**American Society of Regional Anesthesia and Pain Medicine**



CME Policy

## Disclosure and Conflict of Interest Mitigation

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| **Title** | **Disclosure and Conflict of Interest Mitigation** |
| **Original Approval** | **02/2012** |
| **Revisions** | **07/2022, 11/2019, 02/2018, 07/2017, 09/2014, 05/2014, 09/2013** |

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| **Purpose** |

1. **Independence of CME**

ASRA Pain Medicine will ensure that the following decisions are made free of the control of an ineligible interest and planned in a way to protect learners from commercial bias and marketing:

* Identification of educational needs
* Determination of educational objectives
* Selection and presentation of content
* Selection of all persons and organizations controlling content
* Selection of educational methods
* Evaluation of the activity

1. **Disclosure and Conflict of Interest Mitigation of All Individuals in Control of Content**

In accordance with the ACCME’s Standards for Integrity and Independence in Accredited CE and related policies, ASRA Pain Medicine is committed to ensuring balance, independence, objectivity, and scientific rigor in all of its continuing medical education activities. Accordingly, those in control of the educational content must disclose all relevant financial relationships with any ineligible company that they have had within the past 24 months. If an individual refuses to disclose, they are disqualified from contributing to the planning and implementation of the CME activity. Disclosure information is thoroughly evaluated and all conflicts of interest are resolved via several methodologies (including peer review of content, onsite monitoring, etc.). Disclosure of this information is made to participants prior to the educational activity in the program guide, on the event website, and verbally at the beginning of each educational session. Discussion of unlabeled use of a therapeutic product, or the investigational use not yet approved, is also disclosed.

1. **Ineligible Company Support Disclosure**

If a course is supported, in part, by educational grants and/or in-kind support from an ineligible company, all support is managed in strict accordance with the ACCME’s Standards for Integrity and Independence in Accredited CE. Appropriate acknowledgement of all supporting organizations (company name only, no logos, trade names, or product group messages) is made to participants prior to the educational activity in the program guide, on the event website, and with signage during the meeting.

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| **Definitions** |

1. **Ineligible Compan**y

ACCME has incorporated eligibility information directly into the Standards for Integrity and Independence in Accredited Continuing Education. Companies that are ineligible to be accredited in the ACCME System (ineligible companies) are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples of such organizations include:

* Advertising, marketing, or communication firms whose clients are ineligible companies
* Bio-medical startups that have begun a governmental regulatory approval process
* Compounding pharmacies that manufacture proprietary compounds
* Device manufacturers or distributors
* Diagnostic labs that sell proprietary products
* Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
* Manufacturers of health-related wearable products
* Pharmaceutical companies or distributors
* Pharmacy benefit managers
* Reagent manufacturers or sellers

The ACCME does not consider (1) providing clinical services directly to patients; or (2) the education of healthcare professionals; or (3) serving as fiduciary to patients, the public, or population health; and other organizations as ineligible. Examples of such organizations that do not need to be disclosed include:

* Ambulatory procedure centers
* Blood banks
* Diagnostic labs that do not sell proprietary products
* Electronic health records companies
* Government or military agencies
* Group medical practices
* Health law firms
* Health profession membership organizations
* Hospitals or healthcare delivery systems
* Infusion centers
* Insurance or managed care companies
* Nursing homes
* Pharmacies that do not manufacture proprietary compounds
* Publishing or education companies
* Rehabilitation centers
* Schools of medicine or health science universities
* Software or game developers

The ACCME depends upon the accredited CME provider to evaluate and determine whether or not an entity falls under the definition of an ineligible company, and whether or not there are discussions about health care products. ASRA Pain Medicine will consult with the ACCME to assist in this process, as necessary.

1. **Relevant Relationships**

ASRA Pain Medicine defines relevant relationships as financial relationships with ineligible companies within the prior 24 months. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Disclosure information must include:

* The name of the ineligible company with which the person has a financial relationship.
* The nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual’s institution receives the research grant and manages the funds.

1. **Conflict of Interest**

Circumstances create a conflict of interest when an individual has an opportunity to affect CME content related to the products, services, or business lines of a commercial interest with which he/she has a financial relationship.

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| **Procedure** |

1. **Independence of the CME Planning Process**

Independence during all phases of the CME process is enforced via strict oversight and checks and balances. If there is question that independence has been jeopardized by the influence of an ineligible company, the matter will be examined and escalated to the CME Committee, as necessary. If it is deemed that influence was indeed exercised, the CME Committee reserves the right to revoke/deny credit for any/all portions of the activity and to take appropriate corrective actions.

