



AMERICAN OSTEOPATHIC ASSOCIATION

ACCREDITATION REQUIREMENTS FOR CATEGORY 1 CME SPONSORS

COUNCIL ON OSTEOPATHIC CONTINUING MEDICAL EDUCATION

American Osteopathic Association

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ACCREDITATION OF CATEGORY 1 CME SPONSORS

The purpose of the Accreditation Requirement Manual for AOA-accredited Category 1 CME Sponsors (hereafter “CME Sponsor(s)”) is to provide CME Sponsors with guidance in the production and accreditation of continuing medical education for physicians by providing educational programs that will lead to the growth of physician knowledge; improvement of patient care, and physician-to-physician education.

SECTION I.

INTRODUCTION

The Board of Trustees of the American Osteopathic Association (AOA) is the only body entitled to establish accreditation policy for osteopathic CME sponsors. The Council on Osteopathic Continuing Medical Education (COCME) as delegated by the AOA Board of Trustees is responsible for accrediting AOA Category 1 CME Sponsors, setting standards and procedures for accreditation of osteopathic CME Sponsors. The Council reports to the Bureau of Osteopathic Education.

SECTION II.

STANDARDS OF ACCREDITATION

A. Quality Guidelines

All CME programs developed by CME Sponsors must:

- 2.1 Address one or more of the AOA seven core competencies; and
- 2.2 Utilize evidence-based medicine. Evidenced based medicine includes:
 - a. A Needs Assessment for each subject area, unless included in one of the Needs Assessment exclusions.
 - b. A definition of anticipated targeted audience, including relevant subjects based on the needs assessment.
 - c. Stated and printed educational objectives.
 - d. Credentialed subject experts on topics presented.
 - e. Active audience participation when feasible. This could include question and answer sessions; hand-on learning labs, and other types of interactive sessions.
 - f. Mechanisms for tracking attendance and maintaining audience records.
 - g. An outcome survey that is sent to all attendees no sooner than fourteen (14) and no later than thirty (30) days following the conclusion of the program.
 - h. Ensure appropriate facilities and equipment are provided to enable the faculty to teach effectively.
 - i. Provide a signed Faculty Disclosure form for all faculty members.

B. Uniform Guidelines for Accrediting Agencies

2.1 Introduction

The purpose of these guidelines is to ensure that all programs presented by AOA-accredited Category 1 CME Sponsors are developed appropriately according to the planning, design, implementation and evaluation standards contained in this document.

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the CME Sponsor of a CME activity to ensure that the educational activity is designed primarily for that purpose. Regardless of the support received from outside agencies, it is the responsibility of the CME Sponsor to ensure that programs adhere to the AOA Uniform Guidelines.

CME Sponsors are encouraged should include the osteopathic tenets and osteopathically recognized elements in programs such as: 1) communication – talking about the holistic approach; 2) developing – a follow-up plan with participatory guidance; 3) facilitating – techniques etc. to help connect patients on a road to better quality of activities of daily living; 4) guiding – looking at whole picture to diagnose and treatment; 5) healing – spiritual, emotional, musculoskeletal, medical; 6) influencing (provide the environment) – acting as a patient advocate and partner to better health; 7) modifying – how to help patient change/alter lifestyle and habits for better health; and 8) restructuring – putting a plan into action, be incorporated into programs to qualify for category 1A.

C. Uniform Guidelines for CME Sponsors

- 2.1 Mission Statement** – A written statement defining the purpose of the CME program identifying the intended audience, and expected outcomes. This statement should be adopted by the CME Sponsor's governing body.
- 2.2 Management Support** – A written statement verifying that the CME Sponsor has sufficient management procedures in place, including sufficient financial support to fulfill the mission of the defined program.
- 2.3 Joint Educational Activities** – CME Sponsors partnering with unaccredited agencies must follow these Guidelines, regardless of programs presented.
- 2.4 Enduring Materials** – Instructional material created in conjunction with a planned CME activity will be developed and administered according to these Guidelines.
- 2.5 Funding Arrangements** – The ultimate decision regarding funding arrangements for CME activities must be the responsibility of the CME Sponsor. Funds from a commercial source should be in the form of an educational grant for the support of programming and made payable to the CME Sponsor. The terms of the grant must be set forth in a written agreement.

There shall be no other funds paid to faculty, CME program directors, or others involved with the supported program except as provided in the written agreement.

All support associated with educational activity must be made under the direction of, and with full knowledge and approval of, the CME Sponsor.

Payment of reasonable honoraria and reimbursement of out-of-pocket expenses for faculty is customary and proper. Commercial support must be acknowledged in printed announcements and brochures; however, reference must not be made to specific commercial products on (the program's) signage or during the presentation. Following the CME activity, the CME Sponsor must be prepared to report to each commercial supporter, information concerning the expenditure of funds each has provided.

Commercial sources may not be involved in the program design, educational content, speaker selection, or as a provision for such funding.

2.6 Marketing CME Activities – A CME Sponsor may authorize a commercial supporter to disseminate information regarding the CME activity to the medical community. This may only be completed with the express, written permission of the CME Sponsor stating the marketing material has been reviewed and approved for distribution. Any marketing material distributed regarding the CME activity must identify the CME Sponsor as the producer of the event.

2.7 Expenses for Attendees – Funds received from commercial support may not be used in any form to pay for the expenses of non-faculty attendees. The CME Sponsor may use commercial support as subsidies for hospitality or social events held as a part of the educational activity.

2.8 Program Design – When designing educational activities, the CME Sponsor must ensure the activities are:

- a. Free of bias for or against any commercial product;
- b. Designed and produced so that content and educational methods are ultimately determined by the CME Sponsor.

If the program includes activities related to commercial products, objective information about the products must be incorporated in the program based on scientific methods generally accepted in the medical community.

2.9 Scholarships – Scholarship or other special funding to permit medical students, interns, or residents and fellows to attend selected educational conferences may be provided. However, the selection of candidates selected for scholarships must be made by the academic or training institution, or by the CME Sponsor, with the full concurrence of the academic or training institution.

2.10 Independence of CME Sponsors – The design and production of educational activities shall be the ultimate responsibility of the CME Sponsor. Commercial supporters of such activities shall not control the planning, content or execution of the activity. This applies to:

- a. **Preparation of educational materials** – The content of slides and reference materials must remain the ultimate responsibility of the faculty of CME Sponsor.

- b. **Educational Planning** – A CME Sponsor must maintain responsibility and control over the selection of content, schedule, faculty, attendees, and educational methods and materials in all of its CME activities. A CME Sponsor may obtain information to assist in planning and producing an educational activity from any outside source.

To maintain independence, the CME Sponsor may not accept advice or services related to educational content, speaker selection, or invitees from a commercial entity. This type of input may not be included in any agreement for commercial support.

