



ACCREDITATION REQUIREMENTS CATEGORY 1 CME SPONSORS

DIVISION OF CONTINUING MEDICAL EDUCATION

American Osteopathic Association

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Accreditation of Category 1 CME Sponsors

The purpose of the AOA's continuing medical education program is: to continually improve the quality of patient care, through the growth of knowledge, the improvement of skills, and physician-to-physician interaction.

I Introduction

The AOA Board of Trustees is the only body entitled to establish accreditation policy for osteopathic CME sponsors. The Council on Continuing Medical Education (CCME) has been delegated authority by the AOA Board of Trustees to monitor osteopathic CME, award Category 1 accreditation status to osteopathic CME sponsors, and conduct accreditation document surveys and on-site surveys of CME sponsors.

The Council on Continuing Medical Education and AOA staff will monitor AOA continuing medical education category one sponsors for adherence to these policies and procedures, audit CME programs for compliance with AOA policies, and investigate all written complaints of deviation from AOA policy using a standard complaint review procedure.

II Standards of Accreditation

This chapter defines the standards of accreditation of Category 1 CME sponsors. Section 1 presents AOA's CME quality standards. Section 2 presents the *Uniform Guidelines for Accrediting Agencies of Continuing Medical Education*.

2.1 Quality Guidelines for Continuing Medical Education Programs

The AOA CME quality guidelines are:

- 2.1.1 CME will be systematically organized and administered.
- 2.1.2 The program shall focus on the needs of the participants, address the AOA seven core competencies, and utilize evidence-based medicine.
- 2.1.3 The programs shall be based on some type of needs assessment. Some examples of these needs assessment tools are as follows:
 - A. Medical Audit (Identifying Needs)
 - 1. Develop criteria of excellence
 - 2. Collect and summarize data.
 - 3. 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)
- 2.1.4 The CME program must establish faculty for CME with adequate credentials.
- 2.1.5 Every program must have stated and printed educational objectives. The objectives must state what the physician must have learned or mastered by the conclusion of the program, for example: the correction of outdated knowledge, and acquisition of new knowledge in specific areas, the mastering of new skills, the changing of attitudes or habits, etc.
- 2.1.6 The primary evaluation and assessment of the program are the responsibility of the accredited CME sponsors.
- 2.1.7 CME programs should include a variety of course-class alternatives and encourage innovative program development.
- 2.1.8 Each program must have a statement as to the type of audience for whom the program is designed, and be relevant to the practice needs of the audience.

- 2.1.9 The sponsors and providers should encourage active participation by the physician wherever possible.
- 2.1.10 Attendance records must be kept as means of assuring that those attending a program are given proper credit toward their CME requirement.
- 2.1.11 Sponsors and providers shall conduct a post-course evaluation.
- 2.1.12 The sponsors and providers must assure that proper facilities and equipment are provided to enable the presenter to teach effectively.
- 2.1.13 If two or more accredited sponsors act in association, the responsibility for complying with the standards for quality is held jointly. If an accredited sponsor acts in association with others in the development, distribution and/or presentation of CME activities, it is mandatory that the identity of the AOA accredited sponsor or sponsors be identified in the title; and all advertising and promotional materials. The responsibility for adherence to the standards of quality rests with the AOA accredited sponsor. The sponsor shall insure that sound educational goal planning takes place in all programs. (AOA Board of Trustees Resolution 85 (A/89))

2.2 Uniform Guidelines For Accrediting Agencies Of Continuing Medical Education

The *Uniform Guidelines for Accrediting Agencies of Continuing Medical Education* outline the principles for conducting of credible continuing medical education programs. The *Guidelines* address all major aspects of continuing medical education, including relationships with pharmaceutical firms and device manufacturers.

The *Guidelines* were developed by the Task Force on CME and Industry Collaboration. The Task Force included leaders of continuing medical education in the United States as well as senior staff members of major pharmaceutical and device manufacturers. Although members of the Task Force are associated with most of the major leaders in CME and health-related commercial interests in the United States, the Task Force has no official status in government, industry, or education.

The AOA adopted, with minor changes, the *Uniform Guidelines for Accrediting Agencies of Continuing Medical Education*. The AOA believes that much mutual benefit will flow from this unity among the professions through application of these policies and procedures.

