AOA Guide for Commercial

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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 Edu

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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 passi

granted Category 2-B credit if they are <u>administrative in nature</u> 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 pr

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 Wesserling 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 American Osteopathic Family Physicians-California Division Linda M. Agresti, DO

Linda M. Agresti, DC President 2120 Profet8n

Clarion Hospital

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

Colorado Society of Osteopathic Medicine

Marie Kowalsky Interim Executive Director 650 S. Cherry Street #440 Denver, CO 80246 303-322-1752

Colorado Springs Osteopathic Foundation

Doris L. Ralston, MPA Director, CME & PR 15 West Cimarron Colorado Springs, CO 80903 719-635-9057; 719-635-2823

Columbia Hospital

Bradley S. Feuer, D.O., J.D. Director of Medical and Academic Affairs 2201 45th Street West Palm Beach, FL 33407 561-863-3910

Doctors Hospital

Judy Prewitt Administrative Assistant 5500 39th Street Groves, TX 77619-2999 409-963-5180; 409-963-5136

Doctors Hospital North

Paula Vasu Continuing Medical Education 1087 Dennison Avenue Columbus, OH 43201-3201 614-297-4245

Doctors Hospital of Stark County

Cindi Prewett Credential and Medical Staff Services Coordinator 400 Austin Avenue, N.W. Massillon, OH 44646-3598 330-830-1600

Eastmoreland Hospital

Kim Lynch Medical Staff Coordinator 2900 S.E. Steele Street Portland, OR 97202-4590 503-231-4556

Edward Via Virginia College of Osteopathic Medicine

Kim Price Director of Medical Education 2265 Krat Drive Blacksburg, VA 24060 540-443-9119

Firelands Regional Medical Center

Mary Bauer, R.N. CME Coordinator 1101 Decatur St. Sandusky, OH 44870-8005 419-626-7523; 419-627-6740

Fisher-Titus Medical Center

Barbara J. Hire, B.Ed., CMSC CME Coordinator 272 Benedict Avenue Norwalk, OH 44857-2399 419-668-8101 Ext. 6535

Florida Hospital East Orlando

Joan Bour CME Coordinator 2501 North Orange Ave., Suite 414 Orlando, FL 32804 407-303-2858

Florida Osteopathic Medical Association

Michelle Winn, CMP Associate Executive Director 2007 Apalachee Parkway Tallahassee, FL 32301-4847 800-226-3662

Florida Osteopathic Medical Association, District #7

Tom Quinn, D.O. Secretary PO Box 4106 Anna Maria, FL 34216 941-779-1958

Florida Society of the American College of Osteopathic Family Physicians

Kenneth Webster, Ed.D. Executive Secretary PO Box 2025 Largo, FL 33779-2025 727-581-9069

Freeman Health System

Mikell D. Bounds Director, CME 1102 West 32nd Street Joplin, MO 64804-2599 417-625-6612

Garden City Hospital Osteopathic

Norville H. Schock, Ph.D., FAODME Vice President of Medical Education 6245 Inkster Road Garden City, MI 48135-2599 734-458-4486

Genesys Regional Medical Center

Sharon Wilson CME Coordinator One Genesys Parkway Grand Blanc, MI 48439 810-606-5988; 810-606-5980

Georgia Osteopathic Medical Association

Holly Barnwell Executive Director 2037 Grayson Hwy, Ste. 200 Grayson, GA 30017 770-493-9278

Golden Valley Memorial Hospital

Karen Bullock, PhD Director of Educational Services 1600 North Second Street Clinton, MO 64735 660-885-5511

Grandview Hospital & Medical Center

Regina Salas Administrative Assistant 405 Grand Avenue Dayton, OH 45405-4796 937-226-3247

Illinois Osteopathic Medical Society

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

Indiana Osteopathic Association

Michael H. Claphan, CAE Executive Director 3520 Guion Road, Suite 202 Indianpolis, IN 46222-1672 317-926-3009; 800-942-0501

Ingham Regional Medical Center

Peg Cunningham

Lake Erie College of Osteopathic Medicine

Pierre Bellicini

Director of Communications/CME Coordinator 1858 West Grandview Blvd.

Erie, PA 16509

814-866-8121

Maine Osteopathic Association

Kellie Pavese Miller, M.S. Executive Director 693 Western Ave., #1 Manchester, ME 04351 207-623-1101

Maryland Association of Osteopathic Physicians

Darleen Won Executive Director 3603 Southside Avenue Phoenix, MD 21131 410-683-8100

Massachusetts Osteopathic Society

Don Halpin Executive Director PO Box 487 Winchester, MA 01890 781-721-9900

Memorial Hospital

Anthony A. Minissale, D.O. VP of Medical Affairs 325 S. Belmont St. York, PA 17403 717-849-5343; 717-849-5341

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

Gerri Navarre Associate Director of Medical Education 1919 Boston, S.E. Grand Rapids, MI 49506-4199 616-252-7078

Michigan Osteopathic Association

Sara Carson Meeting Coordinator 2445 Woodlake Circle Okemos, MI 48864 517-347-1555

Michigan Osteopathic Neuropsychiatric Society (MONS)

Marjory A. Pulk Treasurer 560 Misty Brook Lane Rochester, MI 48307 248-650-7973

Michigan State University, College of Osteopathic Medicine

Pamela Thompson Director, Continuing Medical Education A-306 East Fee Hall East Lansing, MI 48824-1316 517-353-9714

Millcreek Community Hospital

Helen McKenzie Medical Education Coordinator 5515 Peach Street Erie, PA 16509-2695 814-868-8217

