

New information is blue (may include information moved from another section).

Information that has been deleted or moved is in red.

Note:

ACFAS comments are in blue.
CPME changes are in red/purple.

**CPME DOCUMENT 720
STANDARDS, REQUIREMENTS, AND
GUIDELINES FOR APPROVAL OF SPONSORS
OF CONTINUING EDUCATION IN PODIATRIC
MEDICINE**

Council on Podiatric Medical Education

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CPME changes are in red/purple.

INTRODUCTION

The Council on Podiatric Medical Education (CPME) holds the position that continuous study is the fundamental and lifelong responsibility of doctors of podiatric medicine. Technological advances through research, new patterns of health care delivery, and development of clinical procedures have accentuated the need for podiatric physicians to remain aware of professional developments through active participation in continuing education. Moreover, all state boards for examination and licensure require podiatric physicians to participate in continuing education in order to maintain professional licensure.

The council approves sponsors of continuing education (rather than individual activities) that demonstrate and maintain compliance with the standards and requirements in this publication. Approval is based on programmatic evaluation and periodic review by the Council and its Continuing Education Committee (CEC).

The primary purpose of approval is to promote and ensure high-quality education and continuous improvement in educational programs. Approval also ensures the quality of continuing education programs to the public, the podiatric medical profession, and the state boards for examination and licensure.

The council recognizes that sponsors seek approval do so on a voluntary basis. The Council encourages state licensing boards, state associations, and other groups that have continuing education requirements to recognize the sponsors to whom it has extended approval. A list of approved sponsors is available on the Council's website (cpme.org) and is updated on a regular basis. (www.cpme.org).

The council has developed this publication to assist sponsors in providing continuing education activities in podiatric medicine, as well as to identify specific requirements of sponsors and their continuing education activities in order that approval may be achieved. The council's procedures for approving sponsors of continuing education appear in CPME publication 730, *Procedures for Approval of Sponsors of Continuing Education in Podiatric Medicine*.

GLOSSARY

The Council strongly encourages the directors of continuing education to become familiar with the following definitions to ensure complete understanding of this publication.

Advisory/Education Committee

A committee appointed by the sponsor to coordinate the processes of planning, implementing, and evaluating continuing education activities and the sponsor's program of continuing education.

Approval

The recognition accorded a continuing education sponsor that has demonstrated compliance with standards and requirements established by the Council. The Council approves the sponsor itself rather than each of the sponsor's continuing education activities but reserves the right to review any or all of these activities.

Commercial Interest

Any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Commercial Support

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

Content Validity

The extent to which a test measures and adequately samples an intended content area. Content validity is determined by expert judgment and cannot be expressed quantitatively. Individuals who are experts in the area covered by the test assess the content validity of the test by reviewing all items on the test and judging how well the items represent the intended content area. This determination is based on whether all areas that comprise the overall subject matter have been included and are represented in the correct proportions. In other words, a comparison is made between what should be included in the test, given its intended purpose, and what is actually included.

Continuing Education/Continuing Education Activities

Continuing education consists of instructional activities planned, implemented, and evaluated by sponsors. These activities are educational in nature, rather than social, recreational, or commercial. Continuing education activities serve to maintain and/or enhance the knowledge, skills, and professional performance and relationships that the podiatric physician uses to deliver the highest quality of service to patients, the public, and the profession.

Continuing education activities are usually of short duration and are not structured or sequenced to provide academic credit toward a degree, nor lead to any formal advanced standing in the profession. Consequently, certificates provided for such experiences may not resemble diplomas.

Continuing Education Committee (CEC)

The standing committee of the Council responsible for recommending to the Council approval of sponsors of continuing education in podiatric medicine. The Committee reviews applications, petitions, reports of on-site evaluations, requests for reconsideration, progress reports, and annual reports when concerns have been identified through staff review. The CEC may modify its own policies, and/or recommend to the appropriate ad hoc committee modifications in standards, requirements, and procedures for sponsor approval.

Composition of the Committee includes two representatives from approved sponsors of continuing education in podiatric medicine (selected by the Council), one representative from the podiatric practice community (selected by the Council), one representative from state licensing boards (appointed by the Federation of Podiatric Medical Boards), and at least two Council members (one of whom is a public member). The Council and its staff administer the affairs of the CEC.

Continuing Education Contact Hour

A 60-minute period (one clock hour) of interaction between a participant and faculty, or between a participant and materials that have been prepared to result in learning.

Course

A type of continuing education activity in which participants and faculty are present at the same time. Courses include, but are not limited to, lectures, conferences, seminars, clinical and practical workshops, simultaneous live satellite broadcasts, teleconferences, and web-based conferences. Attendance at a course can be verified on-site (or, in the case of a web-based conference, through electronic means).

Director of Continuing Education

The individual responsible for coordination and administration of the program of continuing education offered by the sponsor, as well as its associated continuing education activities.

Educational Methods

The selection of educational methods for a continuing education activity represents a further step in the process of curriculum development and evaluation and takes into consideration the following:

- needs assessment
- identification of the target audience
- establishment of learning objectives
- development and implementation of an appropriate design for the activity that ensures that the activity meets its stated learning objectives

Activities that require direct involvement include, but are not limited to, lectures, practical experience, journal reading, CD, DVD, seminars, patient treatment, problem-solving exercises, grand rounds, case reviews and presentations, question and answer periods, laboratory work, workshops, and discussion groups.

Grand Rounds

Lectures consisting of presenting medical problems and treatment of a particular patient to an audience consisting of doctors, residents, and medical students.

Guideline

The explanatory materials for the requirements. Guidelines are used to indicate how the requirements either must be interpreted or may be interpreted to allow for flexibility, yet remain within a consistent framework. The following terms are used within the guidelines:

- The verbs “is” and “must” indicate how a requirement is to be interpreted, without fail. The approved status of a sponsor is at risk if noncompliance with an “is” or a “must” is identified.
- The verb “should” indicates a desirable, but not mandatory, condition.
- The verb “may” is used to express freedom or liberty to follow an alternative.

Instructional Media

A type of continuing education activity consisting of use of instructional materials that may include, but not be limited to, printed, recorded, and/or computer-assisted materials. Instructional media may be used over time at various locations and in themselves constitute a planned continuing education activity. Examples of instructional media include, but are not limited to, books, journals, audiotapes, videotapes, and computer-assisted instructional programs. The intent of the Council is that this definition anticipates and includes development of future technologies and methods of providing continuing education.

Learning Objective

A written, explicit statement that indicates what the participant is expected to accomplish upon completion of a specific portion or section of the continuing education activity. A learning objective expresses a specific, short range outcome and is stated in behavioral or action-oriented terms. Example of learning objectives would be:

After completing this activity, participants should be able to:

- identify the goals of imaging for tendon pathology;
- review the potential benefits of magnetic resonance imaging for tendon pathology;
- assess the pros and cons of ultrasound for identifying tendon pathology; and
- cite the three phases (and associated findings) of the triphase bone scan.

Mission

A statement of broad, long range expectations and purposes of the sponsor in providing continuing education.

Needs Assessment

The process of identifying specific information or skills needed by participants and/or interests of participants, based on information provided by prospective participants and/or objective sources. The specific needs provide the rationale and focus for the continuing education activity.

Off-label and Unlabeled Products

Off-label: Uses of Food and Drug Administration (FDA) approved drugs for indication, dosage form, dose regimen, population, or other use parameter not mentioned in the approved labeling.

Unlabeled Uses of Products: When an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose, is discussed during an educational activity.

Participant

An individual engaged in a continuing education activity.

Product

Therapeutic and/or diagnostic materials such as human and animal drugs, biological products, and medical devices that are manufactured and/or advertised by a company.

Program of Continuing Education

The total efforts of the sponsor as they relate to continuing education activities.

Requirement

Related to each standard is a series of specific requirements. Viewed together, compliance with the requirements provides an indication of whether the broader educational standard has been satisfied. During an on-site evaluation of a sponsor of continuing education or during review of a progress report, petition, or annual report submitted by the sponsor, the CEC/Council determines whether these requirements have been satisfied. Based upon the extent to which the requirements have been satisfied, the Council determines the compliance of the sponsor with each standard. In the requirements, the verb “shall” is used to indicate conditions that are imperative to demonstrate compliance.

Sponsor

See page 9-7 in “Information for Sponsors” section.

Standard

Serves to evaluate the quality of education. These standards are broad statements that embrace areas of expected performance on the part of the sponsor and its educational programs. Compliance with the standards ensures good educational practice in the field of podiatric medicine and thus enables the Council to grant or confirm approval.

Validity

The degree to which a test measures what it is supposed to measure. Validity, which is the most important quality of any test, emerges from the process of test construction.

ABOUT THIS DOCUMENT

This publication describes the standards and requirements for approval of continuing education sponsors. The standards and requirements, along with the procedures for approval, serve as the basis for evaluating sponsors of continuing education activities regardless of the educational format in which the continuing education activity is provided. The standards, requirements, and guidelines in this document apply to all sponsors of continuing education except where prohibited by federal or state laws or regulations.

The **standards** for approval of a continuing education sponsor serve to promote and ensure high-quality education and continuous improvement in educational activities. These standards are broad statements that embrace areas of expected performance on the part of the sponsor. Compliance with the standards ensures the quality of continuing education activities to the public, the podiatric medical profession, and the state boards for examination and licensure which enables the council to grant or extend approval.

Related to each standard is a series of specific **requirements**. Compliance with the requirements provides an indication of whether the broader educational standard has been satisfied. During the application and/or petition process, the continuing education committee gathers detailed information about whether these requirements have been satisfied. Based upon the extent to which the requirements have been satisfied, the council determines the compliance of the sponsor with each standard. In the requirements, the verb “shall” is used to indicate conditions that are imperative to demonstrate compliance.

The **guidelines** are explanatory materials for the requirements. Guidelines are used to indicate how the requirements either must be interpreted or may be interpreted to allow for flexibility, yet remain within a consistent framework. The following terms are used within the guidelines:

- The verbs “must” and “is” indicate how a requirement is to be interpreted, without fail. The approval status of a sponsor is at risk if noncompliance with a “must” or an “is” is identified.
- The verb “should” indicates a desirable, but not mandatory, condition.
- The verb “may” is used to express freedom or liberty to follow an alternative.

INFORMATION FOR SPONSORS

The Council uses the standards, requirements, and guidelines outlined in this publication in evaluating all continuing education activities, regardless of the educational format in which the continuing education activity is provided.

The standards, requirements, and guidelines in this document apply to all sponsors of continuing education except where prohibited by federal or state laws or regulations.

INFORMATION FOR SPONSORS

Requirements for Sponsorship and Content of Continuing Education

The concepts of sponsorship, definition of continuing education, and content of continuing education activities appear in the glossary, appendices and throughout the standards and requirements. ~~Explanatory information related to these critical concepts is provided below.~~

Sponsorship

The sponsor is the institution, organization, or individual assuming the responsibility for all aspects of the program of continuing education. These include:

- planning
- publications
- implementation
- evaluation
- maintenance of records
- calculation and awarding issuance of continuing education contact hours
- ensuring independence and absence of commercial bias
- ~~other administrative duties~~

The sponsor assumes both the professional and fiscal review liability for the conduct and quality of each continuing education activity. ~~The sponsor may provide either type or combination of continuing education activities (i.e. courses and/or instructional media) and the mission statement must allow for both types of activities.~~ The sponsor may not be a commercial interest. A commercial interest is any entity manufacturing, producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients, and/or proprietary in nature.

