



AOA Guide for Commercial
Supporters

Division of Continuing Medical Education

American Osteopathic Association
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Accreditation of AOA CME for Commercial Supporters

Introduction

The American Osteopathic Association (AOA) is organized to advance the philosophy and practice of osteopathic medicine by promoting excellence in education, research, and the delivery of quality, cost-effective health care in a distinct, unified profession.

CME Accreditation

The AOA Board of Trustees and AOA House of Delegates have granted the Council on Continuing Medical Education (CCME) the authority:

- To grant accreditation status to osteopathic CME Sponsors according to the guidelines approved by the AOA Board of Trustees;
- To conduct periodic accreditation surveys and on-site surveys of CME sponsors; and
- To approve or deny credit for osteopathic CME.

The AOA Board of Trustees has approved Standards of Accreditation, which includes Quality Guidelines, the *Uniform Guidelines*, and Standards for Osteopathic Category 1-A Programs. The Council on Continuing Medical Education monitors these policies and procedures on an ongoing schedule, monitors CME programs for compliance with AOA policies and the approved “Uniform Guidelines,” and investigates all written complaints of deviation from AOA policy using a standard complaint review procedure. (see Appendix 1)

1. CME Requirements

All AOA members engaged in active clinical practice are required to meet specified CME credit hour requirements to remain eligible for continued membership in the association. The requirement for membership of the American Osteopathic Association (AOA) is 120 hours with a minimum of 30 hours in AOA Category 1-A. For those members with 120 CME hour requirement, thirty CME hours must be obtained in Category 1-A. The remaining 90 hours of CME requirement may be satisfied in either Category 1-A, 1-B, 2-A or 2-B credit. Physicians who are board certified must earn a minimum of 50 credit hours (Category 1 or 2) in their primary specialty. Members who obtain 150 hours or more of AOA approved CME credit in a 3-year CME cycle will be given a certificate of excellence in CME. (NOTE: there are additional requirements for board certification, as well as exemptions and CCME – approved reduction or waiver of requirements, as described elsewhere.)

The AOA assigns CME credit to four categories: 1-A, 1-B, 2-A, and 2-B.

Category 1-A Credit

AOA category 1-A credits comprised of formal educational programs that are designed to enhance clinical competence, improve patient care and are sponsored by an AOA-accredited CME sponsor.

Formal Osteopathic CME

Formal face-to-face programs that meet the Category 1 Quality Guidelines and faculty requirements and are sponsored by AOA-accredited CME sponsors.

Osteopathic Medical Teaching

Delivery of formal osteopathic medical education in a didactic format is eligible for Category 1-A credit on an hour-for-hour basis. Methods of such education would include: formal delivery of osteopathic medical education lectures in colleges of osteopathic medicine, and formal delivery of osteopathic medical education to students, interns, residents, and staff of AOA approved healthcare facilities. Teaching credit must be submitted by the CME department of an AOA-accredited Category 1 CME college of osteopathic medicine or Category 1 CME hospital.

Category 1-B credit

Category 1-B credit may include: development and publication of scientific papers and electronically communicated osteopathic educational programs; serving as osteopathic healthcare facility and college accreditation inspectors or consultants; OPTI inspections, conducting and developing certifying board examinations and test construction committee work; participating on an osteopathic state licensing professional review board; and healthcare committee and departmental meetings which review and evaluate patient care whether the committee work is in an osteopathic or allopathic institution. Serving as a preceptor in any AOA-Approved osteopathic medical education program may be granted Category 1-B credit. A maximum of 60 hours of AOA Category 1B preceptoring may be applied to the 120 hour requirements designated by the approved Category 1 college of osteopathic medicine. Fifteen hours of Category 1-B credit will automatically be awarded to AOA members who pass a recertification examination or obtain a certification of added qualifications. AOA Category 1-B credit may also be obtained through:

a. Activities in Non-AOA-accredited Institutions

Category 1-B may be granted to osteopathic physicians who participate in a non-AOA-accredited institution/hospital, hospital staff activities, educational lectures, and lecturing when the institution/hospital is an AOA recognized associate institution/hospital that trains osteopathic interns and/or residents. A non-AOA accredited institution/hospital (or associate institution/hospital) is an institution/hospital that is directly associated with an OPTI for purposes of training osteopathic students, interns and/or residents. Accreditation of the hospital/institution by the healthcare facility accreditation program (HFAP) of the AOA is not required.