- c. **Distribution of Advertising** – No commercial promotional materials shall be displayed or distributed in the same room immediately before, during, or immediately after an accredited educational activity. Representatives of commercial supporters may attend an educational activity for which they have provided support, but may not engage in sales activities while in the room where the educational activity takes place.

2.11 Exhibits – When commercial exhibits are part of an overall program, arrangements for these must not influence educational planning or interfere with the presentation of CME activities. Exhibit placement must not be a condition of support for a CME activity. Exhibits at scientific meetings are marketing, not educational activities and are beyond the scope of the present report. The physical separation of exhibits from conference rooms and meeting halls in which teaching activities take place underscores the distinction between education and marketing/promotional efforts. The AOA awards no CME credit for scientific exhibits. Scientific poster displays cannot occur in the same room as industry exhibits if CME credit is being awarded (i.e., to poster judges' attendees who view the posters).

2.12 Proprietary Names of Products – While the use of proprietary names of products is permissible during educational activities, generic names should be used by the faculty whenever possible. Moreover, it is the responsibility of the CME Sponsor to ensure presentations give a balanced view of diagnostic, therapeutic, or appliance options. If proprietary names are used, those of several companies that make relevant products must be used rather than only those of a single company.

D. Educational Standards and Practices

2.1 Needs Assessment – CME Sponsors shall systematically identify the CME needs of prospective participants and use that information in planning CME activities.

Needs Assessments must be:

- a. Conducted on an annual basis for each program.
- b. Included for each presentation.
- c. Based on current data and analysis
- d. Documented with at least one evidenced-based source

Programs exempt from providing needs assessments include:

- a. OMM/OMT/OPP – state that it is “part of the profession” in documentation.
- b. Core competencies that are not clinical (professionalism, communications, systems based practices, etc.) – state “Core competency required for specialty”
- c. Faculty development programs
- d. State requirements – such as risk management
- e. Board preparation courses – state “based on pass rate on board scores”

Examples of needs assessment tools include:

- a. Medical Audit (Identifying Needs)
 - i. Develop criteria of excellence
 - ii. Collect and summarize data
 - iii. Analyze and interpret data
- b. Pre-Test item analysis (Identified Needs)
- c. Self-Assessment (Identified Needs and Physician Perceived Needs)
- d. Questionnaire (Physician Perceived Needs)

Needs Assessment forms are required for each program when submitted to the AOA Department of Education for consideration of AOA Category 1 accreditation.

- 2.2** **Objectives** – CME Sponsors shall develop learning objectives, based on identified educational needs, for each CME event.

The objectives shall state what the physician must have learned or mastered by the conclusion of the program such as the correction of outdated knowledge and acquisition of new knowledge in specific areas, the mastering of new skills, the changing of attitudes or habits, or other.

CME Sponsors shall use the objectives developed for an educational activity to select the content and design the educational methods for that activity.

- 2.3** **Disclosure** – CME Sponsors shall have a policy requiring disclosure of any financial interest or other relationship a CME faculty member or the CME Sponsor has with any commercial entities discussed in the educational presentation.

Such faculty or CME Sponsor relationship with commercial entities shall be disclosed to participants prior to educational activities in brief statements in the conference, such as during the introduction of faculty or in the faculty’s slide deck.

In the case of a regularly scheduled event, such as grand rounds, disclosure shall be made by the moderator of the activity after consultation with the faculty member or a representative of the CME Sponsor. Written or electronic documentation that disclosure information was given to participants shall be entered in the file for that activity.

- 2.4 Outcomes Measurement** – CME Sponsors are required to conduct an Outcomes Survey after each event for AOA Category 1-A and Category 1-B CME programs. CME Sponsors shall send program attendees an outcomes survey no sooner than fourteen (14) days and no later than thirty (30) days following the conclusion of the program. Each Category 1-A sponsor may offer up to 3 additional 1-A credits at a ratio of 1-10 for each Category 1-A program in excess of 10 credits and one hour for each program less than 10 credits in which the participant satisfactorily completes an outcomes questionnaire. Programs that provides less than 5 Category 1-A or 1-B credits are exempt.

CME Sponsors can begin an Outcomes Survey at any time after an event ends-but must conclude it no later than 30 days after the conclusion of the live events for which the Survey is been conducted. If the Sponsor wishes to monitor a longer change in learner behavior, they may also follow up with another survey after the initial survey. After participants complete the Survey and submit their answers the CME credits should be reported by the CME Sponsor to the AOA. Sponsors have ninety (90) days after the event’s conclusion to report the credits.

An Outcomes Survey is required for OMM programs; but “exempt” from requiring a needs assessment.

The document survey process for reaccreditation shall include measures to evaluate compliance with CME and specialty credit requirements in reporting activities.

E. Other Guidelines

- 2.1 Communicating Results of Scientific Research** – An offer by a commercial entity to provide a presentation reporting the results of scientific research shall be accompanied by a detailed outline of the presentation, which shall be used by the CME Sponsor to confirm the scientific objectivity of the presentation. Such information must conform to the generally accepted standards of experimental design, data collection and analysis.
- 2.2 Off-Label Uses Of Products** – When an off-label use of a product, or an investigational use not yet approved for any purpose is discussed during an educational activity, the CME Sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion, or that the product is still investigation. Discussions of such uses shall focus on those uses that have been subject of objective investigation.
- 2.3 Repeat Activities** – CME Sponsors offering educational activities that repeat essentially the same information each time must demonstrate that every iteration of that activity meets all of the provisions found in the AOA Uniform Guidelines.

2.4 Online CME Programs

- a. In addition to the accreditation requirements outlined in this document, CME programs provided online, through video transmission, e.g., a podcast, webinar, or through other electronic means must meet the following requirements:
 1. Advertising of any type must not be anywhere within accredited educational materials.
 2. The mention of specific products in the acknowledgement of commercial support must not appear in the program, even if they are not related to the program topic.
 3. The CME Sponsor must give full disclosure to the learner about its policy on privacy and confidentiality as it relates to the CME activities on the Internet.
 4. CME Sponsors may not host CME programs on a pharmaceutical or device manufacturer's website.
 5. The AOA has agreed not to sponsor any Category 1-A accredited continuing educational programs and that accredited CME programs sponsored by the AOA affiliated specialty colleges and AOA affiliated divisional societies set their own fees for CME on the Internet.
 6. AOA Category 1 CME Sponsors have the right to use any CME platform to deliver their CME programming.

- b. **Category 1-A Requirements for Online CME Programs**– Up to fifteen (15) Category 1-A credits may be earned from real time interactive CME or online, on-demand CME programs. To qualify for 1-A credit, online, on-demand CME programs must meet the current requirements in addition to the following requirements:
 1. CME programs shall be allowed to remain available for up to three years from the date of original posting as long as the sponsor ensures that the content is still up-to-date and accurate as determined by the AOA Category 1-A sponsor who produced the program.
 2. All CME programs must have a content expert available for any questions on content from CME participants during the life plus one week of the program. The content expert must answer participant questions within one week of an inquiry.
 3. AOA accredited sponsors are required to implement a general outcome measure of the enduring (online) program.