The following is a list of those which may eligible to be approved as a sponsor:

- 501-C tax exempt organizations (except 501-C groups that advocate for commercial interests.)
- Government organizations
- Non-health care related companies such as education companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For profit rehabilitation centers
- For-profit nursing homes
- Blood banks

- [Diagnostic laboratories](#)¹

Although the council expects that the majority of sponsors will be institutions and organizations, an individual is not precluded from approval as a sponsor.

Approval of a sponsor does not imply approval of the sponsor's satellite organizations or divisions, such as regional or local chapters of a national organization.

In order for a sponsor to be eligible for council approval, the primary administrative office of the sponsor must be located within the United States or Canada and the preponderance of the sponsor's activities must be provided within the United States and/or Canada.

~~The council recognizes that an institution, organization, or individual that provides one or two continuing education offerings per year, for example, may not wish to pursue approval as a sponsor. For this reason, affiliate status sponsorship is permissible and encouraged; the unapproved entity may provide its activity under the auspices of an approved sponsor. An approved sponsor also may extend affiliate status sponsorship to unapproved entities that are located outside the United States or Canada or provide the preponderance of their activities outside the United States or Canada.~~

ACFAS proposes to ~~delete affiliate status~~.

Comment [S1]: ACFAS proposes to delete affiliate status per the rationale in our cover letter.

If that is not acceptable, then the following ~~changes~~ should be considered²:

Comment [S2]: Although not precisely detailed, the following changes are considered best practice in allopathic medicine.

~~Accredited sponsors may choose to provide sponsorship of educational activities by unapproved entities through an affiliate sponsorship, with the understanding that these activities will be viewed by CPME as the same as their own directly sponsored activities. Additional requirements will be enforced during the CPME audit of the approved sponsor. These requirements include:~~

- ~~- Approved sponsor will monitor live activities and review in advance enduring activities designed and developed by affiliate sponsor;~~
- ~~- Approved sponsor will have access to transparent accounting process before and after the affiliate sponsor's activity;~~
- ~~- No commercial support money paid to affiliate (all funds paid to approved sponsor)~~
- ~~- Signed letter of agreement between approved sponsor and affiliate, including the understanding that accreditation will be removed if problems occur or regulations are not~~

¹ <http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/definition-commercial-interest>

² http://www.aao.org/education/joint_sponsorship/index.cfm

followed.

Definition of Podiatric Continuing Medical Education (P-CME)

P-CME consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a podiatrist/foot & ankle surgeon uses to provide services for patients, the public or the profession. The content of P-CME is the body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, behavioral and social sciences, podiatric medicine and surgery, related clinical disciplines, and the provision of health care to the public.³

³ <http://www.ama-assn.org/resources/doc/cme/prc-booklet.pdf>

STANDARDS FOR APPROVAL OF SPONSORS OF CONTINUING EDUCATION IN PODIATRIC MEDICINE

Standards 1.0 — ~~9.013.0~~ — pertain to all sponsors of continuing education for which initial or continued approval is sought.

1.0 ~~The sponsor publishes a clear and appropriate written statement of its continuing educational mission, operates in accordance with this statement, has a well-defined administrative structure, and is sufficiently managed and administered.~~

~~1.0~~ ~~The sponsor publishes a clear and appropriate written statement of its continuing education mission and operates in accordance with this statement.~~

2.0 ~~The sponsor bases its overall program of continuing education and individual activities upon assessment of the documented professional needs and interests of prospective participants.~~

~~2.0~~ ~~The sponsor bases its continuing education activities upon assessment of the documented professional needs and interests of prospective participants.~~

3.0 ~~The sponsor establishes measurable learning objectives and utilizes effective educational methods for each continuing education activity that are based on the needs assessment.~~

~~3.0~~ ~~The sponsor establishes measurable learning objectives for each continuing education activity that are based on the needs assessment.~~

4.0 ~~The sponsor conducts appropriate evaluation processes related to individual continuing education activities, its overall program of continuing education, and reports this information to the Council on Podiatric Medical Education.~~

~~4.0~~ ~~The sponsor utilizes educational methods for each continuing education activity that are effective in view of the format, content, objectives, and intended audience of each activity.~~

~~5.0~~ ~~The sponsor conducts appropriate evaluation processes related to individual continuing education activities and its overall program of continuing education.~~

5.0 ~~The sponsor selects qualified faculty for each continuing education activity.~~

6.0 ~~The sponsor demonstrates its independence, absence of commercial bias, appropriate management of funds from commercial interests and other sources and appropriate management of advertising and exhibits.~~

~~6.0 — The sponsor selects an appropriate complement of qualified faculty for each continuing education activity and coordinates with faculty the objectives and educational methodology of each activity.~~

~~7.0 — The sponsor ensures appropriate administrative processes related to development of publicity, admission, verification of attendance, calculation of continuing education contact hours, and maintenance of records of attendance.~~

~~7.0 — The facilities selected for each continuing education activity are appropriate for the achievement of the stated learning objectives and the educational methods used.~~

~~8.0 — The sponsor ensures the protection and confidentiality of patients involved in continuing education activities.~~

~~8.0 — The sponsor demonstrates its independence, absence of commercial bias, disclosure of required information and relationships, appropriate management of funds from commercial interests, and appropriate management of advertising and exhibits.~~

~~9.0 — The sponsor appropriately manages administration related to instructional media.~~

~~9.0 — The program of continuing education has a well-defined administrative structure and is sufficiently managed and administered.~~

~~10.0 — Financial resources are sufficient to meet the mission of the overall program of continuing education and the learning objectives of individual continuing education activities.~~

~~11.0 — The sponsor appropriately manages administrative processes related to development of publicity, admission, verification of attendance, calculation of continuing education contact hours, and maintenance of records of attendance.~~

~~12.0 — The sponsor ensures the protection of patients in continuing education activities involving patient treatment by faculty or participants.~~

~~13.0 — The sponsor reports periodically to the Council on Podiatric Medical Education and at least annually regarding the conduct of its continuing education activities.~~

1.0 The sponsor publishes a clear and appropriate written statement of its continuing educational mission, operates in accordance with this statement, has a well-defined administrative structure, and is sufficiently managed and administered.

1.1 The continuing education mission statement shall set forth the broad, long-range goals of the sponsor in providing activities continuing education, describe the scope and nature of the sponsor's continuing education activities, outline the general characteristics of potential participants, and relate to the health care needs of the public and/or the educational needs and interests of the podiatric medical profession.

This statement is expected to serve as a point of reference for development and evaluation of all of a sponsor's continuing education activities and is separate from any specific learning objectives developed for individual continuing education activities. It must include the:

- include the type of activities provided; purpose in providing continuing education
- content area
- target audience
- type of activities provided
- describe the expected results of the overall program;
- describe the scope and nature of the sponsor's continuing education activities;
- identify the target audience; and
- relate to the health care needs of the public and/or the educational needs and interests of the podiatric medical profession.
- format (instructional media and/or courses)

If the sponsor is an institution or organization, the mission statement should be consistent with the primary purpose or mission of the sponsor. If the sponsor has a governing board, the mission statement should be approved formally by the board as documented by a board agenda or minutes of the board meeting.

1.2 The sponsor shall appoint one individual to serve as director of continuing education who shall be provided proper authority to fulfill all the responsibilities of the position.

The professional background and experience of the individual selected as director of continuing education should be appropriate to the responsibilities of the position.

The sponsor should clearly delineate the responsibilities and scope of authority of the director of continuing education.

1.3 The director of continuing education shall be the primary individual responsible for: coordinating and administering all continuing education activities, devoting sufficient time in order to fulfill the responsibilities

required of the position, communicating with the council on all matters related to the application and approval process, and ensuring the sponsor achieves and maintains compliance with the council's standards and requirements.

Responsibilities of the director, in cooperation with the activity planning committee include, but are not limited to the following:

- participating in development of the mission statement
- conducting the needs assessment
- developing measurable learning objectives
- developing the agenda
- selecting educational methods
- evaluating individual activities
- annual review of the program of continuing education
- coordinating the process of examination development, administration, and scoring
- selecting, communicating and consulting with faculty
- selecting facilities
- executing agreements
- tracking financial resources
- developing and distributing marketing materials
- registering participants
- verifying attendance
- maintaining and issuing documented records of attendance
- calculating and awarding continuing education contact hours
- adhering to patient protection policies

- 1.4 **The sponsor shall ensure continuity in the overall program of continuing education by appointing an advisory/education committee responsible for coordinating and administering all continuing education activities. The committee shall include at least onea majority of DPMs podiatric physician.**

Continuity of administration is necessary for the stability and growth of the program in continuing education.

Terms of office for committee members should be of sufficient duration (i.e., at least one year) to assure continuity of administration. Members' terms should expire on varying dates. Minutes of committee meetings should be maintained.

- 1.5 **Designated support staff shall be available, as needed, to ensure efficient administration of continuing education activities.**

- 1.6 **ACFAS recommends deleting this section.**

Comment [S3]: ACFAS proposes to delete affiliate status per the rationale in our cover letter.

If that is not approved, we recommend the following changes.

When the sponsor provides a continuing education activity in conjunction with another entity, the sponsor shall ensure that the activity meets the council's

standards and requirements. An signed affiliation agreement shall be established to delineate the specific responsibilities of the sponsor and the entity, and the understanding that sponsorship shall be withdrawn should the expectations not be upheld.

The sponsor has the same responsibility for an activity that it sponsors in conjunction with another entity as for an activity that it sponsors alone.

In addition, the approved sponsor must

- Arrange for on-site monitoring of live affiliate programs, and review all enduring or pre-recorded activities;
- Demonstrate they had access to the affiliate sponsor's accounting process before and after the activity, including access to the budget and income/expense statements;
- Demonstrate no commercial support money is paid directly to the affiliate sponsor (all funds paid to approved sponsor) to ensure transparency;

Affiliation may take either of two forms:

- An approved sponsor may be asked by an entity to extend sponsorship for an activity (with the unapproved entity identified as the affiliate of the sponsor). This information must be clearly indicated in all materials advertising the activity and in materials provided at the time the activity is conducted. This information also must be submitted to the council in CPME 740: Annual Report for Sponsor of Continuing Education in Podiatric Medicine.
- An approved sponsor affiliates with another approved sponsor. In this event, one sponsor assumes primary responsibility for the activity. This information must be clearly indicated in all materials advertising the activity and in materials provided at the time the activity is conducted. This information must be submitted to the council in CPME 740.

Any cooperative educational undertaking between a sponsor and another entity must have the approval of the chief administrative officer(s) of both entities.

1.7 The sponsor shall establish and implement a nondiscrimination policy.

1.8 The sponsor shall ensure the ethical conduct of its program and each continuing education activity.

2.1 *The sponsor bases its overall program of continuing education and individual continuing education activities upon assessment of the documented professional needs and interests of prospective participants.*

2.1 **The sponsor shall establish and document use of a process that provides objective identification and analysis of the current professional needs ~~and interests~~ of prospective participants.⁴**

The educational need is defined as a documented difference between what should be done in practice (based on published research, best practice guidelines, expert consensus, etc) compared to what is currently being done (as measured by hospital quality department data, epidemiological data, medical literature, etc). The need must be appropriate for an educational intervention.

The needs assessment of the overall program of continuing education must be conducted at least annually and documented in some written format, including but not limited to committee minutes, report to the committee, PowerPoint presentation, etc. Needs ~~and interests~~ must be identified from multiple data sources.

