

FINANCIAL DISCLOSURE FOR ACCREDITED

CONTINUING EDUCATION (ACE)

MITIGATION TO

VALIDATING INTEGRITY OF CONTENT

POLICY AND PROCEDURES

# **Accredited Continuing Education (ACE) Financial Disclosure Policy**

The American College of Medical Genetics and Genomics (ACMG) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Accredited Continuing Education (ACE) for physicians. ACMG is an organization committed to improvement of patient care and general health by the incorporation of genetics and genomics into clinical practice.

ACMG requires that all ACE activities are scientifically based, accurate, current, and objectively presented. All recommendations for patient care must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options. All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation. Education may not advocate for, or promote, practices that are not, or not yet adequately based on current science, evidence, and clinical reasoning, such as new and evolving topics.

ACMG is committed to provide accredited continuing medical education that offer healthcare professionals with a protected space to learn, teach, and engage in scientific discourse free of the influence from organizations that may have an incentive to insert commercial bias into the education. Education must be free of the influence or control of ineligible entities, and protect learners from promotion, marketing, and commercial bias. Presentation materials may not include logos or product messaging from ineligible companies and shall use generic names, rather than trade names, when referencing pharmaceutical or medical device products. Owners and employees of ineligible companies are considered to have unresolvable financial relationships and shall have no role in accredited continuing education.

Financial relationships held with ineligible companies have the potential to influence and create bias in the content of accredited education. *Ineligible companies are defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.* Financial relationships are defined as any relationship held with an ineligible company within the prior 24 months, regardless of the amount and whether relevant to the education. Examples of such relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patient beneficiary, executive role, ownership interest, individual stock and stock options, institutional research funding if principal or named investigator.

ACMG education and designated content experts without any relevant conflicts will identify and review all financial relationships held by planners, faculty, and others who would be in position to control the content of accredited education, and determine which relationships are relevant. Relevant financial relationships will be mitigated prior to individuals assuming their roles in the activity. Persons who fail or refuse to disclose all financial relationships, or do not cooperate with mitigation strategies implemented, will be disqualified. Relevant financial relationships will be disclosed to learners prior to their engagement with the accredited

education and include information about the names of ineligible companies and nature of relationships. All activities will be evaluated to determine if the content was free of commercial bias and met acceptable scientific standards.

# **Accredited Continuing Education Financial Disclosure Procedure**

ACMG has implemented the following procedures to ensure the independence of ACE activities from commercial influence/promotional bias, the ACCME requires that providers (ACMG) must be able to demonstrate that: 1) everyone in a position to control the content of an ACE activity has disclosed all financial relationships that they have had in the past 24 months with ineligible companies; 2) ACMG has implemented a mechanism to mitigate relevant financial relationships; and 3) all financial relationships with ineligible companies are disclosed to the learners before the beginning of the educational activity. The learners must also be informed if no relevant financial relationships exist.

ACMG uses a selection of mitigation strategies and necessary steps for implementation must be documented and communicated to individuals prior to them assuming their role. It is the expectation that faculty and planners participate in this process, whenever deemed appropriate, to ensure that implementation has taken place. Attestation of implementation of mitigation strategies by faculty and planners may be required.

ACMG does not view the existence of financial relationships with ineligible companies as implying bias or decreasing the value of a presentation. It is intended that such relationships be identified openly so that the learner may form their own judgments about the presentation and the presence of commercial bias

## I. Collect and Identify Information

ACMG Education will collect and identify all financial relationships during the activity planning process. All persons in a position to influence or control content (course directors, program planning committee members, speakers, authors, staff, etc.) will complete a comprehensive online disclosure form providing information about all financial relationships held in the prior **24 months**, regardless of the amount and whether relevant to the education, before assuming their role in the activity. Disclosure forms will be updated every 24 months and/or whenever relationships change.

During the submission of financial relationship information, attestation that recommendations in activities involving clinical medicine will be based on current science, evidence, and clinical reasoning, give a fair and balanced view of diagnostic and therapeutic options, and all scientific research referred to, reported, or used, will conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation, will be required.

#### II. Review and Determination of Relevant Financial Relationships:

ACMG Education in collaboration with ACMG content experts, such as faculty, committee members, and staff without relevant financial relationships, will review all financial relationships to determine if relationships are relevant to the education.

Owners and employees of ineligible companies are considered to have unresolvable financial relationships and will automatically be excluded from participating as planners or faculty and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the

limited circumstances outlined in Standard 3.2 of the ACCME Standards for Integrity and Independence in Accredited Continuing Education.

Owners and employees of ineligible companies are allowed to participate as planners or faculty in ACE activities under these circumstances:

- 1. When the content of the activity is not related to the business lines or products of their employer/company.
- 2. When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
- 3. When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

#### Financial relationships are deemed relevant if:

A financial relationship, in any amount, exists between the person in control of content and an ineligible
company, AND
The financial relationship existed during the prior 24 months, AND
The content of the education is related to the business line or products of the ineligible company with
whom the person has a financial relationship.
Note that it is the content area of the entire activity or session (in the case of Regularly Scheduled Series),
not the specific presentation, that serves as basis for this determination.