2.2.1 Introduction to the AOA Uniform Guidelines

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the accredited sponsor of a CME activity to assure that the educational activity is designed primarily for that purpose.

Accredited sponsors often receive financial and other support from commercial organizations. Such support can contribute significantly to the quality of CME activities.

The purpose of the "Uniform Guidelines" is to describe appropriate parameters of performance expected of accredited sponsors in planning, designing, implementing, and evaluating CME activities. Further, the "Uniform Guidelines" apply to those continuing medical education activities for which an accredited sponsor receives commercial support.

2.2.2 Management of CME Activities

2.2.2.1 Mission Statement - An accredited sponsor shall define the role, scope and intended audience of its educational functions by having a written statement of its CME mission formally approved by its governing body.

2.2.2.2 Management Support - An accredited sponsor shall provide evidence that management procedures and other necessary resources are available and effectively used to fulfill its CME mission.

2.2.2.3 Joint Educational Activities - An accredited sponsor that provides educational activities jointly with a non-accredited entity shall assure that such activities are conducted entirely according to these "AOA Uniform Guidelines".

2.2.2.4 Enduring Materials - An accredited sponsor that offers instructional materials in conjunction with a planned activity of CME, shall develop and administer those materials entirely according to these "AOA Uniform Guidelines".

2.2.2.5 Funding Arrangements - The ultimate decision regarding funding arrangements for CME activities must be the responsibility of the accredited sponsor. Funds from a commercial source should be in the form of an educational grant for the support of programming made payable to the accredited 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 an educational activity must be made under the direction of, and with the full knowledge and approval of, the accredited 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. Following the CME activity, the accredited sponsor must be prepared to report to each commercial supporter, information concerning the expenditure of funds each has provided.

2.2.2.6 Marketing CME Activities - A CME sponsor may authorize a commercial supporter to disseminate to the medical community information about a CME activity. However, the content of such information must always be explicitly approved by, but not necessarily prepared by, the accredited sponsor, and must always identify the educational activity as produced by the accredited sponsor.

2.2.2.7 Expenses for Attendees - In connection with an educational activity, it is not permissible to use funds originating from a commercial source to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. Subsidies for hospitality should not be provided outside of modest meals or social events that are held as a part of the educational activity.

Scholarship or other special funding to permit medical students, interns, or residents and fellows to attend selected educational conferences may be provided, as long as the selection of students, interns or residents and fellows who will receive the funds is made either by the academic or training institution, or by the accredited sponsor, with the full concurrence of the academic or training institution.

2.2.3 Educational Standards and Practices

2.2.3.1 Needs Assessment - An accredited sponsor shall systematically identify the CME needs of prospective participants and use that information in planning CME activities.

2.2.3.2 Objectives - An accredited sponsor shall, for each CME event, develop objectives based on identified educational needs.

2.2.3.3 Educational Design

2.2.3.3.1 Objectives Influence Design - An accredited sponsor shall use the objectives developed for an educational activity to select the content, and design the educational methods, for that activity.

2.2.3.3.2 Basic design requirements for CME activities - In designing educational activities, the accredited sponsor must assure that the activities have the following characteristics:

They must be free of bias for or against any commercial product;

They must be designed and produced so that content and educational methods are ultimately determined by the accredited sponsor;

If the activities are concerned with commercial products, the program must present objective information about such products based on scientific methods generally accepted in the medical community.

2.2.3.3.3 Independence of Accredited Sponsors - The design and production of educational activities shall be the ultimate responsibility of the accredited sponsor. Commercial supporters of such activities shall not control the planning, content or execution of the activity. To assure compliance with the "Uniform Guidelines" the following requirements must be adhered to:

2.2.3.3.3.1 Help with the preparation of educational materials - The content of slides and reference materials must remain the ultimate responsibility of the faculty of accredited sponsor. The accredited sponsor may ask a commercial supporter to help with the preparation of conference related educational materials, but these shall not specifically promote the proprietary interests of the commercial supporter.

2.2.3.3.3.2 Assistance with Educational Planning - An accredited sponsor must maintain responsibility for and control over the selection of content, schedule, faculty, attendees, and educational methods and materials in all of its CME activities.