~~The needs assessment is to be conducted as frequently as is necessary to ensure that continuing education activities remain relevant to the needs and/or interests of prospective participants. A separate needs assessment is not necessary for every continuing education activity provided by the sponsor; a well-conducted needs assessment may lead to increasingly well defined learning activities.~~

~~2.2 Needs and interests shall be identified from multiple data sources that extend beyond the sponsor's own perceptions of participants' needs and interests.~~

~~The needs assessment process is conducted systematically to provide factual information rather than assumptions for planning of continuing education activities.~~

~~The sponsor should utilize various means to gather objective data related to needs and interests.~~ Information should be obtained through methods that involve prospective participants in assessing their own needs and interests. Such methods include, but are not limited to:

Participant Data

- ~~an ad hoc~~ committee representing a cross section of the prospective audience
- surveys of prospective participants ~~that may be conducted by computer, fax, mail, telephone, or during continuing education activities and/or experts~~
- analysis of participants' examination results and activity evaluations from previous continuing education activities

⁴ Criterion 2, <http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>

~~Additional resources for identification of needs and interests may include:~~Scientific Data

- review of epidemiological data
- patient care audits including morbidity and mortality data
- searches of current literature including that available through ~~the National Institutes of Medicine and other~~ national repositories of relevant medical and health information
- consensus of experts ~~in podiatric medicine as well as other medical specialty organizations~~
- regional census information
- hospital quality data

The needs assessment must include at least one method from each of the above data sources.

~~2.23~~ **The sponsor shall state the overall needs and interests identified by the process and use these in planning continuing education activities.**

~~Written~~ Documentation of the results of this process is critical to planning the program of continuing education and developing objectives for activities. ~~Based upon the results of the needs assessment process, the sponsor should establish priorities regarding the potential continuing education activities to be developed.~~

Demonstrated need for specific activities rather than anticipated income or profit is to be the determining factor in developing continuing education activities.

3.0 *The sponsor establishes measurable learning objectives and utilizes effective educational methods for each continuing education activity that are based on the needs assessment.*

3.1 **The sponsor shall develop and communicate the measurable ~~written educational~~ learning objectives for each continuing education activity prior to implementation of the activity. The objectives shall specify expected learning outcomes in terms of knowledge, skills, attitudes, and/or patient care.**

Learning objectives are ~~explicit written statements or anticipated outcomes derived by the participant in a continuing education activity.~~ They are specific, short range, and action oriented in nature. Summary statements that describe the content or curriculum of the activity are not learning objectives. Learning objectives may address areas such as, but not be limited to, the following:

- enhanced practice performance
- improved patient outcomes
- identifying changes in the ~~attitude and approach of the practice participant to~~

- ~~the solution of~~
- ~~podiatric medicine and surgery problems~~
- ~~providing ision of~~ new knowledge in specific areas ~~and/or correction of~~
- ~~outdated knowledge~~
- ~~introducing tion to~~ ~~and or attaining competence in new mastery of specific~~ skills and techniques
- ~~improving ement in~~ the professional performance and habits of the participant
- ~~any special background requirements of prospective participants~~

~~The sponsor should publish the objectives in announcements and other advance publicity for all continuing education activities; the objectives must be published in the final brochure or program publication.~~

The ~~primary~~ purposes of objectives are to:

- ~~direct the sponsor in planning and implementing educationally effective activities;~~
- ~~state the knowledge and/or skill expected to be obtained as a result of participating in the activity;~~
- ~~evaluate the educational effectiveness of continuing education activities; and~~
- ~~assist prospective participants in selecting educational activities appropriate to their individual needs and interests.~~

The number of objectives ~~that should be~~ developed for a particular continuing education activity is determined by the needs addressed by the activity and the curricular design of the activity. ~~A single objective may address m~~Multiple presentations, ~~at a conference may be addressed by a single objective,~~ while ~~several objectives may be required for~~ one presentation ~~may require development of several objectives.~~ ~~A regularly scheduled series~~ An activity that takes place over a period of time (e.g., a lecture series) may be covered by a single set of ~~general/global~~ objectives with more specific objectives developed for each ~~topic~~ presentation.

3.2 The sponsor shall select and utilize educational methods for each continuing education activity that are effective in view of the format, content, learning objectives, and intended audience of each activity.

~~4.0—The sponsor utilizes educational methods for each continuing education activity that are effective in view of the format, content, learning objectives, and intended audience of each activity.~~

~~4.1 The sponsor shall select and utilize educational methods that are consistent with the stated learning objectives and content for each continuing education activity.~~

The selection of educational methods for a continuing education activity ~~represents~~

~~a further step in the process of curriculum development and evaluation and~~ takes into consideration the following:

- needs assessment
- identification of the target audience
- establishment of learning objectives
- development and implementation of an appropriate design ~~for the activity that ensuring the attainment of the es that the activity meets its~~ stated objectives

Instructional strategies for continuing education activities are as important as content. Activities encouraging active involvement of participants, the use of audiovisual aids and/or other instructional media may result in more effective learning experiences. The sponsor should select ~~methods that appropriate methods appeal for to~~ the diverse learning styles of participants.

~~The selection and organization of content and decisions about educational formats, methods, media, and faculty should be based upon the most effective and efficient means of meeting the stated objectives of the activity. Above all, the planning and design process should ensure that participants are involved actively in the learning process and have an opportunity to process the presented information and to receive feedback related to enhanced knowledge, skills, and/or competence.~~

The number of faculty shall be sufficient for a continuing education activity to ensure attainment of stated educational objectives. The ratio of faculty to participants must be conducive to maximize learning potential for activities that require performance of complex hands-on tasks. Such activities require a higher ratio of faculty to participants than do lecture activities. Adequate support staff should be available for the activity.

~~Activities that require dynamic involvement of participants and the appropriate use of audiovisual aids and other quality instructional media result in more effective learning experiences.~~

~~The sponsor is responsible for ensuring the production quality of instructional media. Sponsors that develop instructional media must consult with individuals who have technical expertise in both media and self-directed learning techniques and in the application of these techniques to adult learning.~~

~~4.2 The sponsor shall ensure that, for an activity where direct participation is involved, enrollment is related to available resources and that participants are afforded a sufficient level of involvement in the activity.~~

~~For activities involving participation, the size of the group must be based upon the nature of the available facilities and number of faculty. Particular attention to group size is necessary for activities that require participants to perform complex tasks requiring supervision and evaluation.~~

~~For instructional media, the sponsor must establish conditions for effective participation in the activity. The approved sponsor must indicate, at the start of each continuing education activity, the requirements necessary for successful participation and completion, including all hardware and software requirements if the activity is provided on the Internet. Additionally, a mechanism must be in place for the participant to be able to contact the sponsor if there are questions about the continuing education activity.~~

~~**45.0 The sponsor conducts appropriate evaluation processes related to individual continuing education activities, and its overall program of continuing education, and reports this information to the Council on Podiatric Medical Education.**~~

~~**45.1 At the conclusion of the continuing education activity, the sponsor shall provide opportunity for participants to complete an written evaluation process through which they may provide feedback assessing the effectiveness of the continuing education activity.** At the conclusion of the continuing education activity, the sponsor shall assess the effectiveness of the continuing education activity in meeting the learning objectives, in terms of improved strategies, skills and/or patient care. This assessment may be effected through a variety of methods including pre- and post test, pre- and post-audience response polling, post-activity evaluation, participant interview, etc.⁵~~

~~Evaluation of the continuing education activity provides a measure of the overall quality and effectiveness of the activity. The evaluation process is to be appropriate to the objectives and educational methods of the activity.~~

⁵ - [Achieving Desired Results and Improve Outcomes \(Donald E. Moore, Jr. PhD\):
http://cme.vanderbilt.edu/articles/Achieving%20desired%20results%20and%20improved%20outcomes%20Integrating%20planning%20and%20assessment%20throughout%20learning%20activities.pdf](http://cme.vanderbilt.edu/articles/Achieving%20desired%20results%20and%20improved%20outcomes%20Integrating%20planning%20and%20assessment%20throughout%20learning%20activities.pdf)

~~Evaluation of the activity by participants allows the sponsor to determine the extent to which the stated objectives of the activity were met. The written evaluation must request participants to assess areas including, but not limited to, the following:~~

~~content (including the extent to which the content was practically useful, comprehensive, appropriate, and adequately in-depth to meet the stated objectives in meeting the educational needs and interests of the participant)~~

~~participants' perception of methods by which the activity enhanced professional effectiveness based upon completion of the activity~~

~~quality of the instructional process and presentations including the effectiveness of educational methods and teaching materials~~

~~individual faculty quality, and effectiveness, and avoidance of commercial bias~~

~~adequacy of facilities and resources~~

~~overall management of administration of the activity~~

~~identification of professional needs or interests for future activities~~

Comment [S4]: DELETE

~~The evaluation form should be designed to elicit responses that are specific enough for sponsors to identify where to make improvements in the development and implementation of continuing education activities, with the goal of the process being continual improvement of the sponsor's activities.~~

~~Evaluation forms should provide participants opportunity to suggest future activities and to identify professional needs or interests that could be addressed through future activities. Evaluation [and/or assessment](#) summaries should be reported to appropriate administrative and planning staffs and faculty. [The evaluation process](#) ~~For~~ regularly scheduled [series and activities such as a lecture series, the evaluation process must be](#) ~~ay~~ be conducted [at least annually upon completion of the entire series or on a periodic basis.](#)~~

~~In addition to utilizing an evaluation process, the sponsor of a course may elect to develop an examination to measure the extent to which objectives have been accomplished and to allow participants to assess their mastery of the material in terms of enhanced knowledge, skills, and/or competence. The examination may be written or practical, depending on the format, objectives, and educational methods of the continuing education activity.~~

~~**5.2 Each activity provided in the format of instructional media shall include a content-oriented examination. The examination shall allow the sponsor to measure the extent to which activity objectives have been accomplished and shall allow participants to assess their mastery of the material in terms of enhanced knowledge, skills, and/or competence.**~~

~~Written examinations yield additional value by being scored to assist in documenting completion of the entire activity.~~

~~5.3 If the sponsor utilizes an examination, the sponsor shall ensure that a form of examination validation exists, with establishment of content validity as an absolute minimum.~~

~~Validity is defined as the degree to which a test measures what it is supposed to measure. Validity, which is the most important quality of any test, emerges from the process of test construction. The sponsor must consult with individuals who have expertise in test development and educational measurement and have the examination validated by an impartial educational testing service.~~

~~5.4.2 The sponsor shall conduct a formal annual self-assessment annual review of its overall program of continuing education. Information resulting from this review shall be used in planning and improving future continuing education activities.~~

~~The annual self-assessment review must should include: evaluate, at a minimum, the following aspects of the program of continuing education:~~

- ~~• identification of individuals involved;~~
- ~~• an feedback from participants, faculty, the planning committee, commercial supporters, and other stakeholders~~
- ~~• examination results and participants' evaluation of continuing education activities~~
- ~~• faculty assessment~~
- ~~• the analysis relevance of the mission statement;~~
- ~~• the extent to which the sponsor's continuing education mission statement is being achieved through its continuing education activities;~~
- ~~• the extent to which evaluation processes associated with individual continuing education activities effectively and appropriately assess the activities~~
- ~~• educational learning objectives~~
- ~~• quality of the instructional process~~
- ~~• participants' perception of enhanced professional effectiveness~~
- ~~• whether evaluation and examination methods are appropriate to and consistent with the scope of the continuing education activities~~
- ~~• how effectively evaluation data from individual continuing education activities are used in planning future continuing education activities;~~
- ~~• the extent of the sponsor's compliance with the standards and requirements of the council; and~~
- ~~• result of the review and program modifications, if any.~~

~~This self-assessment directs the planning of future continuing education activities as it identifies areas in which the overall program may be improved. The sponsor must be able to document that evaluation data are used in revising, updating, and developing continuing education activities.~~

~~4.3 The sponsor shall submit a completed CPME 740: Annual Report for Sponsor of~~

Continuing Education in Podiatric Medicine.

