NYU LONG ISLAND SCHOOL OF MEDICINE

NYU Winthrop Hospital

Responsibilities of a CME/CE/CPD Activity Director

The **Course/Activity Director** generates the educational content for an activity which has intrinsic academic validity, and falls within the spectrum of medicine, nursing, or other clinical practice conducted by professional healthcare providers. S/he has prime responsibility for designing a curriculum which fosters improving knowledge, skills and/or attitudes that support practice-based learning and improvement. **Specific responsibilities include*:***

_____1. **Aligning the activity** with the NYULISoM@WH Continuing Professional Development Advisory Committee's Mission Statement.

_____2. **Documenting a needs assessment** with underlying professional practice gaps of the learners, and citing evidence for the gaps, and providing this to the fundraising team as needed.

_____3. **Establishing overall course objectives,** and where applicable, subsidiary learning objectives, to meet the identified needs.

_____4. **Appointing the Activity Planning Committee** (all personnel with any control over content) and identifying them to the CME Office, including Course Directors(s), Planners, Presenters, Moderators, Authors, and **initiating the Pre-Planning Disclosure Process prior to planning the content.**

_____5. **Validating clinical content,** to ensure that it is balanced, objective, scientifically rigorous, evidence-based and independent of commercialism, namely:

_____a. All recommendations involving clinical medicine or clinical practice in the CME/CE/CPD activity are **based on evidence** that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients; and

_____b. All scientific research referred to, reported or used in the CME/CE/CPD activity in support or justification of a patient care recommendation conforms to the **generally accepted standards** of experimental design, data collection and analysis.

_____c. **Resolving Conflicts of Interest** that arise in the planners and faculty, according the NYULISoM@WH "Standards of CME Review and Content Validation".

_____d. Where the Activity Director has commercial relationships with ACCME – defined Commercial Interests (including manufactures and marketers of therapeutics, and diagnostics), **s/he must appointing a non-conflicted**

Independent Reviewer who will perform CME course content validation course content and resolve Conflicts of Interest.

_____**e. At no time will the CME/CE/CPD activity promote recommendations or treatments which are known to have risks or dangers that outweigh the benefits,** or are known to be ineffective in the treatment of patients with the clinical problem being addressed. **Incorporating critical review of evolving topics** into the curriculum is strongly encouraged. **Off-label recommendations must be identified to learners.**

_____f. **All presentations are HIPAA compliant** and respectful of patients and their families.

_____6. **Prioritizing learning,** so that social events do not compete with or take precedence over the educational activity

_____7. **Designing educational interventions**, methods and formats that:

a) Are intended to change competence, performance or patient outcomes
b) Match the learners' current or potential scope of professional activities

_____8. **Managing individual speakers and moderators**. To do this, Course Director will:

a) ***Initiate contact*** with speakers, planners, moderators prior to follow-up confirmation by the CME Office
b) ***Maintain control*** over instructional content, selection of speakers, topics
c) ***Oversee/negotiate honoraria*** amounts paid to guest faculty, based on NYUWH CME honorarium policy.
d) ***Facilitate the Speakers Disclosures process*** as initiated by the CME Office
    i. No later than one month in advance of the course start date;
    ii. Conflicts of interest resolved and documentation in the CME Office no later than 2 weeks prior to the course start date;
    iii. Disclosures and review forms submitted electronically or paper copy
e) ***Implement NYUWH mechanism for resolving potential conflicts of interest*** for those reporting relevant relationships:
    i. **Faculty Disclosure Analysis Form for Speakers** and Content Review Form, when content review is selected as the mechanism to resolve the conflict
    ii. **CME Conflict of Interest (COI) and Resolution and Content Validity** Resolving Conflicts of Interest for Planning Committee Members' - review form for Planners

_____9. **Submitting all course marketing communication materials to the CME Office for approval** prior to publishing, electronic dissemination, or mailing

_____10. **Nominating suggested fundraising sources** for solicitation by the CME Office, including commercial support grants and commercial exhibitors.

_____11. **Allowing the CME Office solely to manage all fundraising activities**, commercial support, exhibit vendors, and advertising sales in compliance with WHU CME policies, Sunshine Act, and/or Accreditation Council for Continuing Medical Education (ACCME) Standards of Commercial Support:

_____a. Assuring that commercial support will be communicated to learners in written format.

_____b. All commercial support is given with CME Office knowledge and approval

_____12. **Maintaining the separation of promotion and education**

c) Ensure that appropriate arrangements are in place for exhibitors, and that exhibitor activities are kept separate from education and kept out of the educational space

_____13. **Keeping within budgetary constraints** for guest faculty honoraria and expenses such as travel, lodging, and meals.