An accredited sponsor may obtain information that will assist in planning and producing an educational activity from any outside source whether commercial or not. However, acceptance by an accredited sponsor of advice or services concerning speakers, invitees or other educational matters, including content, shall not be among the conditions for the provision of support by a commercial organization.

2.2.3.3.3.3 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.

2.2.3.3.3.4 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.

2.2.3.3.3.5 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 accredited sponsor to assure that 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.

2.2.4 Other Guidelines for Relationships between Accredited Sponsors and Commercial Supporters of CME

2.2.4.1 Communicating Results of Scientific Research – Objective, rigorous, scientific research conducted by commercial companies is an essential part of the process of developing new pharmaceutical or other medical products or devices. It is highly desirable that direct reports of such research be communicated to the medical community. An offer by a commercial supporter 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 accredited 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.

2.2.4.2 Disclosure – An accredited sponsor shall have a policy requiring disclosure of the existence of any financial interest or other relationship a CME faculty member or the sponsor has with the manufacturer(s) of any commercial product(s) discussed in an educational presentation. All approved CME activities shall conform to this policy.

Such faculty or accredited sponsor relationship with commercial supporters shall be disclosed to participants prior to educational activities in brief statements in the conference (during the introduction of a speaker) and in conference materials such as brochures, syllabi, exhibits, poster sessions and post meeting publications.

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 accredited sponsor. Written documentation that disclosure information was given to participants shall be entered in the file for that activity.

2.2.4.3 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 accredited sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion, or that the product is still investigational. Discussions of such uses shall focus on those uses that have been subject of objective investigation.

2.2.4.4 Activities that are repeated many times – An accredited sponsor that offers educational activities that repeat essentially the same information each time they are given, must demonstrate that every iteration of that activity meets all of the provisions found in these “Uniform Guidelines”.

2.2.4.5 The accredited sponsor’s use of educational activities or materials prepared by organizations other than the accredited sponsor – When an accredited sponsor offers an educational activity based on concepts or materials prepared by an outside organization, that activity must adhere to these “Uniform Guidelines” in all respects; particularly when the provisions concerning the independence of the accredited sponsor directly affect that sponsor’s planning, designing, delivering, and evaluating all of its educational activities offered for credit.

2.2.4.6 Restrictions on Internet CME Programs – listed below are the policies for CME presentations on the Internet:

- No advertising of any type within accredited educational materials.
- No mention of specific products in the acknowledgement of commercial support, even if they are not related to the topic of the CME program.
- The use of hidden technical mechanisms for transferring learning data (cookies) is prohibited.
- AOA accredited providers may not host CME programs on a pharmaceutical or device manufacturer’s website.
- The AOA has agreed not to sponsor any Category 1-A accredited continuing medical educational programs and that accredited CME programs sponsored by AOA affiliated specialty colleges and AOA affiliated divisional societies set their own fees for CME on the Internet.

III Standards for Osteopathic Category 1-A Programs

CME programs requesting Category 1-A or 1-B credit must meet the following standards. A conference will be deemed to meet the 50% requirement if:

- 3.1.1 (1) At least 50% and the total educational hours are presented by osteopathic physicians; or MD's, PhD's, and other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine; or AOA staff or AOA component society staff who hold a graduate degree, or
- 3.1.2 (2) At least 50% of the presenters are osteopathic physicians; or MD's, PhD's, and other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine; or AOA staff or AOA component society who hold a graduate degree.

The AOA Council has been authorized by the AOA Board of Trustees to review and grant exemption from this requirement for any CME program sponsored by a specialty college or society, or any program for which 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. A copy of the procedures for requesting this exemption may be obtained from the AOA Division of CME (Resolution. 43 (A/94)).

- 3.2 The sponsor must provide evidence of integrating osteopathic principles and practice into the program.
- 3.3 The sponsor shall identify and use presenters who will teach in a planned program. The suggested criteria for presented selection include:
 - A. Appropriate Credentials
 - B. Competence as an educator
 - C. Knowledge of content area
 - D. Qualification by experience
- 3.4 The sponsor must provide the AOA with the name and telephone number of the provider responsible for administration of Category 1-A CME activities.
- 3.5 Involved faculty must have credentials appropriate to expertise required.
- 3.6 Advertising and promotion of CME activities must be carried out in a responsible fashion, clearly showing 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.
- 3.7 Maintenance and availability of records of participation in CME activities must be adequate to serve the needs of participants and others requiring this information.
- 3.8 The participants, upon their request, must be provided with a certificate or some other document attesting to the satisfactory completion of the CME activity.
- 3.9 The sponsor must have a written policy dealing with procedures for the management of grievances and fee refunds.
- 3.10 The sponsor must assure that a sound financial base is established for the 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.

