SUBJECT: REVISIONS TO THE AOA ACCREDITATION REQUIREMENTS FOR AOA CATEGORY 1 CME SPONSORS – GLOSSARY

SUBMITTED BY: Council on Osteopathic Continuing Medical Education (COCME)

REFERRED TO:

1. RESOLVED, that the “Glossary” of the AOA Accreditation Requirements for AOA Category 1 Sponsors be APPROVED AS AMENDED.

Explanatory Statement: The Council on Osteopathic Medical Education (COCME) reviewed and amended the “Glossary” of the Accreditation Requirements for AOA Category 1 CME Sponsors.” There were no public comments on this section.

ACTION TAKEN ____________________________

DATE ________________________________
GLOSSARY

Terms used in this Manual are related to the Federal Food, Drug, and Cosmetic Act, and the Accreditation Requirements for AOA Category 1 CME Sponsors.

This list of terms has been compiled to furnish users of the document, American Osteopathic Association Accreditation Requirements for AOA Category 1 CME Sponsors, with a common terminology. The availability of the glossary, it is hoped, will lead to a clear understanding of the intent of these Requirements and Guidelines.

**Accreditation:** The standard, five-year term awarded to accredit CME Sponsors that meet the appropriate AOA CME requirements. Accreditation is awarded by the AOA Council on Osteopathic Continuing Medical Education (COCME).

**Accreditation with Commendation:** The highest accreditation status, accompanied by a five-year term of accreditation. Accreditation with Commendation is available only to CME Sponsors seeking reaccreditation, not to initial applicants. CME Sponsors must demonstrate compliance with all Accreditation Requirements to achieve Accreditation with Commendation on the first attempt.

**Accreditation Council for Continuing Medical Education (ACCME):** A nonprofit corporation based in Chicago, responsible for accrediting US institutions that offer continuing medical education (CME) to physicians and other health care professionals. The ACCME also has a system for recognizing state medical societies as accreditors for local organizations offering CME. The ACCME’s mission is to identify, develop, and promote rigorous national standards for quality CME that improves physician performance and medical care for patients and their communities. ACCME accreditation is a voluntary, self-regulatory system.

**Accreditation Cycle:** The length of accreditation awarded a CME sponsor by the COCME based on the scoring system as defined on Page 15 and can range from one to five years.

**Accreditation statement:** The standard statement that must appear on all CME activity materials and brochures distributed by CME Sponsors.

**Accredited Sponsor:** See CME Sponsor.

**Accrediting Organizations:** The FDA, in exercise of its administrative discretion, will seek to rely to the extent possible on major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers and ensure that such activities are independent and non-promotional.

**Activity:** A CME activity is an educational offering that is planned, implemented, and evaluated in accordance with the AOA Accreditation Requirements and accreditation policies.
Additional Location: A location that is geographically apart from the main campus at which the institution offers at least 50 percent of an educational program. The additional location will not have separate administration, faculty, or budgetary independence. The additional location must have a common Chief Academic Officer, faculty, budget, and curriculum with the parent COM. Students may be admitted directly to the Additional Location as their primary place of enrollment (34 CFRT §602.22).

Advertisement: Being generally applied to the universe of industry promotional activities designed to provide information on regulated products, but do not fall within the definition of labeling. The promotion of an off-label use, whether or not in a form deemed to be an advertisement, may give rise to a violation of the labeling provisions of the Act.

Associate Member: The AOA Board of Trustees may grant associate membership to the following individuals: teaching, research, administrative professional staff and employees of osteopathic physician members, colleges and healthcare facilities; or administrative personnel of the AOA or its affiliated organizations.

Attestation Form: An affidavit completed by attendees of a CME program verifying the number of credits earned for participation in the CME activity. This form may be completed electronically, so long as the accredited sponsor has evidence that the participant attended the educational program.

Branch Campus: COMs that have their institutional accreditation status from the COCA. A branch campus is any location of an institution other than the main campus which is permanent in nature, offers courses in educational programs leading to the doctor of osteopathy or doctor of osteopathic medicine degree, has its own faculty and administrative or supervisory organization, has its own budgetary and hiring authority, and may have affiliated clinical sites. These will be considered a Branch Campus and COCA may serve as the programmatic or institutional accreditor for COMs wishing to request a Branch Campus. (34 CFR §600.2)

Clinical Assessment Program (CAP): CAP is a Web-based performance measurement program which analyzes data taken directly from patient medical records.