- c. **Category 2-A Requirements for Online CME Programs** – Category 2-A credit will be awarded for interactive live CME activities that meet the additional requirements for interactive live CME activities, but does not meet the standards for osteopathic Category 1-A programs. Examples include programs held by CME Sponsors that do not meet the osteopathic component guidelines, or internet live CME programs accredited by AMA or approved by the AAFP.

- d. **Category 1-B Requirements for Online CME Programs** – CME Sponsors may provide Category 1-B credit through Internet on-demand activities or other on-demand activities provided through non electronic means with video & audio, audio only, or audio and slide deck webinars. These courses are typically programs that are available on an on demand schedule and are not a real-time, interactive simultaneous conference.
- e. **Online CME Programs** – The CME Sponsor of the program must provide the information to the AOA, with the category designation and number of CME credits requested. For reporting “on demand” online programs CME Sponsors have 90 days after the course closes to submit the CME credits to the AOA.
- f. The AOA Council on Osteopathic CME reserves the right to evaluate each interactive CME Internet program and activity and to deny CME credit at its discretion.

SECTION III.

STANDARDS FOR OSTEOPATHIC CATEGORY 1-A PROGRAMS

In addition to the Quality Guidelines and AOA Uniform Guidelines set forth in this document, CME Sponsors requesting Category 1-A credit must meet the following standards.

- 3.1** The CME Sponsor must provide evidence of integrating osteopathic principles and practice into the program.
- 3.2** At least 30% of the total educational credits must be presented by: (1) osteopathic physicians; (2) MDs, PhDs, other professionals with graduate degrees who hold a faculty appointment at a college of osteopathic medicine; (3) AOA staff or AOA component society staff who hold a graduate degree; or (4) clinical COM faculty. Moderators will not be considered faculty if they simply introduce speakers and their topics. To fulfill the definition of faculty, they must actively participate in the educational program.

The AOA Council on Osteopathic CME has been authorized by the AOA Board of Trustees to review and grant exemption from this requirement for any CME program sponsored by a CME Sponsor for whom the audience will consist largely of non-family practice physicians. Such review will occur only on a program-by-program basis. Exemption is solely at the discretion of the AOA Council on Osteopathic CME. A copy of the procedures for requesting this exemption may be obtained from the AOA Department of Education (Resolution. 43 (A/94).

- 3.3** CME Sponsors must include the accreditation statement on their marketing materials. The following language shall be used for advertising AOA Category 1-A CME programs that have been approved by the AOA:

The [name of CME Sponsor] is accredited by the American Osteopathic Association to provide osteopathic continuing medical education for physicians.

The [name of the CME Sponsor] designates this program for a maximum of [number] AOA Category 1-A credits and will report CME and specialty credits commensurate with the extent of the physician's participation in this activity.

- 3.4** CME Sponsors shall provide a signed attendance sheet from each attendee indicating the number of credits earned for each CME activity. CME Sponsors may also use an electronic attestation form with the participant's signature as long as there is evidence the physician attended the educational program.
- 3.5** The CME Sponsor will utilize qualified presenters who have appropriate credentials and experience; illustrate education competence, and thorough knowledge of the topic area.
- 3.6** The CME Sponsor must provide the AOA with the name and telephone number of the provider responsible for administration of Category 1-A CME activities.
- 3.7** Advertising and promotion of CME activities must be carried out in a responsible fashion, clearly displaying the educational objectives of the activity; the nature of the audience that may benefit from the activity; the cost of the activity to the participant, the items covered by the cost; the amount of CME credit that can be earned in compliance with the *AOA CME Guide*; and the credentials of the faculty.
- 3.8** Maintenance and availability of records of participation in CME activities must be adequate to serve the needs of participants and others requiring this information.
- 3.9** The participants must be provided with a certificate or some other document attesting to the satisfactory completion of the CME activity, at the end of the activity or upon request.
- 3.10** The CME Sponsor must have a written grievance policy as well as mechanism for providing fee refunds.
- 3.11** The CME Sponsor must ensure a sound financial base is established for any planned CME programs and activities. Budget planning for CME should be clearly projected. The program should not be presented for the sole purpose of profit.
- 3.12** Adequate supportive personnel to assist with administrative matters and technical assistance shall be available.
- 3.13** The CME Sponsor must provide a means of adequately monitoring the quality of faculty presentations.
- 3.14** The CME Sponsor must insure adequate program participant evaluation.

- 3.15 Some formal educational programs co-sponsored by accredited osteopathic institutions and organizations may be eligible for Category 1-A credit, depending on individual circumstances.
- 3.16 The Federal Drug Administration (FDA) has ruled that a CME Sponsor that demonstrates administrative hardship may allow a third party to handle the financial arrangements for a CME program. The AOA Board of Trustees determined that CME Sponsors having two (2) or fewer full-time equivalent staff would be considered as having administrative hardship (Resolution 26 (M/95)).
- 3.17 Minimum credit requirements and determining CME credits.

Programs must provide a minimum of 0.75 credits to be eligible for CME credit. CME credits will be applied in ¼ (0.25) hour increments.

Partial credits will be awarded as follows:

Length of Program in Minutes	Credits
10-23 (minutes)	0.25
24-37	0.50
38-53	0.75
53-69	1.00

Examples:

- 45 minutes would be awarded 0.75 CME credits
- 1 hour 9 minutes would be awarded 1.00 CME credits
- 1 hour 20 minutes would be awarded 1.25 CME credits

- 3.18 Specialty credit is granted by AOA’s Certifying Boards, which must establish a CME advisory committee to monitor compliance with specialty guidelines.
 - a. Organizations, outside of the designated specialty affiliate, may petition the relevant specialty board to determine if specialty credit may be granted by this third party.
 - b. Physicians may petition the specialty certifying board’s CME Advisory Subcommittee on a case-by-case basis for exception.
- 3.19 CME Sponsors may give specialty continuing medical education if the presentation(s) are deemed acceptable as specialty CME that meet the following criteria:
 - 1. Be presented by:
 - a. An AOA or ABMS board certified physician in the **specialty topic** being discussed. The only exceptions allowed are those listed in paragraph 1.b. below.
 - b. Other qualified professional as indicated below:
 - 1) Foreign-trained physician and non-physician presenters may be reviewed by the specialty certifying board’s CME advisory committee on a case-by-case basis. The respective CME advisory subcommittee should document the criteria for granting an exception for such individuals.

- 2) Physicians currently participating in an AOA or ABMS accredited clinical or research fellowship program would be considered acceptable for specialty CME credit.
 - 3) Individuals who are current faculty members of COCA or LCME accredited medical schools will be considered acceptable for specialty CME credit.
2. Cover topic(s) of concern to osteopathic physicians certified in the specialty for which specialty CME is sought.

