

## **Appendix E: On-Site Survey**

1. Special reviews or complaint reviews may require an on-site survey. The total cost of this on-site survey will be borne by the organization being surveyed and billed through the AOA offices.
2. When on-site 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 weeks prior to the date of the on-site survey.
4. On-site Surveys will be conducted by AOA approved surveyors.
5. The AOA will maintain a list of surveyors approved annually by the Council.
6. CME sponsor program surveyors must submit written reports within 30 days to the CCME on all on-site sponsors/programs surveyed.
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 apparent or actual 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. Failure to respond to deficiencies cited may result in withdrawal of accreditation.
9. The CCME will evaluate survey reports of both document and on-site surveys at its meetings.
10. Sponsors will be notified by certified mail of actions taken by the CCME, usually within ten (10) working days after its meetings.

### **I. Grading Scale Used for These Accreditation Standards**

The grading scale includes three potential levels of response plus a separate category for standards which are non-applicable:

1. **Compliance** - indicates there is evidence of compliance with the requirement.
  2. **Marginal Compliance** - indicates there is evidence of limited compliance with the requirement.
  3. **Non-Compliance** - indicates there is no or inadequate evidence of compliance (pervasive evidence of non-compliance) with the requirement.
- N/A Not Applicable** - indicates that the standard does not apply to the program/activity being surveyed.

## II. AOA General CME Quality Standards

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, advertising and promotional materials and the responsibility for adherence to the standards of quality must rest with the AOA accredited sponsor. The sponsor shall ensure that sound educational planning takes place in all programs.

### A. The AOA CME quality standards are:

1. CME will be systematically organized and administered. 1 2 3 NA
2. Each program should focus on the needs of the participants. 1 2 3 NA  
The program should be based on some type of needs assessment when possible: using a needs-identifying-process to form a priority list for educational programs in *advance*—based on deficiencies, problems, and needs. (that is, every program is to be a planned program of learning, not just one of trial and error conceived by a program chairman.)  
Some examples of these needs assessments are as follows:
  - A. Medical Audit (Identifying Needs)
    1. Develop criteria of excellence (such as for a P.R.O.)
    2. Collect and summarize data.
    3. Analyze and interpret data.
  - B. Pre-Test item analysis (Identified Needs)
  - C. Self-Assessment (Identified Needs and Perceived Needs)
  - D. Questionnaire (Physician Felt Needs)
3. The sponsor ensures that a faculty has been established with adequate 1 2 3 NA  
credentials and is used for each CME program.
4. Every program should have stated and printed educational 1 2 3 NA  
objectives. The objectives should state what the physician should know or be able to do at the end of the program, for example: correction of outdated knowledge, and new knowledge in specific areas; master new skills, change attitudes or habits, etc.
5. Speaker and program primary evaluation responsibility lies 1 2 3 NA  
with the CME sponsor.
6. CME programs include a variety of course-class alternatives 1 2 3 NA  
and encourage innovative program development.
7. Each program should have a statement as to the type of 1 2 3 NA

audience for whom the program is designed--for example: general practitioners, surgeons, cardiologists, etc.--All programs are *relevant* to the practice needs of this audience.

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| 8.  | The sponsors encourage active participation by the learner wherever possible.   | 1 2 3 NA |
| 9.  | Attendance records are kept as means of assuring that those attending a program are given proper credit toward their CME requirement. | 1 2 3 NA |
| 10. | The sponsor uses a post-course evaluation to determine the effectiveness of the program and whether the stated objectives were met.   | 1 2 3 NA |
|     | Examples of evaluation methods are:   |          |
|     | A. Pre and post testing.  |          |
|     | B. Self-assessment.   |          |
|     | C. Practice in hospital medical audits.   |          |
|     | D. Post-course critique.  |          |
| 11. | The sponsor ensures that proper facilities and equipment are provided to enable the presenter to teach effectively.                   | 1 2 3 NA |

### III. AOA Category 1-A Quality Standards

#### Definition:

An AOA-CME sponsor of Category 1-A programs is defined as an osteopathic institution, organization, or affiliate that presents programs that qualify for AOA CME credit.