4.4 The sponsor shall inform the council in writing within 30 calendar days of substantive changes, including, but not limited to:

- ~~change in sponsor status;~~ change in sponsor status
- mission statement; and
- appointment of a new director of continuing education

56.0 The sponsor selects *an appropriate complement of qualified faculty for each continuing education activity for each continuing education activity and coordinates with faculty the objectives and educational methodology of each activity.*

56.1 The faculty selected to teach the continuing education activity shall be qualified by education and experience to provide instruction in the subject matter of the activity.

The sponsor is encouraged to explore a wide variety of sources to select qualified faculty. Faculty must:

- have expertise and demonstrated competence in the appropriate subject area;
- possess demonstrated teaching ability to communicate effectively with professional colleagues;
- be familiar with a sufficient repertoire of instructional strategies to achieve the intended outcomes of the continuing education activity;
- understand the principles and methods of adult education; and
- be made aware of the specific learning objectives, design, and educational methods of the continuing education activity

~~The sponsor is encouraged to explore a wide variety of sources to select qualified faculty. Faculty may include, but not be limited to:~~

- ~~podiatric physicians~~
- ~~professionals in other health-related disciplines~~
- ~~professionals in other fields such as education~~
 - ~~basic science faculty from colleges of podiatric medicine or other institutions~~

6.2—A sufficient number of faculty shall be employed for a continuing education activity to ensure attainment of stated educational objectives.

~~For participatory activities, the sponsor must ensure that close supervision and adequate direct interchange occurs between the faculty and the participant. Such activities require a higher ratio of faculty to participants than do lecture activities.~~

6.3—Faculty shall be involved in planning each continuing education activity in which they participate. The sponsor communicates the specific learning

~~objectives, design, and educational methods of the continuing education activity~~ to faculty early in the planning process. The sponsor should work closely with faculty to ensure that the intended learning outcomes will be addressed in faculty presentations.

~~The sponsor should make available to the faculty expertise and assistance in development and use of instructional materials.~~

5.2 For every activity, the sponsor must obtain from all persons responsible for the content of the activity (members of the planning committee, staff, faculty member, content authors, etc.), a signed financial disclosure in which each person details any and all relevant financial relationships with commercial interests. ~~The sponsor must obtain, from the planning committee and each faculty member, a signed financial disclosure agreement per activity.~~

Sponsors are expected to ensure that their P-CME programs and activities advance the public interest without bias that would influence health professionals to overuse or misuse the products or services of a commercial interest. In order to ensure this, the sponsor must have implemented a documented mechanism to identify and manage all conflicts of interest prior to the education activity being delivered to learners. Conflicts of interest may be created when an individual has an opportunity to affect P-CME content about products or services of a commercial interest with which he/she has a financial relationship. Methods to resolve conflicts of interest include but are not limited to peer review of presentation materials to ensure balance and unbiased content, use of (documented) best available scientific evidence to support clinical recommendations, recusal of the conflicted person from planning or presenting, and divestiture of the financial relationship. At no time should an employee of a commercial interest participate in the planning or presentation of an independent medical education activity.

~~This agreement~~ disclosure must be completed by all individuals who have influence over the content of the educational activity. Disclosure will include the name of the commercial interest, what was received (i.e. honorarium, stock options, consulting fees, etc), and for what role (i.e. consultant, speaker's bureau, IP rights, etc.) ~~Any individual who refuses to disclose relevant financial relationships will be disqualified from influencing continuing education content and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the activity. The intent of the disclosure is not to prevent an individual with a significant financial or other relationship from being involved in an educational activity, but rather to provide the audience with information on which they can make their own judgments and assurance that the approved provider has implemented a process to ensure balance and unbiased presentation of scientific information. Persons who fail to sign and return this form~~ disclose are not eligible to be involved as a presenter/planner.

5.35.2 The sponsor shall provide to participants, prior to the educational activity, disclosure of relevant financial relationships between the faculty/planning committee members and commercial interests.

The disclosure statement must include the following:

- name of the individual
- name of the commercial interest(s)
- nature of the relationship the individual has with each commercial interest what was received
- for what role
- absence of a relevant financial relationship(s)

All relationships which are valued at more than \$1 must be disclosed.

5.45.3 The sponsor shall have a mechanism in place to inform and ensure faculty present a balanced, un-biased view of all therapeutic options.

This mechanism must:

- inform the use of investigational and off-label products,
- encourageing the use of generic names, and
- identify the product names associated with ~~competeing~~ competing companies, if trade names are used, and/or discuss alternative therapeutic options if relevant., the product names associated with competing companies shall be identified

Failure to disclose this information to learners may result in a) onsite audit by CPME, b) probation, c) withdrawal of accreditation.

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~~7.0—The facilities selected for each continuing education activity are appropriate for the achievement of the stated learning objectives and the educational methods used.~~

~~7.1—The sponsor shall conduct the continuing education activity in facilities that provide an appropriate learning environment in view of the content, educational methodology, and number of participants associated with each activity.~~

~~The sponsor should ensure that support services and physical elements such as lighting, acoustics, seating, room temperature, equipment, and work areas enhance the ability of the participants to learn from and participate in the continuing education activity. Facilities must be adequate and appropriate for proper patient care when clinical procedures are performed.~~

~~If participants are required to provide their own materials or equipment, the sponsor's publicity or brochure must inform participants of this requirement and include a specific description of all required materials and equipment.~~

8.0 *The sponsor demonstrates its independence, absence of commercial bias, ~~disclosure of required information and relationships~~, appropriate management of funds from commercial interests and other sources, and appropriate management of advertising*

and exhibits.

~~68.1~~ The sponsor shall have policies and processes to ensure independence its continuing education activities from commercial conflict of interest, bias, or influence. The sponsor shall also document this independence by means of a signed written agreement between the sponsor and any company or organization that provides support for continuing education activities. ~~The independence of the sponsor and its continuing education activities from commercial conflict of interest, bias, or influence shall be documented by means of a signed written agreement between the sponsor and any company or organization that provides support for continuing education activities.~~

The sponsor must ensure through policies and processes that the following decisions are made free of the control of a commercial interest. (a) Identification of P-CME needs; (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 P-CME; (e) Selection of educational methods; (f) Evaluation of the activity.⁶

~~The written agreement must shall address, at a minimum, the areas referenced below in requirements 8.2-8.4.:~~

- ~~• include the name of the sponsor, affiliate sponsor (if applicable), commercial interest, and amount of the unrestricted grant;~~
- ~~• include the title, date(s), and location(s) of the activity;~~
- ~~• include the date, printed names, and authorized signatures;~~
- ~~• confirm that the activity is for scientific or educational purposes only and is not intended to directly or indirectly promote a commercial interest;~~
- ~~• confirm that the sponsor is solely responsible for the design and content of the activity, production of educational and audiovisual materials, and selection of faculty; no suggestions from the commercial interest will be considered;~~
- ~~• confirm that the sponsor ensures the separation of commercial exhibits or activities from the continuing education activity;~~
- ~~• confirm that the sponsor ensures the separation of commercial exhibits or activities from the continuing education activity; and~~
- ~~• confirm that the sponsor exercises full control in managing unrestricted funds provided by commercial interest and that the sponsor will make available, upon request, accurate documentation detailing responsible management of financial support.~~

⁶ ACCME Standard 1.1 <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

The written agreement is to reflect that the sponsor and company concur that the activity is to be educational and non-promotional and that the company has taken steps to ensure that it has no role in the design or conduct of the program that might bias the treatment of the topic.

~~Determination of the independence of a sponsor or a continuing education activity from the substantive influence of a company is based upon whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise use the presentation as an advertising vehicle.~~

The sponsor should be aware that a company is capable of influencing the content of educational programs not only directly, by being involved in the selection of speakers or in the treatment of topics, but also indirectly through the nature of the relationship between the company and the sponsor (e.g., the sponsor may believe that future financial support depends upon development of activities that promote the company's products).

~~8.2 The written agreement shall include a statement of purpose that the sponsor and the company agree that the program is for scientific or educational purposes and not for the purpose of promoting any product and that any discussion of the company's products will be objective, balanced, and scientifically rigorous.~~

~~The continuing education activity should not be focused on a single product marketed by the company or a competing product except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies or products.~~

~~8.3 The sponsor shall be solely responsible for the content, quality, and scientific integrity of all continuing education activities. Specifically, the sponsor shall be solely responsible for identifying continuing education needs and interests of the profession, determining educational learning objectives, selecting content, faculty, educational methods and instructional materials, and implementing and evaluating the activity.~~

In the written agreement, the company agrees not to directly or indirectly influence the content of the program and not to play any role in the selection of faculty other than responding to sponsor requests for suggestions of presenters or sources of possible faculty. The sponsor agrees to seek suggestions for faculty from sources other than the company, to make an independent judgment as to the most appropriate faculty, and to select faculty representing an appropriate diversity of legitimate medical opinions on the topic under discussion when the format permits (e.g., a panel or series of speakers). [All financial relationships with commercial interests must be disclosed to the participants.](#) ~~If the faculty member is on the company's speakers' bureau, this information is disclosed to participants.~~

The sponsor may obtain assistance in educational and conference planning from ~~any~~ ~~outside source~~ ~~it chooses~~, including consultants. ~~Acceptance of advice or services concerning identification of faculty and participants or other educational matters, including the content of the activity, is not to be a condition of support by a company.~~

A ~~commercial interest company~~ cannot take the role of non-accredited partner in a joint sponsorship relationship.