SECTION IV.

CRITERIA FOR AOA-ACCREDITED CATEGORY 1 CME SPONSOR

4.1 Applicant Criteria

Agencies applying for recognition to become an AOA-accredited Category 1 CME Sponsor must meet the criteria listed below.

Applicants are limited to:

- a. AOA accredited colleges of osteopathic medicine;
- b. AOA affiliated specialty colleges;
- c. AOA non-practice affiliates, college of osteopathic medicine alumni groups, and osteopathic philanthropic organizations (foundations);
- d. AOA affiliated divisional societies,
- e. Branch Campuses of accredited colleges of osteopathic medicine (All branch campuses must independently apply to be recognized as an AOA Category 1 CME Sponsor, effective January 1, 2013.),
- f. Healthcare Facilities with osteopathically-recognized GME training programs,
- g. Component societies.

4.2 Applicants must complete a formal application found in this Manual under Appendix A.

4.3 An accredited CME Sponsor may not transfer or assign its accreditation status to another entity. However, it may co-sponsor a Category 1 CME program with another agency, who will be termed “providers.” When co-sponsoring with a provider, it is the CME Sponsor’s responsibility to ensure that the program follows the AOA Category 1 CME requirements.

4.4 A CME Sponsor must make a new application for accreditation as a Category 1 CME Sponsor if it has a significant change in its organizational structure, including but not limited to the purchase, sale, divestiture, merger, or acquisition of the CME Sponsor.

A change in the name of the CME Sponsor without other organizational changes is not considered a significant change in the organizational structure and does not require a new application. However, the CME Sponsor must notify the AOA Department of Education of such a name change.

SECTION V.

POLICIES

A. Requirements of CME Sponsors

- 5.1 **Mandatory Attendance at CME Sponsors Conference** – Each CME Sponsor is required to attend the AOA CME Sponsors Conference at least once during every 3-year CME cycle or required review of a CCME-generated webinar(s) for CME Sponsors. A CME Sponsor that does not attend at least one Conference during each CME cycle will forfeit its CME accreditation.

CME Sponsors, who: (1) are awarded one-year accreditation; (2) **are** on probation; (3) have achieved a score of 60-69% on their document survey, or (4) are a new CME Sponsor accredited by the Council on Osteopathic Continuing Medical Education, must attend the CME Sponsors Conference immediately following the awarding of such accreditation by the Council.

- 5.2 **Annual Minimum Programming Requirements** – Each CME Sponsor must produce at least one 3-credit program or series within its accreditation cycle to retain its status as a CME Sponsor.

A program of 3 credits is defined as: (1) one 3-hour program; or (2) a series of lectures that total 3 credits. A series of lectures of 3 hours in length must have a single theme and must respond to a specific educational needs assessment.

An accreditation cycle is determined by the length of time a CME Sponsor has been awarded accreditation based on the score achieved as outlined in section 8.2.

- 5.3 **Reporting CME Activities** – CME Sponsors must submit a roster of physician attendees for every CME event. Rosters will include the CME Sponsor's name, event name, date and location, the name of each physician, their AOA numbers (if applicable), and the number of CME credits granted per physician attendee. CME Sponsors have up to 90 days following the completion of the program to submit the event roster to the AOA with CME and applicable specialty credits.

- 5.4 **CME Sponsor Accreditation and Registration Fees** – CME Sponsors are assessed both accreditation and registration fees. The AOA Board of Trustees establishes both fees.

- a. **Annual Accreditation Fee** – The annual accreditation fee for each AOA-accredited CME Sponsor is \$200.00.
- b. **Program Registration Fees** – CME Sponsors are responsible for the registration fee for the recording of physician credit hours. There is no program fee for recording outcomes measurement CME credit.

- i. **Registration Fee Schedule for Colleges of Osteopathic Medicine** – The fee for recording Category 1-A credit for colleges of osteopathic medicine is \$25.00 per program conducted and \$0.10 per credit reported, up to a maximum of \$1,500.00 per year.

The fee for recording Category 1-B credit for colleges of osteopathic medicine is \$3,125.00 per year. Colleges may submit an unlimited number of Category 1-B credits under this fee. A college may petition for relief of the \$3,125.00 per year fee for Category 1-B.

- ii. **Registration Fee Schedule for Hospitals** – The fee for the recording of unlimited Category 1-A and Category 1-B credits for hospitals is \$1,250.00 per year.
- iii. **Registration Fee Schedule for Specialty Colleges, Divisional Societies, Practice Affiliates, and Osteopathic Foundations** – The fee for recording Category 1-A and/or 1-B credit for specialty colleges, divisional societies, practice affiliates, and osteopathic foundations is \$25.00 per program conducted, and \$0.10 per credit reported, up to a maximum of \$1,500.00 per year.
- iv. **Exemption of Registration Fees** – The Council on Osteopathic Continuing Medical Education may exempt certain currently approved program areas from the Category 1-B fees. Exempt areas at this time are scientific papers, publications, the conduct of healthcare facilities inspections, and the preparation of specialty board exams.

- c. **Withholding the Recording of CME Credit** – The AOA reserves the right to withhold the registration of CME credit for CME Sponsors which fail to pay their annual fees within 90 days of receipt of the annual invoice.
- d. **On-site survey Expenses** – Sponsors will be billed for the direct cost of on-site surveys.

5.5 Record Retention of the CME and Accreditation Programs – An AOA accredited CME Sponsor must maintain its files for a minimum of 6 years and at least two full 3-year CME cycles.

SECTION VI.

DOCUMENT SURVEY PROCEDURE

- 6.1** Prior to the end of a CME Sponsor's term of accreditation, the AOA Department of Education will review a listing of CME programs and select the appropriate program(s) for review.
- 6.2** The AOA will then notify the CME Sponsor of the program(s) chosen for review via electronic email and will ask the organization to submit the required information within thirty (30) working days of notification.
- 6.3** CME Sponsors may submit document survey requirements electronically, but the documents must be organized and formatted in accordance to the "Document Survey Evaluation Methodology" form as requested by the AOA.
- 6.4** The requested information will be reviewed by the AOA Department of Education and the results of this review will be forwarded to the Council on Osteopathic CME ("Council") to determine the accreditation status of the CME Sponsor at the next Council meeting.
- 6.5** If the Council determines that serious quality problems exist, the Council has the option of notifying the CME Sponsor that it must respond to the cited deficiencies with a plan of corrective action. CME Sponsors will be notified of the need to submit missing documentation and will have ten (10) working days to submit missing information before any points are taken away.
- 6.6** Failure to submit the required documentation, or failure to respond to deficiencies within 30-working days may result in an on-site visit and survey and/or the initiation of procedures that would lead to the loss of AOA Category 1 CME Sponsor Accreditation status.
- 6.7** If a CME Sponsor requests an extension of more than 40 days, only up to 4 years of accreditation may be awarded.