Clinical COM Faculty: A clinical faculty member is an osteopathic or allopathic physician who has undergone a formal committee review of his/her credentials, who has been given a faculty appointment by the COM, such as Assistant, Associate, or full Professor of the relevant department. This appointment is based on merits of various academic criteria, not just a review of the applicant's CV, and it may be paid or unpaid. This is different than a preceptor, who may have been appointed based on a brief review of credentials.

Clinical Didactic Teaching: A CME activity based on the physician learner's preparation to teach in a live CME activity (classroom style).

CME Sponsor: A CME Sponsor is an institution, organization or affiliate that is accredited by the AOA Council on Osteopathic CME to present programs that qualify for AOA Category 1 CME credit.
CME Sponsors have the discretion of allowing other non-AOA accredited organizations, termed “Providers”, to conduct CME programs under their accreditation status. It is the CME Sponsor’s responsibility to ensure that the Provider's programs follow the AOA Category 1 CME Requirements.

CME Provider: A CME Provider is an organization, which is not, itself, a recognized AOA Category 1 CME Sponsor, but is authorized to offer AOA approved Category 1 CME under the direction and approval of a recognized AOA Category 1 CME Sponsor.

Commercial Bias: Content or format in a CME activity or its related materials that promotes the products or business lines of an AOA-defined commercial interest.

Commercial Interest: A commercial interest, as defined by the AOA, is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The AOA does not consider sponsors of clinical service directly to patients to be commercial interests. A commercial interest is not eligible for AOA accreditation.

Commercial support: Monetary or in-kind contributions given to a CME sponsor that is used to pay for all or part of the costs of a CME activity.

Compliance: The finding given when a CME sponsor has fulfilled the AOA’s requirements for the specific criterion in the Accreditation Criteria or policy.

Conflict of interest: The AOA considers financial relationships to create 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 potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias. See also relevant financial relationships.

Continuing Medical Education (CME): Continuing medical education consists of educational activities that 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 the 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.

Core Competencies:

1. **Osteopathic Philosophy/Osteopathic Manipulative Medicine** – Demonstrate and apply knowledge of accepted standards in osteopathic manipulative treatment appropriate to the specialty. Remain dedicated to lifelong learning and to practice habits in osteopathic philosophy and OMM.

2. **Medical Knowledge** – Demonstrate and apply knowledge of accepted standards of clinical medicine in the respective area; remain current with new development in medicine and participate in lifelong activities.

3. **Patient Care** – Demonstrate the ability to effectively treat patients and provide medical care that incorporates the osteopathic philosophy, patient empathy, awareness of behavioral issues, the incorporation of preventive medicine and health promotion.
4. **Interpersonal and Communication Skills** – Demonstrate interpersonal and communication skills that enable you to establish and maintain professional relationships with patients, families, and other members of health care teams.

5. **Professionalism** – Uphold the Osteopathic Oath in the conduct of one’s professional activities that promotes advocacy of patient welfare, adherence to ethical principles, and collaboration with health professionals, lifelong learning, and sensitivity to a diverse patient population; be cognizant of physical and mental health in order to effectively care for patients.

6. **Practice-Based Learning and Improvement** – Demonstrate the ability to critically evaluate methods of clinical practice, integrate evidence based medicine into patient care; who and understanding of research methods; improve patient care practices.

7. **Systems-Based Practice** – Demonstrate an understanding of health care delivery systems; provide effective and qualitative patient care with the system; and practice cost effective medicine.

**Co-sponsored activity:** A CME activity presented by two or more accredited sponsors. One of the accredited sponsors must take responsibility for the activity in terms of meeting AOA requirements and reporting activity data to the AOA. See also directly sponsored activity.

**Credit:** The “currency” assigned to CME activities. Physicians and other health care professionals use credits to meet requirements for maintenance of licensure, maintenance of specialty board certification, credentialing, membership in professional societies, and other professional privileges. The requirements for credit designation are determined by the organization responsible for the credit system.

**Enduring Materials:** CME activities that are printed, recorded, or accessible online and do not have a specific time or location designated for participation. Rather, the participant determines where and when to complete the activity. Examples: online interactive educational module, recorded presentation, podcast.

**Faculty:** The professionals responsible for teaching, authoring, or otherwise communicating the activity content.

**Faculty Development programs:** Faculty Development refers to those programs which focus on the individual faculty member. The most common focus for programs of this type is the **faculty member as a teacher.** Faculty development specialists provide consultation on teaching, including class organization, evaluation of students, in-class presentation skills, questioning and all aspects of design and presentation. They also advise faculty on other aspects of teacher/student interaction, such as advising, tutoring, discipline policies and administration.

