

ASPS CME Activity - Conflict of Interest Mitigation Policy Effective January 1, 2022

The American Society of Plastic Surgeons (ASPS) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education (CME) for physicians. ASPS designates educational activities for *AMA PRA Category 1 Credit™*. As such, ASPS has the obligation to ensure the delivery of education that is balanced, independent from commercial interests, free of commercial bias, objective, and scientifically rigorous. As the ASPS CME Activity Conflict of Interest Policy states, all CME-related persons involved in educational content, including committee members, activity chairs/co-chairs, planners, reviewers, presenters, faculty, moderators, authors, editors, staff, and others as applicable, must complete a relevant financial disclosure statement. ASPS is responsible for identifying and managing relevant financial relationships between individuals in control of educational content and ineligible companies.

The ASPS Continuing Education (CE) Committee ensures that ASPS continues to develop and maintain the standards of excellence that meet the continually evolving medical education guidelines and requirements of FDA, AMA, and the various accreditation governing bodies. The Committee provides continual parameter of continuing medical education including review of disclosure, identification of conflict of interest, and direction on the mitigation of such conflict.

For background, organizations eligible to be accredited in the ACCME System (eligible organizations) are those whose mission and function are: (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 that are not otherwise ineligible. Educational content produced by eligible companies, provided it complies with other ACCME standards, may be offered for *AMA PRA Category 1 Credit™*. In contrast, an ineligible company is defined by ACCME as those whose primary business is producing, marketing, selling, re-selling, or distributing health care products used by or on patients. As such, ASPS defines ineligibility to include bio-medical approval process for submission of the following applications: PMA (pre-market approval), 510(k) clearance, de novo; NDA (new drug application), IND (investigational new drug), IDE (investigational device exemption), BLA (biologic license application) and biomarker qualification program. Content produced, presented, offered or influenced by ineligible companies is necessarily considered biased, and cannot be offered for *AMA PRA Category 1 Credit™*.

Standard Preliminary Mitigation in Advance of Educational Program:

The CE Committee reviews all financial and relevant conflicts of interest disclosures in advance of educational content and proceeds with mitigation steps, to include but not limited to:

- A) Owners and employees of ineligible companies are considered to have unresolvable financial relationships and must 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.
 - a. Owners are defined by ACCME as individuals who have an ownership interest in a company. Stock owners of private companies are identified as owners; however, if the company is publicly traded, or is holder of shares through a pension or diversified mutual fund, they are not considered owners.
 - b. ASPS defines the term “mutual fund”, as used in ACCME standards, to be any investment product that involves the pooling of money from investors that is then invested outside the direct control of the individual investors.
 - c. Employees are defined by ACCME as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.
 - d. Exceptions for ineligible company *owners and employees* can participate as planners or faculty only in the following circumstances:
 - i. When the content of the activity is not related to the business lines or products of their employer/company.
 - ii. 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.
 - iii. 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.
- B) Research grants from ineligible companies are financial relationships that should be disclosed, even if the funds go to the researcher's institution and not to the individual researcher.
- C) Required resolution of education content, to include but not limited to the following:
 - i. Limit the sources and content for presentation and materials to those considered as based on the best available medical and scientific evidence culled from studies and/or literature. Use generic names whenever possible; refrain from referencing name-brand products or entities that produce, market, re-sell or distribute health care goods or services consumed by, or used on, patients. This may require revising the presentation and/or materials originally submitted for committee review.
 - ii. Limit the content of the presentation and materials to a report on findings, without making recommendations regarding products or services.
 - iii. Select another individual, without a relevant conflict, to develop and deliver the necessary content (i.e. replace faculty member/author).

- iv. Divest oneself of relevant financial relationship(s) (i.e. discontinue contracted services so no incentive remains to introduce bias).
- D) A secondary review post resolution to the individual will be performed prior to the presentation. If the conflict of interest is not rectified, the presentation will be removed from the educational program.

Real Time Mitigation of Educational Content Presentations

The CE Committee provides real time mitigation of educational content, to include but not limited to:

- A) Educational session moderator will be provided appropriate steps to redirect a presenter(s) if a conflict of interest is identified and/or pause the presentation to address with the presenter(s) prior to continuing the presentation.
- B) Instruct moderator and presenter(s), should a repeat conflict of interest be identified, the result in interruption and discontinuation of the presentation by the moderator will occur.
- C) All moderators, presenters, faculty and others in control of educational content will be informed of these rules in advance.

Ongoing Mitigation of Education Content

To ensure mitigation efforts with ongoing monitoring for potential conflict of interest, the CE Committee shall assist with, but not limited to the following:

- A) Review educational programming CME surveys for conflict of interest and provide mitigation efforts.
- B) An ongoing audit procedure for educational content with no identified conflict of interest shall be completed for at least every 10th session to validate there have been no relevant conflicts.

Mitigation Disclosures to Learners

When disclosing relevant financial relationships to learners, ASPS shall include a statement that all relevant financial relationships have been mitigated prior to educational content.