Purpose and Background
The MSU College of Human Medicine (CHM) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education (CME) for physicians. The Office of Continuing Medical Education (OCME) is the administrative unit at CHM responsible for ensuring compliance with the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support (SCS), as well as other regulations and policies as they relate to the provision of CME.

The MSU College of Human Medicine Office of CME requires that the following policies and procedures be followed throughout the development and implementation of CME activities. The following requirements are in addition to the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education.

Independence
1. Final authority for all areas relating to the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education will be retained by the OCME.
2. All faculty, meeting, and marketing logistics are to be appropriately handled by OCME staff or their designee(s). Representatives from a commercial interest cannot provide meeting planning or faculty coordination functions.
3. Information on the identity of learners at CME activities is considered to be confidential and the property of OCME. Information on learners will not be released to third parties.

Identification and Resolution of Conflicts of Interest
1. OCME is required to have a mechanism to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners. Therefore, all individuals who are in a position to control the content of an educational activity must complete an attestation that they have read and agreed to abide by this policy and that any and all clinical recommendations that they make for patient care as part of their planning and/or CME presentation/activity materials will be based on the best available evidence, that they will give a balanced view of therapeutic options, and that the content will be in accordance with ACCME’s Content Validation Statement.
2. Mechanisms to resolve conflicts of interest include but are not limited to:
   a) An individual without a conflict of interest replaces the conflicted individual.
   b) The conflicted individual renounces the relationship(s) with the commercial interest(s).
   c) The scope of the conflicted individual’s role is restricted (the conflicted individual will not be determining content and/or making recommendations for clinical practice).
   d) The conflicted individual attests in writing that recommendations s/he will make for clinical practice will be based upon data derived from multiple randomized clinical trials or meta-analyses and s/he will disclose this to learners.
d) The CME materials (presentation, monograph, etc.) prepared by the conflicted individual will be peer reviewed for content validation and fair balance (and modified accordingly, if need be).

3. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity (ACCME Standard 2.3).

### Appropriate Use of Commercial Support

1. The Executive Director is the only allowed signatory for all corporate educational grant’s letter of agreements. The department or joint sponsor is responsible for submitting grant letter of agreements for commercial support to OCME for review and approval.

2. The source of all support from commercial interests must be disclosed to learners prior to the activity occurring. When commercial support is ‘in-kind’ (e.g., provision of equipment) the nature of the support must be disclosed. In order for commercial support acknowledgement to be made, the letter of agreement must be signed by both the commercial supporter representative and OCME prior to printing/production/activity.

3. In the case of jointly or cosponsored activities, the grant letter of agreement will delineate the joint/ co-sponsor’s name and contact information.

4. In the event there are social events or meals at CME activities, they cannot compete with or take precedence over the educational event(s) and should comply with the American Medical Association’s Guidelines on Gifts to Physicians: E-8.061 (http://www.ama-assn.org/).

### Appropriate Management of Associated Commercial Promotion

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.

2. Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support). Exhibitors should sign OCME’s Hold Harmless Letter of Agreement.

3. Exhibit fees shall be set by OCME for each activity and will be standard for that activity; potential exhibitors shall have equal access to purchasing exhibit space (first come-first serve).

4. All exhibitors must be in a room or area separate from the educational activity and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the CME activity.

5. Commercial interest representatives may attend CME activities at the discretion of OCME for the direct purpose of the representatives’ own education; however, they may not engage in sales or marketing activities while in the space or place of the educational activity.

6. OCME will not utilize a commercial interest as the agent providing a CME activity to learners; e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. Distribution of CME activity brochures by representatives of a commercial interest may be allowed by OCME if said distribution is not the sole marketing method, and
commercial interest has signed a grant agreement in support of the activity, and OCME has sent a formal request letter to the commercial interest requesting this assistance.

Content Validation and Fair Balance
1. All sponsored CME activities will comply with ACCME’s Content Validation Statement.
   a) All recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contra-indications in the care of patients.
   b) All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

2. Activities that promote recommendations, treatment, or manners of practicing medicine or pharmacy that are not within the definition of CME or, are known to have risks or dangers that outweigh the benefits or, are known to be ineffective in the treatment of patients will not be certified for credit.

3. Presentations and CME activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CME educational materials or content includes trade names, where available, trade names from several companies must be used.

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

Faculty Honoraria and Travel Reimbursement
1. Honoraria amounts will be negotiated by the OCME or joint sponsor taking financial responsibility for the CME activity and shall be based on fair market value with the realization that the amounts will vary with the specialty, subspecialty, speaker qualifications, length and number of presentation(s), nature of the conference, preparation time, and travel time.

2. No individual involved in a CME activity may receive payment directly from a commercial interest for honoraria, travel, or out-of-pocket expenses.

3. OCME will approve the amount and source of the honoraria and estimated travel expenses prior to the CME activity by reviewing the activities projected budget.

4. Directly sponsored CME activity faculty/authors/content validation reviewers who are employees of MSU will be paid their honoraria in accordance with the MSU Financial Services policy (MSU Outside Work for Pay Policy).

5. Reimbursement or prepayment of travel expenses for faculty (speaker, presenter, moderator, panel member) of MSU certified CME activities must be in compliance with MSU Travel
Center’s Policies (MSU Travel Center’s Policies) and the ACCME Standards for Commercial Support of CME.

**Auditability**
1. For directly sponsored CME activities, CHM Departments are responsible for maintaining auditable records in accordance with MSU policies and procedures.
2. For jointly/cosponsored activities, the joint/cosponsor is responsible for maintaining auditable records and providing a detailed final budget to OCME.