6.2 The sponsor shall exercise full control in managing funds provided by commercial interests and other sources.

~~The grant is made payable to the sponsor or the affiliate and funds are to be unrestricted. All support associated with an activity, whether in the form of an educational grant and/or in-kind, is given with the full knowledge and approval of the sponsor. The sponsor may designate a third party (e.g., affiliate, contracted education company) to act under its direction and control as its agent in payment of grant money to faculty and consultants.~~

~~8.4 The sponsor shall provide participants disclosure of: a) the company's funding of the continuing education activity; and b) past or current financial or other relationship between the sponsor and the company and between individual faculty and the company. The sponsor shall provide this information in written form at the time of the program or, for instructional media, within the materials that are part of the activity.~~

~~The written agreement states the obligation of the sponsor to provide disclosure of the company's funding of the activity and identification of any financial or other relationships with the company. Examples of financial relationships may include being:~~

- ~~• an employee of the company~~
- ~~• a recipient of research grants, honoraria, or consulting fees~~
- ~~• an owner of a interest or stock in the company~~

~~The sponsor, affiliate, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with provider's written policies and procedures.~~

~~The specific nature of a faculty member's relationship to the company should be disclosed to participants prior to the beginning of the educational activity.~~

~~For in-house faculty, one disclosure statement may cover a number of continuing education activities on a single topic. For regularly scheduled activities such as a lecture series, a separate disclosure statement is required from each faculty member.~~

~~If one company supports a series of lectures, one disclosure statement may be used to cover the entire series.~~

~~An individual must disclose to participants any relevant financial relationship(s), to include the following information:~~

- ~~• The name of the individual~~
- ~~• The name of the company(ies)~~
- ~~• The nature of the relationship the person has with each company~~

~~For an individual with no relevant financial relationship(s) the participants must be informed that no relevant financial relationship(s) exist. ———~~

~~Commercial support of continuing education activities is to be acknowledged in printed announcements, brochures, and other educational materials (e.g., syllabi, exhibits, poster sessions, materials published after the activity has been conducted), although reference is not to be made to specific products.~~

~~The sponsor is solely responsible for determining the amount of honorarium or other support it pays to faculty and consultants.~~

~~The sponsor may elect to make available scholarships or other special funding to allow podiatric medical students, residents, and fellows to participate in selected educational activities (e.g., the annual meeting of a national specialty society). Selection of recipients is made either by the academic institution or training program or by the sponsor with the full concurrence of the academic institution or training program. The decision regarding which meetings are appropriate for students, residents, or fellows to attend is to be made by their academic institution or training program or by the sponsor. Support is not to be used to send students, residents, or fellows to meetings selected by the company.~~

~~Hospitality subsidies are to be limited to modest refreshments and meals for participants of the official program. Hotel arrangements may be handled by any agency the sponsor chooses to employ.~~

~~The sponsor may not use commercial support to pay for travel, lodging, registration, honoraria or personal expenses for participants of an educational activity.~~

~~8.5 The sponsor shall be solely responsible for the design, content, and production of continuing education materials produced with financial or other support from the company, both in advance of and following the activity.~~

~~The written agreement states that the company agrees not to engage in scripting, targeting of points for emphasis, or other activities designed to influence the content of the program. The content of audiovisual and reference materials is the responsibility of the faculty selected by the sponsor. The company may provide~~

~~Limited technical assistance in preparing materials related to the topic of the continuing education activity (e.g., a faculty member may request slides that reproduce tables published in scientific reports), but these materials do not, by their content or format, advance the commercial interests of the company.~~

6.3 The sponsor shall ensure that commercial interest exhibits or activities are separate from the continuing education activity.

8.6 The sponsor shall ensure that commercial or promotional exhibits or activities are separate from the continuing education activity.

~~The written agreement includes the following:~~

- ~~d. a. When commercial exhibits are part of the activity, arrangements for exhibits do not influence planning or interfere with the sponsor's presentation of the activity.~~

Exhibit placement is not a condition of support for an activity.

~~b. No exhibits or advertisements promoting the commercial interests company's products are not to be displayed or appear in any materials disseminated during an educational activity or in any materials included within activities provided through instructional media. The company may place its exhibit within an area that is designated for general exhibits and includes exhibits from different companies marketing alternative or competing products or therapies.~~

Promotional activities, such as exhibits, commercial presentations, and printed or electronic advertisements, are prohibited in the physical or virtual location where CE courses are conducted. Likewise, promotional activities are prohibited as part of the instructional portion of CE courses. For example:

- Live, face-to-face CE courses: Display or distribution of advertisements and promotional materials is prohibited in the instructional space where the CE course is conducted.
- Print-based CE courses: Advertisement and promotional materials are prohibited within the pages of the CE content. Advertisements and promotional materials may face the first or last pages of printed CE content.
- Web/computer-based CE courses: Advertisements and promotional materials are prohibited on the screen, the web page, or as "pop-ups" where the CE content is displayed.
- Audio/Video Recorded CE courses: Advertisements and promotional materials are prohibited within the CE course. There will be no "commercial breaks."
- Sponsors must ensure that products, equipment, or devices used in conducting the course are not sold or marketed as part of the instructional portion of the CE course.

6.4 The sponsor shall have a mechanism in place to allow for attendees/participants to provide feedback or complain about commercial bias or influence in a P-CME activity. The sponsor shall

have a policy for reviewing and resolving such complaints.

Complaint process and policy for reviewing and resolving complaints must be advertised to all participants in no less than 10 point font.

- ~~e. Representatives of the company may attend educational activities but are not to be engaged in sales presentations while in the room where the continuing education activity occurs.~~
- ~~d. Activities delivered via the Internet must be in compliance with the standards and requirements in CPME 720.~~
- ~~e. With clear notification that the participant is leaving the educational website, links from the website of a CPME approved sponsor to pharmaceutical and device manufacturers' "product websites" are permitted before or after the educational content of a continuing education activity, but must not be embedded in the educational content of a continuing education activity.~~
- ~~f. Advertising of any type is prohibited within the educational content of the continuing education activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop up ads.~~
- ~~g. The sponsor must indicate at the start of each Internet continuing education activity the minimum hardware and software requirements for participation.~~
- ~~h. The sponsor must have a mechanism in place for the participant to be able to contact the provider if there are questions about the Internet continuing education activity.~~
- ~~i. The sponsor must have, adhere to, and inform the participant about its policy on privacy and confidentiality that relates to the continuing education activities it provides on the Internet.~~
- ~~j. The sponsor 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 continuing education activity on the Internet.~~

~~8.7 A balanced view of all therapeutic options shall be presented. Impartiality shall be demonstrated through use of generic names in titles of continuing education activities and in discussions of products and treatments. If trade names are used, the product names associated with competing companies shall be used and shall be part of a balanced educational presentation for the particular disease or diagnosis (e.g., discussion is provided regarding other drugs and therapeutic options).~~

~~8.8 When an unlabeled or off-label use of a commercial product or an investigational use not yet approved for any purpose is discussed during an educational activity, the sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion or that the product is still investigational. The sponsor shall have a mechanism in place to inform faculty of this requirement. When an off-label use for a drug is discussed during an educational activity, the sponsor shall require that the speaker disclose that the use is not approved by the FDA for that purpose. The sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion or that the product is still investigational.~~

~~8.9 The sponsor shall ensure that there will be meaningful disclosure of any limitations on information that is presented. Such limitations shall include, but are not limited to, data that represent ongoing research, interim analyses, preliminary data, or unsupported opinion.~~

~~8.10 For live presentations, the sponsor shall ensure that meaningful opportunities for scientific debate or questioning are provided during the activity.~~

~~8.11 The sponsor and the company shall agree to, and record in the agreement, the dates, times, and locations of all presentations.~~

~~8.12 The sponsor shall ensure that announcements and advertisements for the continuing education activity focus primarily on the educational content, rather than on leisure or recreational activities.~~

~~The title of the activity is to provide an accurate representation of the scope of the educational offering. The number of hours devoted to the educational portion of the activity is to substantially outweigh the number of hours associated with social events.~~

~~The sponsor may authorize the company to publicize the continuing education activity to the podiatric medical community. The sponsor is, however, responsible for the content of such advertisements.~~

~~8.13 The sponsor shall exercise full control in managing funds provided by commercial sources.~~

~~• The written agreement outlines the terms (including amount), conditions, and purposes of educational grants provided by the company in support of continuing education programming and states that the ultimate decision regarding funding arrangements and grant support for continuing education activities is the responsibility of the sponsor.~~

~~• The grant is made payable to the sponsor and funds are to be unrestricted. All support associated with an activity, whether in the form of an educational grant or not, is given with the full knowledge and approval of the sponsor.~~

~~No funds from the company are paid directly to the director of the activity, faculty, or others involved with the continuing education activity.~~

~~• The sponsor may elect to use grant support to offset the total costs of a continuing education activity in order to reduce registration fees.~~

~~• The sponsor may elect to use grant support in paying faculty and consultants for reasonable honoraria and expense reimbursement (e.g., travel, lodging, and meals). The sponsor is solely responsible for determining the amount of honorarium or other support that it pays to faculty and consultants.~~

- ▲ If the sponsor is prohibited from accepting grant support, the sponsor, rather than the company, is responsible for determining how faculty and consultants will be paid. The sponsor may designate a third party (e.g., affiliate or contracted-education company) to act under its direction and control as its agent in payment of grant money to faculty and consultants.
- ▲ Following each continuing education activity supported by corporate funds, the sponsor and the company should each report to the other on the expenditure of funds each has provided.
- ▲ The sponsor must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

8.14 The sponsor shall provide responsible management of financial support for participants in continuing education activities.

The sponsor may elect to make available scholarships or other special funding to allow podiatric medical students, residents, and fellows to participate in selected educational activities (e.g., the annual meeting of a national specialty society). Selection of recipients is made either by the academic institution or training program or by the sponsor with the full concurrence of the academic institution or training program. The decision regarding which meetings are appropriate for students, residents, or fellows to attend is to be made by their academic institution or training program or by the sponsor. Support is not to be used to send students, residents, or fellows to meetings selected by the company.

Hospitality subsidies are to be limited to modest refreshments and meals for participants or social events on the official program.

Hotel arrangements and social event planning may be handled by any agency the sponsor chooses to employ, but all such activities must be coordinated with and approved by the sponsor.

The sponsor is not to use funds from a company to pay any direct personal expenses of participants (e.g., travel, lodging, registration, honoraria). The sponsor is to ensure that no inducements other than meals or token gifts are provided to encourage participation in the program. Any gifts presented to participants are to benefit patients or be related to the professional activities of the podiatric physician. Such gifts should not be of significant cost or value (e.g., pens, pads, monographs). Cash gifts to participants are inappropriate, as is compensation provided for the time taken by the podiatric physician to participate in the activity. Gifts are to be unencumbered by conditions such as establishment of a relationship to prescribing practices.

9.0 — The program of continuing education has a well-defined administrative structure and is sufficiently managed and administered.

~~9.1 The sponsor shall ensure continuity in its overall program of continuing education.~~

~~Continuity of administration is necessary for the stability and growth of the program in continuing education.~~

~~9.2 The sponsor shall appoint one individual to serve as director of continuing education.~~

~~The professional background and experience of the individual selected as director of continuing education should be appropriate to the responsibilities of the position.~~

~~9.3 The director of continuing education shall be provided proper authority by the sponsor.~~

~~The sponsor should clearly delineate the responsibilities and scope of authority of the director of continuing education.~~

~~9.4 The director of continuing education shall provide coordination and administration for all continuing education activities and be able to devote sufficient time in order to fulfill the responsibilities required of the position. The director of continuing education shall be responsible for communication with the Council on all matters related to the application and approval process for the sponsor and for ensuring that the sponsor achieves and maintains compliance with the Council's standards and requirements.~~

~~Responsibilities of the director, in consultation with the advisory/education committee include, but are not limited to:~~

- ~~• participates in development of the mission statement~~
- ~~• assesses and analyzes needs and interests~~
- ~~• develops learning objectives~~
- ~~• develops hour-by-hour schedules of topics~~
- ~~• selects educational methods~~
- ~~• evaluates individual activities and annual review of the program of continuing education~~
- ~~• coordinates the processes of examination development, administration, and scoring~~
- ~~• selects faculty and communicates and consults with faculty~~
- ~~• selects facilities and assures that all facilities and materials needed are available~~
- ~~• participates in development of the sponsor's written agreement related to commercial support of continuing education activities~~
- ~~• manages financial resources~~
- ~~• develops publicity~~
- ~~• admits and registers participants~~
- ~~• verifies attendance~~

- maintains and issues records of attendance
- calculates and awards continuing education credit accurately and appropriately
- adheres to the sponsor's patient protection policies
- ensures proper marketing and distribution of activities

The director of continuing education is the primary individual responsible for communication with the Council on all matters related to the application and approval process for the sponsor. The director of continuing education is responsible for ensuring that the sponsor achieves and maintains compliance with the Council's standards and requirements.