A second frequent focus of such programs is the **faculty member as a scholar and professional.** These programs offer assistance in career planning, professional development in scholarly skills such as grant writing, publishing, committee work, administrative work, supervisory skills, and a wide range of other activities expected of faculty.

A third area on which faculty development programs focuses is the **faculty member as a person.** This includes wellness management, interpersonal skills, stress and time management,
assertiveness development and a host of other programs which address the individual's well-being.

Not all faculty development programs include all these areas, most of them have as their philosophy the faculty member as the driving force behind the institution; therefore, assisting that person to be as productive as possible will make the entire institution more productive.

Financial Relationships: Financial relationships are 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. The AOA considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

Gap Analysis: (See practice gap analysis).

Grand Rounds Programs: Grand rounds are an important teaching tool and ritual of medical education and inpatient care, consisting of presenting the medical problems and treatment of a particular patient to an audience consisting of doctors, residents and medical students. Grand rounds help doctors and other healthcare professionals keep up to date in important evolving areas which may be outside of their core practice. Most departments at major teaching hospitals will have their own specialized, often weekly, Grand Rounds. Grand rounds tend to present the bigger picture, including experience with patients over many years, and the newest research and treatments in an area.

Internet Enduring Material Activity: An enduring material provided via the Internet, meaning that there is no specific time designated for participation. Rather, the participant determines when to complete the activity. Examples: online interactive educational module, recorded presentation, podcast.

Internet live activity: An online course available at a certain time on a certain date and is only available in real-time, just as if it were a course held in an auditorium (i.e., webcast).

Internet On-Demand Activity: A pre-recorded online course that can be viewed at any time.

Joint Sponsorship: Sponsorship of a CME activity by one accredited and one non-accredited organization. The accredited sponsor must take responsibility for a CME activity when it is presented in cooperation with a non-accredited organization and must use the appropriate accreditation statement.

Journal-based CME activity: An activity that includes three phases: the participant reads an article in print or in a format adapted for special needs, engages in a self-directed phase stipulated by the accredited sponsor that may include reflection, discussion, or debate about the article, and completes a pre-determined set of questions or tasks related to the article content.
Labeling: Include not only product labels but also other written, printed, or graphic matter that "accompanies" a product.

Maintenance of Certification (MOC): The process by which ABMS board certified physicians maintain their time-dated certifications. MOC requires four components: Licensure and Professional Standing; Lifelong Learning and Self-Assessment; Cognitive Expertise; and Practice Performance Assessment.

Marketing: Marketing is the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large.

Noncompliance: The finding given when a CME Sponsor does not fulfill the AOA’s requirements for the specific criterion in the Accreditation Requirements or policy.

Objectives: Statements that clearly describe what the learner will know or be able to do after participating in the CME activity. The statements should result from the needs assessment data. Providers may also state the purpose of an individual activity in lieu of developing specific objectives.

Online CME: Continuing medical education obtained from various sources on the Internet.

Osteopathic Continuous Certification (OCC): The process by which AOA board certified physicians maintain their time-dated certifications. OCC requires five components: Unrestricted Licensure; Lifelong Learning/Continuing Medical Education; Cognitive Assessment; Practice Performance Assessment and Improvement; and AOA Membership.

Osteopathic Faculty: The following shall be considered osteopathic faculty: 1) Osteopathic Physicians, 2) MDs, PhDs, and other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine, 3) Presenting employees of the American Osteopathic Association or AOA component society staff who hold a graduate degree and clinical faculty.

Osteopathic Graduate Medical Educator (OGME): Full-time clinical faculty of OGME Programs.

Osteopathic Recognition – An extra designation secured by ACGME-accredited programs that offer training in osteopathic manipulative medicine and the osteopathic philosophy.

Outcome Measurement: The tabulation, calculation or recording of activity or effort that can be expressed in a quantitative or qualitative manner (when attempting to measure shifts or progress toward desired levels of quality).

Osteopathic Principles and Practice (OPP): The fundamental approach to patient health and wellness guided by the tenants of osteopathic medicine.

Participant: An attendee at a CME activity.
Performance Improvement CME: An activity based on a learner’s participation in a project established and/or guided by a CME provider. A physician identifies an educational need through a measure of his/her performance in practice, engages in educational experiences to meet the need, integrates the education into patient care, and then re-evaluates his/her performance.