SECTION VII.

DOCUMENT SURVEY EVALUATION METHODOLOGY

The Council uses the following checklist to evaluate the document survey. Points are awarded when the items are clearly marked in the document survey.

A CME Sponsor who achieve a perfect score of 100 points on the document survey and collect outcomes data on their CME programs, will be awarded “Accreditation with Commendation.”

Checklist Items	Points
1. A description of the needs assessment process and procedure used in determining the content and topic of the program (include any supporting documents). (MAJOR)	8
2. A copy of the CME program brochure or agenda distributed to participants at the CME program. (MINOR)	4
3. Copies of all program speakers’ (in chronological order) curriculum vitae or bio-sketch defining their qualifications for involvement in the CME program. (MAJOR) . Partial credit is awarded based on the percentage of CVs and bio-sketches provided during the document survey review. (e.g., 5 CVs provided from a total of 10 speakers yields 4 points) All fractions are rounded down. <u>Less than 50% - 0 50% - 4 90% - 8</u>	8
4. A copy of each speaker’s Disclosure Declaration Statement in chronological order. (MAJOR) Partial credit is awarded based on the percentage of the disclosure statements provided during the document survey. <u>Less than 90 - 0 90% - 4</u>	8
5. A copy of the CME credits requested by the CME Sponsor for each participating physician in accordance with the attestation document and specialty credits. (MINOR)	4
6. A copy of the program administration evaluation document and the total number of evaluation documents returned by conference attendees. Provide two copies of the program evaluation documents that were returned by conference attendees, or a completed electronic evaluation/summary. (MINOR)	4
7. A statement indicating the total number of attendees, and the number of attestation forms returned by conference participants. (MAJOR) <u>25% - 2 50% - 4 95% - 8</u>	8
8. A statement reflecting the distribution of program evaluation documents (e.g., The beginning of the program, random survey, etc.) (MINOR)	4
9. A policy statement on managing grievances relative to the returned program administration and evaluation document(s). (MINOR)	4
10. A copy of the program outcomes questionnaire and the total number of outcomes questionnaire documents returned by conference attendees. Provide two copies of the outcomes questionnaire documents that were returned by conference attendees, or a completed electronic evaluation/summary. (MINOR) (Within 14 days and no later than 30 days).	4

11A. Provide needs assessment per program topic. (MAJOR) Partial credit is awarded. <u>25% - 2 50% - 4 75% - 6 95% - 12</u>	12
11B. A statement relative to how topics and/or speakers were selected in direct response to needs assessment procedures. (MINOR)	4
12. If the program was commercially supported, the following additional items must be submitted: A) A copy of the formal written agreement between the CME Sponsor and each Commercial Supporter reflecting that activity (program) is educational and not promotional. (MAJOR) Partial credit is awarded. <u>Less than 90 - 0 90% - 4</u>	8
B) Proof that commercial support is appropriately acknowledged in any printed promotional materials. (MINOR)	4
C) A brief statement regarding all funding arrangements, include how funds received from commercial supporters were expended, how speakers were paid, i.e., if speakers were directly funded by a third party agent (someone besides the AOA CME Sponsor/Provider), attach copy of the funding arrangement between the CME Sponsor and the third party agent. (MAJOR) Partial credit is awarded. <u>Less than 90 - 0 90% - 4</u>	8
D) A statement indicating how disclosure of potential conflict of interest regarding each speaker was given to the participants. (MAJOR) Partial credit is awarded. <u>Less than 90 - 0 90% - 4</u>	8
Total Score	100

The Council on Osteopathic Continuing Medical Education will award accreditation based on the following document survey scores:

Scoring Key:

Major – 8-12 points; Minor – 4 points (Total of 100 points)

Accreditation:

- 100 points on the document survey (first attempt) is awarded 5 years continuing accreditation with Commendation; 100 points on the document survey (after additional missing material is submitted to the AOA) is awarded 5 years continuing accreditation.
- 96-99 points on the document survey is awarded 5-year accreditation;
- 90-95 points on the document survey is awarded 4-year accreditation;
- 85-89 points on the document survey is awarded 3-year accreditation;
- 80-84 points on the document survey is awarded 2-year accreditation;
- 70-79 points on the document survey is awarded 1-year accreditation;
- 60-69 points on the document survey is awarded 1-year accreditation with required review of a CCME-generated webinar(s) for CME Sponsors;
- Less than 60 points on the document survey accreditation is withdrawn.

SECTION VIII.

ACCREDITATION

- 8.1 Accreditation Status of New Programs** – Newly accredited CME Sponsors will be awarded 1-year accreditation. At the end of the first year, the CME Sponsor must submit a document survey to the Council on Osteopathic CME.
- 8.2 Accreditation Actions** – The Council on Osteopathic CME shall evaluate the document survey using the checklist. The Council shall award accreditation based on the score achieved on the checklist:
- a. 100 points on the document survey (first attempt) is awarded 5 years continuing accreditation with Commendation; 100 points on the document survey (after additional missing material is submitted to the AOA) is awarded 5 years continuing accreditation.
 - b. 96-99 points on the document survey is awarded 5-year accreditation;
 - c. 90-95 points on the document survey is awarded 4-year accreditation;
 - d. 85-89 points on the document survey is awarded 3-year accreditation;
 - e. 80-84 points on the document survey is awarded 2-year accreditation;
 - f. 70-79 points on the document survey is awarded 1-year accreditation;
 - g. 60-69 points on the document survey is awarded 1-year accreditation, with required review of a CCME-generated webinar(s) for CME Sponsors;
 - h. Less than 60 points on the document survey accreditation is withdrawn.
- 8.3 Probation** – A CME Sponsor shall be placed on probation if it is awarded 1-year accreditation for three (3) years in a row. For CME Sponsors on probation, the Council on Osteopathic CME may choose to require an on-site survey and/or require the CME Sponsor to attend a Council meeting to discuss their accreditation status.

The Council on Osteopathic CME has the authority to revoke accreditation for any CME Sponsor on probation if the information obtained at either the on-site survey or council meeting does not justify continued accreditation status. The CME Sponsor on probation is responsible for all costs associated with an on-site survey or attendance at a council meeting.

The Council on Osteopathic CME has the authority to place a CME Sponsor on probation if that CME Sponsor is found in violation of the AOA Uniform Guidelines.

- 8.4 Revocation of Accreditation Status** – The Council on Osteopathic CME has the authority to revoke Category 1 CME Sponsor accreditation status if a CME Sponsor is found in violation of the AOA Uniform Guidelines.

SECTION IX.

COMPLAINTS

Complaints made against CME Sponsors are taken very seriously by the Council on Osteopathic Continuing Medical Education (COCME). CME Sponsors found to be out of compliance may be required to: (1) undergo an on-site visit, (2) attend a Council meeting to discuss a plan of corrective action, (3) be placed on probation, (4) be denied accreditation status, or (5) other action as approved by the Council.