- A. To receive AOA Category 1-A CME credit sponsors agree to apply quality standards as defined in Section IV.
- B. Sponsors agree to apply additional quality standards as defined below:

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|----|---|---|---|---|----|
| 1. | Ensures that at least 50% of the presenters shall be DOs or staff members of osteopathic institutions.  | 1 | 2 | 3 | NA |
| 2. | Provides evidence of integrating osteopathic principles and practice into the program.  | 1 | 2 | 3 | NA |
| 3. | Identifies appropriate presenters who will teach in a planned program.  | 1 | 2 | 3 | NA |
|    | Suggested criteria for presenter selection includes:  |   |   |   |    |
|    | A. Appropriate Credentials  |   |   |   |    |
|    | B. Competence as a teacher  |   |   |   |    |
|    | C. Knowledgeable in content area  |   |   |   |    |
|    | D. Additional qualifications by experience  |   |   |   |    |
| 4. | Provides the AOA with the name and telephone number of the chairperson responsible for administration of Category 1-A CME activities.   | 1 | 2 | 3 | NA |
| 5. | Involves faculty with credentials appropriate to expertise required.  | 1 | 2 | 3 | NA |
| 6. | Ensures advertising and promotion of CME activities are 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 and 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. | 1 | 2 | 3 | NA |
| 7. | Adequately maintain and make available records of participation in CME activities adequate to serve the needs of participants and others requiring this information.  | 1 | 2 | 3 | NA |
| 8. | Provides participants with a certificate or some other document   | 1 | 2 | 3 |    |

	attesting to the satisfactory completion of the CME activity.	NA
9.	Has a written policy dealing with procedures for the management of grievances and fee refunds.	1 2 3 NA
10.	Ensures that a sound financial base is established for the planned CME programs and activities. Budget planning for CME should be clearly projected. Programs will not be presented for the sole purpose of profit.	1 2 3 NA
11.	Ensures an appropriate number of qualified faculty for each activity.	1 2 3 NA
12.	Ensures adequate supportive personnel to assist with administrative matters and technical assistance are available.	1 2 3 NA
13.	Has the means for adequately monitoring the quality of faculty presentations.	1 2 3 NA
14.	Ensures that an adequate program participant evaluation system is in place as suggested in the quality standards.	1 2 3 NA

#### **IV. Fundamental Management of CME**

##### **A. Mission Statement**

The sponsor shall have a written statement of its CME mission which defines the role, scope, intended audience of its educational functions, and is formally approved by its governing body.

1 2 3  
NA

##### **B. Management Support**

The sponsor shall provide evidence that management procedures and other necessary resources are available and effectively used to fulfill its CME mission.

1 2 3  
NA

##### **C. Needs Assessment**

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

1 2 3  
NA

##### **D. Objectives**

An accredited sponsor shall, for each CME event, develop objectives based on identified education needs of prospective participants.

1 2 3  
NA

##### **E. Joint Educational Activities**

The sponsor shall assure that educational activities provided jointly with a non-accredited entity are conducted entirely according to the "Uniform Guidelines" and these AOA accreditation requirements.

1 2 3  
NA

Surveyor's check:

1. Determine if the sponsor has co-sponsored any educational activities of a non-AOA accredited entity.

2. If so, determine if the sponsor has followed the "Uniform Guidelines".

**F. Enduring Materials**

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| 1. | The sponsor shall assure that instructional materials, (textbooks, published proceedings of a symposium, etc.), that in themselves constitute a planned activity of CME, will be developed and administered entirely according to the "Uniform Guidelines".   | 1 2 3<br>NA |
| 2. | Commercially supported Enduring Materials presented for CME credit are the full responsibility of the Accredited Sponsor.   | 1 2 3<br>NA |
| 3. | The Enduring Materials will provide for full disclosure of commercial support, and of potential or real conflicts of interest of the faculty or the Accredited Sponsor.   | 1 2 3<br>NA |
| 4. | Prior to publication, republication, or distribution, the enduring materials must be reviewed by qualified individuals or groups other than the author or faculty.  | 1 2 3<br>NA |
| 5. | The enduring materials may include commercial advertising; however, such advertising must be limited to non-product-specific promotion by the commercial supporter. The materials must not be used as a part of marketing efforts by the commercial supporter. Advertising should not distract from the presentation, delivery or content of the CME program. | 1 2 3<br>NA |
| 6. | Pharmaceutical and medical device industry distribution of commercially supported enduring materials, including promotion by industry representatives, is acceptable if the CME Sponsor is responsible for and formally approves such distribution.   | 1 2 3<br>NA |