Physician: A physician is a healthcare provider who is licensed to practice medicine and surgery in all its branches. In the United States, osteopathic physicians DOs and allopathic physicians MDs are the two recognized types of physicians under this definition. This type of physician is also described as having full practice privileges, and is sometimes referred to as a “complete” physician. Each state will have laws which define the practice privileges of various healthcare providers and which may permit these providers to use the physician descriptor when referring to their practices.

Planning Process: The method(s) used to identify needs and assure that the designed educational intervention meets the need(s) and produces the desired result.

Practice Gap Analysis (Needs Assessment): A practice gap analysis is an analysis of the type of CME that is needed by the intended audience for a CME program, which has been proposed or conducted. The results of practice gap assessments are used in the design and planning of the content and delivery modality for CME programs. There are four criteria that must be met when requesting AOA Category 1-A or Category 1-B credit for approval.

Probation: Accreditation status given to accredited sponsors that have serious problems meeting AOA requirements. Probation may also be given to providers whose document surveys are rejected. The accredited sponsor is allotted 10 working days to correct the noncompliance issues in order to achieve accreditation status before submitted to the AOA Council on Osteopathic CME. While on probation, a sponsor/provider may not sponsor/jointly sponsor new activities.

Program: A formal educational program presented.

Program Sponsor: A program sponsor is an organization that is recognized by non-AOA accredditor and/or offers CME programs recognized by non-AOA organizations. An example of one suchaccrediting agency is the Accreditation Council for Continuing Medical Education (ACCME) that accredits CME sponsors, but does not approve individual programs. The American Academy of Family Physicians (AAFP) approves individual programs, but does not accredit sponsors.

Provider: A non-AOA accredited organization that provides CME programs under the discretion and approval of an AOA Accredited Category 1 CME Sponsor.

Reduction: The act of decreasing a physician’s CME requirement based on individual mitigating circumstances.
Regularly Scheduled Conferences (RSC's): A course is identified as an RSC when it is planned to have 1) a series with multiple sessions that 2) occur on an ongoing basis (offered weekly, monthly, or quarterly) and 3) are primarily planned by and presented to the accredited organization’s professional staff.

Regulated Industry: Persons or entities that manufacture, sell, or conduct research on human and animal drugs, biological products, and medical devices.

Safe Harbor: Scientific and educational activities that are supported by the regulated industry but are independent of promotional influences that may emanate from the supporting companies. Within the perimeters of the safe harbor, activities may be funded by the regulated industry, may be designed to provide information on the use of regulated products, and yet be left free from regulation under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act.

Safe harbor is based not on a distinction between promotion and education, but rather on a distinction between activities that are subject to influence by the regulated industry and independent activities that are free from promotional influences. Educational value does not provide a safe harbor from agency regulation; educational activities that are designed or influenced by the regulated industry, even if of the highest educational quality, are subject to regulation.

The general characteristics of the traditional safe harbor for industry-supported scientific and educational activities are (1) an understanding between the provider and supporting company that the activity is to be a scientific or educational activity, and not designed to promote the supporting company's product, (2) functional independence on the part of the provider from influence over content by the supporting company, and (3) adequate disclosure of supporting company involvement.

Sponsors Overall Program: The range and scope of CME (clinical educational) activities which are offered by an AOA accredited CME Sponsor.

Staff Physician: A staff physician is a physician who has been given practice privileges at a healthcare facility. Such privileges are granted after review of credentials that include: an unrestricted license to practice medicine; completion of postdoctoral education; attainment of certification.

Standards to Ensure Independence in CME Activities: AOA requirements designed to ensure that CME activities are independent and free of commercial bias.

Supporter: See commercial interest and commercial support.


Test-item writing: A CME activity based on a learner’s participation in the pre-publication development and review of any type of test item. Examples: multiple choice questions, standardized patient cases.
**Waiver:** The act of modifying a physician’s CME requirement due to mitigating circumstances. Waivers granted do not affect the CME requirement for state licensing boards, specialty colleges, or other organizations.

**Written Agreement:** Companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities based on written agreement between the company and the provider documenting that the provider will be solely responsible for designing and conducting the activity, and that the program will be educational and non-promotional in nature.

The written agreement shall provide for appropriate disclosure. If the company abides by such an agreement and does not otherwise circumvent the purpose of the agreement, the FDA does not intend to regulate the activity under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act.