

AMERICAN OSTEOPATHIC ASSOCIATION

ACCREDITATION REQUIREMENTS FOR CATEGORY 1 CME SPONSORS

BUREAU OF OSTEOPATHIC EDUCATION

American Osteopathic Association 142 E. Ontario St. Chicago, IL 60611-2864 January 1, 2022

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Section I: Who May Apply

Institutions must meet the following standards to be considered for accreditation by the Bureau of Osteopathic Education.

- 1. The institution must have an osteopathic affiliation:
 - a. State societies and their component societies must be chartered by the AOA House of Delegates
 - b. Specialty colleges and their component societies must be chartered by the AOA House of Delegates
 - c. Colleges of Osteopathic Medicine (including branch campuses) must have accreditation by the Commission on Osteopathic College Accreditation (COCA) and have graduated its first class or received pre-accreditation status by COCA
 - d. Osteopathic non-practice affiliates (foundations, alumni groups, philanthropic organizations) chartered by the AOA House of Delegates
 - e. Healthcare facilities with at least one osteopathic physician on staff.
- 2. Complete and submit an application for CME accreditation, along with an application fee of \$2,500.

Special Notes:

An accredited CME Sponsor may not transfer or assign its accreditation status to another entity. However, it may co-sponsor a Category 1 CME activity 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 activity follows the AOA Category 1 CME requirements.

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 BOE of such a name change.

Section II: Quality Guidelines for CME Activities

The purpose of accreditation is to ensure that all activities 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 activities adhere to the AOA accreditation standards.

CME activities must meet the following requirements:

A. Core Competencies

CME activities must address one or more of the AOA seven core competencies:

- a. Osteopathic Principles and Practice;
- b. Medical Knowledge and Its Application into Osteopathic Medical Practice;
- c. Osteopathic Patient Care;
- d. Interpersonal and Communication Skills in Osteopathic Medical Practice
- e. Professionalism in Osteopathic Medical Practice
- f. Osteopathic Medical Practice-Based Learning and Improvement
- g. System-Based Osteopathic Medical Practice

In order to document this requirement, the AOA requires that at least one learning objective be aligned with an osteopathic core competency listed above. This can be documented on the practice gap analysis, or elsewhere, and will be requested when an activity is selected for review by the AOA. See the template on Osteopathic.org for a complete example and definitions of each competency.

B. Practice Gap Analysis

CME Sponsors shall systematically identify the practice gaps of prospective participants and use that information in planning CME activities.

Practice gap analysis must be:

- a. Conducted on an annual basis for repeated activities.
- b. Produced for each topic.
- c. Based on current data and analysis.
- d. Documented with at least one evidenced-based source.

Activities exempt from providing a practice gap analysis include:

- a. OMM/OMT/OPP.
- b. Activities addressing non-clinical core competencies (professionalism, communications, systems-based practice).
- c. Faculty development activities.
- d. State licensure requirements, such as risk management.
- e. Board preparation courses.
- f. Topics for which the AOA has specific policy endorsing or encouraging CME (need only refer to the specific policy e.g., Inhalation of Volatile Substances; Teenage Alcohol Abuse;

and Training on Extended Release-Long Acting (ER/LA) Opioid Risk Evaluation and Mitigation Strategy (REMS), and Stimulant Abuse.

Examples of practice gap analysis 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)

C. Educational Objectives

CME Sponsors shall develop learning objectives, based on identified gaps in knowledge, for each CME topic. The objectives shall state what physician knowledge, skills and attitudes are impacted or mastered by the conclusion of the activity, such as the correction of outdated knowledge and acquisition of new knowledge in specific areas, the mastering of new skills, or the changing of attitudes or habits.

CME Sponsors shall use the objectives developed for an educational activity to select the content and design the educational methods for that activity. Bloom's Taxonomy Action Verbs list is an excellent source for writing and developing learning objectives.

https://teachingcommons.stanford.edu/resources/course-preparation-resources/course-designaids/bloom%E2%80%99s-taxonomy-educational-objectives

D. Outcomes Measurement

An outcomes measurement of the effectiveness of a activity shall be conducted. No CME shall be awarded for this activity. This can be conducted by survey following the activity <u>or</u> by a simple question or series of questions such as "List at least one thing you learned from this activity"; or "will you implement anything learned from this activity into your practice? If so, what and how? If not, why not?" as a component of your activity evaluation.