_____14. **Following Required Milestones of CME/CE/CPD Course Planning.The purpose of this section is to delineate the schedule of deliverables and their dates due to the NYUWH CME office.** Prior to the Course Date or online start date, these deliverables must be submitted at various milestones:

_____a. **Complete Curriculum Planner** (including a Needs Assessment citing evidence basis, learning/practice gap analysis, measureable learning objectives and an outcomes measurement strategy) must be received by the CME Office prior to any course announcement or promotion. – due 26 weeks prior to the activity date

_____b. First-time courses may NOT book any NYU conference center space or consider the activity date to be confirmed **until the initial Curriculum Proposal for that activity has been approved by the CME Office**

_____c. **Any and all Save-the-Date materials, brochure, and web site must receive CME Office written approval** *prior to printing or going live on web, email, printing or any other written promotion of the activity*, but at least 12 weeks prior to the activity date

_____15. **Assuring that the CME Office receives materials for Compliance review** NO LATER THAN 14 calendar days prior to course start date:

_____a. **Completed Disclosure documents** for all planners and faculty

_____b. **Speaker Presentation Materials (Slides)** must be substantially complete (>95%) at the time of Compliance Review

_____c. **Resolution of Conflict of Interest management forms** must be completed for all planners and faculty who have a disclosed relationship with a commercial interest

_____d. **Letters of Agreement for Commercial Support** (Grants)

_____e. **Draft syllabus/course materials for approval** prior to printing –

_____f. **Honorarium Guest Lecturer/Performer** Agreement (if applicable)

_____g. **Speaker Authorization to audio or video record** speaker presentation – if applicable, is due 7 NO LATER THAN calendar days prior to the start of the activity

_____16. **Evaluating Course planning cycle** for effectiveness and improvement after Course completion:

_____a. CME Office will prepare attendance statement, and exit survey results for the Course Activity Director, within 30 days after course completion use it to issue a Learning Outcomes Report

_____b. Course Activity Director will review exit survey data and/or follow-up survey data from learners, and use it to issue a Needs Assessment Progress due 45 days after course completion

_____c. Post Meeting –CME Office will meet with Course Activity Director within 60 days after course completion to discuss End of Course Review and how to build upon lessons learned in preparation for future courses.

My signature below indicates that I have read, understand, and accept all the duties of CME Activity Director, as described above:

Name of Activity I will Direct:_____

Date(s) of Activity I will Direct:_____

Name:_____

Signature:_____

Date of Term: From _____20_____ to_____20_____

NYU Winthrop Hospital

NYU LONG ISLAND SCHOOL OF MEDICINE

CME/CE Activity Directors Toolkit:

I. Getting Started: (upon course Kickoff, 7-9 months prior to course date)

A. Assign Roles

_____1. Complete your own Financial Disclosure, and direct your planning team members to complete theirs as well
_____2. Read, Understand, Sign and Return the Activity Director Letter of Responsibility
_____3. Return all Disclosures immediately to the CME Office
_____4. Convene a Curriculum Planning Team meeting
_____5. Analyze disclosures for Conflict of Interest, map any needed recusals, find replacements
_____6. Identify a Content Validation Reviewer and Conflict Resolution Reviewer and ask them to execute Reviewer Letters of Responsibility
_____7. Verbally contact proposed speakers/ instructors, and collect their Financial Disclosures
_____8. Analyze Speaker disclosures for Conflict of Interest and plan for recusals/replacements

B. Develop the Course Proposal

_____9. Develop a Timed Agenda for the Course, with topics, timespans, (and speakers if known)
_____10. Identify your target audience(s) for the course
_____11. Gather/Document your Courses Needs Assessment Data
_____12. Develop your Course's Learning Objectives, specific to your audience's scope of practice
_____13. Design an Outcomes Measurement strategy (assessment, quiz, test, survey, chart-audit)

C. Develop a funding plan for your Course:

_____14. Estimate course expenses (large costs are speakers, travel, meals/venue rental, printing)
_____15. *(Optional)* Identify grantors/sponsors and target dollars for each
_____16. *(Optional)* Identify prospective paid exhibitors and target sales revenue
_____17. Identify registration pricing levels.
_____18. Project a Break-Even Budget including all estimated expenses and revenues
_____19. Choose a Financial Management Model for your Course **(more info here)**