b. Non-Osteopathic CME Programs

The Council on Continuing Medical Education may recognize allopathic specialty or subspecialty programs for Category 1-B credit, when in the Council's opinion there are

essentially no equivalent courses available within the osteopathic profession, and that such recognition will apply to all physicians in that specialty or subspecialty. These courses must be sponsored by an ACCME accredited provider, or AAFP approved. To request consideration of a non-osteopathic course for Category 1-B credit, write to the Division of CME at AOA Headquarters in Chicago and supply a copy of the printed program (or syllabus) and documentation of attendance.

c. Reading the JAOA Journal and other Approved Journals by the CCME and Passing the CME Quiz

Osteopathic physicians can earn 2 hours of AOA Category 1-B credit for reading the JAOA and other approved journals by the CCME and passing the respective CME quiz by a minimum of 70%.

d. Faculty Development Programs

Faculty development programs are granted Category 1-B credit if they are sponsored by an AOA-accredited Category 1 CME sponsor and meet the 1-A faculty/hours requirement.

Category 2-A Credit

Category 2-A includes formal educational programs that are ACCME-Accredited, AAFP approved, or programs sponsored by AOA-accredited Category 1 CME sponsors which do not meet the 1-A faculty/hours requirement for Category 1-A credit.

Category 2-B Credit

Category 2-B credit includes the preparation and presentation of scientific exhibits at a county, regional, state, or national professional meeting (10 hours per scientific exhibit); home study; reading medical journals and viewing non-osteopathic medical video and audio tapes and cassettes; journal type CME on the Internet; faculty development; physician administrative training; quality assessment programs; observations at medical centers; medical economics; CME programs on the Internet; risk management programs that are administrative in nature; and programs dealing with experimental and investigative areas of medical practice. Five credit hours may be granted for reading medical textbooks. A copy of the home CME certification form is published monthly in the JAOA.

2. Risk Management and Managed Care Programs

Risk management programs are granted Category 1-A credit if they are clinical in nature, sponsored by an AOA-accredited Category 1 CME sponsor, and meet the 1-A faculty/hours requirement for AOA Category 1-A credit.

Risk management programs are granted Category 2-A credit if they are clinical in nature and are sponsored by an AOA-accredited Category 1 CME sponsor but the 1-A faculty/hours requirement is not met; or sponsored by an ACCME-accredited organization; or an AAFP approved program.

Risk management programs are granted Category 1-B credit if they are administrative in nature, and sponsored by an AOA-accredited Category 1 CME sponsor. Risk management programs are

granted Category 2-B credit if they are administrative in nature and are sponsored by an ACCME-sponsor or if the programs are AAFP approved.

Managed care programs are granted Category 1-A if they are sponsored by an AOA-accredited Category 1 CME sponsor and meet the 1-A faculty/hours requirement for AOA Category 1-A credit. Managed care programs are granted Category 1-B credit if they are sponsored by an AOA-accredited Category 1 CME sponsor but the program does not meet the AOA Category 1-A faculty/hour requirement. Managed care programs are granted Category 2-A credit if they are sponsored by an ACCME-sponsor or if the programs are AAFP approved. (The maximum of CME credits which may be earned for managed care courses is 5 hours per year with a total of 15 hours within any one three-year cycle.)

3. CME on the Internet

Osteopathic physicians may earn up to 30% of their Category 1-A requirement from Internet CME (i.e., up to 9 hours of Category 1-A CME for members with a requirement of 30 hours of Category 1-A credit). Category 1-A Internet CME credit earned in excess of 9 hours will be applied to the Category 1-B and Category 2 CME requirements. Category 1-A credit will be awarded to real-time, interactive, simultaneous conferencing CME on the Internet. The CME event must meet AOA quality guidelines, the 1-A faculty/hours requirement, and it must be sponsored by an AOA-accredited Category 1 CME sponsor. These courses would be considered live on the Internet.

To be awarded credit for Internet CME, osteopathic physicians must complete a CME quiz with a passing grade of 70% or better, and the sponsor of the program must provide this information to the AOA, along with the category and amount of CME credit that the sponsor believes the course should receive.

What other types of Internet CME courses can receive CME credit?

Category 1-B credit may be awarded to audio and video programs on the Internet sponsored by AOA-accredited Category 1 CME sponsors. These courses are typically programs a physician could view anytime – day or night--that are primarily audio and video CME events.

Category 2-A credit may be awarded to real-time, interactive CME programs on the Internet that are produced by CME providers accredited by the Accreditation Council on Continuing Medical Education or courses approved by the American Academy of Family Physicians. These courses must be live on the Internet.