E. Commercial Support

1. <u>Funding Arrangements</u> – The ultimate decision regarding funding arrangements for CME activities must be the responsibility of the CME Sponsor. Funds from a commercial source must be in the form of an unrestricted 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 activity 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 activity's materials signage or during the presentation.

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

- 2. <u>Marketing CME Activities</u> A CME Sponsor may authorize a commercial supporter to disseminate information regarding the CME activity to the medical community. This may only occur 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.
- 3. <u>Expenses for Attendees</u> Funds received from commercial support may not be used in any form to pay for the expenses of non-faculty attendees.
- 4. <u>Activity Design</u> When designing educational activities, the CME Sponsor must ensure the activities are:
 - a. Free of bias for or against any commercial product;
 - b. If the activity includes activities related to commercial products, objective information about the products must be incorporated in the activity based on scientific methods generally accepted in the medical community.
 - c. 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:
 - 1. Preparation of educational materials The content of slides and reference materials must remain the ultimate responsibility of the CME Sponsor.
 - 2. 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.
- 5. <u>Scholarships</u> Scholarships or other special funding to permit medical students, interns, or residents and fellows to attend selected educational conferences may be provided by commercial supporters. However, the selection of candidates selected for scholarships must be made by the academic or training institution or by the CME Sponsor.
- 6. Exhibits When commercial exhibits are part of an overall activity, 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. There must be physical separation of exhibits from conference rooms and meeting halls in which teaching activities take place underscoring 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 and/or attendees who view the posters).

No commercial promotional materials shall be displayed or distributed in the same room immediately before, during, or immediately after an educational activity approved for credit. Representatives of commercial supporters may attend an educational activity, but may not engage in sales activities while in the room where the activity takes place. Promotional materials should never be mixed with an educational offering.

- 7. **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.
- 8. <u>Disclosure</u> 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 within the conference, such as during the introduction of faculty, in the faculty's slide deck or in disseminated materials and/or electronic communications including web-based and app-based conference materials.

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.

- 9. <u>Communicating Results of Scientific Research</u> 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.
- 10. <u>Off-Label Uses of Products</u> 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 under investigation.

F. Administrative Requirements for CME Sponsors

Administrative responsibilities of CME Sponsors include:

- 1. Tracking and maintaining attendance records.
- 2. Ensuring appropriate facilities and equipment are provided to enable the faculty to teach effectively.

- 3. Marketing materials utilizing the following language for advertising AOA Category 1-A CME activity:
 - 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 activity 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.
- 4. CME Sponsors shall provide evidence that the physician attended the educational activity, including the number of credits earned for each CME activity.

 Examples of adequate evidence include signed (including electronic signatures) attestation forms or electronic check-in software or apps.
- 5. 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.
- 6. 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. The certificate can be accessed via an online portal.
- 7. The CME Sponsor must have a written grievance policy as well as mechanism for providing fee refunds.
- 8. The CME Sponsor must encourage adequate activity participant evaluation.
- 9. The Food and 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 activity. 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)).

11. Minimum credit requirements and determining CME credits.

Activities must provide a minimum of 0.25 credits to be eligible for CME credit. CME credits will be applied in ½ (0.25) credit increments.

Partial credits will be awarded as follows:

Length of Activity in Minutes	Credits
10-23 (minutes)	0.25
24-37	0.50
38-52	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
- 12. CME Sponsors offering educational activities that repeat essentially the same information each time must meet AOA Standards.

G. Faculty

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 activity.

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

H. Online CME Activities

- 1. Category 1 CME Sponsors have the right to use any CME platform to deliver their CME programming, with the exception that they may not host CME activities on a pharmaceutical or device manufacturer's website. In addition to the accreditation requirements outlined in this document, CME activities provided online, through video transmission, e.g., a podcast, webinar, or through other electronic means must meet the following requirements:
 - a. Advertising of any type must not be anywhere within accredited educational materials.
 - b. The mention of specific products in the acknowledgement of commercial support must not appear in the activity, even if they are not related to the activity topic.
 - c. 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.