- 3.11 An appropriate number of qualified faculty for each activity shall be secured by the sponsor.
- 3.12 Adequate supportive personnel to assist with administrative matters and technical assistance shall be available.
- 3.13 The sponsor must provide a means of adequately monitoring the quality of faculty presentations.
- 3.14 The sponsor must insure adequate program participant evaluation as suggested in the quality standards.
- 3.15 AOA accredited CME sponsors shall comply with the Uniform Guidelines for Accrediting Agencies of CME as adopted by the AOA.
- 3.16 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.
- 3.17 Some formal educational programs co-sponsored by accredited osteopathic institutions and organizations may be eligible for Category 1-A credit, depending on individual circumstances.
- 3.18 The FDA has ruled that a CME sponsor who can demonstrate administrative hardship may allow a third party to handle the financial arrangements for a CME program. The AOA Board of Trustees determined that sponsors having two (2) or fewer full time equivalent staff would be considered as having administrative hardship (Resolution 26 (M/95)).

IV Who May Apply to be an AOA-Accredited Category 1 CME Sponsor

4.1 **Who may apply** - osteopathic sponsors are limited to the following:

- AOA accredited colleges of osteopathic medicine;
- AOA affiliated Specialty Colleges;
- AOA Non-practice Affiliates, College of Osteopathic Medicine Alumni Groups, and Osteopathic Philanthropic Organizations (Foundations); and
- AOA affiliated Divisional societies.

Accredited sponsors have the discretion of allowing other non-AOA accredited organizations, termed “Providers” to conduct CME programs under their accreditation status. It is the Accredited Sponsor’s responsibility to ensure that the Provider’s programs will follow the AOA Category 1 CME Requirements.

4.2 **New Applications to be an AOA-accredited Category 1 CME Sponsor** -Each CME sponsor seeking AOA accreditation as a Category 1 CME sponsor shall complete the application and its attached forms.

4.3 **Non-Assignability of Accreditation Status** - of CME sponsors is not transferable or assignable to another entity. A Category 1 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 Category 1 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 Division of Continuing Medical Education of such a name change.

V Policies

Requirements of CME Sponsors

- 5.1 Mandatory Attendance at CME Sponsors Conference** - Each AOA Accredited CME Sponsor is required to attend an AOA CME Conference at least one during every 3-year cycle. An AOA-accredited CME Sponsor that does not attend at least one Conference during each CME cycle will forfeit its CME accreditation.

CME sponsors, who are awarded one-year accreditation, are on probation, have achieved a score of 60-69% on their document survey, or are a new CME sponsor accredited by the Council on Continuing Medical Education must attend the CCME Sponsors Conference immediately following the awarding of such accreditation by the Council.

- 5.2 Annual Minimum Programming Requirements** - Each accredited Category 1 CME Sponsor must produce at least one program annually of 3 hours or more in length during its accreditation cycle in order to retain its status a Category 1 CME Sponsor.

A program of 3 hours in length is defined as: (1) one 3-hour program; or (2) a series of lectures that total 3 hours in length. 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 that a CME Sponsor has been awarded accreditation based on the score achieved as outlined in section 8.2. Accreditation is awarded for either 3 years for a perfect document survey or 1 year for a document survey with deficiencies. A minimum floor for maintaining proficiency in CME sponsorship is the provision of at least 1 program annually of 3-hours in length during an accreditation cycle. The document survey for the accreditation would encompass 3 hours of program review per year.

- 5.3 Reporting CME Activities** – It is the responsibility of the CME sponsor to submit a roster of physicians who attended a CME event. Rosters should include the name of each physician, their AOA numbers, the number of hours of CME credit obtained by each physician, the name of the program, and the date of the program.

