

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*
2 *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.

45 **Additional Location:** A location that is geographically apart from the main campus at which the
46 institution offers at least 50 percent of an educational program. The additional location will not
47 have separate administration, faculty, or budgetary independence. The additional location must
48 have a common Chief Academic Officer, faculty, budget, and curriculum with the parent COM.
49 Students may be admitted directly to the Additional Location as their primary place of
50 enrollment (34 CFRT §602.22).

51
52 **Advertisement:** Being generally applied to the universe of industry promotional activities designed
53 to provide information on regulated products, but do not fall within the definition of labeling.
54 The promotion of an off-label use, whether or not in a form deemed to be an advertisement,
55 may give rise to a violation of the labeling provisions of the Act.

56
57 **Associate Member:** The AOA Board of Trustees may grant associate membership to the following
58 individuals: teaching, research, administrative professional staff and employees of osteopathic
59 physician members, colleges and healthcare facilities; or administrative personnel of the AOA or
60 its affiliated organizations.

61
62 **Attestation Form:** An affidavit completed by attendees of a CME program verifying the number of
63 credits earned for participation in the CME activity. This form may be completed electronically,
64 so long as the accredited sponsor has evidence that the participant attended the educational
65 program.

66
67 **Branch Campus:** COMs that have their institutional accreditation status from the COCA. A
68 branch campus is any location of an institution other than the main campus which is permanent
69 in nature, offers courses in educational programs leading to the doctor of osteopathy or doctor
70 of osteopathic medicine degree, has its own faculty and administrative or supervisory
71 organization, has its own budgetary and hiring authority, and may have affiliated clinical sites.
72 These will be considered a Branch Campus and COCA may serve as the programmatic or
73 institutional accreditor for COMs wishing to request a Branch Campus. (34 CFR §600.2)

74
75 **Clinical Assessment Program (CAP):** CAP is a Web-based performance measurement program
76 which analyzes data taken directly from patient medical records.

77
78 **Clinical COM Faculty:** A clinical faculty member is an osteopathic or allopathic physician who has
79 undergone a formal committee review of his/her credentials, who has been given a faculty
80 appointment by the COM, such as Assistant, Associate, or full Professor of the relevant
81 department. This appointment is based on merits of various academic criteria, not just a review
82 of the applicant's CV, and it may be paid or unpaid. This is different than a preceptor, who may
83 have been appointed based on a brief review of credentials.

84
85 **Clinical Didactic Teaching:** A CME activity based on the physician learner's preparation to teach
86 in a live CME activity (classroom style).

87
88 **CME Sponsor:** A CME Sponsor is an institution, organization or affiliate that is accredited by the
89 AOA Council on Osteopathic CME to present programs that qualify for AOA Category 1 CME
90 credit.

91

92 CME Sponsors have the discretion of allowing other non-AOA accredited organizations, termed
93 “Providers”, to conduct CME programs under their accreditation status. It is the CME
94 Sponsor's responsibility to ensure that the Provider's programs follow the AOA Category 1
95 CME Requirements.

96
97 **CME Provider:** A CME Provider is an organization, which is not, itself, a recognized AOA
98 Category 1 CME Sponsor, but is authorized to offer AOA approved Category 1 CME under the
99 direction and approval of a recognized AOA Category 1 CME Sponsor.

100
101 **Commercial Bias:** Content or format in a CME activity or its related materials that promotes the
102 products or business lines of an AOA-defined commercial interest.

103
104 **Commercial Interest:** A commercial interest, as defined by the AOA, is any entity producing,
105 marketing, re-selling, or distributing health care goods or services consumed by, or used on,
106 patients. The AOA does not consider sponsors of clinical service directly to patients to be
107 commercial interests. A commercial interest is not eligible for AOA accreditation.

108
109 **Commercial support:** Monetary or in-kind contributions given to a CME sponsor that is used to
110 pay for all or part of the costs of a CME activity.

111
112 **Compliance:** The finding given when a CME sponsor has fulfilled the AOA’s requirements for the
113 specific criterion in the Accreditation Criteria or policy.

114
115 **Conflict of interest:** The AOA considers financial relationships to create conflicts of interest in
116 CME when individuals have both a financial relationship with a commercial interest and the
117 opportunity to affect the content of CME about the products or services of that commercial
118 interest. The potential for maintaining or increasing the value of the financial relationship with
119 the commercial interest creates an incentive to influence the content of the CME – an incentive
120 to insert commercial bias. See also relevant financial relationships.