1. **Disclosure and Conflict of Interest Mitigation of All Individuals in Control of Content**

In order to promote independence and objectivity in CME, all contributors controlling content are required to follow a 3-step process:

1. **Disclosure/Identification of Financial Relationships**

All individuals in control of the educational content of the activity must disclose all relevant financial relationships. Information that an individual has no relationships must also be disclosed. Disclosure must be made prior to the CME activity. If an individual refuses to disclose, or fails to do so prior to the activity commencement, they will be disqualified from participating in the CME activity.

**Faculty Disclosure Form**

Disclosure information is collected and verified via several modalities, including but not limited to: standardized CME Faculty Disclosure Form, e-mail, verbally, etc.

**Faculty Attestation**

ASRA Pain Medicine conflict of interest management process requires an attestation (included in the Faculty Disclosure Form and faculty invitation) on the part of all CME activity collaborators that their contributions will adhere to the following guidelines:

* Submit presentation in advance for peer review.
* All presentations will be monitored onsite for compliance.
* No use of promotional content of a commercial entity (includes product/trade names, photos, logos, company names, etc.).
* Logos appearing on ultrasound images/machines should not be visible in presentations.
* Use of scientific/generic names; trade names should be used only if absolutely necessary for educational clarity; in such cases the name may be included parenthetically once, but no more. If more than one company makes the product, all applicable trade names should be identified.
* No patient Protected Health Information; materials must be de-identified.
* ASRA Pain Medicine Faculty, Associate Faculty, Board of Directors, CME Committee Chair and Vice Chair, Scientific Program Committee Chair, RAPM Editor and Associate Editor in Chief will not speak in any non-CME promotional events (e.g. promotional presentations or product theaters) during dates of the ASRA Pain Medicine meeting (e.g. Thursday, Friday or Saturday) or ASRA Pain Medicine course (e.g. Saturday or Sunday) at the official meeting/course headquarters or offsite locations. This does not preclude consulting relationships.
* Faculty should not allow industry representatives to influence CME content in any way. If approached, please refrain from discussing presentation content.
* Disclosure slide included and verbal disclosure made, even if nothing to disclose, at beginning of presentation(s).
* The same disclosure information/slide should be included for all presentations; faculty may verbally indicate if not “directly” relevant to the topic being presented.

**Faculty Disclosure Grid**

Faculty disclosure information for all those controlling content is compiled and comprehensively recorded in the Faculty Disclosure Grid.

1. **Mitigation of Conflict of Interest**

Disclosure and conflict of interest information is reviewed by the activity planning committee, or other qualified reviewer. All identified conflicts of interest must be mitigated via several modalities prior to the activity, including:

* Reminder of CME guidelines for integrity and independence
* Reminder that learners will be evaluating the presentations for independence
* Shift the focus of the speaker’s presentation from the area with conflict of interest to one without
* Faculty member divests himself/herself of the financial relationship with a commercial interest
* Faculty member is excused from participating in the activity or conflicted portion thereof
* CME credit revoked for presentation(s)
* Peer review of content prior to activity (changes made, if necessary for compliance), review done by:
  + Chair/Co-Chair, CME Committee (primary review, escalated to the below, as necessary)
  + Moderator/Lead of the session
  + Chair, Scientific/Education Planning Committee
* Additional on-site monitoring of activity by the moderator

**Employees of an Ineligible Company**

Per ACCME policy, employees of ineligible companies cannot participate in accredited CME activities if the content of the CME activity relates to the business lines and products of the commercial interest. Exceptions to this policy include:

* Teaching about the scientific or discovery process itself, reporting research results that would be considered at the level of biology or physics – but not about products.
* Demonstrating the operational aspects or ensuring proper functioning of the use of a device during a hands-on learning activity. Although participating in the activity, the company representative is not influencing CME content and must abide by the ASRA Pain Medicine policy on Separation of Promotional from Educational Activities.

Strict guidelines regarding these exceptions will be followed to ensure the independence and compliance with ACCME’s Standards for Integrity and Independence in Accredited Continuing Education of accredited CME that involves the employees of ACCME-defined commercial interests.

**Process Documentation**

The conflict of interest mitigation process will be documented using the Conflict of Interest Mitigation Form and/or Spreadsheet.

1. **Communication/Disclosure to Learners**

Communication of disclosure information and conflicts of interest for all contributors to the CME activity must be presented to the learners prior to the activity. Various mediums for disclosure include:

* Activity Website
* Program Guide/Syllabus
* Meeting App
* Verbally from the podium along with inclusion on the first slide of the presentation (template provided to all speakers)

1. **Learner Feedback via Evaluation**

Questions are included in the overall activity evaluation asking learners to provide feedback on whether the activity was balanced, objective, and free from bias. Responses are reviewed by the CME Committee with corrective actions taken as necessary, including: increased education of returning faculty regarding the requirements, guest faculty not invited back, increased peer review of content, etc.