II. Submit your Course Accreditation Application to the CME office (6-7 months prior)

_____20. Consider an accreditation verbal Interview, but bring all the above materials
_____21. Apply for other and non-physician credit types (ANCC, CEU, MOC, other clinical CE)
_____22. Be available to answer follow-up questions from the CME office, **and await the determination of the CME Office of eligibility(2 weeks)** for the credits requested

III. *Upon receiving your credit notification from the CME Office (but not before),*

D. Plan and Promote your Course (5 months prior to course)

_____23. Book your venue,
_____24. Rent commercial mailing lists of target audiences, if appropriate
_____25. Send all speakers/instructors a Confirmation Letter, with presentation and assessment due dates, speaker expectations, and conflict resolution procedures
_____26. Finalize your agenda, Design brochure, website, and any other course promotion materials **(4 month prior to course)**
_____27. Contact your Fundraising Team in the CME office and provide them with ALL of the above items, to be used to construct a successful academic grant-writing campaign
_____28. Open registration on the course website
_____29. CME Office exclusively submits all grants, receives and disburses all grant awards. **Activity Director and content planners are not permitted do this.**
_____30. CME Office exclusively contracts with all paid exhibitors**. Activity Director and content planners are not permitted to do this.**
_____31. Print your brochures **(3 months prior to course)**
_____32. Develop Course format and optimize layout of the instructional venue for active learning

E. Content Validation (1 month prior to course)

_____33. Collect Speaker Presentations
_____34. Review for Commercial Independence
_____35. Assign to Reviewer for Content Validation
_____36. Assign Assessments for Peer Review
_____37. Resolve Conflicts of Interest, **and request speakers modify presentations as needed**
_____38. Produce final versions of presentations that communicate disclosures or lack thereof
_____39. Produce final version of assessments, quizzes, polls, tests
_____40. Confirm with Vendors and suppliers (Two weeks prior to course)
_____41. Finalize Catering Contracts
_____42. (if provided)Finalize Lodging, Travel, transportation
_____43. Finalize Course Audiovisual plan

F. On the Course Date

_____44. Register, check-in, or attest attendance from all participants
_____45. Monitor vendors for code of conduct, and separation of promotion from education
_____46. Supervise speaker adherence to timed agenda
_____47. At exit or within 24 hours, send Evaluation survey and assessment to learners

G. Post-Course (< 30 days after course)

_____1. Reconcile all expense and income to budget
_____2. Analyze tabulated evaluations and determine learning outcomes attained
_____3. Meet with planning team to convey survey results and debrief on next-cycle improvements

Required Content Validation Steps for CME activities

1. ☐ prior to Course receiving CME recognition, Activity Director completes Financial Disclosure
   - **a)** ☐ **If Activity Director has Commercial Relationships that are relevant to the teaching content,** this constitutes a Conflict of Interest(COI), therefore s/he must appoint an Independent Reviewer who has NO financial relationships, who will perform Content Validation.
     - ☐ Independent Reviewer **must complete** a Financial Disclosure prior to being appointed to review.
     - ☐ Independent Reviewer ***must NOT*** be involved in the CME content as planner or speaker
   - **b)** ☐ **If Activity Director is unconflicted**, s/he may perform the required Content Validation, following steps on the Content Validation Policy and Form, and COI Resolution. Content Validation and COI Resolution, including directing that speakers must remove biased or commercial content, should occur 1 week prior to activity.
   - **c)** ☐ Disclosures for all parties, including those with "Nothing to Disclose", **must be conveyed to learners in advance of content delivery,** and listed on course promotion flyer.

Department: **Office of Academic Affairs**
Continuing Medical Education

Policy: **CME Content Validation and Definition of CME Content**

1. Preamble

As an ACCME-accredited educational provider, NYU Winthrop Hospital shall remain in compliance at all times with ACCME requirement that "**Accredited providers are responsible for validating the clinical content of CME activities that they provide"**

A. Specifically, all the recommendations involving clinical medicine in a CME activity must be **based on evidence that is accepted within the profession of medicine** as adequate justification for their indications and contraindications in the care of patients.