Category 2-B credit may be awarded to journal-type CME on the Internet that is produced by an AOA-accredited sponsor, ACCME sponsor, or a CME course approved by the AAFP. These courses are essentially static, textbook type programs. They may have hypertext jumps to help the reader pursue specific information.

The AOA Council on CME reserves the right to evaluate each CME Internet program and activity and to deny CME credits at its discretion.

4. Guidelines for Commercial Support of CME Programs Sponsored by AOA–Accredited CME Sponsors

- 1.1 AOA Category 1 credit will be awarded only to programs conducted by AOA accredited CME sponsors.
- 1.2 The CME program must meet the “Standards for Osteopathic Category 1-A Programs” as defined above. 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:
 - (1) At least 50% of the total educational hours are presented by osteopathic physicians, or MD's, PhD's, or other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine, or
 - (2) at least 50% of the presenters are osteopathic physicians, or MD's, PhD's, or other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine
- 1.3 A written agreement is required between the commercial supporter(s) and the accredited sponsor(s), and must state that the purpose of the program is for continuing medical education and that control of the content, faculty, educational methods and materials is the responsibility of the accredited sponsor.
- 1.4 The accredited sponsor may obtain information that will assist in planning and producing an educational activity from any outside source, whether commercial or not, for example: faculty recommendations, preparation of conference related educational materials, marketing CME activities to the medical community, or logistical assistance at the activities themselves. However, requests for such assistance cannot be a condition of support for an activity; and, any assistance accepted by the CME sponsor cannot advance the specific proprietary interests of the commercial supporter.
- 1.5 If the CME sponsor agrees to permit exhibits or commercial activity as part of an overall program, such arrangements should not influence planning nor interfere with the presentation of the CME activity
- 1.6 No commercial promotional materials shall be displayed or distributed in the same room as the CME activity.
- 1.7 Representatives of commercial supporters may attend an educational activity, but may not engage in promotional activities while in the room where the CME activity takes place.
- 1.8 Description of unlabeled or investigational uses not yet approved of medications must be identified as such, and all such information shall be objective and scientifically rigorous.

- 1.9 There must be a meaningful opportunity for participants to debate or discuss if the program is a live presentation.

5. Enduring Materials

- 2.1 CME credit may be granted enduring materials that meet the same requirements as “Faculty Development Programs” described above, i.e., that are sponsored by an AOA accredited CME sponsor and provide a faculty of which 50% of the faculty/authors (1) at least 50% of the total educational hours are presented by osteopathic physicians, or MD's, PhD's, or other professionals with graduate degrees who hold a full-time faculty appointment at a college of osteopathic medicine, or (2) at least 50% of the presenters are osteopathic physicians, or MD's, PhD's, or other professionals with graduate degrees who hold a full-time faculty appointment at a college of osteopathic medicine.
- 2.2 Such enduring materials can include printed monographs, audio-and videotapes, CD-ROMS, archived online materials, and other electronic teaching aids, which are most often intended for CME self-study.
- 2.3 Credit will be awarded at the rate of one (1) credit per hour of direct participation if an accompanying CME quiz is completed with a passing grade of 70%, and the sponsor confirms this to the AOA.
- 2.4 Requests for certification of enduring materials beside those planned and executed by an AOA accredited CME sponsor should be submitted to the AOA Division of CME for review by the AOA Editor-in-Chief, who will make a recommendation to the Council on Continuing Medical Education. This process will ordinarily take approximately 30 days.

Listing of AOA Accredited CME Sponsors

Alabama Osteopathic Medical Association

Robert Coleman, D.O.

President

3079-A Palisades Court

Tuscaloosa, AL 35405

205-562-2245

Alaska Osteopathic Medical Association

Jim C. Sanders, DO

President

245 N. Brinkley Street, Ste. 201

Soldonta, AL 99669

907-262-7700

Altoona Hospital

Robert F. Barnes, M.D.

