



ASSOCIATION OF PHYSICIANS OF PAKISTANI-DESCENT OF NORTH AMERICA

APPNA Office of CME Continuing Medical Education Policies and Procedures

PURPOSE AND BACKGROUND:

The Association of Physicians of Pakistani-descent of North America (APPNA) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor (designate credit) continuing medical education (CME) for physicians. APPNA Office of CME is the administrative unit at APPNA responsible for ensuring compliance with the [ACCME Essential Areas, Elements, Criteria, Policies](#), and [Standards for Commercial Support \(SCS\)](#), as well as other regulations and laws as they relate to the provision of CME. APPNA CME also requires that the following policies and procedures be followed throughout the development and implementation of CME activities:

INDEPENDENCE – In addition to SCS 1:

1. Each activity certified for credit by APPNA CME will be in compliance with the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education.
2. Final authority for all areas relating to the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education will be retained by APPNA CME.
3. All faculty, meeting, and marketing logistics are to be appropriately handled by APPNA staff or their designee(s). Representatives from a commercial interest cannot provide meeting planning or faculty coordination functions.
4. Information on the identity of learners at CME activities is considered to be the confidential property of APPNA. Information on learners will only be released to third parties when learners have prospectively signed a document authorizing this release of information.
5. At the discretion of APPNA, anonymous evaluation summaries of the supported activity may be shared with industry representatives.

IDENTIFICATION AND RESOLUTION OF CONFLICTS OF INTEREST – In addition to SCS 2:

1. APPNA is required to have a mechanism to identify and resolve (manage, minimize, or mitigate) all conflicts of interest prior to the educational activity being delivered to learners; the primary mechanism is to have all individuals who are in a position to control the content of an educational activity complete an attestation that they have read and agreed to abide by this policy and that any and all clinical recommendations that they make for patient care as part of their planning and/or CME presentation/activity materials will be based on the best available evidence, that they will give a balanced view of therapeutic options, and that the content will be in accordance with ACCME's Content Validation Statement.
2. Additional and supplemental mechanisms to resolve conflicts of interest include but are not limited to:
 - a) An individual without a conflict of interest replaces the conflicted individual.
 - b) The conflicted individual renounces the relationship(s) with the commercial interest(s).
 - c) The scope of the conflicted individual's role is restricted (the conflicted individual will not be determining content and/or making recommendations for clinical practice).
 - d) The conflicted individual attests in writing that recommendations s/he will make for clinical practice will be based upon data derived from multiple randomized clinical trials or meta-analyses and s/he will disclose this to learners.
 - d) The CME materials (presentation, monograph, etc.) prepared by the conflicted individual will be peer reviewed for content validation and fair balance (and modified accordingly, if need be).
3. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity (ACCME Standard 2.3).

APPROPRIATE USE OF COMMERCIAL SUPPORT – In addition to SCS 3:

1. APPNA CME is responsible for the review and signing of all CME grant letter of agreements; the Meeting CME Committee or joint sponsor is responsible for prospectively submitting grant letter of agreements for commercial support to APPNA CME for review and approval.
2. The source of all support from commercial interests must be disclosed to learners prior to the activity occurring. When commercial support is 'in-kind' (e.g., provision of equipment) the nature of the support must be disclosed. In order for commercial support acknowledgement to be made, the letter of agreement must be signed by both the commercial supporter representative and APPNA CME prior to printing/production/activity.



ASSOCIATION OF PHYSICIANS OF PAKISTANI-DESCENT OF NORTH AMERICA

APPNA Office of CME Continuing Medical Education Policies and Procedures

3. In the case of jointly or cosponsored activities, the grant letter of agreement will delineate the joint/ co-sponsor's name and contact information.
4. In the event there are social events or meals at CME activities, they cannot compete with or take precedence over the educational event(s) and should comply with the American Medical Association's Guidelines on Gifts to Physicians: E-8.061 (<http://www.ama-assn.org/>).

APPROPRIATE MANAGEMENT OF ASSOCIATED COMMERCIAL PROMOTION – In addition to SCS 4:

1. Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
 - a) Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support). Exhibitors should sign APPNA's Written Agreement for Commercial Support.
 - b) Exhibit fees shall be set by APPNA for each activity and will be standard for that activity; potential exhibitors shall have equal access to purchasing exhibit space (first come-first serve).
 - c) All exhibitors must be in a room or area separate from the educational activity and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the CME activity.
 - d) Commercial interest representatives may attend CME activities at the discretion of APPNA for the direct purpose of the representatives' own education; however, they may not engage in sales or marketing activities while in the space or place of the educational activity.
2. APPNA CME will not utilize a commercial interest as the agent providing a CME activity to learners; e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. Distribution of CME activity brochures by representatives of a commercial interest may be allowed by APPNA CME if said distribution is not the sole marketing method, AND commercial interest has signed a grant agreement in support of the activity, AND APPNA CME has sent a formal request letter to the commercial interest requesting this assistance.

