policy Implementation

ECMCC adheres to the highest ethical standards and legal requirements to avoid conflicts of interest, improper relationships and other exchanges with industry that may suggest impropriety, bias or a conflict of interest. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain. Industry representatives are expected to be aware of this policy and adhere to its principles. When conflicts arise, they must be addressed appropriately and expeditiously.

If a department or individual have been offered or in receipt of a "gift," please contact the ECMCC Compliance Office to ensure the gift can be compliantly received.

Individuals who may have questions about compliance with this policy should contact the ECMCC Compliance Office at 898-6439 or Compliance Hotline at 1-855-222-0758.

III. Definitions

Gift: A "Gift" means, for the purpose of this Policy, anything of value an affected Individual receives from Industry for which the Individual has not paid or performed services in a manner that is routine in commercial transactions. Gifts include, but are not limited to: cash of any amount, gift certificates, loans, trade show/office trinkets or promotional items (e.g., pens, calculators, notepads, coffee mugs), flowers, food and beverage, entertainment tickets, golf related items, stocks or other securities, or participation in stock offerings, Industry invitations to be their guests at charitable events sponsored by ECMCC or other charitable organizations, raffle prizes, and use of Industry's vehicles or vacation facilities.

Affected Individuals: are individuals who are covered by ECMCC's Compliance program requirements. This includes employees, senior administrators, managers, contractors, governing body and corporate officers.

Industry: Pharmaceutical, biotechnology, medical device and other health care related entities and their employees, representatives and other agents both on and off-premises owned or leased by ECMCC,

except where off-premises locations are specifically noted. This policy applies to conduct with Industry whether or not the particular Industry entity actually does business with ECMCC.

Open Payments: A national disclosure program that promotes a more financially transparent and accountable healthcare system by making available to the public, the financial relationships between drug and medical device companies (Reporting Entities) and health care providers (Covered Recipients). Payments or transfers of value from Reporting Entities made to certain Covered Recipients for consulting fees, meals, gifts, research and other forms of compensation or ownership interest are submitted to the Centers for Medicare and Medicaid Services (CMS) and published through the Open Payments website www.cms.gov/openpayments.

Sample or Drug Sample: Free pharmaceutical products obtained from an Industry representative intended for clinical administration to a patient.

Interested Source:

IV. Procedure

1. Gifts, Compensation and other Benefits from Industry

1. Gifts from Industry are prohibited regardless of any value because even gifts of a nominal value may be viewed to influence or potentially influence Individuals in the conduct of their duties or responsibilities. Gifts that are impermissible to Individuals are also impermissible when given to family members or guests of Individuals.
2. Section 3 of this paragraph contains rules for specific Industry benefits related to educational and professional support.
 - a. **Gifts as Compensation for Referrals.** Affected individuals may not accept gifts from Industry in exchange for ordering a health care item or service. For example, Individuals may not accept payment for prescribing a drug or changing a patient's prescription.
 - b. **Other Gifts or Benefits.** All affected individuals are advised not to accept any form of a Gift from Industry under any circumstances, as the acceptance of gifts creates a degree of risk under anti-kickback laws or an actual or apparent conflict of interest or appearance of improper influence.
 - c. **Gifts Related to Sales Presentations.** Affected individuals may not accept Gifts or compensation for listening to a sales talk by an Industry representative.
 - d. **Gifts of Educational Materials** (e.g. books). Affected individuals may not directly accept such Gifts but they may be directed to personnel (including students and other trainees) through an ECMCC component, department or departmental division if they are deemed to be of educational value and de-identified as to their source before being provided to recipient.
 - e. **Samples, Patient Education Gifts.** Certain Gifts for patients are permitted. Medication samples for patients may be accepted as long as use complies with ECMCC policies (see *FRM-004*). Gifts of anatomical models directed at patients (without Industry's identification), such as those used

for exam rooms are permitted, and if items are occasionally provided. Gifts of educational materials directed at patients are permitted only if appropriate materials are not available from a public source (e.g. government agency, foundation) and does not include Industry identification.