- 2. <u>Category 1-A Requirements for Online CME Activities</u>—Category 1-A credits may be earned from real time interactive CME or online, on-demand CME activities. To qualify for 1-A credit, online, on-demand CME activities must meet the current requirements in addition to the following requirements:
 - a. CME activities 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.
 - b. All CME activities must have a content expert available for any questions on content from CME participants during the life plus one week of the activity. The content expert must answer participant questions within one week of an inquiry.
 - c. AOA accredited sponsors are required to implement a general outcome measure of the enduring (online) activity. Online courses will require the physician to complete an "evaluation" in a text field such as "List at least one thing you learned from this activity" or "Will you implement anything learned in this activity into your practice? If so, what will you implement and how?" Upon completion the physician will receive the certificate of completion and CME credit.
- 3. <u>Category 2-A Requirements for Online CME Activities</u> 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 activities.
 - Examples include activities held by CME Sponsors that do not meet the osteopathic faculty component guidelines, or internet live CME activities accredited by AMA or approved by the AAFP.
- 4. Category 1-B Requirements for Online CME Activities 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 activities that are available on an on demand schedule and are not a real-time, interactive simultaneous conference.
- 5. Reporting Credit for Online CME Activities The CME Sponsor of the activity must provide the information to the AOA, with the category designation and number of CME credits requested. For reporting "on demand" online activities CME Sponsors have up to one year from the date of physician completion of the activity to report earned CME credits to the AOA.

The AOA Bureau of Osteopathic Education reserves the right to evaluate each interactive CME Internet activity and to require its removal from any platform at its discretion.

Section III: Requirements of CME Sponsors

<u>Mandatory Attendance at CME Sponsors Conference</u> – Each CME Sponsor is required to attend the AOA CME Sponsors Conference at least once during every 3-year CME cycle and/or required review of BOE-generated webinar(s) for CME Sponsors. A CME Sponsor that does not attend at least one Conference or participate in the required webinars 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 Bureau of Osteopathic Education, must attend the CME Sponsors Conference immediately following the awarding of such accreditation by the Bureau.

1. <u>Annual Minimum Programming Requirements</u> – Each CME Sponsor must produce at least one 3-credit activity or series within its accreditation cycle to retain its status as a CME Sponsor.

A activity of 3 credits is defined as: (1) one 3-hour activity; 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 gap analysis.

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

- 2. **Reporting CME Activities** All AOA accredited CME Sponsors are required to submit data about their activities in the traCME platform. CME Sponsors have up to one year following the completion of an activity to enter the data.
- 3. <u>CME Sponsor Accreditation and Registration Fees</u> CME Sponsors are assessed annual accreditation fees. For more information on annual fees, please contact <u>cmesponsors@osteopathic.org</u>
 - 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.
- 4. **Record Retention of the CME and Accreditation Activities** 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 IV: Document Survey Procedure

- 1. Prior to the end of a CME Sponsor's term of accreditation, the AOA Department of Physician Education and CME will review a listing of CME activities and select the appropriate activity(ies) for review.
- 2. The AOA will then notify the CME Sponsor of the activity(ies) chosen for review via electronic email and will ask the organization to submit the required information within thirty (30) working days of notification.
- 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.
- 4. The requested information will be reviewed by the AOA Department of Physician Education and CME and the results of this review will be forwarded to the Bureau of Osteopathic Education ("Bureau") to determine the accreditation status of the CME Sponsor at the next Bureau meeting.
- 5. If the Bureau determines that serious quality problems exist, the Bureau 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. 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.
- 7. If a CME Sponsor requests an extension their accreditation status will be reduced by one (1) year.

Section V: Document Survey Evaluation Methodology

The Bureau 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 activity(ies), will be awarded "Accreditation with Commendation."