B. All scientific research referred to, reported, or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

Providers such as NYU Winthrop are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment, or manners of practicing medicine that are not within the definition of 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 CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for ACCME accreditation. **Therefore, Winthrop shall avoid and eliminate advocacy of unscientific modalities.**

Definition of CME: Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

In all areas where NYU Winthrop written policy is silent, ambiguous, or non-dispositive, staff shall follow the latest version ACCME Accreditation Criteria 7 SCS1.

Procedural requirements

All CME Content must be reviewed (prior to activity occurring) for clinical content validation by a qualified clinician or scientist. This should be the Course Activity Director, her/his supervising clinical chair or designee of that chair, or a qualified house office of PGY-3 or higher. Clinical Content Review shall be documented using the Clinical Content Review Attestation Form.

Date Issued: June 2018

Steps to Operationalize the Peer Review Requirement:

A. Peer reviewer must be appointed by the CME office

B. Peer reviewer cannot have any relevant commercial relationships

C. **Peer reviewers may not have a direct-reporting employment relationship** to any author, speaker or activity director in control of CME course content. *(This includes house staff when materials to be reviewed were authored by their supervising program faculty)*

D. **Peer reviewers must have adequate time to conduct peer review:**

1. Authors must submit materials to CME office 3-4 weeks prior to course date (No "night-before" slides syndrome!)
2. CME office must provide review materials to content reviewer 3 weeks prior to course date
3. Content Reviewer must submit completed reviewer feedback at least 1-2 weeks prior to course date
4. COI management shall be completed by CME office 1 week prior to course date

Content Reviewer Duties include examination of presentations using four standards: **Evidence Based Science, Fair-Balance, Non-commercial, Non-promotional.** Specific examination duties of the Content Review shall document that the reviewer was able to:

A. Attest whether Presentation does or does not contain a prefatory disclosure slide:
B. Attest whether Presentation does or does not contain brand names or product logos of commercial Tx, Rx or Dx or devices used in diagnosing or treating patients
C. Attest whether Presentation does or does not use scientific or general class names when referring to commercial products
D. Attest whether Presentation promotes or emphasizes any branded product over its market peers and competitors and biosimilars or bioequivalents
E. Attest, when overemphasis on a branded product is found, whether the speaker discloses a relationship with this product's manufacturer?
F. Attest whether Presentation makes off-label recommendations, referencing uses of drugs or devices for indications not approved by FDA
G. Describe any off-label product uses that are reference
H. Attest whether Presentation cites published source evidence (preferably in peer-reviewed reference) for each scientific assertion it makes
I. Annotate where published evidence or citation for assertions is lacking.

Date Revised: February 2019
Addendum Approved By CPE Governance Committee: Feb 5, 2019

CME-CE Annual Disclosure Form

For Faculty, Planners, Course Directors, Managers, and Independent Reviewers of Content (ACCME Required)

Name _____Mobile Phone_____

E-mail _____ Title of Presentation:_____

Affiliation/Title/Institution(attach a CV please):_____

Live Presentation Date: _____Online Module Start Date: _____

Please indicate your role in this CME-CE activity:

☐ Speaker ☐ Planner/Activity Director ☐ Independent Reviewer (ICR)

A. DISCLOSURES

Have you (or your spouse/partner) had a relevant financial relationship with, and/or received or anticipate any form of remuneration from, in the last 12 months with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients?

Yes ☐ No ☐ If "YES", please list your disclosures:

Check Relevant Boxes	***Type of Financial Relationship (within the past 12 months) Include spousal/life partner relationships***	***Indicate Applicable Healthcare Manufacturers or Commercial Entities by Name***
☐	Salary, Royalty, or Honoraria	
☐	Receipt of Intellectual Property Rights / Patent Holder	
☐	Consulting Fees (e.g., advisory boards)	
☐	Speakers' Bureaus	
☐	Supported/Contracted Research	
☐	Ownership Interest (stocks, stock options, or other ownership interest excluding diversified mutual funds)	
Required by WUH Policy	***Indicate the dollar amount of remuneration from the above relationships for the past 12 months.***	**$**

B. ATTESTATIONS/DECLARATIONS: *Initial below to acknowledge/ agree to ALL items*

____As a planner, I will ensure that any speakers or content I suggest is independent of commercial bias.

____As a planner, I will recuse myself from planning activity content in which I have a conflict of interest.

____In my role as a planner or speaker at a Winthrop-accredited CME-CE activity, I agree to plan/ present only valid, balanced, independent, objective, and scientifically-based educational content that is free of commercial bias and influence. I agree to comply with all ACCME Standards of Commercial Support and all Federal requirements to protect health information under the Health Insurance Portability & Accountability Act of 1996 (HIPAA). I agree to resolve any relevant conflicts of interest that the CME Office identifies via this disclosure **prior** to the activity, and to comply with ACCME, ANCC and Winthrop CME-CE compliance policies.