**G. Disclosure**

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| 1. | The Sponsor shall have a policy that ensure meaningful disclosure, at the time of the presentation to the audience of (a) the company's funding of the activity, and (b) any significant relationship between the Provider and the company and between individual presenters or moderators and the company (e.g., employee grant recipient, owner of a significant interest of stock).  | 1 2 3<br>NA |
| 2. | All approved CME activities conform to this policy.   | 1 2 3<br>NA |
| 3. | In the case of a regularly scheduled event, such as grand rounds, tumor board, etc. where topics and speakers may be determined just prior to a presentation, disclosure shall be made by the moderator of the activity after consultation with the faculty member or a representative of the accredited sponsor. (A disclosure statement and curriculum vitae (CV) or bio-sketch of each commercially supported speaker shall be on file). | 1 2 3<br>NA |
| 4. | Written documentation that disclosure information was given to all participants shall be entered in the file for that activity (whether the program was commercially supported or not).   | 1 2 3<br>NA |

## V. Guidelines For Commercially Supported Programs

### A. Financial Arrangements

1. Handling of funds by third parties
  - a. All decisions regarding funding arrangements for CME activities are the responsibility of the CME sponsor. The use of third party payors may be approved by the AOA if the CME Sponsor can show proof of “Administrative Hardship.” 1 2 3 NA  
*Interpretive Guideline: "Administrative hardship for CME sponsors" is defined as a total of two or fewer full time equivalent units (FTEs).*
  - b. Funds from a commercial source made payable to the accredited sponsor are in the form of an educational grant for the support of programming 1 2 3 NA  
*Interpretive Guideline: Payment of reasonable honoraria and reimbursement of out-of-pocket expenses for faculty is customary and proper.*
  - c. There are no other funds paid to faculty, CME program directors, or others involved with the supported program except as provided in the written agreement. 1 2 3 NA
  - d. All commercial support associated with an educational activity is made under the direction of, and with the full knowledge and approval of, the accredited sponsor. 1 2 3 NA
  - e. Commercial support is acknowledged in printed announcements and brochures; however, reference is not made to specific commercial products. 1 2 3 NA
  - f. Following the CME activity, upon request, the sponsor is prepared to report to each commercial supporter, information concerning the expenditure of funds each has provided. 1 2 3 NA
  
2. Expenses for Attendees 1 2 3 NA  
Funds originating from a commercial source may not be used to directly pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. Any subsidy shall be accepted by the conference sponsor, who, in turn, can use the funds to reduce the conference registration fee.  
*Interpretive Guideline: Exceptions to the above. Scholarships 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 by either the academic or training institution, or by the accredited sponsor, with the full concurrence of the academic or training institution.*

3. Written Agreement
  1. For each CME program which is commercially supported the sponsor shall:
    - a. Have a formal written agreement signed by the AOA Accredited CME Sponsor and the Commercial Supporter, reflecting that both parties agree that the activity is to be educational and nonpromotional, and that there will be no role in the design or conduct of the program that might bias the treatment of the topic.

1 2 3 NA

**B. Program Preparation, Advertising and Presentation**

1. Program Preparation

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

a. Independence

1. "Independence" requires that the role of the pharmaceutical company, or any other commercial supporter of the program, must be limited to facilitating, not creating or influencing, scientific exchange.

1 2 3 NA

*Interpretive Guideline: Independence - It is the FDA's view that provider control over content means not only final editorial control, but also insulation from substantive input from the supporting company that could influence content. Although limited technical assistance may be provided by the supporting company upon request, it cannot amount to scripting of presentation content. The proposed agreement also indicates that independence requires that the supporting company not be involved in the selection of presenters or moderators, other than in response to an unsolicited request for assistance in identifying possible presenters.*



2. Help with the preparation of educational materials. 1 2 3 NA  
The content of slides and reference materials must remain the ultimate responsibility of the faculty of the accredited sponsor.

*Interpretive Guideline: This responsibility for preparation may be shared with the commercial supporter of the accredited sponsor. The content of the program remains the responsibility of the sponsor. The accredited sponsor may ask a commercial supporter to help with the preparation of conference related educational material (e.g., slides prepared per the request of the presenter that reproduce tables published in scientific reports), but these shall not specifically promote or otherwise suggest the proprietary interest of the commercial supporter.*

3. 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, especially in regards to the provisions concerning the independence of the accredited sponsor in planning, designing, delivering, and evaluating all of its educational activities offered for credit. 1 2 3 NA

b. Program Design

The CME sponsor shall maintain evidence that the event has been developed, marketed, and produced in accordance with the AOA monitoring process and the signed written agreement. 1 2 3 NA

1. Objectives Influence Design. 1 2 3 NA  
An accredited sponsor shall use the objectives developed for an educational activity to select the content, and design the educational methods, for that activity.