Checklist Items	Points
Provide practice gap analysis per activity. (MAJOR)	
1A. A description of the practice gap analysis process and procedure used in determining the content and topic of the activity or program (include any supporting documents). (MAJOR) 1B. Osteopathic Distinction	24
Practice gap analysis includes alignment of at least one activity learning objective to osteopathic core competency (MAJOR)	
2. A copy of the CME program brochure or agenda distributed to participants at the CME program to validate the following speaker information: (MINOR)	4
A) Copies of all program speakers' (in chronological order) curriculum vitae defining their qualifications for involvement in the CME program. Partial credit is awarded based on the percentage of CVs 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. (MAJOR) Less than 50% - 0 89% - 4 100% - 8	8
B) A copy of each speaker's Disclosure Declaration Statement in chronological order. Partial credit is awarded based on the percentage of the disclosure statements provided during the document survey. (MAJOR) <u>Less than 90 - 0 90% - 4</u>	8
3. A copy of the CME credits entered into traCME by the CME Sponsor to verify that the data was entered into traCME and reported within the one year time limit. (MAJOR)	8
4. A copy of the program administration evaluation document and the total number of evaluation documents returned by conference attendees. Provide an overall summary of the completed evaluations for that program. (MAJOR)	8
5. A policy statement on managing grievances relative to the returned program administration and evaluation document(s). (MINOR)	4

6. An outcomes measurement of the effectiveness of a program shall be conducted. No CME shall be awarded for this activity. This can be conducted by survey following the program or by a simple question or series of questions such as "List at least one thing you learned from this activity"; or "will you implement anything learned from this activity into your practice? If so, what and how? If not, why not?" as a component of your program evaluation. (MINOR)		
 7. 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. Written agreement must adhere to AOA standards for commercial support. (MAJOR) 		
B) Proof that commercial support is appropriately acknowledged in any printed promotional materials. (MINOR)		
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)		
D) A statement indicating how disclosure of potential conflict of interest regarding each speaker was given to the participants. (MAJOR)		
Total Score	100	

The Bureau of Osteopathic Education will award accreditation based on the following document survey scores:

Scoring Key:

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

Length of Accreditation:

- 100 points on the document survey (first attempt) is awarded 5 years continuing accreditation with Commendation with an outcomes survey; 100 points on the document survey (after additional missing material is submitted to the AOA) is awarded 5 years continuing accreditation.
- 7-99 points on the document survey is awarded 5-year accreditation;
- 90-96 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 BOE-generated webinar(s) for CME Sponsors and attendance at next scheduled Sponsor's Conference;
- Less than 60 points on the document survey accreditation is withdrawn.

Section VI: Accreditation

- 1. <u>Accreditation Status of New Programs</u> 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 Bureau of Osteopathic Education.
- 2. <u>Accreditation Actions</u> The Bureau of Osteopathic Education shall evaluate the document survey using the checklist. The Bureau shall award accreditation based on the score achieved on the checklist as noted.

<u>Probation</u> – 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 Bureau of Osteopathic Education may choose to require an on-site survey and/or require the CME Sponsor to attend a Bureau meeting to discuss their accreditation status. (The CME Sponsor on probation is responsible for all costs associated with an on-site survey or attendance at a Bureau meeting.)

The Bureau of Osteopathic Education has the authority to place a CME Sponsor on probation if that CME Sponsor is found in gross violation of the AOA accreditation standards.

<u>Withdrawal of Accreditation Status</u> – The Bureau of Osteopathic Education has the authority to withdraw a Category 1 CME Sponsor's accreditation status if a CME Sponsor score is less than 60 points on the document survey. Also, if failure to respond to deficiencies cited in an on-site survey within the 60 days of notice after completion of the on-site survey.

Section VII: Complaints

Complaints made against CME Sponsors are taken very seriously by the Bureau of Osteopathic Education (BOE). CME Sponsors found to be out of compliance may be required to: (1) undergo an on-site visit, (2) attend a Bureau 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 Bureau.