121
122 **Continuing Medical Education (CME):** Continuing medical education consists of educational
123 activities that serve to maintain, develop, or increase the knowledge, skills, and professional
124 performance and relationships that a physician uses to provide services for patients, the public,
125 or the profession. The content of CME is the body of knowledge and skills generally recognized
126 and accepted by the profession as within the basic medical sciences, the discipline of clinical
127 medicine, and the provision of health care to the public.

128
129 **Core Competencies:**

- 130 1. **Osteopathic Philosophy/Osteopathic Manipulative Medicine** – Demonstrate and
131 apply knowledge of accepted standards in osteopathic manipulative treatment appropriate to
132 the specialty. Remain dedicated to life-long learning and to practice habits in osteopathic
133 philosophy and OMM.
- 134 2. **Medical Knowledge** – Demonstrate and apply knowledge of accepted standards of clinical
135 medicine in the respective area; remain current with new development in medicine and
136 participate in life-long activities.
- 137 3. **Patient Care** – Demonstrate the ability to effectively treat patients and provide medical care
138 that incorporates the osteopathic philosophy, patient empathy, awareness of behavioral
139 issues, the incorporation of preventive medicine and health promotion.

- 140 4. **Interpersonal and Communication Skills** – Demonstrate interpersonal and
141 communication skills that enable you to establish and maintain professional relationships
142 with patients, families, and other members of health care teams.
- 143 5. **Professionalism** – Uphold the Osteopathic Oath in the conduct of one’s professional
144 activities that promotes advocacy of patient welfare, adherence to ethical principles, and
145 collaboration with health professionals, lifelong learning, and sensitivity to a diverse patient
146 population; be cognizant of physical and mental health in order to effectively care for
147 patients.
- 148 6. **Practice-Based Learning and Improvement** – Demonstrate the ability to critically
149 evaluate methods of clinical practice, integrate evidence based medicine into patient care;
150 who and understanding of research methods; improve patient care practices.
- 151 7. **Systems-Based Practice** – Demonstrate an understanding of health care delivery systems;
152 provide effective and qualitative patient care with the system; and practice cost effective
153 medicine.

154
155 **Co-sponsored activity:** A CME activity presented by two or more accredited sponsors. One of the
156 accredited sponsors must take responsibility for the activity in terms of meeting AOA
157 requirements and reporting activity data to the AOA. See also directly sponsored activity.

158
159 **Credit:** The “currency” assigned to CME activities. Physicians and other health care professionals
160 use credits to meet requirements for maintenance of licensure, maintenance of specialty board
161 certification, credentialing, membership in professional societies, and other professional
162 privileges. The requirements for credit designation are determined by the organization
163 responsible for the credit system.

164
165 **Enduring Materials:** CME activities that are printed, recorded, or accessible online and do not
166 have a specific time or location designated for participation. Rather, the participant determines
167 where and when to complete the activity. Examples: online interactive educational module,
168 recorded presentation, podcast.

169
170 **Faculty:** The professionals responsible for teaching, authoring, or otherwise communicating the
171 activity content.

172
173 **Faculty Development programs:** Faculty Development refers to those programs which focus on
174 the individual faculty member. The most common focus for programs of this type is **the faculty**
175 **member as a teacher.** Faculty development specialists provide consultation on teaching,
176 including class organization, evaluation of students, in-class presentation skills, questioning and
177 all aspects of design and presentation. They also advise faculty on other aspects of
178 teacher/student interaction, such as advising, tutoring, discipline policies and administration.

179
180 A second frequent focus of such programs is **the faculty member as a scholar and**
181 **professional.** These programs offer assistance in career planning, professional development in
182 scholarly skills such as grant writing, publishing, committee work, administrative work,
183 supervisory skills, and a wide range of other activities expected of faculty.

184 A third area on which faculty development programs focuses is **the faculty member as a**
185 **person.** This includes wellness management, interpersonal skills, stress and time management,

186 assertiveness development and a host of other programs which address the individual's well-
187 being.

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

191 **Financial Relationships:** Financial relationships are those relationships in which the individual
192 benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria,
193 ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified
194 mutual funds), or other financial benefit. Financial benefits are usually associated with roles such
195 as employment, management position, independent contractor (including contracted research),
196 consulting, speaking and teaching, membership on advisory committees or review panels, board
197 membership, and other activities from which remuneration is received, or expected. The AOA
198 considers relationships of the person involved in the CME activity to include financial
199 relationships of a spouse or partner.