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| 2. | Control of Program Content   | 1 2 3 NA |
| 3. | An accredited Sponsor retains and is responsible for exercising full control over the program's content, including the selection of presenters and moderators.   |          |
| 3. | Assistance with Educational Planning<br><br>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 of advice or services concerning speakers, invitees or other educational matters, including content, is the responsibility of the accredited sponsor.                                     | 1 2 3 NA |
| 2. | Advertising  |          |
|    | a. Marketing CME Activities  |          |
| 1. | A CME sponsor may not authorize a commercial supporter to disseminate to the medical community information about a CME activity.   | 1 2 3 NA |
| 2. | 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.   | 1 2 3 NA |
|    | b. Exhibits  |          |
| 1. | 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.   | 1 2 3 NA |
| 2. | The proposed agreement must further provide that there will be no ancillary promotional activities as part of the program. Exhibits must be provided in a separate room and away from an obligate pathway to the program. Obligate pathways may be used, if the exhibit is within an area that is designed for general exhibits and includes exhibits from different companies marketing alternative or competing therapies. | 1 2 3 NA |

3. Presentation
  - a. Objectivity and Balance
    1. Objectivity and Balance. "Objectivity and balance" requires that the material presented during the activity not be biased toward or against specific products. 1 2 3 NA
    - aa. Discussions of uses shall focus on those uses that have been the subject of objective investigation. The data presented during an activity should be scientifically valid and reliable. 1 2 3 NA
    - bb. The accredited sponsor ensures that both favorable and unfavorable information about the product will be fairly represented, and that there is balanced discussion. 1 2 3 NA
    2. 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. 1 2 3 NA
    3. If proprietary names are used, those of several companies that make relevant products must be used rather than only those of a single company. 1 2 3 NA
    4. 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. 1 2 3 NA
    5. Limitations on data. Limitations on data must be disclosed, un-approved uses be identified as such, and for live presentations there must be opportunities for questioning or debate. 1 2 3 NA
  - b. Communicating Results of Scientific Research.
    1. CME presentation of scientific research reports on commercially prepared medical products or devices must be objective, accurate, and unbiased. 1 2 3 NA

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|----|---|----------|
| 2. | Research information must conform to the generally accepted standards of experimental design, data collection and analysis.   | 1 2 3 NA |
|    |   |          |
| c. | Product Promotional Activities  |          |
| 1. | No commercial promotional materials shall be displayed or distributed in the same room before, during, or after an accredited educational activity.   | 1 2 3 NA |
| 2. | 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.                                  | 1 2 3 NA |
| d. | 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". | 1 2 3 NA |

**VI. Guidelines for "Hands-on" Procedure Based CME Programs**

*Interpretive Guideline: Hands-On procedure based educational programs offer instruction with a medical device used by a physician in the conduct of a procedure or intervention (e.g., an endoscope used in identifying the source of an upper GI bleed, a stent used to prevent restenosis of coronary artery).*

Procedure based programs will be eligible for CME credit, provided that the following guidelines are followed:

The program must be offered in conjunction or combination with lecture programs which meet:

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|----|--|----------|
| 1. | The requirements in the AOA CME Guide, and;  | 1 2 3 NA |
| 2. | The requirements for industry supported CME as described in this manual,                           | 1 2 3 NA |
| 3. | Include instructional materials that identify specific goals for the program, and                  | 1 2 3 NA |
| 4. | Exclude the use of promotional displays and promotional materials in the educational presentation. | 1 2 3 NA |

**VII.**

**Grievance Procedure for Program Attendees**

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| A. | The CME Sponsor shall have a grievance procedure for program attendees to file complaints or questions regarding whether the CME program was designed, prepared, and delivered within the AOA Uniform Guidelines, and AOA Accreditation Requirements. | 1 2 3 NA |
|    |   |          |
| B. | Program agenda materials shall include a notice to attendees that:  |          |
| 1. | They may contact staff representatives of the accredited sponsor at the CME program to resolve any problems such as facilities, hand-outs, and program content.   | 1 2 3 NA |
| 2. | Concerns about the CME program's compliance with the AOA "Uniform Guidelines" may be expressed to the accredited sponsor.   | 1 2 3 NA |
| 3. | Unresolved issues regarding compliance with the AOA "Uniform Guidelines" can be brought to the attention of the AOA Division of CME.  | 1 2 3 NA |
| 4. | Include an AOA 800 phone number (800-621-1773, Ext. 5836) and a direct phone number (312-280-5836), in addition to the AOA CME address  | 1 2 3 NA |

*Interpretive Guideline: Telephone complaints will be acknowledged and referred to the CME sponsor for resolution. Any formal action by the AOA Division of CME or the AOA Council on Continuing Medical Education (CCME) will require a formal written complaint.*