CONTENT VALIDATION AND FAIR BALANCE – In addition to SCS 5:

1. The CME activity will comply with ACCME's Content Validation Statement (Policy 2002-B-09):
 - a) All recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contra-indications in the care of patients.
 - b) All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
2. Activities that promote recommendations, treatment, or manners of practicing medicine or pharmacy that are not within the definition of CME or, are known to have risks or dangers that outweigh the benefits or, are known to be ineffective in the treatment of patients will not be certified for credit.
3. Presentations and CME activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CME educational materials or content includes trade names, where available, trade names from several companies must be used.

OFF-LABEL USE DISCLOSURE

1. Faculty (speaker or presenter), activity medical directors, and moderators are required to disclose to the learners when products or procedures being discussed are off-label, unlabeled, experimental, and/or investigational (not FDA approved); and any limitations on the information that is presented, such as data that are preliminary or that represent ongoing research, interim analyses, and/or unsupported opinion.

FACULTY HONORARIA AND TRAVEL REIMBURSEMENT

1. Honoraria amounts will be negotiated by the Meeting CME Committee taking financial responsibility for the CME activity and shall be based on fair market value with the realization that the amounts will vary with the specialty, subspecialty, speaker qualifications, length and number of presentation(s), nature of the conference, preparation time, and travel time.
2. No individual involved in a CME activity may receive payment directly from a commercial interest for honoraria, travel, or out-of-pocket expenses.
3. APPNA CME will approve the amount and source of the honoraria and estimated travel expenses prior to the CME activity by reviewing the activities projected budget.



**APPNA Office of CME Continuing Medical Education
Policies and Procedures**

4. APPNA CME faculty/authors for directly sponsored CME activities will be paid their honoraria through an APPNA discretionary account or through APPNA Payroll, in accordance with the APPNA Financial policy; the current fringe benefit rate will be applied. Faculty/authors/content validation reviewers for jointly or co-sponsored CME activities who are APPNA Members will be paid their honoraria through the educational partner.
5. Reimbursement or prepayment of travel expenses for faculty (speaker, presenter, moderator, panel member) of APPNA CME-certified CME activities must be in compliance with APPNA's Travel policy and the ACCME Standards for Commercial Support of CME.

AUDITABILITY

1. For directly sponsored CME activities, Meeting CME Committees are responsible for maintaining auditable records in accordance with the policies and procedures of APPNA Financial Services.
2. For jointly/cosponsored activities, the joint/cosponsor is responsible for maintaining auditable records and providing a detailed final budget to APPNA CME.

JOINT/CO-SPONSORSHIP

1. A commercial interest cannot take the role of non-accredited partner in a joint/co-sponsorship relationship.
2. Jointly/co-sponsored activities must be consistent with APPNA CME's CME mission and purpose statements..
3. APPNA's RESA Chair must review and approve the proposed activity.
4. APPNA CME must review and approve all materials associated with the activity prior to their release; once these materials have been reviewed and approved by APPNA CME, no further changes can be made.
5. Any and all funds solicited on behalf of a CME activity must either (a) be received by APPNA, or (b) be delivered to the joint/co-sponsor with APPNA CME's written authorization.
6. The responsibilities and role of the joint/co-sponsor will be clearly delineated in a letter of agreement between the joint/co-sponsor and APPNA CME. APPNA CME has the right to withdraw from any activity if the joint/co-sponsor fails to meet its obligations as described in the letter of agreement or fails to comply with APPNA CME policies and procedures.
7. The joint/co-sponsor shall submit a projected budget for each CME activity to APPNA CME for review and approval. APPNA CME will review the projected budget to ensure that adequate resources have been devoted to the development of an activity consistent with meeting the activity's objectives. APPNA will withdraw from an activity if resources are inadequate for the development of a high quality educational product or activity.
8. At APPNA CME's discretion and with written authorization, the joint/co-sponsor may solicit funds under the direction of APPNA CME but may not make any representations or commitments to commercial supporters as to educational content, choice of speakers, learning objectives, marketing, and/or evaluation.
9. All potential joint/co-sponsorship relationships will be examined on their individual merits. Although all CME activities joint/co-sponsored with APPNA CME must comply with this policy, APPNA CME reserves the right to refuse to enter into a joint/co-sponsorship agreement for any reason whatsoever, regardless of that organization's willingness to comply with this policy.
10. APPNA CME will charge fees for its services. These fees and the terms for its payment will be mutually agreed upon and delineated in an exhibit to the aforementioned letter of agreement between APPNA CME and the joint/co-sponsor:
 - a) Administrative Fee reflects: (a) oversight and involvement in the planning process by members of APPNA CME's staff and/or consultants that represent APPNA CME; (b) expertise in the rules and responsibilities of providers, joint/co-sponsors, and commercial supporters of continuing medical education activities as derived from the ACCME and AMA; and (c) fees required to maintain full accreditation.
 - b) Content reviewer fee represents fees to be paid by APPNA CME to selected content reviewers. These fees will be negotiated between APPNA CME and the content reviewer(s) and will be submitted as a line item to the joint/co-sponsor for inclusion in the projected budget for the CME activity.
 - c) Certificate fee represents the costs to APPNA CME associated with the awarding of credit and the maintenance of six years of detailed records of participation in CME activities certified by APPNA. Certificate fees will be established with each joint sponsor applicant.