Director of Medical Education, Acting

620 Howard Avenue

Altoona, PA 16601-4899

814-946-2263

American Academy of Osteopathy

Diane Finley

Associate Executive Director

3500 DePauw Blvd. #1080

Indianapolis, IN 46268

317-879-1881

American College of Osteopathic Emergency Physicians

Janice Wachtler

Executive Director

142 East Ontario Street, Suite 1250

Chicago, IL 60611

312-587-3709

American College of Osteopathic Family Physicians

Patt L. Moskal, CEM/CMP

Director of Meetings and Exhibits

330 East Algonquin Road, Suite 1

Arlington Heights, IL 60005

800-509-9204; 847-952-5102

American College of Osteopathic Internists

Susan Karicher

Director of Administration and Finance

3 Bethesda Metro Center, Suite 508

Bethesda, MD 20814

800-327-5183; 301-656-8877

American College of Osteopathic Neurologists & Psychiatrists

Sue Wesslerling

Executive Assistant

28595 Orchard Lake Road, Suite 200

Farmington Hills, MI 48334-2977

248-553-0010 Ext. 295

American College of Osteopathic Obstetricians/Gynecologists

Jaki Holzer

Administrator

900 Auburn Road

Pontiac, MI 48342-3365

248-332-6360

American College of Osteopathic Pediatricians

Elizabeth Harano

Assistant Director, Management

Services

142 E. Ontario Street

Chicago, IL 60611

1-877-231-ACOP

American College of Osteopathic Sclerotherapeutic Pain Management

Linda Pavina

Executive Secretary

303 South Ingram Court

Middletown, DE 19709

302-376-8080

American College of Osteopathic Surgeons

Jennifer Colwell

Director of Education & Meetings Services

123 North Henry Street

Alexandria, VA 22314-2903

703-684-0416 x202

**American Osteopathic Academy of Addiction
Medicine**

Elizabeth Harano
Assistant Director, Management
Services
142 E. Ontario
Chicago, IL 60611
312-202-8183

**American Osteopathic Academy of
Orthopedics**

Morton J. Morris, D.O., J.D.
Executive Director
P.O. Box 291690
Davie, FL 33329-1690
954-262-1700

**American Osteopathic Academy of Sports
Medicine**

Susan M. Rees
Executive Director
7600 Terrace Avenue, Suite 203
Middleton, WI 53562
608-831-4400 x138

**American Osteopathic Association Bureau of
Conventions**

Frank J. McDevitt, D.O.
Chairman, Bureau of Conventions
142 East Ontario
Chicago, IL 60611
312-202-8013

**American Osteopathic College of
Anesthesiologists**

Mrs. Glenna Vazanno
Executive Director
6500 NW Tower Drive, Suite 103
Kansas City, MO 64151
800-842-2622; 816-373-4700

**American Osteopathic College of
Dermatology**

Rebecca A. Mansfield
Director
P.O. Box 7525
Kirksville, MO 63501-7525
660-665-2184

**American Osteopathic College of
Occupational and Preventive Medicine**

Tom Loftus, FACHE
Executive Director
307 Lake View Way, NW
Leesburg, VA 20176
800-558-8686

**American Osteopathic College of Physical
Medicine and Rehabilitation Medicine**

Peter G. Markos, DO
Interim Ex. Dir., Immed. Past-Pres. of
AOCPMR
PO Box 732
Dover, NH 03821-0732
603-343-1937

American Osteopathic College of Proctology

Paul Broderick, DO
Executive Director
2209 John R. Wooden Drive
Martinsville, Indiana 46151
740-594-7252

American Osteopathic College of Radiology

Rhonda Thompson
Assistant Executive Director
119 East Second Street
Milan, MO 63556-1331
660-265-4011

**American Osteopathic College of
Rheumatology**

Robert Maurer, D.O.
Secretary/Treasurer
193 Monroe Avenue
Edison, NJ 08820-3755
732-494-6688

**American Osteopathic Colleges of
Ophthalmology and Otolaryngology, Head
and Neck Surgery**

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Dayton, OH 45405
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**American Osteopathic Family Physicians-
California Division**

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President
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Roseville, CA 95661
916-786-5908

Arizona Osteopathic Medical Association

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Executive Director
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Phoenix, AZ 85016-3925
602-266-6699

Arkansas Osteopathic Medical Association

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412 Union Station
Little Rock, AR 72201
501-374-8900

**Association of Military Osteopathic
Physicians & Surgeons**

James M. Yonts
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**Association of Osteopathic Directors and
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Bi-County Community Hospital

William D. Geddy
Horizan Medical Education, Office Manager
13355 East Ten Mile Road
Warren, MI 48089-2065
800-626-0679; 586-759-7690

Botsford General Hospital

Barbara Latra/Bert Rabinowitz, DO
CME Coordinator/CME Director
28050 Grand River Avenue
Farmington Hills, MI 48336
248-471-8350/248-471-8972

**Broward County Osteopathic Medical
Association, District 6**

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**Burlington County Society of Osteopathic
Physicians & Surgeons**

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Program Director
P.O. Box 1128, 1125 Madison Street
Jefferson City, MO 65101-1128
573-632-5025

Carson City Hospital

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406 E. Elm Street, PO Box 879
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CCOM-Midwestern University