____ As a speaker, I agree to disclose to learners any discussion of unapproved products or devices, or off-label use of FDA approved products or devices.

Signature_____Date_____

Please return completed form to: Peter Sandre, Office of CME, 222 Station Plaza North, Suite 510 or via scan and email to peter.sandre@nyulangone.org

Peer Reviewer Documentation Form (page 1 of 4)

NYU Winthrop Hospital

Name of Peer Reviewer:_____

Email of Peer Reviewer:_____

Name of CME Activity: _____

Date of CME Activity: _____day,_____/_____/20____.

Date Content Review is Assigned: _____day,_____/_____/20____.

Date Content Review is Due for Completion: _____day,_____/_____/20____.

Peer Reviewer: Please complete pages 3, 4 , and 5 for EACH presentation you've been assigned to review.

Scope of Review

Reviewer is assigned ___Slide Presentations authored by: _____@_____.____

Reviewer is assigned ___Assessment Questions, authored by: _____@_____.____

Learning Objectives of the activity:_____

_____

_____

Peer Reviewer Attests that (please initial next to each item to attest)

_____1. This Presentation ___does/___does not **contain a prefatory disclosure slide**.

_____2. This Presentation ___does/___does not **contain brand names or product logos of commercial Tx, Rx or Dx or devices** used in diagnosing or treating patients.

_____3. This Presentation ___does/___does not **use scientific or general class names** when referring to commercial products, drugs and devices.

_____4. When mention of a branded product is found in the presentation, the speaker ___has/___has not **disclosed a relationship with this product's manufacturer**.

a. *Please list all slide numbers wherein a branded product name, logo, or manufacturer appears* _____
_____

_____5. This Presentation ___does/___does not **make off-label recommendations** for drug or device indications unapproved by FDA

a. Describe any off-label product uses that are referenced in the presentation, and the slide or page number: _____
_____

_____6. This Presentation ___does/___does not promote or emphasize any branded product over its market peers, competitors, biosimilars or bioequivalents. If so, list the slide numbers where this appears:_____

_____7. This Presentation cites published source evidence (preferably in peer-reviewed reference) for each scientific assertion it makes

a. Please list all slide numbers where therapeutic asserts lack citation:
_____
_____ *(continued, next page)*

NYU Winthrop Hospital
Continuing Medical Education

CME-CE RESOLUTION OF CONFLICT OF INTEREST and Content Review Attestation
Return to Office of Academic Affairs Prior to the Activity

Activity:_____**Date:**_____

Faculty Name:_____

Title of Presentation:_____

Name of Reviewer:_____

A. CONTENT VALIDATION:

☐ The faculty member will submit presentation materials in advance to allow for adequate peer review.

☐ I reviewed the CME-CE presentation and it meets all the following criteria: a) content is valid and aligned with the interests of the public; b) all recommendations involving clinical medicine are based on the best available evidence and referenced; c) all scientific research referred to, reported, or used in the CME-CE activity in support or as justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection and analysis.

B. CONFLICT RESOLUTION: I have reviewed the speaker's individual disclosure statement and resolved his/her conflicts of interest by the following methods (Check all that apply):

☐ The faculty member will or have divested his/herself from this financial relationship.

☐ The relationship(s) disclosed were determined not to be relevant to the CME-CE presentation.

☐ I have assigned the faculty member to present on a different topic.

☐ Elimination: I have eliminated the speaker from participating in the CME-CE activity.

☐ The faculty member will recommend an alternative presenter for this topic for the planning committee's consideration.

☐ I have altered, or directed the speaker to alter, the CME-CE content of the presentation, including recommendations for patient care, to conform to WUH content validation standards stated above.

☐ The faculty member will refrain from making recommendations, regarding products or services, unless all relevant products or services applicable to the same procedure or treatment are presented in an unbiased manner.

☐ **Other Resolution mechanism (please describe):**_____

Is the faculty member approved as speaker/instructor for the activity? ☐ **Yes** ☐ **No**

Signature of Reviewer: I attest to the accuracy of this form and the integrity of the content as complying with ACCME standards.