CME sponsors have until May 31 of the year following the end of a CME cycle with which to report CME credit for the previous CME cycle. After May 31, CME credit will not be accepted.

- 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.

- 5.4.1 Annual Accreditation Fee** - The annual accreditation fee for each AOA-accredited CME sponsor is \$200.00.

- 5.4.2 Annual Registration Fees** - In addition to the annual accreditation fee, CME sponsors are responsible for registration fees for the recording of physician credit hours.

- 5.4.1.1 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 hours 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.

- 5.4.1.2 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.
- 5.4.1.3 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 hours reported, up to an maximum of \$1,500.00 annually.
- 5.4.1.4 Exemption of Registration Fees** - The Council on 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.
- 5.4.3 Withholding the Recording of CME Credit** - The AOA will withhold the awarding of CME credit for all CME Sponsors that do not pay their annual fees within 120 days of receipt of the annual invoice. This invoice is usually mailed in January of each calendar year. Sponsors will be notified that their CME credit will not be recorded until payment is made. Also, the AOA staff will inform physicians of the reason their CME credit was not recorded on their CME Activity Reports.
- 5.4.4 On-site survey Expenses** - Sponsors will be billed for the direct cost of on-site surveys.
- 5.5 Advertising for AOA Category 1A CME Credit** – AOA Category 1 CME Sponsors shall use the following language, when there has been no prior AOA approval, for advertising AOA Category 1-A CME programs: “This program anticipates being approved for X number of AOA Category 1-A CME credit pending approval by the AOA CCME.
- 5.6 On-site Monitoring for Continuing Medical Education Program** – AOA Category 1 CME Sponsors shall provide a signed attendance sheet from each attendee indicating the number of hours actually attended for each sponsors CME activity.
- 5.7 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.

VI Document Survey Procedure

Document Survey Procedure

- 6.1** Prior to the end of a CME sponsor’s term of accreditation, the AOA Division of CME will review a listing of CME programs and select an appropriate program(s) for review.
- 6.2** The AOA will then notify the sponsoring organization of the program(s) chosen for review via certified mail and will ask the organization to submit the required information within thirty working days of notification.
- 6.3** The requested information will be reviewed by the AOA Division of CME and the results of this review will be forwarded to the Council on CME to determine the accreditation status of the applying organization at the next CCME meeting.
- 6.4** If the Council determines that serious quality problems exist, the Council has the option of notifying the sponsoring organization that it must respond to the cited deficiencies with a plan of corrective action. Organizations will be notified of the need to submit missing documentation and will be given 10-working days to submit missing information before any points are taken away.

- 6.5** Failure to submit the required documentation, or failure to respond to deficiencies within the 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.
- 6.6** If an organization requests an extension of more than 40 days, only up to 2-years of accreditation will be awarded.

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.

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Checklist Items	Pts
1. A copy of the CME program brochure or agenda distributed to participants at the CME program. (MAJOR) _____ _____	8
2. A description of the needs assessment process and procedure used in determining the content and topic of the program (include any supporting documents). A statement relative to how topics and/or speakers were selected in direct response to needs assessment procedures. (MAJOR) _____ _____	8
3. Copies of ALL program participants' (speakers and moderators) curriculum vitae or biosketch defining their qualifications for involvement in the CME program. (MAJOR). Partial credit is awarded based on the percentage of CVs and biosketches 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. _____ _____	8
4. A copy of each speaker's signed Disclosure Declaration Statement. (MAJOR) Partial credit is awarded based on the percentage of the disclosure statements provided during the document survey. _____ _____	8
5. A copy of the CME hour credits requested by the AOA-accredited sponsor for each participating physician in accordance with the attesting document). (MINOR) _____ _____	4
6. A copy of the program administration evaluation document and the total number of evaluation documents returned by conference registrants. Provide two copies of the program evaluation documents that were returned by conference attendees. (MINOR) _____ _____	4
7. A statement indicating the total number of registrants, and the number of attestation forms returned by conference participants. (MAJOR) _____ _____	8
8. A statement reflecting the distribution of program evaluation documents (i.e.: 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 registrants. Provide two copies of the outcomes questionnaire documents that were returned by conference attendees. (MINOR) _____ _____	4
11. A statement indicating whether or not the program was commercially supported. (MAJOR)	8