9.1 Initial Complaint Review Procedure – A complainant shall first seek to resolve the problem directly with the CME Sponsor. If the complainant is unable to reach an agreeable solution to the grievance through the CME Sponsor, the responsibility for filing a formal complaint to the AOA Council on Osteopathic CME remains with the complainant. The CME Sponsor shall notify the complainant of this option.

9.2 Formal Complaint Procedure – The complainant shall submit a complaint in writing to the Council on Osteopathic CME. The complainant must identify the standard or standards alleged to be violated. The complainant must produce evidence that an effort has been made to resolve the problem with the CME Sponsor. The complainant shall include information about all other actions initiated to resolve the problem(s).

The Secretary of the Council on Osteopathic CME will forward all material to the CME Sponsor for response. The CME Sponsor has 30 days in which to respond to the written allegations.

The information received from the CME Sponsor will be forwarded to the Chair of the Council on Osteopathic CME for review. The Chair will determine which review body will be assigned to review the complaint. The Chair may select the Administrative Committee of the Council, or call a special subcommittee to review the complaint. In the event the Chair has a conflict of interest, the Vice-Chair shall select the review body. In the event the Vice-Chair has a conflict of interest in the matter, the Chair of the Bureau of Osteopathic Education shall select the review body.

9.3 Actions of the Review Body – The review body may take any of the following actions:

- a. Dismiss** – The review body may dismiss the complaint if it concludes that the CME Sponsor is in compliance with CME standards.
- b. Postpone** – The review body may postpone action on the complaint if there is evidence that the CME Sponsor in question is making responsible progress in rectifying the situation that warranted the complaint. If a postponement is made, the matter must come before the Council on Osteopathic CME within one year from the time of postponement for final resolution.

- c. **Probation** – Based on the evidence, the review body may conclude that the CME Sponsor is failing to meet the CME standards. The review body may recommend to the Council that the CME Sponsor be placed on probation.
- d. The CME Sponsor will be notified if the review body plans on recommending this action to the Council. The CME Sponsor may appear at the Council on Osteopathic CME meeting to present the sponsor’s perspective.
- e. **Withdrawal of Accreditation** – Based on the evidence, the review body may conclude that CME Sponsor has failed to meet the CME standards. The review body may then recommend to the Council on Osteopathic CME that the accreditation of the CME Sponsor be withdrawn. The CME Sponsor will be notified if the review body plans on recommending this action to the Council. The CME Sponsor may appear at the Council on Osteopathic CME meeting to present the sponsor’s perspective.

SECTION X.

RECONSIDERATIONS AND APPEALS

Reconsideration and/or Appeal Procedures

- 10.1** CME Sponsors may request a reconsideration of an accreditation action by the Council on Osteopathic Continuing Medical Education (COCME) or appeal to the Bureau of Osteopathic Education.
 - a. A request for reconsideration or a request for appeal will include a detailed description of errors in fact from the survey report, and the documentation of correction of noncompliance.
 - b. The reconsideration/appeal procedures permit the CME Sponsor to show that it has corrected or is attempting to correct deficiencies that were found at the time of survey.
 - c. Presentation of such corrections does not bind the Council on Osteopathic CME or the Bureau of Osteopathic Education to either reverse or accept the initial recommendations of the Council on Osteopathic CME.
 - d. CME Sponsors requesting appeals will maintain their current accreditation status until the appeal hearing has been conducted, recommendations made, and acted upon by the AOA Bureau of Osteopathic Education.
- 10.2** Requests for reconsideration must be made in writing to the Council on Osteopathic CME, and must be filed within 30 days following receipt of the recommendation of the Council on Osteopathic CME.
- 10.3** Requests for appeal must be made in writing to the Bureau of Osteopathic Education, and must be filed within six (6) months of receipt of the action by the Council on Osteopathic CME. CME Sponsors must submit a \$2,500 appeal fee with the formal written appeal request.

Appeal fees do not apply to individual requests from students or physicians, including trainees. Should the BOE Appeal Committee overturn a decision from one of the education councils, half the application fee (\$1,250) will be returned to the appellant, whether the decision was fully or partially over-turned.

- 10.4** CME Sponsors may seek a final appeal and hearing before the AOA Board of Trustees.

SECTION XI

ON-SITE PROGRAM SURVEY

- 11.1** Special reviews or complaint reviews may require an on-site survey. The total cost of this on-site program survey will be borne by the CME Sponsor being surveyed and billed through the AOA.
- 11.2** When on-site program surveys are scheduled, the CME Sponsor will be advised in writing of the date of survey.
- 11.3** A notification letter to the CME Sponsor will be sent at least six (6) weeks prior to the date of the on-site survey. (See Appendix E)
- 11.4** On-site Program Surveys will be conducted by AOA approved surveyors.
- 11.5** The AOA will maintain a list of surveyors approved annually by the Council on Osteopathic CME.
- 11.6** CME Sponsor program surveyors must submit written reports within 30 days to the Council on Osteopathic CME on all on-site sponsors/programs surveyed.
- 11.7** Within 60 days after completion of the on-site survey of the CME Sponsor/program, the AOA Department of Accreditation will notify the CME Sponsor of any areas of noncompliance by certified mail.
- 11.8** CME Sponsors are required to respond formally with a plan of corrective action addressing all identified areas of noncompliance within 60 days of notice. Failure to respond to deficiencies cited may result in withdrawal of accreditation.
- 11.9** The Council on Osteopathic CME will evaluate survey reports of both document and on-site program surveys at its meetings.
- 11.10** CME Sponsors will be notified by certified mail of actions taken by the Council on Osteopathic CME, usually within ten (10) working days after its meeting.

Appendix A: Application Form for Category 1 Sponsor Accreditation

Instructions for Completing Category 1 Sponsor Accreditation Application Form

The attached form should be completed in duplicate. Forward the original copy to the AOA, Department of Education, 142 E. Ontario St., Chicago, IL, 60611-2864. Retain the duplicate copy for your records.

The AOA Council on Osteopathic CME requests that each item be answered as completely, yet concisely, as possible. Please be sure the form is signed and dated.

The Council on Osteopathic CME will accredit those organizations who meet the criteria established and printed in the Accreditation Requirements for AOA Category 1 CME Sponsors and in the AOA CME Guide. Please consult these documents prior to submission of this application form.