200
201 **Gap Analysis:** (See practice gap analysis).

202
203 **Grand Rounds Programs:** Grand rounds are an important teaching tool and ritual of medical
204 education and inpatient care, consisting of presenting the medical problems and treatment of a
205 particular patient to an audience consisting of doctors, residents and medical students. Grand
206 rounds help doctors and other healthcare professionals keep up to date in important evolving
207 areas which may be outside of their core practice. Most departments at major teaching hospitals
208 will have their own specialized, often weekly, Grand Rounds. Grand rounds tend to present the
209 bigger picture, including experience with patients over many years, and the newest research and
210 treatments in an area.

211
212 **Internet Enduring Material Activity:** An enduring material provided via the Internet, meaning
213 that there is no specific time designated for participation. Rather, the participant determines
214 when to complete the activity. Examples: online interactive educational module, recorded
215 presentation, podcast.

216
217 **Internet live activity:** An online course available at a certain time on a certain date and is only
218 available in real-time, just as if it were a course held in an auditorium (i.e., webcast).

219
220 **Internet On-Demand Activity:** A pre-recorded online course that can be viewed at any time.

221
222 **Joint Sponsorship:** Sponsorship of a CME activity by one accredited and one non-accredited
223 organization. The accredited sponsor must take responsibility for a CME activity when it is
224 presented in cooperation with a non-accredited organization and must use the appropriate
225 accreditation statement.

226
227
228 **Journal-based CME activity:** An activity that includes three phases: the participant reads an article
229 in print or in a format adapted for special needs, engages in a self-directed phase stipulated by
230 the accredited sponsor that may include reflection, discussion, or debate about the article, and
231 completes a pre-determined set of questions or tasks related to the article content.

232
233 **Labeling:** Include not only product labels but also other written, printed, or graphic matter that
234 "accompanies" a product.
235
236 **Maintenance of Certification (MOC):** The process by which ABMS board certified physicians
237 maintain their time-dated certifications. MOC requires four components: Licensure and
238 Professional Standing; Lifelong Learning and Self-Assessment; Cognitive Expertise; and Practice
239 Performance Assessment.
240
241 **Marketing:** Marketing is the activity, set of institutions, and processes for creating, communicating,
242 delivering, and exchanging offerings that have value for customers, clients, partners, and society
243 at large.
244
245 **Noncompliance:** The finding given when a CME Sponsor does not fulfill the AOA's requirements
246 for the specific criterion in the Accreditation Requirements or policy.
247
248 **Objectives:** Statements that clearly describe what the learner will know or be able to do after
249 participating in the CME activity. The statements should result from the needs assessment
250 data. Providers may also state the purpose of an individual activity in lieu of developing
251 specific objectives.
252
253 **Online CME:** Continuing medical education obtained from various sources on the Internet.
254
255 **Osteopathic Continuous Certification (OCC):** The process by which AOA board certified
256 physicians maintain their time-dated certifications. OCC requires five components:
257 Unrestricted Licensure; Lifelong Learning/Continuing Medical Education; Cognitive
258 Assessment; Practice Performance Assessment and Improvement; and AOA Membership.
259
260 **Osteopathic Faculty:** The following shall be considered osteopathic faculty: 1) Osteopathic
261 Physicians, 2) MDs, PhDs, and other professionals with graduate degrees who hold a full-
262 time paid faculty appointment at a college of osteopathic medicine, 3) Presenting employees
263 of the American Osteopathic Association or AOA component society staff who hold a
264 graduate degree and clinical faculty.
265
266 **Osteopathic Graduate Medical Educator (OGME):** Full-time clinical faculty of OGME
267 Programs.
268
269 **Osteopathic Recognition** – An extra designation secured by ACGME-accredited programs that
270 offer training in osteopathic manipulative medicine and the osteopathic philosophy.
271
272 **Outcome Measurement:** The tabulation, calculation or recording of activity or effort that can be
273 expressed in a quantitative or qualitative manner (when attempting to measure shifts or
274 progress toward desired levels of quality).
275
276 **Osteopathic Principles and Practice (OPP):** The fundamental approach to patient health and
277 wellness guided by the tenants of osteopathic medicine.
278
279 **Participant:** An attendee at a CME activity.