<p>_____</p> <p>_____</p>	
<p>12. If the program was commercially supported, the following additional items must be submitted:</p> <p>A) A copy of the formal written agreement between the AOA CME Sponsor and each Commercial Supporter reflecting that activity (program) is educational and nonpromotional. (MAJOR) Partial credit is awarded.</p> <p>_____</p> <p>_____</p>	8
<p>B) Proof that commercial support is appropriately acknowledged in announcements and brochures (submit brochures, flyers, etc. indicating such). (MINOR)</p> <p>_____</p> <p>_____</p>	4
<p>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.</p> <p>_____</p> <p>_____</p>	8
<p>D) A statement indicating how disclosure information regarding each speaker was given to the participants. (MAJOR) Partial credit is awarded.</p> <p>_____</p> <p>_____</p>	8
<p>E) A statement indicating how the commercial exhibit area was arranged. For example, were promotional activities provided in a separate room, or was there any arranged exhibit hall, which included promotional activities from alternative companies? (MAJOR)</p> <p>_____</p> <p>_____</p>	8
<p>Total Score</p>	104

Scoring Key:

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

Accreditation:

- 90 points or better on the document survey is awarded 3-year accreditation
- 80 – 89 points on the document survey is awarded 2-year accreditation
- 70 – 79 points on the document survey is awarded 1-year accreditation
- 60 to 69 points on the document survey is awarded 1-year accreditation with required attendance at the next CME sponsors conference less than 60 points on the document survey accreditation is withdrawn
- 4 points may be awarded for Outcomes Measurement. This is optional for extra credit.

VIII Accreditation

Accreditation

- 8.1 Accreditation Status of New Programs** – New AOA-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 CME.
- 8.2 Accreditation Actions** - The Council on CME shall evaluate the document survey using the checklist. The Council shall award accreditation based on the score achieved on the checklist:
- 90% or better on the document survey is awarded 3-year accreditation
 - 80% to 89% on the document survey is awarded 2-year accreditation
 - 70% to 79% on the document survey is awarded 1-year accreditation
 - 60 to 69% on the document survey is awarded 1-year accreditation with required attendance at the next CME sponsors conference
 - Below 60% on the document survey accreditation will be denied
- 8.3 Probation** – An AOA-accredited CME Sponsor shall be placed on probation if it is awarded 1-year accreditation 3 years in a row. For CME sponsors on probation, the Council on 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 CME has the authority to revoke accreditation for any CME sponsor on probation, if the information obtained at either the on-site survey or counsel 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 CME has the authority to place an AOA-accredited 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 CME has the authority to revoke CME sponsor accreditation status if a CME sponsor is found in violation of the “AOA Uniform Guidelines.”

IX Complaints

Complaints made against CME sponsors are taken very seriously by the Council on Continuing Medical Education. CME sponsors that are found to be out of compliance may have the following actions taken against them: be required to undergo an on-site visit, be required to attend a Council meeting to discuss a plan of corrective action, be placed on probation, or be denied accreditation status.

- 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 meeting with the CME sponsor, the responsibility for filing a formal complaint to the AOA Council on Continuing Medical Education 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 Continuing Medical 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 Council on Continuing Medical 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 Council on Continuing Medical Education 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:

9.3.1 Dismiss – The review body may dismiss the complaint if it concludes that the CME sponsor is in compliance with CME standards.

9.3.2 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 Continuing Medical Education within one year from the time of postponement for final resolution.

9.3.3 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. 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 Continuing Medical Education meeting to present the sponsor’s perspective.

9.3.4 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 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 Continuing Medical Education meeting to present the sponsor’s perspective.

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 Continuing Medical Education 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 CCME or the Bureau of Osteopathic Education to either reverse or accept the initial recommendations of the CCME.

- d. CME sponsors requesting appeals are automatically continued 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 Continuing Medical Education, and must be filed within 30 days following receipt of the recommendation of the Council on Continuing Medical Education.
- 10.3** Requests for appeal must be made in writing to the Bureau of Osteopathic Education, and must be filed within 30 days following receipt of the action by the Council on Continuing Medical Education.
- 10.4** CME sponsors may seek a final appeal and hearing before the AOA Board of Trustees.