**Joint/Co-Sponsorship**
1. A commercial interest cannot take the role of non-accredited partner in a joint/co-sponsorship relationship.
2. Jointly sponsored activities must be consistent with OCME’s mission and purpose statements.
3. A faculty member from CHM must review and approve the proposed activity.
4. OCME must review and approve all materials associated with the activity prior to their release. Once materials have been reviewed and approved by OCME, no further changes can be made.
5. Any and all funds solicited on behalf of a CME activity must either (a) be received by OCME, or (b) be delivered to the joint sponsor with OCME’s written authorization.
6. The responsibilities and role of the joint sponsor will be clearly delineated in a letter of agreement between the joint sponsor and OCME. OCME has the right to withdraw from any activity if the joint sponsor fails to meet its obligations as described in the letter of agreement or fails to comply with OCME policies and procedures. In addition to the aforementioned letter of agreement, joint sponsors must be in compliance with HIPAA regulations.
7. The joint sponsor shall submit a projected budget for each CME activity to OCME for review and approval. OCME will review the projected budget to ensure that adequate resources have been devoted to the development of an activity consistent with meeting the activity’s objectives. OCME will withdraw from an activity if resources are inadequate for the development of a high quality educational product or activity.
8. At OCME’s discretion and with written authorization, the joint sponsor may solicit funds under the direction of OCME but may not make any representations or commitments to commercial supporters as to educational content, choice of speakers, learning objectives, marketing, and/or evaluation.
9. All potential joint sponsorship relationships will be examined on their individual merits. Although all CME activities joint sponsored with OCME must comply with this policy, OCME reserves the right to refuse to enter into a joint sponsorship agreement for any reason whatsoever, regardless of that organization’s willingness to comply with this policy.
10. OCME will charge fees for its services. These fees and the terms for its payment will be mutually agreed upon and delineated in an exhibit to the aforementioned letter of agreement between OCME and the joint sponsor.
On-line Activities
1. OCME-sponsored activities only appear on websites identified by OCME as appropriate. For example, OCME will not approve their posting on a pharmaceutical or medical device manufacturer’s website.

2. Links from OCME-approved websites to the websites of pharmaceutical and medical device manufacturers are permitted before or after the educational content of an OCME-sponsored activity, but shall not be embedded in the educational content of the CME activity. The learner must be clearly notified that s/he is leaving the educational website.

3. OCME prohibits advertising of any type within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.

4. At the start of each sponsored Internet CME activity, the hardware and software required for the learner to participate shall be delineated.

5. Sponsored Internet CME activities shall include a mechanism for the learner to contact OCME if there are any questions about the Internet CME activity. A contact for technical issues is also required.

6. Sponsored Internet CME activities must have, adhere to, and inform the learner about the site’s policy on privacy and confidentiality and said policy must be approved by the OCME.

7. OCME must be able to document that it owns the copyright for, or has received permission for use of, or is otherwise permitted to use copyrighted materials within a CME activity on the Internet.

Regularly Scheduled Series
The following requirements are in addition to the policies described above and the ACCME Essential Areas, Elements, Criteria, Policies, and Standards for Commercial Support of Continuing Medical Education.

1. In addition to the application review and approval process required for all sponsored CME activities, the OCME requires submission of information for each specific session within the series including the following items:
   a. Agenda with Speakers Identified (required prior to the session)
   b. Disclosure Forms for all speakers (required prior to the session)
   c. Learning Objectives (required prior to the session)
   d. Changes in Planning Committee since original application and corresponding Disclosure Forms (required prior to the session)
   e. Proof that each session complies with the ACCME Standards for Commercial Support (required prior to the session)
   f. Attendance Sheets (required within 30 days following the session)
   g. Session Evaluation Summaries (required within 30 days following the session)
2. Staff may perform periodic, random, on-site evaluation visits to document compliance. A summary report of the on-site evaluation visits will be kept in each RSS file.

3. Academic units and/or regional institutions that plan and execute RSS's certified by OCME are required to provide the necessary resources and staffing needed to carry-out regularly scheduled CME conferences and to fully comply with ACCME Essentials, Policies, Standards and pertinent OCME Policies and Procedures.

4. RSS planning committees are required to participate in a planning process that links identified needs, objectives, and educational format to desired results. As such, it is expected that the individuals responsible for RSS’ will take part in an annual planning cycle that documents these connections. Also, global learning objectives for an RSS series will be prepared and communicated to learners.

5. Following confirmation of compliance with ACCME Essentials, Policies, Standards and OCME Policies and Procedures, OCME will assure that records of attendance and/or participation are entered into the database. CME Credit for sessions found to be noncompliant will not be awarded and OCME will notify the Activity Director of this action. Noncompliance will be addressed with consultation and education with the Activity Director for the RSS. In the event OCME does not award CME credit for an RSS activity session or series due to noncompliance, OCME fees will not be refunded.

6. OCME will maintain participant credit records for a minimum of six years.

References
Accreditation Council for Continuing Medical Education (ACCME) Essential Areas and Elements, Criteria and Standards for Commercial Support
American Medical Association Council on Ethical and Judicial Affairs (AMA CEJA) – 8.061 Gifts to Physicians from Industry and 9.011 Continuing Medical Education
Duke University School of Medicine Office of Continuing Medical Education - CME Policy and RSC Policy
Food and Drug Administration (FDA) – Final Guidance on Industry-Supported Scientific and Educational Activities
Office of Inspector General (OIG) – OIG Compliance Program Guidance for Pharmaceutical Manufacturers
PhRMA – PhRMA Code on Interactions with Healthcare Professionals

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