- 1. <u>Initial Complaint Review Procedure</u> 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 Bureau of Osteopathic Education remains with the complainant. The CME Sponsor shall notify the complainant of this option.
- 2. <u>Formal Complaint Procedure</u> The complainant shall submit a complaint in writing to the Bureau of Osteopathic Education. 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 Bureau of Osteopathic Education 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 Bureau of Osteopathic Education for review. The Chair will determine which review body will be assigned to review the complaint. The Chair may select the Subcommittee Committee of the Bureau, 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.

- 3. <u>Actions of the Review Body</u> 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 Bureau of Osteopathic Education 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 Bureau 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 Bureau. The CME Sponsor may appear at the Bureau of Osteopathic Education 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 Bureau of Osteopathic Education 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 Bureau. The CME Sponsor may appear at the Bureau of Osteopathic Education meeting to present the sponsor's perspective.

Section VIII: Reconsiderations and Appeals

- 1. CME Sponsors may request a reconsideration of an accreditation action by the Bureau of Osteopathic Education (BOE) or appeal to the AOA Board of Trustees.
 - 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 Bureau of Osteopathic Education to either reverse or accept the initial recommendations
 - 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.
- 2. Requests for reconsideration must be made in writing to the Bureau of Osteopathic Education, and must be filed within 30 days following receipt of the recommendation.
- 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. CME Sponsors must submit a \$2,500 appeal fee with the formal written appeal request.
 - 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.
- 4. CME Sponsors may seek a final appeal and hearing before the AOA Board of Trustees.

Section IX: On-Site Program Survey

- 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.
- 2. When on-site program surveys are scheduled, the CME Sponsor will be advised in writing of the date of survey.
- 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)
- 4. On-site Program Surveys will be conducted by AOA approved surveyors.
- 5. The AOA will maintain a list of surveyors approved annually by the Bureau of Osteopathic Education.
- 6. CME Sponsor program surveyors must submit written reports within 30 days to the Bureau of Osteopathic Education on all on-site sponsors/programs surveyed. A member from the Bureau will serve as a surveyor.
- 7. Within 60 days after completion of the on-site survey of the CME Sponsor/program, the AOA Department of Education will notify the CME Sponsor of any areas of noncompliance by certified mail.
- 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.
- 9. The Bureau of Osteopathic Education will evaluate survey reports of both document and on-site program surveys at its meetings.
- 10. CME Sponsors will be notified by certified mail of actions taken by the Bureau of Osteopathic Education, 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 Physician Education and CME, 142 E. Ontario St., Chicago, IL, 60611-2864. Retain the duplicate copy for your records.

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

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

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

Part 1: General Information Name of Organization Address State Zip Code Contact Person Phone Ext Fax Email Type of Sponsor Who May Apply: A) Healthcare facilities with at least one osteopathic physician on staff College of Osteopathic Medicine accredited by COCA and graduated its first class or received pre-accreditation status by COCA College of Osteopathic Medicine Branch Campus Osteopathic Specialty College and their Component Societies (Practice D) Affiliate) State Osteopathic Medical Association and their Component Societies E) __ (Divisional Society) F) 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 activities contemplated by the sponsoring organization for the coming year.
- **6.** Indicate which, if any, activities may be supported to some extent by commercial interests.

7.	-	areas and commercial companies from which commercial support is anticipated and the estimated dollar value of that support.
8.	Indicate the tappropriate b	ype of commercial support you anticipate for your activities by checking all oxes.
	a	Funding
	b	Materials supplied
	c	Product information
		Speaker
		Other
9.	support.	nated percentage of total costs of the CME activities to be covered by commercial
10.		ganization conduct CME activities through joint sponsorship with other?
	No	If yes, name organization(s) so involved
11.	a. A p b. The c. An d. The	his form the following: rogram administration and evaluation document. applicant policy on advertising and promotion. outline of the applicant method of maintaining records. means used by the applicant to certify CME participation by physicians. olicy on managing fee grievances and refunds.
12.	America Departu 142 E. (oove items along with the established fee to: an Osteopathic Association ment of Physician Education and CME Ontario St. o, IL 60611-2864
Signe		
	Au	thorized sponsoring organization representative
Print	Name:	
Title		
11116	·	