_____**Date:**_____

Activity Director or Delegate

The ACCME Standards for Commercial Support:
Standards to Ensure Independence in CME Activities℠

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a "commercial interest" and some exemptions.)

(a) Identification of 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 CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint provider.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

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

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4: Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring

(printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For **computer based CME activities**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content. Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.
- For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For l**ive, face-to-face** CME, advertisements andpromotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.
- For **Journal-based CME,** None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.⌘

STANDARD 6: Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

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

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.⌘

ACCREDITATION CRITERIA

Initial applicants seeking to achieve Provisional Accreditation, a two-year term, must comply with Criteria 1, 2, 3, and 7–12. Providers seeking full Accreditation or reaccreditation for a four-year term must comply with Criteria 1–13. Providers also have the option to aim to achieve Accreditation with Commendation, a six-year term. Providers that are receiving accreditation decisions through November 2019 have the choice of using either Option A: Commendation Criteria (C16-C22) or Option B: Menu of Commendation Criteria (C23-C38) to seek Accreditation with Commendation. Providers that will receive accreditation decisions after November 2019 must use Option B to seek Accreditation with Commendation. More information on Accreditation with Commendation options is available here.

Criterion 1 The provider has a CME mission statement that includes expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

Criterion 2 The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.

Criterion 3 The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.

Criterion 4 This criterion has been eliminated effective February 2014.

Criterion 5 The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity.

Criterion 6 The provider develops activities/educational interventions in the context of desirable physician attributes [eg, Institute of Medicine (IOM) competencies, Accreditation Council for Graduate Medical Education (ACGME) Competencies].

Criterion 7 The provider develops activities/educational interventions independent of commercial interests. (SCS 1, 2, and 6).

Criterion 8 The provider appropriately manages commercial support (if applicable, SCS 3 of the ACCME Standards for Commercial Support[SM]).

Criterion 9 The provider maintains a separation of promotion from education (SCS 4).

Criterion 10 The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).

Criterion 11 The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions.

POLICIES SUPPLEMENTING THE STANDARDS FOR COMMERCIAL SUPPORT

COMMERCIAL EXHIBITS AND ADVERTISEMENTS

Commercial exhibits and advertisements are promotional activities and not continuing medical education. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered to be *commercial support*. However, accredited providers are expected to fulfill the requirements of SCS 4 and to use sound fiscal and business practices with respect to promotional activities.

COMMERCIAL SUPPORT: ACKNOWLEDGMENTS

The provider's acknowledgment of commercial support as required by SCS 6.3 and 6.4 may state the name, mission, and areas of clinical involvement of an ACCME-defined commercial interest but may *not* include corporate logos and slogans.

COMMERCIAL SUPPORT: DEFINITION AND GUIDANCE REGARDING WRITTEN AGREEMENTS

Commercial Support is 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.

When there is commercial support there must be a written agreement that is signed by the commercial interest and the accredited provider *prior* to the activity taking place.

An accredited provider can fulfill the expectations of SCS 3.4 - 3.6 by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.

A provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the accreditation requirements.

Definition of a Commercial Interest

A *commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

A commercial interest is not eligible for ACCME accreditation. Commercial interests cannot be accredited providers and cannot be joint providers. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501-C Non-profit organizations (Note, ACCME screens 501c organizations for eligibility. Those that advocate for commercial interests as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- Government organizations
- Non-health care related 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

ACCME reserves the right to modify this definition and this list of eligible organizations from time to time without notice.

Disclosure of Financial Relationships to the Accredited Provider

Individuals need to disclose relationships with a commercial interest if both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

Financial Relationships and Conflicts of Interest

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

With respect to personal **financial relationships**, *contracted research* includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

The ACCME considers **financial relationships** to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest. The ACCME considers "content of CME about the products or services of that commercial interest" to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

With respect to **financial relationships** with commercial interests, when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest, but it must be disclosed to the learners for 12 months.

Verbal Disclosure to Learners

Disclosure of information about relevant financial relationships may be disclosed verbally to participants at a CME activity. When such information is disclosed verbally at a CME activity, providers must be able to supply the ACCME with written verification that appropriate verbal disclosure occurred at the activity. With respect to this written verification:

1. A representative of the provider who was in attendance at the time of the verbal disclosure must attest, in writing:
    a. that verbal disclosure did occur; and
    b. itemize the content of the disclosed information (SCS 6.1); or that there was nothing to disclose (SCS 6.2).
2. The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.