3. ECMCC is a public benefit corporation in the State of New York and all employees and governing body members must abide by Public Officers Law §73(5), regarding the acceptance of gifts.
 - a. If the item, service, or any other thing of value solicited, received, or accepted by an employee or governing body member meets the definition of Gift and is from an Interested Source, it is presumptively impermissible. Such Gift is only permissible if, under the circumstances, all of the following criteria are met:
 - i. it is not reasonable to infer that the Gift was intended to influence the individual; and
 - ii. the Gift could not reasonably be expected to influence the individual in the performance of his or her official ECMCC duties; and
 - iii. it is not reasonable to infer that the Gift was intended as a reward for any official action on the individual's part.
 - b. You cannot redirect an impermissible Gift to a third party, including your spouse or child or a charitable organization.
 - c. If you accept multiple permissible Gifts from the same source - even if each gift is worth less than \$15 (an amount deemed "nominal" by NYS) - you could, depending on the circumstances, violate Public Officers Law § 74 by creating an actual or an apparent conflict of interest or an appearance of improper influence.
 - d. Non-employed medical staff is strongly discouraged from accepting gifts, regardless of whether they are on-site or at non-ECMCC operated clinical facilities or non-health care settings, but are not proscribed by this policy from doing so.

2. **Site Access by Sales and Marketing Representatives (see PUR-001 Vendor Access Policy)**

- A. **Access to Patient Care Areas.** Sales and marketing representatives are not permitted in any patient care areas except by appointment and only for the purpose of providing in-service training on devices and other equipment.
- B. **Access to Non-Patient Care Areas.** Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments are made for:
 1. In-service training of ECMCC personnel for clinical equipment or devices already purchased.
 2. Evaluation of new purchases of equipment, devices or related items.

3. Provision of useful information about formulary medications or approved devices with the approval of appointment by the participating clinician.

- C. **Appointments Related to Formulary Drugs and New Devices.** Appointments to provide information about new drugs that are in the formulary or are possible additions to the formulary will be with Pharmacy staff. Appointments to provide information about new devices will be arranged with the Purchasing Department.
- D. **Distribution of Drug Information.** Representatives may not directly distribute promotional materials or drug information via interoffice mail of the medical center, nor may representatives have direct access to student, resident or staff mailboxes. Representatives may initiate distribution of drug information and educational materials to faculty, staff, fellows, residents or students at ECMCC sites after the prior approval and personal review of the material content by the Pharmacy Department or its designee. Such approved materials may be sent via US mail or delivered directly to an office for distribution at the discretion of office staff.

3. Support for Educational and Other Professional Activities

- A. **Accreditation Council for Continuing Medical Education (ACCME) or Equivalent Standards.** Personnel should be aware of the ACCME Standards for Commercial Support or equivalent standards such as those of the American Nurses Credentialing Center's (ANCC) Commission on Accreditation. They both provide guidelines for evaluating all forms of Industry exchange, including ECMCC sponsored and other events. ACCME standards can be found at www.accme.org.
- B. **ACCME or Equivalent Standards at ECMCC Sponsored Events.** All educational events sponsored by ECMCC and its departments or departmental divisions must be compliant with ACCME Standards for Commercial Support or equivalent standards whether or not continuing medical education (CME) or equivalent credits are awarded. Meetings governed by ACCME or equivalent standards, and the individuals who actively participate in meetings and conferences supported in part or in whole by Industry, should adhere to the following guidelines:
1. Financial support by Industry is fully disclosed by the meeting sponsor and conference speakers.
 2. The meeting content is determined by the speaker and not the Industry supporter.
 3. The lecturer is expected to provide a fair assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
 4. ECMCC department or participant is not required by an Industry supporter to accept advice or services concerning speakers, content, etc., as a condition of the supporter's contribution of funds or services.
 5. The lecturer makes clear that content reflects individual views and not the views of ECMCC or any of its affiliates.
 6. The use of the ECMCC name in non-ECMCC event is limited to the identification of an ECMCC individual by his or her title and affiliation.

- C. **Industry Support of ECMCC Sponsored Events.** Educational grants that are compliant with the ACCME Standards may be received from Industry for public conferences and programs administered by ECMCC departments or departmental divisions under the following circumstances:
1. Public conferences typically organized through ECMCC that have registration fees and provide CME credits may receive support from Industry, whether such public conference is held onsite or offsite, to offset any conference expense, such as speaker fees, speaker travel costs, reasonable meals, preparation of materials and room rental fees. Individuals attending such a conference typically pay a registration fee that, at a minimum, proportionally covers any meals or incidental expenses.
 2. Public programs (e.g. Grand Rounds or regional specialty events), whether held onsite or offsite, typically organized by ECMCC departments or departmental divisions and offered for free, may receive support from Industry to offset speaker honoraria or travel expenses.
- D. **Industry Provided Meals Prohibited.** Meals from Industry may be deemed to be gifts. Therefore, no industry-funded meals, food, or beverage of any nature or value are allowed, under limited exceptions, as follows:
1. **Widely Attended Event Exclusion criteria:**
 - i. Complimentary food and beverage at a Widely Attended Event is only permissible if food and beverage are offered to all participants. Widely Attended Event-four conditions below must be met to qualify:
 1. Complimentary admission must be offered by the sponsor of the event; and,
 2. 25 individuals who are not from ECMCC attend or are in good faith invited to attend; and
 - i. The event is related to the Individual's official duties or responsibilities or allows the Individual to perform a ceremonial function appropriate to your position; or,
 - ii. a speaker or attendee at the event addresses an issue of public interest or concern; and,
 3. The Individual informs the Director of Compliance in writing of the Widely Attended Event before the event takes place.
- E. **Industry Support of Private ECMCC Educational Activities.** Grants or gifts to fund meals at private educational activities, whether held onsite or offsite, such as noon conferences and journal clubs, may be received by ECMCC components but not by individual departments or department divisions. These funds shall be pooled centrally within ECMCC components and distributed proportionally among eligible