Date:

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

Part 2		
Sponsoring Organization		

Anticipated CME activities for the Coming Year

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

FOR OFFICE USE ONLY	
Date Appl Recd	
Approval Date	
Code #	

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 #	<u> </u>

Please rate the	Excellent	Good	Satisfactory	Fair	Poor
following			-		
Value of subject					
Quality of					
speakers					
Knowledge of					
subject					
Activity 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 Bureau of Osteopathic 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 Bureau of Osteopathic 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. Providing an unrestricted educational grant for support of the CME activity: YES____ or NO___. 2. In the amount of \$_____. **CONDITIONS**

- Statement of Purpose: activity is for scientific and educational purposes only and will not 1. promote the Company's products, directly or indirectly.
- Control of Content & Selection of Presenters & Moderators: AOA Accredited Category 1 2. 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 Sponsors, who will disclose financial or other relationships between company and speakers, and will provide this information in writing.
- Disclosure of Financial Relationships: Accredited Sponsor will ensure disclosure to the 3. 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.
- Involvement in Content: there will be no "scripting," emphasis, or influence on content by 4. the Company or its agents.
- 5. Ancillary Promotional Activities: no promotional activities will be permitted in the same room or obligate path as the educational activity. No product advertisements will be permitted in the activity room.
- Objectivity & Balances: Accredited Sponsor will make every effort to ensure that data 6. 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.
- Limitations of Data: Accredited Sponsor will ensure, to the extent possible, disclosure of 7. limitations of data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
- Discussion of Unapproved Uses: Accredited Sponsor will require that presenters disclose 8. 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 qu	aestioning	or
	scientific debate.						

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 activity support from the Company in activity brochures, syllabi, and other activity 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 or Designee (name)	
Signature	Date

Appendix D: Faculty Disclosure Form

Faculty Disclosure Declaration

participating in anyaudience any real or apparent conflict(s) of intercontinuing education activity. This pertains to redevice manufacturers, or other corporations whether presentation topic. The intent of this policy from making a presentation. It is merely intendent that the listeners may form their own judgments	
DATE:	
TITLE OF PRESENTATION:	
	est in relation to this activity or presentation.
Signature	
I have a financial interest/arrangement or affilia as a real or apparent conflict of interest in the co	tion with one or more organizations that could be perceived ontext of the subject of this presentation.
Affiliation/Financial Interest Grant/Research Support	Name of Organization(s)
Consultant	
Speakers' Bureau	
Major Stock Shareholder	
Other Financial or Material Support	
Signature	

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. The Bureau of Osteopathic Education (BOE) 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 BOE 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 BOE.

3. Define Formal Complaint

- a. A formal complaint may be lodged with the BOE 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

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 Bureau of Osteopathic Education (BOE).

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 Cycle: The length of accreditation awarded a CME sponsor by the BOE based on the scoring system as defined on Page 14 and can range from one to five years.

Accredited Sponsor: See CME Sponsor.

Activity: A CME activity is an educational offering that is planned, implemented, and evaluated in accordance with the AOA Accreditation Requirements and accreditation policies.

Attestation Form: An affidavit completed by attendees of a CME activity 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 activity.

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

Clinical 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.

- **CME Sponsor:** A CME Sponsor is an institution, organization or affiliate that is accredited by the AOA Bureau of Osteopathic Education to present activities 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 activities under their accreditation status. It is the CME Sponsor's responsibility to ensure that the Provider's activities 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:

- 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.
- **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.

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

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

Gap Analysis: (See practice gap analysis).

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

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

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

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

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

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

Objectives: Statements that clearly describe what the learner will know or be able to do after participating in the CME activity. The statements should result from the practice gap analysis 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 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.

Outcomes 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.

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

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 Bureau of Osteopathic Education. While on probation, a sponsor/provider may not sponsor/jointly sponsor new activities.

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 Bureau for Continuing Medical Education (ACCME) that accredits CME sponsors, but does not approve individual activities. The American Academy of Family Physicians (AAFP) approves individual activities, but does not accredit sponsors.

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

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 activity 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.