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20201 S. Crawford Avenue, Room B373
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708-747-4000 x1681

Clarion Hospital

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Medical Education Coordinator
One Hospital Drive
Clarion, PA 16214
814-226-1306

Colorado Society of Osteopathic Medicine

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Interim Executive Director
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15 West Cimarron
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Columbia Hospital

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Director of Medical and Academic Affairs
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West Palm Beach, FL 33407
561-863-3910

Community Hospital

Michelle R. Baier
Medical Staff Services
2021 North 12th Street
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970-256-6202

Community Hospital of Lancaster

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1100 E. Orange Street
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717-239-4353

Connecticut Osteopathic Medical Society

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P.O. Box 487
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Crozer-Chester Medical Center, Springfield Division, Crozer-Keystone Health System

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Doctors Hospital

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Administrative Assistant
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Doctors Hospital North

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614-297-4245

Doctors Hospital of Stark County

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Clinton, MO 64735
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Massachusetts Osteopathic Society
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Memorial Hospital
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VP of Medical Affairs
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Mercy General Health Partners
Patrick E. Walsh, D.O.
Director of Medical Education
1700 Oak Avenue
Muskegon, MI 49442-2497
616-777-6451

Mercy Suburban Hospital
Harold Schreiber, D.O., FACOFP
Director of Medical Education
2701 DeKalb Pike
Norristown, PA 19401-1849
610-278-2003

Mesa General Hospital Medical Center
Sandy Elcock, CMSC
Director, Medical Staff Services
515 N. Mesa Drive
Mesa, AZ 85201-9840
480-461-6433

Metropolitan Hospital
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616-252-7078

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Meeting Coordinator
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Okemos, MI 48864
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Excerpted from the AOA Manual for Accreditation of AOA Category 1 CME Sponsors

2. 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 should focus on the needs of the participants.
- 2.1.3 The programs should 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 Felt Needs)
 - D. Questionnaire (Physician Felt 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 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.
- 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 the program should 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 should assure that proper facilities and equipment are provided to enable the presenter to teach effectively.
- 2.1.13 If two or more 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 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* are guiding principles for conducting 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 players in the CME and the health-related commercial interests in the U.S., 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 the unity among the professions through application of these policies and procedures.

2.2.1 Introduction to the 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 behaviors 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 "Uniform Guidelines".

2.2.2.4 Enduring Materials - An accredited sponsor that offers instructional materials, that in themselves constitute a planned activity of CME, shall develop and administer those materials entirely according to these "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, upon request, 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 significant 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) be prohibited.

AOA accredited provider does not host CME programs on a pharmaceutical or device manufacturer's website.

3. Standards for Osteopathic Category 1-A Programs

CME programs requesting Category 1-A or 1-B credit must meet the following standards:

- 3.1** (1) At least 50% of the total educational hours are presented by osteopathic physicians, or MD's, PhD's, or other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine, or
- (2) at least 50% of the presenters are osteopathic physicians, or MD's, PhD's, or other professionals with graduate degrees who hold a full-time paid faculty appointment at a college of osteopathic medicine

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 a teacher
 - 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 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.

- 3.7 Maintenance and availability of records of participation in CME activities should 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 should 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 provides a means for 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 will be considered as having administrative hardship (Resolution 26 (M/95)).

Definitions

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

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 nonpromotional.

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.

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.

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 Category 1 CME Sponsor shall provide a faculty of which at least 50% of the presenters are: (1) osteopathic physicians, or (2) MDs, PhDs, or other professionals with graduate degrees who hold a full-time faculty appointment at a college of osteopathic medicine.

Osteopathic Manipulative Treatment (OMT) – Hands-on treatment where osteopathic physicians (D.O.s) use their hands to examine the back and other parts of the body such as joints, tendons, ligaments and muscles, for pain and restriction during motion that could signal an injury or impaired function.

Osteopathic Medicine – Treating the patient as a “whole” person, instead of just treating specific symptoms.

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 (D.O.s) and allopathic physicians (M.D.s) 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 which is recognized by non-AOA accreditor(s) 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) which accredits CME sponsors, but does not approve individual programs. The American Academy of Family Physicians (AAFP) approves individual programs, but does not accredit sponsors.

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 which include: license to practice; completion of postdoctoral education; attainment of certification.

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

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 – 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, 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 B – 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 judgements 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.

Affiliation/Financial Interest

Name of Organization(s)

Grant/Research Support

Consultant

Speakers' Bureau

Major Stock Shareholder

Other Financial or Material Support

Signature

Date

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