activities within that ECMCC component. This will ensure that any grants or Gifts will be dissociated from the receiving center, department or department division and avoid conflict of interest or the perception of a conflict of interest by the public.

- F. **Industry Support of Non-ECMCC Educational Events.** ECMCC Individuals may attend non-ECMCC offsite or out-of-town conferences with meals provided by Industry so long as the conference adheres to ACCME or equivalent requirements, as evidenced by the availability of CME or equivalent continuing education credits, and the presentation by a bona fide faculty member or expert clinician. However, ECMCC Individuals may not directly accept compensation, including consultancy payments or the defraying of costs, for simply attending a CME or other activity or conference (that is, if the individual is not presenting).

All Individuals should evaluate their own participation in non-ECMCC meetings and conferences that are fully or partially supported or run by Industry because of the potential for perceived or real conflict of interest.

- G. **Meetings of Professional Societies.** This section does not apply to meetings of professional societies governed by ACCME or equivalent standards and hosted at ECMCC facilities that may receive partial Industry support.

4. **Disclosure of Relationships with Industry** (see *Conflict of Interest Policy CORP-004*)

- A. **Purchasing and Procurement.** Individuals having a direct or committee role in making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to their making of any such decision, any financial interest they or their immediate family have in companies that might benefit from the decision.
- B. **Therapeutics and New Technology.** Individuals recommending institutional decisions on equipment or drug procurement must disclose any conflicts of interests. Such committees must decide whether the individual must recuse him/herself from making the recommendation to the committee and also may seek guidance regarding Conflict of Interest issues.
- C. **Educational presentations.** For disclosure requirements related to educational activities see the ACCME Standards for Commercial Support.

5. **Training of Students, Trainees, Faculty and Staff Regarding Potential Conflicts of Interest in Exchanges with Industry.**

All students and other trainees (e.g. residents, fellows), faculty and staff within ECMCC components shall receive initial and subsequent training regarding potential conflicts of interest in exchanges with Industry. ECMCC shall develop education materials and each ECMCC component shall implement training.

6. **Violations**

A. **Violations.**

- a. Punishment for personnel violations of these policies shall be imposed consistently with applicable ECMCC and policies, including, but not limited to, the ECMCC Code of Conduct.
 - i. Violations of these policies by Industry representatives will be

managed through warnings and restrictions on access.

- b. Committee on Ethics and Lobbying in Government (COELIG) is authorized pursuant to Executive Law §94 to investigate possible violations of Public Officers Law §73 and §74 and their corresponding regulations and take appropriate action as authorized in these statutes.
 - i. Any person who knowingly and intentionally violates Public Officers Law § 73(5) is subject to a maximum civil penalty of \$40,000.00 and the value of any gift, compensation, or benefit relating to that violation.

B. **Reporting Violations.** Personnel witnessing violations of these policies shall report violations to the appropriate supervisor or department, to the AVP of Compliance at 716-898-6439, or to Executive Senior Management. Alternatively, they may make an anonymous report to the ECMCC Compliance & HIPAA Hotline at 1-855-222-0758.

Reference:

Public Integrity Reform Act of 2022

NYS Commission on Public Integrity Advisory Opinion No. 08-01.

Title 19 NYCRR Part 933

Conflict of Interest Policy

ECMCC's Code of Conduct

POL §73 and 74

ECMCC has developed these policies and procedures in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team in making clinical decisions about patient care. These policies and procedures should not be construed as dictating exclusive courses of treatment and/or procedures. No health care team member should view these documents and their bibliographic references as a final authority on patient care. Variations from these policies and procedures may be warranted in actual practice based upon individual patient characteristics and clinical judgment in unique care circumstances.

Approval Signatures

Step Description

Approver

Date

Lindy Nesbitt: Assistant VP
Compliance & Senior Counsel

Pending

Applicability

Erie County Medical Center

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