**American Osteopathic Association
Department of Education
Accreditation Application for AOA Category 1 CME Sponsor**

Part 1: General Information

1. Name of Organization _____
Address _____
City _____ State _____ Zip Code _____

2. Contact Person _____
Title _____
Phone _____ Ext _____
Fax _____ Email _____

3. Type of Sponsor:
 - A) _____ Healthcare Facilities with osteopathically-recognized GME training programs
 - B) _____ College of Osteopathic Medicine
 - C) _____ College of Osteopathic Medicine Branch Campus
 - D) _____ Osteopathic Specialty College (Practice Affiliate)
 - E) _____ Osteopathic Specialty Board
 - F) _____ State Osteopathic Medical Association (Divisional Society)
 - G) _____ Osteopathic Alumni Group, Osteopathic Philanthropic organization, or Osteopathic Non-practice Affiliate

4. Attach a dated and signed copy of sponsoring organization CME mission statement indicating formal approval by sponsoring organization's board of trustees.
5. List on the attached form the CME programs/activities contemplated by the sponsoring organization for the coming year.
6. Indicate which, if any, programs/activities may be supported to some extent by commercial interests.
7. Indicate topic areas and commercial companies from which commercial support is anticipated with the type and the estimated dollar value of that support.
8. Indicate the type of commercial support you anticipate for your programs/activities by checking all appropriate boxes.
 - a. _____ Funding
 - b. _____ Materials supplied
 - c. _____ Product information
 - d. _____ Speaker
 - e. _____ Other
9. Give an estimated percentage of total costs of the CME programs to be covered by commercial support.
 _____ % (estimate)
10. Does your organization conduct CME programs through joint sponsorship with other organizations?
 _____ Yes _____
 _____ No _____
 If yes, name organization(s) so involved _____
11. Attach with this form the following:
 - a. A program administration and evaluation document.
 - b. The applicant policy on advertising and promotion.
 - c. An outline of the applicant method of maintaining records.
 - d. The means used by the applicant to certify CME participation by physicians.
 - e. A policy on managing fee grievances and refunds.
12. Submit the above items along with the established fee to:
 American Osteopathic Association
 Department of Education
 142 E. Ontario St.
 Chicago, IL 60611-2864

Signed _____
 Authorized sponsoring organization representative

Title: _____

Date: _____

FOR OFFICE USE ONLY
Date Appl Recd _____
Approval Date _____
Code # _____

American Osteopathic Association
Department of Education
Accreditation Application for AOA Accredited Category 1 CME Sponsor

Part 2

Sponsoring Organization _____

Anticipated CME programs/activities for the Coming Year

Programs/Activities	Date of Activity	General Topic	Name of Commercial Supporter(s)	Projected \$ Support

Appendix B: Sample Information

These are meant to be neither all-encompassing nor exclusionary.

Sample Bio-sketch:

John C. Jones, DO, FAAP will speak on “Attention Deficit Hyperactivity Disorder (ADHD).” He is a graduate of the University of Olympia and the Atlanta College of Osteopathic Medicine. He is Board certified in Pediatrics. Dr. Jones completed an internship at Suburban Hospital, Boise, Montana, and a residency in Pediatrics at Children’s Hospital, Oregon, Indiana. He currently practices at ABC Pediatric Hospital and Clinic. He is a fellow of the American College of Pediatrics, and is a member of the American College of Osteopathic Pediatricians.

Sample Evaluation Document:

Cardiology

Wednesday, April 28, 1:00 – 5:30 p.m. Ballroom A

Name _____

AOA # _____

<i>Please rate the following</i>	<i>Excellent</i>	<i>Good</i>	<i>Satisfactory</i>	<i>Fair</i>	<i>Poor</i>
Value of subject					
Quality of speakers					
Knowledge of subject					
Program length					
Presentation style					
Response to questions					

Please write any comments on this session on the back of this sheet.

Sample Grievance Policies:

Sample Grievance Policy 1:

All grievances should be in writing and specify the nature of the grievance and any “particulars.” Initially, all grievances should be directed to the educational committee.

If the participant does not receive a satisfactory response, they may then notify the Council on Osteopathic Continuing Medical Education of the AOA at: 142 E. Ontario St., Chicago, IL 60611-2864.

Sample Grievance Policy 2:

Grievances shall be submitted in writing to the executive director or educational program chairperson. All grievances will receive an initial response in writing within 30 days of receipt.

The Executive Director will review all grievances and resolve if possible. If no resolution is possible, the Executive Director may then pass the information on to the President of the Association for resolution.

If the President is unable to resolve the grievance he may then pass the grievance on to the Executive Committee of the Board of Trustees and if no resolution can be made the grievance will then be presented to the full Board of Trustees

Further appeals shall be addressed to the Council on Osteopathic Continuing Medical Education of the AOA at: 142 E. Ontario St., Chicago, IL 60611-2864.

Appendix C: Sample Commercial Support Form

Letter of Agreement Regarding Terms, Conditions and Purposes of an Educational Grant

Between _____ (Accredited Sponsor) and _____ (Company)

Title of CME Activity _____

Location _____ Date(s) _____

Company (name/Branch) _____

Address _____

City, State, Zip _____

Telephone _____ Fax _____ Contact Person _____

The above Company wishes to provide support for the named continuing medical education activity by means of (indicate which option):

1. Unrestricted educational grant for support of the CME activity in the amount of \$ _____

2. Restricted grant to reimburse expenses for:

A. 1) _____

2) _____

To include all Expenses _____ Travel Only _____ Honorarium Only _____
(Honorarium Amount to be determined by Course Director)

B. Support for catering functions (specify) _____
in the amount of \$ _____ (see 10.d. on the back of this agreement)

C. Other (e.g. equipment loan, brochure distribution, etc.) _____

CONDITIONS

1. Statement of Purpose: program is for scientific and educational purposes only and will not promote the Company's products, directly or indirectly.
2. Control of Content & Selection of Presenters & Moderators: AOA Accredited Category 1 CME Sponsor ("Accredited Sponsor") is ultimately responsible for control of content and selection of presenters and moderators. Company, or its agents, will respond only to Accredited Sponsor, who will disclose financial or other relationships between Company and speaker, and will provide this information in writing. Accredited Sponsor will record role of Company, or its agents, in suggesting presenter(s); will seek suggestions from other sources, and will make selection of presenter(s) based on balance and independence.
3. Disclosure of Financial Relationships: Accredited Sponsor will ensure disclosure to the audience of (a) Company funding and (b) any significant relationship between the Accredited Sponsor and the Company (e.g. grant: recipient) or between individual speakers or moderators and the Company.

