Policies and Procedures
For Regularly Scheduled Series (RSSs)

PURPOSE AND BACKGROUND:
The University of Massachusetts Medical School (UMMS) is accredited by the Accreditation Council for
Continuing Medical Education (ACCME) to sponsor (designate credit) continuing medical education (CME) for
physicians. The UMass Office of Continuing Medical Education is the administrative unit at UMMS OCME
responsible for ensuring compliance with the ACCME Essential Areas, Elements, Criteria, Policies, and
Standards for Commercial Support (SCS) as well as other regulations and laws as they relate to the provision of
CME.

The ACCME requires UMMS OCME to describe and verify it has a system in place to monitor regularly scheduled
series (RSSs) for compliance with the above guidelines. ACCME expects that each session of each RSS series
be planned and implemented with the intention of being in compliance. In accordance with ACCME Policy 2003-
A-08, this Policy and Procedure exists to provide guidance for faculty and staff who plan and execute RSSs.

REGULARLY SCHEDULED SERIES (RSSs)
1. All RSSs are expected to be planned, implemented, and evaluated in compliance with the ACCME Essentials,
Policies, Standards for Commercial Support, and pertinent UMMS OCME Policies and Procedures. All RSS
sessions are expected to meet the ACCME definition of an RSS and the AMA definition of continuing medical
education (see "Definitions").

2. The emphasis of UMMS OCME's RSS oversight is a system of audit and review that will ensure there is
documented compliance with all pertinent ACCME Elements, Policies, Standards for Commercial Support,
and UMMS OCME Policies and Procedures. UMMS OCME staff will perform regular documentation audits as
well as periodic, random, on-site evaluation visits to document compliance. A summary report of the audit
findings and 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 UMMS 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 UMMS OCME
Policies and Procedures.

4. RSS activity medical directors and their departments 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 RSSs 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. RSS planners must obtain signed CME grant letters of agreement from any commercial supporter(s) of a
RSS. If commercial support is obtained, activity medical directors, or their designee, must communicate the
existence of that support to the participants PRIOR to the activity session.

6. Following an audit by UMMS OCME to confirm compliance with ACCME Essentials, Policies, Standards and
UMMS OCME Policies and Procedures, UMMS 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; UMMS OCME will notify the RSS activity medical director and staff support person of this action.
Noncompliance will be addressed with consultation and education with the activity medical director and staff
support personnel for the RSS.

7. The following critical data and information elements will be captured in UMMS OCME’s database: learner
identifier, session date, name/topic, credit designated and posted per session, unique pin number for series.

8. UMMS OCME will maintain participant credit records for a minimum of six years. UMMS OCME healthcare
providers can receive CME transcripts by contacting the Memorial Campus CME office.
IDENTIFICATION AND RESOLUTION OF CONFLICTS OF INTEREST – In addition to SCS 2:

1. UMMS OCME is required to have a mechanism to identify and resolve (manage, minimize, or mitigate) all conflicts of interest prior to the educational activity being delivered to learners; the primary mechanism is to have all individuals who are in a position to control the content of an educational activity complete an attestation that they have read and agreed to abide by this policy and that any and all clinical recommendations that they make for patient care as part of their planning and/or CME/CE presentation/activity materials will be based on the best available evidence, that they will give a balanced view of therapeutic options, and that the content will be in accordance with ACCME’s Content Validation Statement.

2. Additional and supplemental mechanisms to resolve conflicts of interest include but are not limited to:
   a) An individual without a conflict of interest replaces the conflicted individual.
   b) The conflicted individual renounces the relationship(s) with the commercial interest(s).
   c) The scope of the conflicted individual’s role is restricted (the conflicted individual will not be determining content and/or making recommendations for clinical practice).
   d) The conflicted individual attests in writing that recommendations s/he will make for clinical practice will be based upon data derived from multiple randomized clinical trials or meta-analyses and s/he will disclose this to learners.
   e) 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).

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

1. The CME/CE activity will comply with ACCME’s Content Validation Statement (Policy 2002-B-09):
   a) All recommendations involving clinical medicine in a CME/CE 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/CE 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/CE 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/CE activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CME/CE educational materials or content includes trade names, where available, trade names from several companies must be used.

OFF-LABEL USE DISCLOSURE

1. Faculty (speaker or presenter), activity medical directors, and moderators are required to disclose to the learners when products or procedures being discussed are off-label, unlabeled, experimental, and/or investigational (not FDA approved); and any limitations on the information that is presented, such as data that are preliminary or that represent ongoing research, interim analyses, and/or unsupported opinion.
REFERENCES:
Accreditation Council for Continuing Medical Education (ACCME) Essential Areas and Elements, Criteria and Standards for Commercial Support

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

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

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

PhRMA – PhRMA Code on Interactions with Healthcare Professionals
DEFINITIONS

Activity Medical Director: The UMMS OCME faculty member in charge of planning, implementing, and evaluating the CME/CE activity and who is responsible for collaborating with UMMS OCME to ensure compliance.

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

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

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/services of that commercial interest.

Continuing Medical Education (CME): Educational activities, which serve to maintain, develop, or increase the knowledge, skills, 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. (Sources: ACCME and AMA).

Continuing Education (CE): Those educational experiences that are structured, organized, and delivered in accord with professional standards and provide documentation to the public served of pharmacy practitioners’ participation in life-long professional education. (Source: Accreditation Council for Pharmacy Education).

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

Financial Relationships: Those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.
   a) Personal financial relationships: ‘contracted research’ includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.
   b) Financial relationships with commercial interests: when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.
   c) Relevant financial relationships: financial relationships in any amount occurring within the past 12 months that create a conflict of interest (per ACCME). ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant.

Learner: An individual in attendance at a CME/CE activity.

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

Regularly Scheduled Conferences (RSSs): “The daily, weekly or monthly CME activities of ACCME accredited providers that are primarily planned by and presented to the institution's professional staff. These activities are often known as ‘Grand Rounds,’ ‘Tumor Boards,’ or ‘Morbidity/Mortality Conferences.” (Source: ACCME).

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