ASSOCIATION OF PHYSICIANS OF PAKISTANI-DESCENT OF NORTH AMERICA

APPNA Office of CME Continuing Medical Education Policies and Procedures

- d) Honoraria for a APPNA clinician serving as Activity Medical Director, Activity Co-Director, author, speaker, moderator, steering committee chair, etc. will be separately negotiated between the joint/co-sponsor and the individual faculty member (e.g., APPNA CME does not enter into these negotiations).

INTERNET (*ACCME Internet Policy 2002-A-11*)

1. APPNA CME-sponsored activities only appear on websites identified by APPNA CME as appropriate – they cannot be posted on a pharmaceutical or medical device manufacturer’s website.
2. Links from APPNA CME-approved websites to the websites of pharmaceutical and medical device manufacturers are permitted before or after the educational content of an APPNA CME-sponsored activity, but shall not be embedded in the educational content of the CME activity. The learner must be clearly notified that s/he is leaving the educational website.
3. APPNA CME prohibits advertising of any type within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.
4. At the start of each APPNA CME-sponsored Internet CME activity, the hardware and software required for the learner to participate shall be delineated.
5. APPNA CME-sponsored Internet CME activities shall include a mechanism for the learner to contact APPNA CME if there are any questions about the Internet CME activity. A contact for technical issues is also required.
6. APPNA CME-sponsored Internet CME activities must have, adhere to, and inform the learner about the site’s policy on privacy and confidentiality and said policy must be approved by APPNA CME.
7. APPNA CME must be able to document that it owns the copyright for, or has received permission for use of, or is otherwise permitted to use copyrighted materials within a CME activity on the Internet.

REFERENCES:

Accreditation Council for Continuing Medical Education (ACCME) [Essential Areas and Elements, Criteria](#) and [Standards for Commercial Support](#)

American Medical Association Council on Ethical and Judicial Affairs (AMA CEJA) – [8.061 Gifts to Physicians from Industry](#) and [9.011 Continuing Medical Education](#)

Food and Drug Administration (FDA) – [Final Guidance on Industry-Supported Scientific and Educational Activities](#)

Office of Inspector General (OIG) – [OIG Compliance Program Guidance for Pharmaceutical Manufacturers](#)

PhRMA – [PhRMA Code on Interactions with Healthcare Professionals](#)



**APPNA Office of CME Continuing Medical Education
Policies and Procedures**

DEFINITIONS

Activity Medical Director: The CME Committee member in charge of planning, implementing, and evaluating the CME activity and who is responsible for collaborating with APPNA CME to ensure compliance.

Commercial Interest: Any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

Commercial Support: Financial, or in-kind, contributions given by a commercial interest, which are used to pay all or part of the costs of a CME activity.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship. The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

Continuing Medical Education (CME): Educational activities that serve to maintain, develop, or increase the knowledge, skills, professional performance, and relationships a physician uses to provide services for patients, the public, or the profession. The content of CME is 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. (Sources: ACCME and AMA).

Co-sponsor: An ACCME-accredited organization working in partnership with APPNA CME to develop, implement, and evaluate a CME activity.

Exhibit Fee: A fee paid by a commercial interest to display and promote its products. Exhibit fees are considered a business transaction (e.g., they are not considered "commercial support").

Faculty: An individual speaking at or giving a presentation at a CME activity.

Financial Relationships: Those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, 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. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

- a) 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.
- b) Financial relationships with commercial interests: when a person divests himself of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.
- c) Relevant financial relationships: financial relationships in any amount occurring within the past 12 months that create a conflict of interest (per ACCME). ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

Joint Sponsor: A non-ACCME accredited organization that plans and presents a CME activity in partnership with an ACCME-accredited organization.

Learner: An individual in attendance at a CME activity.

Moderator: The individual moderating or hosting the CME activity (introduces the presenters, facilitates question & answer and/or panel discussions, etc.).

Sponsor: The ACCME accredited provider certifying an activity for continuing education credit and, therefore, responsible for ensuring compliance with the ACCME Essential Areas, Elements, Criteria, and Standards for Commercial Support of CME.