Minnesota Osteopathic Medical Society

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Mississippi Osteopathic Medical Association

Jeffrey J. LeBoeuf Executive Director P. O. Box 16890 Jackson, MS 39236 601-366-3105

Missouri Association of Osteopathic Physicians & Surgeons

Bonnie M. Bowles Executive Director 1423 Randy Lane Jefferson City, MO 65101 573-634-3415

Montana Osteopathic Association

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Mount Clemens General Hospital

Suzanne G. Wilson, RN, MSN Administrative Director 1000 Harrington Blvd. Mt. Clemens, MI 48043 810-493-8185

Munson Medical Center

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Naval Medical Education and Training Command (NMETC)

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Nevada Osteopathic Medical Association

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New Hampshire Osteopathic Association

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New Jersey Association of Osteopathic Physicians and Surgeons

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New Mexico Osteopathic Medical Association

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New York College of Osteopathic Medicine/New York Institute of Technology

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New York Society of the American College of General Practitioners in Osteopathic Medicine and Surgery

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New York State Osteopathic Medical Society, Inc.

Elizabeth Harano Assistant Director, Management Services 142 East Ontario Chicago, IL 60611 312-202-8188

North Carolina Osteopathic Medical

Association

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North Dakota Osteopathic Medical Association

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Southwest Florida Osteopathic Medical Society, District #11

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Tulsa Regional Medical Center

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UHHS Richmond Heights Hospital

Laura Whitt Administrative Director of Medical Education 27100 Chardon Rd. Richmond Heights, OH 44143-1116 440-585-6230

Union Hospital

Vermont State Association of Osteopathic Physicians and Surgeons

John Peterson, D.O. Executive Director 72 Barre Street Montpelier, VT 05602 802-229-9418

Via Christi Riverside Medical Center

Betty Mitchem Administrative Assistant, Medical Education 2622 West Central Wichita, KS 67203-4999 316-946-8551

Virginia Osteopathic Medical Association

Maria S. Harris Executive Director 48 East Square Lane Richmond, VA 23233 804-784-2204

Washington Osteopathic Medical Association

Kathleen S. Itter Executive Director P.O. Box 16486 Seattle, WA 98116-0486 206-937-5358

West Virginia School of Osteopathic Medicine Foundation, Inc.

Linda B. Smith Executive Director 400 North Lee Street Lewisburg, WV 24901-1128 304-645-6270 x374

West Virginia Society of Osteopathic Medicine, Inc.

Charlotte Ann Cales Pulliam Executive Director P.O. Box 5266 Charleston, WV 25361-0266 304-345-9836

Western New York Osteopathic Medical Society

Cary Vastola, DO CME Director 4017 Harlem Road Amherst, NY 14226 716-839-8000

Western University of Health Sciences/ (COMP), College of Osteopathic Medicine

Ronald Berezniak, PhD Associate Dean for Academic Affairs 309 E. Second Street Pomona, CA 91766 909-469-5257

Westview Hospital

Darci Sieracki Medical Staff Coordinator 3630 Guion Road Indianapolis, IN 46222-0650 317-920-7280; 317-920-7384

Wisconsin Association of Osteopathic Physicians and Surgeons

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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*

that sound educational goal planning takes place in all programs (AOA Board of Trustees

- **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 bjs93seaotely

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 conduced 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.
- activ.4 ActivTcredite(7fod sp-i)06(onsor)6.1('J-i)0(of a protionc0.008.945D0.001 Tc0f the)TJ-19.2al activity, thhatr 2.2.4.4 Activities that are repeated many times An accredited sponsor that offers educational on t5 recoe007 Tc090f the oTc0.006.93990.0005 Tc0.0009 Tw[the cuse)TJd foi

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 activiti 50.2(70.00090005 9TJ1)-0titm- opriat-18.7TT2 have

- 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

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 <u>CME sponsor</u> 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 <u>needs assessment</u> 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

- <u>assessment</u> 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 <u>presenter</u> 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 <u>program sponsor</u> 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 <u>staff physician</u> is a <u>physician</u> 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

between	(Acc	credited Sponsor) and	(Company)
Title of CME Activ	ity		
Location		Date(s)	
City, State, Zip			
Telephone	Fax	Contact Person	
2. Restricted grant t	eational grant for support	rt of the CME activity in the amount of \$ or:	
2)		
(Hono	rarium Amount to be de	OnlyHonorarium Only etermined by Course Director)	
B Support for cat	of ¢	(see 10.d. on the back of this agree	ment)
B. Support for cat in the amount	DI \$	(see 10.d. on the such of this agree.	iliciit)
in the amount		listribution, 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.

Appendix B – Faculty Disclosure Form

Faculty Disclosure Declaration		
scientific rigor in all its individually sponsore participating in any	to insure balance, independence, objected or jointly sponsored educational programs. sponsored programs are expected to disclect(s) of interest that may have a direct bearing. This pertains to relationships with pharmaceuts, or other corporations whose products or serve. The intent of this policy is not to prevent a seresentation. It is merely intended that any potents may form their own judgements about the pass for the audience to determine whether the spetch of the exposition or the conclusions presented.	All faculty ose to the on the subject cical cices are related peaker with a ential conflict presentation
CME PROGRAM:		
DATE:		
TITLE OF PRESENTATION:		
PRESENTER'S NAME:		
(please print	or type)	
I have no actual or potential conflict of int	erest in relation to this program or present	ation.
	Signature	Date
	iliation with one or more organizations that co erest in the context of the subject of this prese	
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.