~~9.5 The sponsor shall identify an advisory/education committee responsible for coordination and administration of all continuing education activities. The committee shall include at least one podiatric physician.~~

~~The committee is appointed by the sponsor to coordinate the processes of planning, implementing, and evaluating continuing education activities. The committee may consist of a number of people with different responsibilities in the design and implementation of activities that comprise the sponsor's program of continuing education.~~

~~Terms of office for committee members should be of sufficient duration (e.g., at least one year) to assure continuity of administration. Members' terms should expire on varying dates. Minutes of committee meetings should be maintained.~~

~~9.6 Staff support shall be available to ensure efficient administration of continuing education activities.~~

~~9.7 When the sponsor provides a continuing education activity in conjunction with another entity, the sponsor shall ensure that the activity meets the Council's standards and requirements. A written affiliation agreement shall be established to delineate the specific responsibilities of the sponsor and the entity.~~

~~Continuing education activities provided in conjunction with another entity must be consistent with the sponsor's mission statement. The sponsor has the same responsibility for an activity that it sponsors in conjunction with another entity as for an activity that it sponsors alone.~~

~~Affiliation may take either of two forms:~~

- ~~An approved sponsor may be asked by an entity to extend sponsorship for an activity (with the unapproved entity identified as the affiliate of the sponsor). This information must be clearly indicated in all materials advertising the activity and in printed materials provided at the time the activity is conducted.~~

~~This information also must be submitted to the Council office in the sponsor's annual report.~~

- ~~• An approved sponsor affiliates with another approved sponsor. In this event, one sponsor assumes primary responsibility for the activity. This information must be clearly indicated in all materials advertising the activity and in printed materials provided at the time the activity is conducted. This information must be submitted to the Council office in the sponsor's annual report.~~

~~Any cooperative educational undertaking between a sponsor and another entity should have the approval of the chief administrative officer(s) of both entities.~~

~~9.8 The sponsor shall establish written criteria and procedures that assure nondiscriminatory treatment of all individuals involved in the program of continuing education.~~

~~9.9 The sponsor shall ensure that its program of continuing education and each activity under its purview are established and conducted in an ethical manner.~~

~~10.0 — Financial resources are sufficient to meet the mission of the overall program of continuing education and the learning objectives of individual continuing education activities.~~

~~10.1 The sponsor shall have available adequate resources to fund the administrative and support services necessary to manage the program of continuing education.~~

~~Resources should be adequate for the continual improvement of the program of continuing education.~~

~~Although anticipated income from tuition may be sufficient to cover the costs of a continuing education activity, the sponsor should not depend solely on tuition fees to support the program of continuing education.~~

~~10.2 In instances where continuing education is only one aspect of the sponsor's activities, financial resources for the program of continuing education shall be a clearly identifiable component of the sponsor's total budget and resources.~~

~~10.3 The sponsor shall develop and utilize a budget for the program of continuing education, to include all income and expenditures, both direct (e.g., faculty honoraria, costs for publicity and preparation of instructional materials, tuition fees, refunds, or foundation grants) and indirect (e.g., use of classroom facilities or equipment, unpaid faculty time).~~

~~The sponsor should develop separate budgets for each continuing education activity.~~

~~A continuing education activity is not to be presented for the sole purpose of profit. Demonstrated need for specific activities rather than anticipated income or profit is to be the determining factor in developing continuing education activities.~~

~~Tuition or registration fees for continuing education activities must be reasonable for the type of education and number of hours in the activity.~~

~~10.4 The sponsor shall establish a reasonable refund policy for tuition or registration received from individuals who provide sufficient notice that they will be unable to participate in the activity. The sponsor shall establish a refund policy for use in the event that the activity is canceled.~~

~~This policy should be published in advertisements and/or registration materials.~~

~~711.0 The sponsor shall ensure appropriately manages administrative processes related to development of publicity, admission, verification of attendance, calculation of continuing education contact hours, and maintenance of attendance records of attendees.~~

~~711.1 The sponsor shall ensure that publicity for continuing education activities and descriptive materials utilized during the activity provide complete and accurate information.~~

~~The sponsor should publish the learning objectives in announcements and other advance publicity for all continuing education activities.~~

~~The following information must be published in the final activity brochure or program publication:~~

- ~~a. title of the activity~~
- ~~b. learning objectives~~
- ~~c. detailed hourly agenda~~
- ~~d. the intended audience, including any prerequisite levels of skill, knowledge, or experience required of participants if applicable~~
- ~~e. costs to the participant (activity is identified as complimentary if there is no charge)~~
- ~~f. and if applicable, the items covered by the costs~~
- ~~g. the names of the sponsor and director of continuing education or other contact information (phone and/or email address) person~~
- ~~h. list of faculty and their professional qualifications and professional degree(s)~~
- ~~i. participant refund and activity cancellation policies~~
- ~~j. identification of affiliate(s) (activity is identified as complimentary if there is no charge)~~
- ~~k. identification of any commercial interest(s) providing financial support company or organization providing financial support~~

Comment [S5]: ACFAS proposes to delete affiliate status per the rationale in our cover letter.

~~ki. the approval status of the sponsor and the number of continuing education contact hours to be awarded~~

~~For an activity provided in the format of a course, the sponsor also must publishes the following information in the final brochure or program publication:~~

~~j. location(s)~~

~~k. date(s) and time(s)~~

~~The For an activity provided through instructional media, the sponsor also must publishes the following information in the final brochure or program publication:~~

~~l. medium or combination of media used (i.e., hardware and software needs.)~~

~~m. method of participation in learning process~~

~~n. total length of recorded materials and estimated time for completion of activity~~

~~o. date of original release, and if applicable, of most recent review and update~~

~~p. examination and evaluation methods, including the passing score for the examination~~

~~An approved sponsor must use the following approval statement in reference to its approval status in the brochures, certificates, instructional media, and other publications pertaining to the program of continuing education activity:-~~

(Name of sponsor) is approved by the Council on Podiatric Medical Education as a sponsor of continuing education in podiatric medicine. (Name of sponsor) has approved this activity for a maximum of _____ continuing education contact hours. Learners should only claim hours commensurate with the extent of their participation in the activity.⁷

⁷ <http://www.ama-assn.org/resources/doc/cme/prs-booklet.pdf>

~~No other statements regarding approval by the Council may be used without the permission of the Council.~~

~~The sponsor must publish the objectives of the continuing education activity in materials utilized at the time of the activity.~~

~~The Council believes that podiatric physicians are responsible for selecting continuing education activities based upon assessment of their own perceived professional needs and interests, preferred learning methods, and practice settings. For this reason, the sponsor is obligated to publicize the activity in a manner that provides information that is as complete and accurate as possible.~~

~~Moreover, participants' expectations concerning content and anticipated learning are based on publicity for the activity. Complete, detailed publicity will help ensure that those who want and need to participate in the continuing education activity will attend and that they will be motivated to learn.~~

7.2 The sponsor shall ensure the primary focus of announcements and advertisements for the continuing education activity is on educational content, rather than leisure/recreational activities.

The title of the activity must accurately represent the content of the continuing education activity.

The sponsor may authorize a commercial interest(s) to publicize the continuing education activity. The sponsor is responsible for the content of such advertisements.

11.2 In general, the sponsor shall provide continuing education activities that are available to all podiatric physicians.

~~The sponsor may elect to provide activities designed for individuals with prerequisite levels of skill, knowledge, or experience.~~

~~If the activity requires that prospective participants possess previous training or preparation, the sponsor must:~~

- ~~a. Provide a precise definition of the knowledge, skill, or experience required for admission.~~
- ~~b. Be able to demonstrate the necessity for any admission restriction, based on the content and objectives of the activity.~~
- ~~c. Specify in advance, and make available, an objective, specific method for prospective participants to demonstrate that they have satisfied the admission requirement. The method must be clearly related to the activity content and stated admission requirements.~~

If the sponsor provides activities that are offered at an advanced level, the sponsor also should provide activities at basic and intermediate levels to afford participants the opportunity to prepare for the advanced activity.

711.3 ~~The sponsor shall perform a minimum of two (2) attendance verifications during each a single day of a live in a continuing medical education activity, but for an activity of four (less than 4) hours or less requires a in length only a single attendance verification is required.~~

~~The council does not designate the method used for attendance verification.~~

~~For activities provided through instructional media, the sponsor must require that participants document their completion of the entire activity, including the examination.~~

11.7.4 ~~The sponsor shall determine the number of continuing education contact hours credit in accordance with the council's requirements related to the appropriate content of continuing education activities and calculation of continuing education contact hours.~~

~~The council's requirements related to the appropriate content of continuing education activities appear on pages 9-10 of this publication. The council's requirements for the related to calculation of continuing education contact hours as described appear in Appendix B, on page 11.~~

The sponsor is responsible for notifying CPME if the activity concludes more than 30 minutes earlier than originally planned. A formal letter on organizational letterhead must be submitted to CPME within 15 days of the conclusion of the event. Should CPME learn of an early conclusion through the whistleblower process (described in 730) and NOT receive a notice from the sponsor, this may trigger a) onsite audit, b) probation, c) withdrawal of approval. Should a sponsor have more than three activities conclude early in one accreditation time period, this may also trigger a) onsite audit, b) probation, c) withdrawal of approval.

711.5 ~~The sponsor shall maintain a roster of complete record verifying each individual's participation in each its continuing education activities.~~

~~The sponsor is responsible for maintaining proper records to verifying which participants successfully completion of ed the activity and number of qualified for award of continuing education contact hours awarded to each participant credit. The sponsor must be able to issue a copy of each individual's record of participation when authorized by the participant. Records must be securely, with their privacy and release protected by the sponsor. Records should be maintained for a minimum at least of five (5) years. The sponsor should obtain legal counsel regarding the length of time for which records must be kept.~~

~~The roster must Records and documentation should include, but not be limited to, the~~

include the following information:

- sponsor
- title
- maximum continuing education contact hours available
- date(s)
- name of individual participants and number of continuing education contact hours awarded to each individual (based on hours they claim)

The sponsor should be aware of professional and legal requirements for continuing education ~~that may affect~~ing individuals participating in its activities. The sponsor should cooperate with regulatory agencies and other institutions/ ~~and~~ organizations in providing documentation of attendance. ~~, as necessary.~~

711.6 The sponsor shall provide a documented record of attendance to each participant upon satisfactory completion of the entire continuing education activity.

The documented record must include the following information:

- sponsor
- title
- date(s)
- city/state
- approval statement
 - name of participant
 - number of continuing education contact hours awarded to that individual

~~, each participant shall receive from the sponsor an accurate record of attendance. The record shall include items listed in requirement 11.5. Any record granted in connection with the continuing education activity shall not be, nor resemble, a diploma.~~

The documented record ~~ation~~ (e.g., certificate, letter, transcript) must not resemble a diploma ~~or certificate that attests, or might appear to attesting,~~ to a specific skill, ~~or~~ specialty, or advanced educational status. ~~The sponsor is to ensure in designing~~ such documentation, ~~the sponsor is to ensure that the record i~~s not subject to misinterpretation by the public or professional colleagues.

The approved sponsor must be the ~~entity to issuing~~ entity of the documented record, ~~e the certificate of attendance, not the unapproved entity.~~

The sponsor must issue a copy of the documented record upon authorized request of the participant.

~~8.12.0~~ The sponsor ensures the protection and confidentiality of patients involved in ~~in~~ continuing education activities involving patient treatment by faculty or participants.