4. Involvement in Content: there will be no “scripting,” emphasis, or influence on content by the Company or its agents.
5. Ancillary Promotional Activities: no promotional activities will be permitted in the same room or oblique path as the educational activity. No product advertisements will be permitted in the program room.
6. Objectivity & Balances: Accredited Sponsor will make every effort to ensure that data regarding the Company's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
7. Limitations of Data: Accredited Sponsor will ensure, to the extent possible, disclosure of limitations of data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. Discussion of Unapproved Uses: Accredited Sponsor will require that presenters disclose when a product is not approved in the United States for the use under discussion.
9. Opportunities for Debate: Accredited Sponsor will ensure opportunities for questioning or scientific debate.
10. Independence of Accredited Sponsor in the use of Contributed Funds:
 - a. Funds should be in the form of an educational grant made payable to _____ (Accredited Sponsor).
 - b. All other support associated with this CME activity (e.g. distributing brochures, preparing slides) must be given with the full knowledge and approval of _____ (Accredited Sponsor).
 - c. No other funds from the Company will be paid to the program director, faculty, or other involved with the CME activity (additional honoraria, extra social events, etc.).
 - d. Funds may be used to cover the cost of one or more modest social activities held in conjunction with the educational program, which furthers the CME educational experience and/or allows an educational discussion and exchange of ideas. If Company sponsors a social event, the requirements set forth in Sections 1, and 3-5 will still apply.

The Company agrees to abide by all requirements of the AOA Guidelines for Relationships between Accredited Sponsors and Company of CME.

The Accredited Sponsor agrees to: 1) abide by the AOA Guidelines for Relationships between Accredited Sponsors and Company of CME; 2) acknowledge educational support from the Company in program brochures, syllabi, and other program materials, and 3) upon request, furnish the Company a report concerning the expenditure of the funds provided.

AGREED	
Company Representative (name) _____	_____
Signature _____	Date _____
Course Director (name) _____	Dept _____
Signature _____	Date _____
CME Department Director of Designee (name) _____	_____
Signature _____	Date _____

Appendix D: Faculty Disclosure Form

Faculty Disclosure Declaration

It is the policy of the _____ to insure balance, independence, objectivity, and scientific rigor in all its individually sponsored or jointly sponsored educational programs. All faculty participating in any _____ sponsored programs are expected to disclose to the program audience any real or apparent conflict(s) of interest that may have a direct bearing on the subject matter of the continuing education program. This pertains to relationships with pharmaceutical companies, biomedical device manufacturers, or other corporations whose products or services are related to the subject matter of the presentation topic. The intent of this policy is not to prevent a speaker with a potential conflict of interest from making a presentation. It is merely intended that any potential conflict should be identified openly so that the listeners may form their own judgments about the presentation with the full disclosure of the facts. It remains for the audience to determine whether the speaker's outside interests may reflect a possible bias in either the exposition or the conclusions presented.

PROGRAM: _____

DATE: _____

TITLE OF PRESENTATION: _____

PRESENTERS

NAME: _____

(Please print or type)

I have no actual or potential conflict of interest in relation to this program or presentation.

Signature

Date

I have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Affiliation/Financial Interest

Name of Organization(s)

Grant/Research Support _____

Consultant _____

Speakers' Bureau _____

Major Stock Shareholder _____

Other Financial or Material Support _____

Signature

Date

Your cooperation in complying with this standard is appreciated. Please return this form as soon as possible to the program director or Office of Continuing Education.

Appendix E: Random On-site Visit Guidelines

1. Trigger Event

- a. AOA's Council on Osteopathic Continuing Medical Education (COCME) reserves the right to inspect any provider of CME for just cause.
- b. Violations must be received in writing and of sufficient severity and/or repeated violation to endanger provider's accreditation.
- c. Rule must be clear and not open to interpretation.
- d. Violation is willful and not based on ignorance of rules and requirements.
- e. Complaints would require onsite verification of offense and are not paperwork in nature.
- f. Nature of violation would be under control of the provider.
- g. Provider has not made attempt to correct violation after notice.
- h. Written complaints to COCME will result in provider being asked to provide any complaints received directly by provider and report of outcome.
- i. An onsite visit is a last resort to assist a Sponsor with keeping their accreditation.

2. Procedure for Audits

- a. Written notification would be sent to provider for response. Failure to respond would be reason enough to trigger onsite inspection.
- b. Event audited would have to be of like nature as event which received complaints.
- c. A minimum number of auditors will be sent – regardless of hardship.
- d. Strict adherence to Crosswalk will be required.
- e. Onsite audit must be approved by COCME.

3. Define Formal Complaint

- a. A formal complaint may be lodged with the COCME by any physician, student, staff, or outside individual. Complaint must be in writing and must be signed.
- b. Anonymous complaints will not be deemed sufficient to require onsite inspection.

4. Define Financial Hardship

- a. It is up to the provider to declare and demonstrate financial hardship. Financial hardship is the inability to pay for travel expenses incurred during the audit.
- b. It is assumed that hardship would generally be an issue for a small state society rather than a hospital or COM.
- c. Suggested requirement would include a letter from President/CEO, appropriate financial reports, current profit and loss statements for 6 and 12 months.
- d. Standards indicate requirements for expenses including air travel, accommodations, per diem and honoraria for inspector.

Purpose of process is to protect accreditation status of the group and to maintain highest CME standards. Remediation and correction is desired outcome. Failure to correct may result in removal of accreditation, probationary status or additional training/oversight of meetings. Appeal process would apply.

GLOSSARY

Terms used in this Manual are related to the Federal Food, Drug, and Cosmetic Act, the AOA Uniform Guidelines, 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.

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

Accredited Sponsor: See *CME Sponsor* – Page 34.

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.

Act: Federal Food, Drug, and Cosmetic Act.

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 Locations: A location that is geographically apart from the main campus at which the institution offers at least 50 percent of an educational program. An additional location is geographically apart from the main campus, and offers at least 50 percent of an educational program. The additional location will not have separate administration, faculty, or budgetary independence, all of which are required for a branch campus or for a new COM. Students may be admitted directly to the additional location as their primary place of enrollment. Students from the entire program can take classes at the additional location.

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.

Agency: Food and Drug Administration (FDA).

Agency Policy: Covers not only human drugs, which were the subject of the concept paper, but also covers devices, biologics, and veterinary medicines, which are all subject to regulation with regard to labeling and advertising.

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 must follow the procedures outlined under Chapter VI: USDE Requirements.

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 life-long 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 life-long 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.

Course: A live CME activity where the learner participates in person and which is planned on a one-by-one basis and designated for credit as a single activity. (Examples: annual meeting, conference, seminar.)

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.

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 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.

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.

Needs Assessment: A needs assessment 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 a needs assessment 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. See Section II, Part D, for the criteria for needs assessment Pages 6-7).

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.

Presenter: A presenter at an AOA-accredited CME program is an individual who chairs a portion of the program or who delivers a lecture or other formal portion of the program.

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 accreditor and/or offers CME programs recognized by non-AOA organizations. An example of one such accrediting 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-BOA accredited organization that provides CME programs under the discretion and approval of an BOA 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 BOA 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: BOA requirements designed to ensure that CME activities are independent and free of commercial bias.

Supporter: See commercial interest and commercial support.

Survey: See Accreditation Survey – Pages 17-18.

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.

Uniform Guidelines: Uniform Guidelines for Accrediting Agencies of Continuing Medical Education as adopted by the AOA (Page 4).

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.