## III. Mitigation of relevant financial relationships:

ACMG uses a variety of mechanisms to mitigate financial relationships. If a relevant financial relationship is identified, one or more of the following mitigation strategies will be implemented appropriate to the role of the individual:

- Divest the financial relationships
- Recusal from controlling aspects of planning and/or content with which there is a financial relationship
- Peer review of planning decisions by a person without relevant financial relationship
- Peer review of content by a person without relevant financial relationship
- Refrain from making any recommendations
- ACMG education will manage a peer review all accredited content/PowerPoint presentations with a
  relevant financial interest prior to launch. ACMG education will identify content reviewers (with no
  RFRs) and provide them with guidelines for content review.
- Other mechanisms may be implemented if deemed necessary. If mitigation strategies cannot sufficiently be implemented, an alternate individual must be selected and/or credit will not be approved/awarded.

# Communication and Implementation of Mitigation Strategies:

Selection of mitigation strategies and necessary steps for implementation must be documented and communicated to individuals prior to them assuming their role. It is the expectation that ACMG faculty and planners participate in this process, whenever deemed appropriate, to ensure that implementation has taken place. Attestation of implementation of mitigation strategies by faculty and planners may be required.

#### IV. Disclose all relevant financial relationships to learners:

All relevant financial relationships, and the nature of those relationships, will be disclosed to the learners prior to engagement in the ACE activity. Reporting of disclosures will include:

- Individual's name with relevant financial relationship
- Name of ineligible company(ies)
- Nature of the relationship
- A statement that all relevant financial relationships have been mitigated
- The absence of relevant relationships will also be disclosed.

Oversight: All accredited continuing education activities will be evaluated by participants and peer reviewers to determine if the content was free of bias and met acceptable scientific standards. If a high commercial bias rating (>8%) is noted or other complaints emerge of a biased presentation, appropriate measures will be taken. Such measures may include further education about standards and expectations, enhanced oversight in future years, and/or refusal to accredit the same activity again. In addition, peer review is mandatory for all activities in which concerns about commercial bias have been raised in the past.

**NOTE**: ACMG will not identify, mitigate, or disclose relevant financial relationships for any of the following:

- 1. Accredited education that is non-clinical, such as leadership or communication skills training.
- 2. Accredited education where the learner group is in control of the content, such as a spontaneous case conversation among peers.
- 3. Accredited self-directed education where the learner controls their educational goals and reports on changes that resulted, such as learning from teaching, remediation, or a personal development plan. When accredited providers serve as a source of information for the self-directed learner, they should direct learners only to resources and methods for learning that are not controlled by ineligible companies.

Approved by ACMG Education Committee 12/10/2021 Approved by ACMG Board of Directors 1/24/2022

# Accreditation Council for Continuing Medical Education (ACCME®) and American Medical Association (AMA) Glossary of Terms and Definitions

#### **Commercial bias**

Content or format in a CME activity or its related materials that promotes the products or business lines of an ineligible company. As described in the Standards for Integrity and Independence in Accredited Continuing Education, providers are responsible for protecting learners from commercial bias and marketing. In addition to preventing influence from ineligible companies, the Standards prohibit faculty from actively promoting or selling products or services that serve their professional or financial interests.

## **Ineligible Company**

Companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

## **Relevant financial relationships**

As defined in the Standards for Integrity and Independence in Accredited Continuing Education, specifically, Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships, relevant financial relationships are financial relationships of any amount with ineligible companies if the educational content is related to the business lines or products of the ineligible company. Providers are required to collect information from all those individuals in control of educational content about all of their financial relationships with ineligible companies within the prior 24 months. The provider is then responsible for determining which relationships are relevant.

#### Standards for Integrity and Independence in Accredited Continuing Education

ACCME requirements designed to ensure that accredited continuing education serves the needs of patients and the public, is based on valid content, and is free from commercial influence. The Standards comprise five standards: Ensure Content is Valid; Prevent Commercial Bias and Marketing in Accredited Continuing Education; Identify, Mitigate, and Disclose Relevant Financial Relationships; Manage Commercial Support Appropriately; Manage Ancillary Activities Offered in Conjunction with Accredited Continuing Education. Released in December 2020, the Standards for Integrity and Independence replace the Standards for Commercial Support.

#### **Diagnostic Laboratory**

A diagnostic laboratory is not considered an ACCME-defined ineligible company if its business is limited to the provision of diagnostic services that provide clinical results or information to healthcare professionals for their treatment of patients.

A diagnostic laboratory is considered an ACCME-defined ineligible company if its primary business is producing, marketing, distributing, selling, or re-selling proprietary diagnostic products or devices used by or on patients such as other laboratories, clinics, clinicians, or patients for the provision of clinical service—for example, providing on-site or in-home clinical results.