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 organization 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 weeks prior to the date of the on-site survey.
- 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.
- 11.6** CME sponsor program surveyors must submit written reports within 30 days to the CCME 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 Division of Continuing Medical Education 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 CCME will evaluate survey reports of both document and on-site program surveys at its meetings.
- 11.10** Sponsors will be notified by certified mail of actions taken by the CCME, usually within ten (10) working days after its meetings.

XII Definitions

Definitions

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.

Accredited Sponsor - An AOA-CME Category 1 sponsor is, an institution, organization or affiliate that is accredited by the AOA Council on CME to present programs that qualifies for AOA-CME category 1 credit.

Accredited sponsors have the discretion of allowing other non-AOA accredited organizations, termed "Providers" to conduct CME programs under their accreditation status. It is the Accredited Sponsor's responsibility to ensure that the Provider's programs will follow the AOA Category 1 CME Requirements.

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

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.

CME Sponsor - A CME Sponsor is an institution, organization or affiliate that is accredited by the AOA Council on CME to present programs that qualify for AOA-CME Category 1 credit.

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.

Enduring Materials - Commercially supported enduring materials are planned educational programs and materials designed and developed with financial or other support from commercial interests, and used for CME purposes beyond their initial presentation. Such enduring materials include printed, photographed, or electronically modulated programs and materials, such as, but not limited to, printed educational material, audio cassettes, video cassettes, computer assisted instruction, broadcast by television or radio of any type, and electronic teaching aids.

Labeling - Include not only product labels but also other written, printed, or graphic matter that "accompanies" a product.

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.

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.

Outcome Measure -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).

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.

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.

Program - A formal educational program presented in a live setting.

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

Reduction – the act of decreasing a physician's CME requirement based on individual mitigating circumstances.

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

Safe Harbor - Scientific and educational activities that are supported by the regulated industry but are independent of promotional influences that may emanate from the supporting companies. Within the perimeters of the safe harbor, activities may be funded by the regulated industry, may be designed

to provide information on the use of regulated products, and yet be left free from regulation under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

Uniform Guidelines - Uniform Guidelines for Accrediting Agencies of Continuing Medical Education as adopted by the AOA.

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.

Appendix A – Application Form

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, Division of Continuing Medical Education, 142 East Ontario Street, Chicago, Illinois, 60611. Retain the duplicate copy for your records.

The AOA Council on 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 CME will accredit those sponsors 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
Division of Continuing Medical Education
Accreditation Application for AOA Category 1 CME Sponsor
Part 1

General Information

1. Sponsoring Organization _____
Address _____
City _____ State _____ Zip Code _____
2. Contact Person _____
Title _____
Phone number _____ Ext. _____
FAX _____
3. Type of Sponsor:
A) ___ Osteopathic Acute Care Hospital
B) ___ College of Osteopathic Medicine
C) ___ Osteopathic Specialty College (Practice Affiliate)
D) ___ Osteopathic Specialty Board
E) ___ State Osteopathic Medical Association (Divisional Society)
F) ___ Osteopathic Alumni Group, Osteopathic Philanthropic organization,
or Osteopathic Non-practice Affiliate
G) ___ Other _____
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.

10. Does your organization conduct CME programs through joint sponsorship with other organizations?

YES If yes, name organization(s) so involved.

NO

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
Division of Continuing Medical Education
142 E. Ontario Street
Chicago, IL 60611

Signed: _____
Authorized sponsoring organization representative

Title: _____

Date: _____

FOR OFFICE USE ONLY
Date Appl Recd Approval Date Code #

American Osteopathic Association
Division of Continuing Medical 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. F.A.A.P. 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 continuing medical education of the AOA at: 142 East Ontario Street, Chicago, IL 60611.

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 Continuing Medical Education of the AOA at: 142 East Ontario Street, Chicago, IL 60611.

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. Speaker(s) 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: 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 initiated requests for suggestions of presenters or sources of possible presenters. Company will suggest more than one name (if possible); will provide speaker qualifications, 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 obligate 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.

CME PROGRAM: _____

DATE: _____

TITLE OF PRESENTATION: _____

PRESENTER'S 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.

<u>Affiliation/Financial Interest</u>	<u>Name of Organization(s)</u>
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.