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Owner:	<i>Vanessa Gray: Director Continuing Medical Education</i>
Area:	<i>Continuing Medical Education</i>
References:	
Applicability:	<i>Des Moines University</i>

## Financial Relationships and Conflicts of Interest Policy – Continuing Education

### I. PURPOSE

Des Moines University must ensure balance, independence, objectivity, and scientific rigor in all its continuing education activities. The intent of this policy is not to prevent an individual with a relevant financial relationship from being involved in a continuing education activity but to provide learners with information they can use to make their own judgment. The content or format of a continuing education activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.

### II. SCOPE

This policy applies to all continuing education activities accredited by Des Moines University.

### III. REFERENCES

- A. [Accreditation Council of Continuing Medical Education \(ACCME\) Standards for Commercial Support: Standards to Ensure Independence in CME Activities](#)
- B. [American Osteopathic Association \(AOA\) Accreditation Requirements Category 1 CME Sponsors](#)
- C. [Iowa Board of Nursing 655 Iowa Administrative Code, Chapter 5](#)
- D. [Council on Podiatric Medical Education Standards and Requirements for Approval of Providers of Continuing Education in Podiatric Medicine](#)
- E. [American Academy of Physician Assistants \(AAPA\) Category 1 CME Credit to PA Preceptors](#)

### IV. DEFINITIONS

#### A. Accredited Provider

An organization accredited as a provider of continuing medical education. For the purposes for this policy, Des Moines University is the accredited provider. Accredited providers assume the responsibility and accountability for developing certified educational activities. Accredited providers represent a range of organizational types and offer continuing education primarily to national or international audiences of physicians and other health care professionals.

## **B. Commercial Bias**

Content or format in an accredited continuing education activity or its related materials that promotes the products or business lines of an ACCME-defined commercial interest.

## **C. Commercial Interest**

Any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients to be commercial interests. A commercial interest is not eligible for accreditation or participation in joint providership.

## **D. Commercial Support**

Monetary or in-kind contributions given by a defined commercial interest that is used to pay all or part of the costs of an accredited continuing education activity. The requirements for receiving and managing commercial support are explained in the [ACCME Standards for Commercial Support](#). Advertising and exhibit income are not considered commercial support.

## **E. Conflict of Interest**

Des Moines University considers financial relationships to create conflicts of interest in accredited continuing education when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content about the products or services of that commercial interest.

## **F. Continuing Education**

Educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships a clinician uses to provide services for patients, the public, or the profession. Continuing education represents that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

## **G. In-Kind Commercial Support**

Non-monetary resources provided by a commercial interest in support of an accredited continuing education activity. Examples of in-kind support include equipment, supplies, and facilities.

## **H. Jointly Provided Activity**

An activity that is planned, implemented, and evaluated by an accredited provider and one or more non-accredited entities.

## **I. Off-Label Use**

The use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, dosage, or route of administration. Both prescription drugs and over-the-counter drugs can be used in off-label ways, although most studies of off-label use focus on prescription drugs. Off-label use is generally legal unless it violates ethical guidelines or safety regulations. The ability to prescribe drugs for uses beyond the officially approved indications is commonly used to good effect by health care providers.

## **J. Relevant Financial Relationships**

The accredited provider will require anyone in control of content to disclose relevant financial relationships. Individuals must also include in their disclosure the relevant financial relationships of a spouse or domestic partner. A relevant financial relationship is defined as financial relationships in any amount that create a conflict of interest and that occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the continuing education activity. There is not set a minimum dollar amount.

## **K. Standards for Commercial Support: Standards to Ensure Independence in CME Activities<sup>SM</sup>**

Requirements designed to ensure that continuing education activities are independent and free of commercial bias. The Standards comprise six standards: independence, resolution of personal conflicts of interest, appropriate use of commercial support, appropriate management of associated commercial promotion, content and format without commercial bias, and disclosures relevant to potential commercial bias.

## **V. POLICY**

The accredited provider considers financial relationships to create actual conflicts of interest when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content about the products or services of that commercial interest. The accredited provider considers “content of continuing education about the products or services of that commercial interest” to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers’ bureau, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. The accredited provider considers relationships of the person involved in the continuing education activity to include financial relationships of a spouse or domestic partner

Any amount, regardless of how small, creates the incentive to maintain or increase the value of the relationship. Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers’ bureau, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. With respect to personal financial relationships, contracted research includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

# VI. PROCEDURE

## A. Identification

All individuals who are involved with planning of continuing education activities must complete a [Disclosure of Relevant Financial Relationships form](#) prior to planning the activity disclosing all relevant financial relationships with any commercial interest company. Individuals subject to this requirement include, but are not limited to, activity directors, planning committee members, faculty/speakers/presenters, authors and editors, expert reviewers, moderators, panel members, and all individuals in position to control content. This disclosure must be made on the [Disclosure of Relevant Financial Relationships form](#) or other pre-approved format.