~~12.18.1~~ The sponsor ~~In continuing education activities involving patient treatment by either faculty or participants, the sponsor~~ shall ensure patient protection through the following means:

- ~~participants confirmation shall be obtained before the activity that participants possess the~~ skills and knowledge ~~basic skill, knowledge, and expertise required to learn and perform the treatment techniques to be taught.~~
- ~~prior written~~ written informed consent shall be obtained from the patient ~~prior to treatment.~~
- ~~utilization of if warranted, aseptic conditions, and appropriate equipment and instruments shall be utilized.~~
- faculty shall provide sufficient clinical supervision ~~during patient treatment to ensure that procedures are performed competently.~~
- ~~provision of continuity of care arrangements shall be made for completion of treatment by a qualified clinician as necessary.~~ provision
- ~~adequate and appropriate arrangements and/or facilities for of~~ emergency services ~~and postoperative care shall exist.~~

9.0 The sponsor appropriately manages administration related to instructional media.

9.1 The sponsor is responsible for ensuring quality content and production of the activity.

Sponsors developing instructional media must consult with individuals who have technical expertise in both media and self-directed learning techniques and in the application of these techniques to adult learning.

Sponsors producing instructional media must review the instructional material at least bi-annually or more frequently if indicated by new scientific developments. The instructional media must not be certified for contact hours for more than two years without some review on the part of the sponsor ensuring current and accurate content.

9.2 The sponsor must establish conditions for effective participation in each activity.

The conditions include the following:

- hardware and software requirements
- method of participation in learning process
- total length of recorded materials and estimated time for completion of activity
- date of original release, most recent review, and update

- examination and evaluation methods, including the passing score for the examination
- contact information
- faculty
- learning objectives
- faculty disclosure

9.3 **The sponsor must have, adhere to, and inform the participant about its policy on privacy and confidentiality.**

9.4 **The sponsor must be able to document ownership of the copyright, permission or otherwise permitted use, of materials in a continuing education activity.**

9.5 **Each activity shall include a content-oriented examination.**

The examination shall allow the sponsor to measure the extent to which activity objectives have been accomplished and shall allow participants to assess their mastery of the material in terms of enhanced knowledge, skills, and/or competence. The examination shall allow the sponsor to measure the extent to which activity

objectives have been accomplished and shall allow participants to assess their mastery of the material in terms of enhanced strategies, skills, and patient care.

The sponsor shall ensure the existence of a process for examination validation.

Comment [S6]: The ACFAS recommends this definition be loosened, per the rationale in our cover letter. "Validation" implies the engagement of psychometricians, etc. We recommend that exams measure attendees' enhanced strategies, skills and patient care.

The exam should be developed in consultation with individuals with experience and/or expertise in test development and education measurement. Validity is defined as the degree to which a test measures what it is supposed to measure. Validity, which is the most important quality of any test, emerges from the process of test construction. The sponsor must consult with individuals who have expertise in test development and educational measurement and have the examination validated by an impartial expert.

9.6 The sponsor shall ensure appropriate regulation of advertisement.

Related to printed activities:

Advertisements and promotional materials will not be interleaved within the pages of the content. These materials may face the first or last pages of printed content as long as they are not related to the content they face and are not paid for by the commercial interests of the activity. Information required to be communicated before an activity (e.g., disclosure information, disclosure of commercial support, objectives), content (e.g., articles, lectures, handouts, and slide copies), content-specific post-tests, and education evaluation are all elements of a journal-based activity. These elements shall not contain advertising, trade names, or product group messages.

Related to computer-based activities:

Advertisements and promotional materials will not be visible on the screen at the same time as the content and not interleaved between computer “windows” or screens of the content. The participants must be clearly notified when leaving the educational website.

Links to pharmaceutical and device manufacturers’ “product websites” from the activity website are permitted before or after the educational content, and must not be embedded in the educational content. Advertising of any type is prohibited within the educational content of the continuing education activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up ads.

Related to audio and video recorded activities:

Advertisements and promotional materials will not be included within the activity. There will be no “commercial breaks.”

The sponsor, faculty, and participants must have liability protection. Unless malpractice coverage for participants is arranged by the sponsor, participants must be given notice to provide written documentation of coverage from their carriers.

The sponsor is responsible for ensuring that faculty and participants treating patients are in compliance with applicable laws and regulations. The sponsor must ensure that participation in its activities by podiatric physicians not

~~licensed in the state or jurisdiction where the activity is presented does not violate the state practice act.~~

~~The sponsor should obtain the advice of legal counsel regarding informed consent requirements and procedures.~~

~~12.2 The sponsor shall inform participants about the potential risks of using limited knowledge when integrating new techniques into their practices.~~

~~Participants should be cautioned about the potential risks of incorporating techniques and procedures into their practices if the activity has not provided them adequate, supervised clinical experience in the technique or procedure to allow them to perform it competently.~~

~~13.1 The sponsor reports periodically to the Council on Podiatric Medical Education and at least annually regarding the conduct of its continuing education activities.~~

~~13.1 The sponsor shall report to the Council through progress reports and the annual self-assessment the following:~~

- ~~• institutional or organizational data~~
- ~~• calculation of continuing education contact hours~~
- ~~• continuing education activities projected for the forthcoming year~~
- ~~• other information that may be requested by the Council related to the annual review described in 5.4~~

~~13.2 The sponsor shall inform the Council in a timely matter (within 60 days) regarding significant changes in its administration.~~

~~The sponsor is responsible for informing the Council in a timely manner of changes in areas including, but not limited to:~~

- ~~• sponsorship~~
- ~~• mission~~
- ~~• appointment of a new director of continuing education~~
 - ~~development of additional continuing education activities (e.g., activities that were not included on the sponsor's most recent annual report.)~~

~~9.7 The sponsor is expected to establish a justifiable, standard amount of continuing education contact hours to be granted for completion of each activity.~~

~~Continuing education contact hours must be based on an average number of hours required of several representative participants (pilot group) to complete the activity. Members of the pilot group must not have participated in development of the~~

activity. The sponsor is expected to continue to monitor the amount of time required for participants to complete the activity and to make adjustments in the amount of continuing education contact hours as necessary. A process of ongoing validation affords credibility to the standard determined by the sponsor.

9.8 The sponsor shall provide opportunity for participants to complete an evaluation process at the completion of the activity.

The evaluation must request participants to assess areas including, but not limited to, the following:

- content (comprehensive, appropriate, and adequately in-depth to meet the stated objectives)
- methods by which the activity enhanced professional ~~effectiveness~~ strategies, skills and/or patient care
- quality of the instructional process and presentations including the effectiveness of educational methods and teaching materials
- individual faculty quality, effectiveness, and avoidance of commercial bias
- overall management of the activity
- identify professional needs ~~or interests~~ for future activities

GLOSSARY

The council strongly encourages the directors of continuing education to become familiar with the following definitions to ensure complete understanding of this publication.

Activity

A single educational interaction which is based on a need, has measurable objectives, and is evaluated to assure the needs are met.

Advisory/Education Committee

A committee appointed by the sponsor to coordinate the processes of planning, implementing, and evaluating continuing education activities and the sponsor's program of continuing education. The committee shall include at least one podiatric physician.

Affiliate/Affiliation

Any cooperative educational undertaking between an approved sponsor and another entity. The entity would be identified as an affiliate of the sponsors. The approved sponsor has the same responsibility for an activity sponsored in conjunction with another entity as it does for a solely sponsored activity. If the other entity is also an approved sponsor, one sponsor assumes primary responsibility for the continuing education activity.

A sponsor planning to present one or more activities with a non-CPME approved sponsor or a CPME approved sponsor are engaging in "affiliation." CPME expects all continuing education activities are to be conducted in compliance with the current CPME publication 720, *Standards, Requirements, and Guidelines for Approval of Sponsors of Continuing Education in Podiatric Medicine*.

Annual Report

CPME collects data yearly from each approved sponsor to monitor changes in their continuing education program.

Approval

Approval is the recognition of a sponsor of continuing education that has attained compliance with standards established by the council on Podiatric Medical Education. The council approves the sponsor itself rather than each of the sponsor's continuing education activities and reserves the right to review any or all of these activities.

Approval Statement

(Name of sponsor) is approved by the Council on Podiatric Medical Education as a sponsor of continuing education in podiatric medicine. (Name of sponsor) has approved this activity for a maximum of _____ continuing education contact hours.

Commercial Interest

Any entity manufacturing, producing, marketing, re-selling, or distributing health care goods or services consumed by or used on patients. Such entities are not eligible for approval as a sponsor.

Commercial Support

Monetary, or in-kind, contributions given by a commercial interest which are used to pay all or part of the costs of a continuing education activity.

Conflict of Interest

When an individual or entity has an opportunity to affect the content of educational activities regarding products or services in which they have a financial relationship.

Content Validity

Approved providers are responsible for validating the clinical content of P-CME activities that they provide. Specifically,

1. All the recommendations involving clinical medicine in a P-CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
2. All scientific research referred to, reported, or used in P-CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
3. Providers are not eligible for approval if they present activities that promote recommendations, treatment, or manners of practicing medicine that are not within the definition of P-CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. An organization whose program of P-CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for CPME approval.⁸

The extent to which a test measures and adequately samples an intended content area. Content validity is determined by an impartial expert and may not be expressed quantitatively. Individuals who are experts in the area covered by the test assess the content validity by

⁸ ACCME <http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/cme-clinical-content-validation>

reviewing all items and judging how well the items represent the intended content area. This determination is based on whether all areas comprising the overall subject matter have been included and are represented in the correct proportions.

Continuing Education

Continuing education serves to maintain, develop, and/or enhance the knowledge, skills, and professional performance and relationships used by podiatric physicians to deliver the highest quality of service to patients, the public, and the profession.

Continuing Education Activity

An educational intervention for physicians, which is based upon identified needs, has objectives, and is evaluated to determine the extent to which change or improvement has been effected. ~~An educational event for physicians, which is based upon identified needs, has objectives, and is evaluated to assure the needs are met.~~ Continuing education activities include, but are not limited to, lectures, conferences, seminars, moderator-guided panel discussions, clinical and practical workshops, electronically-mediated learning, and self-instruction. These activities are educational in nature, rather than social, recreational, or commercial, and do not provide academic credit toward a degree, nor lead to any formal advanced standing in the profession.

Continuing Education Committee (CEC)

The standing committee of the council responsible for recommending to the council approval status of sponsors of continuing education in podiatric medicine. The committee reviews applications, petitions, reports of on-site evaluations, requests for reconsideration, progress reports, and annual reports. The CEC may modify its own policies, and/or recommend to the appropriate ad hoc committee modifications in standards, requirements, and procedures for sponsor approval.

Composition of the committee includes two representatives from approved sponsors of continuing education in podiatric medicine (selected by the council), one representative from the podiatric practice community (selected by the council), one representative from state licensing boards (appointed by the Federation of Podiatric Medical Boards), at least two council members (one of whom is a public member), and one observer from ASPE (appointed by the American Society of Podiatric Executives). The council and its staff administer the affairs of the CEC.

Continuing Education Contact Hour

A 60-minute period (one clock hour) of interaction between a participant and faculty, or between a participant and prepared materials to result in learning.

Director of Continuing Education

The individual responsible for coordination and administration of the program of continuing education offered by the sponsor, as well as its associated continuing education activities.

Educational Methods

The systematic plan or procedure by which information or educational material is made available to the participant. Examples include lecture, discussion, grand rounds, case reviews and presentations, question and answer periods, laboratory work, workshops, discussion groups, self-instruction, and internet-based or other electronically mediated formats.