280
281 **Performance Improvement CME:** An activity based on a learner’s participation in a project
282 established and/or guided by a CME provider. A physician identifies an educational need
283 through a measure of his/her performance in practice, engages in educational experiences to
284 meet the need, integrates the education into patient care, and then re-evaluates his/her
285 performance.

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

293
294 **Planning Process:** The method(s) used to identify needs and assure that the designed educational
295 intervention meets the need(s) and produces the desired result.

296
297 **Practice Gap Analysis (Needs Assessment):** A practice gap analysis is an analysis of the type of
298 CME that is needed by the intended audience for a CME program, which has been proposed or
299 conducted. The results of practice gap assessments are used in the design and planning of the
300 content and delivery modality for CME programs. There are four criteria that must be met when
301 requesting AOA Category 1-A or Category 1-B credit for approval.

302
303 **Probation:** Accreditation status given to accredited sponsors that have serious problems meeting
304 AOA requirements. Probation may also be given to providers whose document surveys are
305 rejected. The accredited sponsor is allotted 10 working days to correct the noncompliance issues
306 in order to achieve accreditation status before submitted to the AOA Council on Osteopathic
307 CME. While on probation, a sponsor/provider may not sponsor/jointly sponsor new activities.

308
309 **Program:** A formal educational program presented.

310
311 **Program Sponsor:** A program sponsor is an organization that is recognized by non-AOA
312 accreditor and/or offers CME programs recognized by non-AOA organizations. An example of
313 one such accrediting agency is the Accreditation Council for Continuing Medical Education
314 (ACCME) that accredits CME sponsors, but does not approve individual programs.
315 The American Academy of Family Physicians (AAFP) approves individual programs, but does
316 not accredit sponsors.

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

324
325 **Reduction:** The act of decreasing a physician’s CME requirement based on individual mitigating
326 circumstances.

327
328 **Regularly Scheduled Conferences (RSC's):** A course is identified as an RSC when it is planned to
329 have 1) a series with multiple sessions that 2) occur on an ongoing basis (offered weekly,
330 monthly, or quarterly) and 3) are primarily planned by and presented to the accredited
331 organization's professional staff.
332

333 **Regulated Industry:** Persons or entities that manufacture, sell, or conduct research on human and
334 animal drugs, biological products, and medical devices.
335

336 **Safe Harbor:** Scientific and educational activities that are supported by the regulated industry but
337 are independent of promotional influences that may emanate from the supporting companies.
338 Within the perimeters of the safe harbor, activities may be funded by the regulated industry, may
339 be designed to provide information on the use of regulated products, and yet be left free from
340 regulation under the labeling and advertising provisions of the Federal Food, Drug, and
341 Cosmetic Act.
342

343 Safe harbor is based not on a distinction between promotion and education, but rather on a
344 distinction between activities that are subject to influence by the regulated industry and
345 independent activities that are free from promotional influences. Educational value does not
346 provide a safe harbor from agency regulation; educational activities that are designed or
347 influenced by the regulated industry, even if of the highest educational quality, are subject to
348 regulation.
349

350 The general characteristics of the traditional safe harbor for industry-supported scientific and
351 educational activities are (1) an understanding between the provider and supporting company
352 that the activity is to be a scientific or educational activity, and not designed to promote the
353 supporting company's product, (2) functional independence on the part of the provider from
354 influence over content by the supporting company, and (3) adequate disclosure of supporting
355 company involvement.
356

357 **Sponsors Overall Program:** The range and scope of CME (clinical educational) activities which are
358 offered by an AOA accredited CME Sponsor.
359

360 **Staff Physician:** A staff physician is a physician who has been given practice privileges at a
361 healthcare facility. Such privileges are granted after review of credentials that include: an
362 unrestricted license to practice medicine; completion of postdoctoral education; attainment of
363 certification.
364

365 **Standards to Ensure Independence in CME Activities:** AOA requirements designed to ensure
366 that CME activities are independent and free of commercial bias.
367

368 **Supporter:** See commercial interest and commercial support.
369

370 **Survey:** See Accreditation Survey – Pages 14-15.
371

372 **Test-item writing:** A CME activity based on a learner's participation in the pre-publication
373 development and review of any type of test item. Examples: multiple choice questions,
374 standardized patient cases.

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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.