### Disclosures Relevant to Potential Commercial Bias

- A. An individual must disclose to learners any relevant financial relationship(s), to include the following information:
  1. The name of the individual;
  2. The name of the commercial interest(s);
  3. And the nature of the relationship the person has with each commercial interest.
- B. For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.
- C. The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.
- D. Disclosure must never include the use of a corporate logo, trade name or a product-group message of a defined commercial interest.
- E. A provider must disclose the above information to learners prior to the beginning of the educational activity.
- F. Disclosure must be made by a declaration in writing and available to the attendees.

For an individual with a relevant financial relationship(s), the learners must be informed in writing of that relevant financial relationship(s). Example statements are below:

Joseph Doe, DO, Speaker

*Relevant to the content of this educational activity, Dr. Joseph Doe indicated he is an advisory board member for XYZ Pharma Company.*

John Doe, DPM, Planner

*Relevant to the content of this educational activity, Dr. John Doe indicated he is a consultant for ABC Pharma Company.*

For an individual with no relevant financial relationship(s), the learners must be informed in writing that no relevant financial relationship(s) exist. Example statements are below:

Jane Doe, PhD, Activity Director/Speaker

*Relevant to the content of this educational activity, Dr. Jane Doe indicated she has no financial*

*relationships with commercial interest companies to disclose.*

Jonis Doe, Administrative Staff

*Relevant to the content of this educational activity, Ms. Jonis Doe indicated she has no financial relationships with commercial interest companies to disclose.*

## **B. Independence**

A commercial interest cannot take the role of non-accredited partner in a joint provider relationship. The accredited provider must ensure that the following decisions were made free of the control of a commercial interest.

- A. Identification of professional practice gaps related to knowledge, competence, performance, patient outcomes, or community change
- B. Determination of educational objectives
- C. Selection and presentation of content
- D. Selection of all persons and organizations that will be in a position to control the content of the continuing education content
- E. Selection of educational methods
- F. Evaluation of the activity

## **C. Resolution of Personal Conflicts of Interest**

The accredited provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider.

The accredited provider will have a mechanism to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners. Methods to resolve conflicts of interest include but are not limited to the following:

- A. Peer review of presentation materials to ensure balance and unbiased content.
- B. Limiting the scope of the presentation.
- C. Recommendations based on structured review of best evidence.
- D. Altering the course design to ensure fair and balanced treatment or topic.
- E. Suggestion of an alternative speaker or planning committee member.
- F. On-site monitor.
- G. Divestiture of the financial relationship.

### **Refusal to Disclose**

- 1. Non-Speaker
  - a. The activity director and/or accredited provider will work with individuals who fail to provide disclosure, ensuring that a [Disclosure of Relevant Financial Relationships form](#) is received. If a completed form is not received, that individual will be disqualified and cannot have control of, or responsibility for, the development, management, or evaluation of the continuing education activity.

## 2. Speaker

- a. If a speaker refuses to disclose, their presentation will forfeit credit, or they will be replaced and not considered to present until such disclosure is made.
- b. The activity director and/or accredited provider will work with individuals who fail to provide disclosure, ensuring that a [Disclosure of Relevant Financial Relationships form](#) is received. If a completed form is not received, their presentation will forfeit credit, or that person will be disqualified and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the continuing education activity.

## D. Off-Label Disclosure

When an off-label use of a product or an investigational use not yet approved for any purpose is discussed during an educational activity, the speaker and/or moderator must disclose that the product is not labeled for the use under discussion, or that the product is still investigational.

## E. Proprietary Names of Products

Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

## F. Patient Confidentiality

Within the [Disclosure of Relevant Financial Relationships form](#), all speakers and/or moderators must agree to protect patient confidentiality by removing any identifying factors within their presentation materials.

## G. Evaluation/Monitoring for Bias

Participants will be surveyed about perceived commercial bias as part of the post-activity evaluation.

## Approved By:

Angela Franklin, Ph.D., President

### General Disclaimer

The information available in PolicyStat is not to be treated or implied as a contract but rather as a unilateral statement of University policies. The University reserves the right to revoke, modify or suspend any of its policies or procedures at any time without notice.

## Attachments

No Attachments

## Approval Signatures

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Approver	Date
Ralitsa Akins	06/2020
Nehad El-Sawi	02/2020
Vanessa Gray	01/2020

## Applicability

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