Evaluation Process

The measurement tool used by sponsors to assess participants and determine the effectiveness of the continuing education activity. The opportunity for participants to provide feedback assessing the effectiveness of the continuing education activity.

Faculty

The speakers or instructors responsible for communicating the educational content of an activity to a participant.

Financial Disclosure

The reporting of relevant financial relationships with commercial interests within 12 months of the activity start date.

Financial Relationships

Any relationship in which an individual involved in planning, administering, or presenting an activity benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (self-managed), contracted research or other financial benefit within 12 months of the activity start date. CPME considers relationships of the person involved in the activity to include financial relationships of a spouse or domestic partner.

In-Kind Commercial Support

A non-monetary contribution made to a sponsor for a continuing education activity. Examples of such support include: Equipment, facilities/space, supplies, human/animal parts/tissue, etc.

Instructional Media

A type of continuing education activity utilizing instructional materials including, but not be limited to, printed, recorded, and/or computer-assisted materials. Instructional media may be used over time at various locations and in themselves constitute a planned continuing education activity. Examples of instructional media include, but are not limited to, books, journals, audiotapes, videotapes, and computer-assisted instructional programs. The intent of the council is to anticipate the inclusion of the development of future technologies and methods of providing continuing education in the definition.

Mission Statement

Broad, long-range goals, expectations and purposes of the sponsor in providing continuing education.

Needs Assessment

The process of identifying problems in practice which result from the lack of strategies, skills or patient care in the target audience, as well as the identification of educational strategies which might alleviate this problem. The specific needs provide the rationale and focus for the educational activity. ~~The process of identifying specific information or skills directly benefiting or of interest to participants, based on information provided by prospective participants and/or objective sources. The specific needs provide the rationale and focus for the educational activity.~~

Noncompliance

The sponsor is not meeting the standard of practice for the judged approve requirement.

Objectives

Written, measurable statements indicating what the participant is expected to accomplish, by expressing specific, short-range outcomes. Objectives are stated in behavioral or action-oriented terms.

Off-label and Unlabeled Products

Off-label: Uses of Food and Drug Administration (FDA) approved drugs for indication, dosage form, dose regimen, population, or other use parameter not mentioned in the approved labeling.

Unlabeled Uses of Products: When an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose, is discussed during an educational activity.

Participant

An individual engaged in a continuing education activity.

Petition

A form that must be completed by an approved sponsor seeking continued approval, as a sponsor of continuing education in podiatric medicine.

Planning Committee

A committee in charge of designing and developing continuing education activities.

Probation

The approval decision by CPME indicating an approved sponsor has not met all the standards for a continuing education sponsor as outlined by CPME. The approved sponsor must correct the deficiencies to receive a decision of approval. While on probation, a sponsor may not jointly sponsor new activities.

Product

Therapeutic and/or diagnostic materials such as pharmacologic and biologic products, and medical devices manufactured and/or advertised by a commercial interest.

Program

The overall composition of sponsors' continuing education activities.

Progress Report

A report prepared for CPME by the approved sponsor communicating changes in the sponsor's program to demonstrate compliance with the standards and requirements found to be in noncompliance during the most recent approval review.

Regularly Scheduled Series

Activities occurring daily, weekly, monthly, or quarterly (e.g., grand rounds).

Self-assessment

Data and observations collected by the sponsor to document its accomplishments and assess areas where improvements may be necessary, and outline a plan for making those improvements.

Sponsor

Institution, organization, or individual responsible for organizing, administering, publicizing, presenting, and keeping records for the continuing education program.

Appendix A - Definition of Continuing Education

~~See page 3 in the “Glossary” section.~~

Content of Continuing Education

The content of continuing education activities is that which is appropriate to each individual podiatric physician in carrying out his or her professional responsibilities more effectively and efficiently. Because the professional needs of podiatric physicians are varied, this definition is necessarily broad. In general, however, activities should result in improvement in the quality of patient care, education of students and residents, and administration of educational programs.

The content of continuing education activities is often that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, behavioral and social sciences, podiatric medicine ~~and surgery, and~~ related clinical disciplines, and the provision of health care to the public. If the needs assessment indicates a documented difference between what should be done in practice (based on published research, best practice guidelines, expert consensus, etc) compared to what is currently being done (as measured by hospital quality department data, epidemiological data, medical literature, etc), then activities may be designed to narrow the difference between current practice and best practice. If the need indicates, activities may be designed to review and affirm existing concepts and techniques, and to advance participants’ competence through exposure to new or additional techniques/skills/strategies in podiatric and medical sciences. Activities may be designed to review existing concepts and techniques, to convey information beyond basic podiatric education, and to update knowledge on advances in podiatric and medical sciences. Participation in activities concerned with such topics should result in enhanced ability to deliver high-quality patient care.

The content of continuing education activities may be related to areas including, but not limited to:

- health care reform
- legislative and legal issues related to the provision of patient care
- managed care
- professional faculty development activities such as administrative, organizational, and teaching skills for directors and faculty of residency programs
- educational methodology for faculty at colleges of podiatric medicine and residency program faculty and staff
- risk management associated with patient care (e.g., electronic health records, ICD – International Classification of Diseases, understanding of and proper documentation of complications, effective communication with patients, and informed consent)
- medical and professional ethics
- management of health care facilities
- public health
- epidemiology and related issues
- structured abstract presentations

- faculty-led classroom or meeting time, regardless of whether faculty and participants are in the same location or whether the activity is conducted at the same time but in different locations as through satellite broadcasts, teleconferencing, or electronic communications media (e.g., web-based conferences)
- moderator-guided panel discussions
- activities in which the participant is engaged in a planned learning experience whereby his or her progress is monitored or the participant receives feedback from faculty (e.g., web-based conferences, computer-assisted instruction, etc.)
- regularly scheduled series (grand rounds)
- laboratory work
- assigned self-directed learning activities integral to the course
- pilot group activities to determine the validity of the final examination associated with instructional media

Specialty boards reJCRSB recognized by the Joint Commission on the Recognition of Specialty Boards specialty boards and the National Board of Podiatric Medical Examiners may apply for sponsor approval in order to grant credit to podiatric physicians who serve on committees for development and validation of examinations.

Topics such as practice management and maintenance of medical records may be acceptable if the sponsor is able to demonstrate the benefits of the activity in enhancing the quality of patient care (e.g., an activity related to setting up an office may be beneficial to a target audience consisting of podiatric physicians entering practice).

Activities or portions of activities that do not meet the previously cited definitions for continuing education and the appropriate content of continuing education are ineligible for contact hours. Contact hours are not to be granted for activities or topics including, but not limited to:

- personal financial gain (e.g., financial planning, real estate investments), -
- practice management (e.g. marketing, exclusive CPT – Current Procedural Terminology, - and billing) except as noted above)
- academic credit courses
- association membership and leadership
- participation in committee meetingscommittee meetings, except as noted above
- participation in on-site evaluations (e.g., for the purposes of accreditation, approval, or state recognition)
- individual scholarship, research, -and teaching
- on-the-job experiences
- mass media presentations that are not part of an organized, supervised activity-
- registration
- introductory or welcoming speeches
- announcements
- committee business or reports
- exhibit attendance
- unsupervised independent study or assigned reading, travel, meals, breaks, and social

gatherings

Any questions regarding the appropriate content of continuing education activities must be addressed to the cCouncil office well in advance of the presentation, publication, and/or distribution of the activity.

Commercial Support of Continuing Education Activities

The Food & Drug Administration (FDA) has indicated that it will rely on to the extent possible, approval agencies such as the Council to monitor company-supported educational activities conducted by approved sponsors and to ensure that such activities are independent and non-promotional. Consequently, the requirements and guidelines appearing within Standard 8.0 specifically reflect the regulations set forth by the FDA.

If an approved sponsor elects to provide a continuing education activity that is promotional in nature, this activity is outside of the scope of its approval by the Council. All publicity and materials associated with this activity must indicate clearly and specifically that the activity is not approved by the Council. Failure to provide such a disclaimer may jeopardize the continued approval of the sponsor by the Council, as well as deny the participants continuing education contact hours for the activity. As noted previously, promotional activities fall under the jurisdiction of FDA regulations.

~~Appendix B – Calculation of Continuing Education Contact Hours~~ALCULATION OF CONTINUING EDUCATION CREDIT

A council-approved sponsor of continuing education is responsible for calculating and awarding continuing education contact hours and reporting this information to the council at least annually. The sponsor must identify the number of contact hours granted for each activity, provide justification for the number determined, and describe the methods used to calculate the number of continuing education contact hours.

The number of continuing education contact hours is to be determined through use of the council's policies as described below. Except where noted, these policies apply to all activities, regardless of the length of the activity or whether the activity is structured as a course or provided through instructional media. ~~Activities that are eligible for continuing education contact hours are to be identified using the Council's policies regarding content of continuing education (see pages 9-10).~~ Any questions regarding calculation of continuing education contact hours must be addressed to the council office well in advance of the presentation, publication, and/or distribution of the activity.

The 60-minute hour is utilized by council-approved sponsors as the standard for all continuing education activities. When calculating the number of continuing education contact hours for an activity, the number of contact minutes of instruction is totaled and divided by 60 to arrive at the number of continuing education contact hours.

A continuing education activity must be a minimum of 30 minutes in length in order to be an activity for which participants are awarded continuing education contact hours. Sessions within an activity, however, may be of any length. The council anticipates that a minimum of a 15 minute break will be provided every four hours.

~~As indicated on pages 9-10, continuing education contact hours are allowed for a wide range of educational activities, including:~~

- ~~• faculty led classroom or meeting time, regardless of whether faculty and participants are in the same location or whether the activity is conducted at the same time but in different locations as through satellite broadcasts, teleconferencing, or electronic communications media (e.g., web-based conferences)~~
- ~~• activities in which the participant is engaged in a planned learning experience whereby his or her progress is monitored or the participant receives feedback from faculty (e.g., CD, DVD, web-based conferences, computer-assisted instruction, etc.)~~
- ~~• grand rounds (regularly scheduled conferences)~~
- ~~• laboratory work~~
- ~~• homework assignments that are an integral part of a course; and discrete, self-directed learning activities~~

~~No continuing education contact hours are allowed by sponsors for non-instructional activities including, but not limited to:~~

- registration
- introductory or welcoming speeches
- announcements
- committee business or reports
- exhibit attendance
- unsupervised independent study or assigned reading, travel, meals, breaks, and social gatherings

Specific to continuing education ~~activities~~ ~~courses~~, no continuing education contact hours are allowed for participants' completion of examination and evaluation processes. Instruction presented during a meal function may be counted toward the total number of continuing education contact hours.

~~Calculation of continuing education contact hours for activities presented through instructional media is based upon the format of the media. If a combination of instructional media is used within a single activity, the number of continuing education contact hours awarded for the activity is the total amount of continuing education contact hours granted for all aspects of the activity.~~

~~For other forms of self-paced instructional media (e.g., books, journals, and computer-assisted instructional programs), the sponsor is expected to establish a justifiable, standard amount of continuing education contact hours to be granted for completion of each activity based on an average number of hours required of several representative participants (pilot group) to complete the activity. Members of the pilot group must not have participated in development of the activity. The sponsor is expected to continue to monitor the amount of time required for participants to complete the activity and to make adjustments in the amount of continuing education contact hours as necessary. A process of ongoing validation affords credibility to the standard determined by the sponsor.~~

~~A pilot group used to validate the amount of time required to complete the final examination associated with instructional media activities may be granted continuing education contact hours. No continuing education contact hours are granted for completion of the pretest (if utilized as part of the activity).~~

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