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CODE FOR INTERACTIONS WITH COMPANIES

I. Preamble

Medical Specialty Societies play an important role in reaching out to health professionals, patients, and other groups. Our members guide biomedical research, discover new therapies, and engage in high quality medical practice. Societies offer educational opportunities that help translate scientific and medical progress into the efficient delivery of effective medical care. Societies develop resources that guide our members in advancing medical care. Societies provide a forum for presenting new skills and scientific developments.

For-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions,¹ referred to in this Code as “Companies,” also strive to help patients live longer and healthier lives. Companies invest resources to bring new drugs, devices and therapies out of the laboratory and to the patient while maximizing value for shareholders.

Members and patients count on Societies to be authoritative, independent voices in the world of science and medicine. Public confidence in our objectivity is critical to carrying out our mission. We know the public relies on us to minimize conflicts of interest. The Council of Medical Specialty Societies (CMSS) believes every Society must be sure its interactions with Companies meet high ethical standards.²

Societies’ interactions with Companies may include receiving charitable contributions, applying for grants in support of programmatic activities, and conducting a range of business transactions.³ In all of these interactions, Societies are committed to acting with integrity and transparency.

We adopt this Code to reinforce the core principles that help us maintain actual and perceived independence. Adopting this Code helps to ensure that a Society’s interactions with Companies will be for the benefit of patients and members and for the improvement of care in our respective specialty fields.

¹ See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. <http://www.advaemed.org/MemberPortal/About/code/>. Accessed May 4, 2009; Accreditation Council for Continuing Medical Education. Definition of commercial interest. http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm. Accessed December 17, 2009

² Lo B. Field MJ (eds): Conflict of interest in medical research, education and practice. Washington, DC, National Academies Press, 2009.

³ This Code does not address a Society’s interactions with non-profit entities or entities outside of the healthcare sector

II. About the Code

The Council of Medical Specialty Societies is a 501(c)(3) non-profit organization committed to education, professionalism and quality of care⁴. In Spring 2009, at the request of the CEOs of the CMSS member organizations, the CMSS Board of Directors charged the CMSS Task Force on Professionalism and Conflicts of Interest (“Task Force”) with developing and recommending a voluntary “code of conduct” for Medical Specialty Societies to “enhance professionalism and to disclose, manage, and resolve relationships with industry.” For nearly one year, Task Force representatives from more than 30 Member Organizations worked collaboratively to draft a document in response to this charge. In the Spring of 2010, the Task Force recommended the CMSS Code for Interactions with Companies to the CMSS Council for adoption. The Code was officially adopted by CMSS on April 17, 2010. Modest revisions to the Code were adopted by CMSS on March 19, 2011.

The purpose of the Code is to guide Societies in the development of policies and procedures that safeguard the independence of their programs, policies, and advocacy positions. Because Societies can vary in their activities and corporate structures, these policies and procedures need not be uniform. Each Society that chooses to sign on to the Code is encouraged to adopt policies and procedures that are tailored to meet its individual organizational needs. Societies may choose to adopt policies that are more rigorous than the Code.

The Code is divided into Principles and Annotations. The Principles state what is expected of Societies that sign on to the Code. The Principles are expected to remain relatively constant, and may be changed only by the CMSS Board of Directors. The Annotations, on the other hand, reflect CMSS’ current interpretation of a given Principle. An Annotation may explain the purpose of a Principle, or give examples of Society policies and safeguards that are consistent with the Code. Annotations may be clarified periodically by CMSS in response to questions or to changes in the landscape of Society-Company interactions.

III. Definitions

The following terms are defined for purposes of this Code. CMSS recognizes that some of these terms may be used or defined differently by individual Societies or outside groups. Some of these terms refer to types of interactions in which Societies may engage with non-profit organizations and individuals as well as with Companies. They are defined here in terms of for profit Companies in order to create a common vocabulary for the Principles under this Code.

Advertising: Advertising is a Business Transaction in which a Company pays a fee to a Society in exchange for the Society’s publication of a promotional announcement that highlights the Company or

⁴ The following organizations are CMSS Member Societies: American Academy of Allergy, Asthma & Immunology (AAAAI); American Academy of Dermatology (AAD); American Academy of Family Physicians (AAFP); American Academy of Hospice and Palliative Medicine (AAHPM); American Academy of Neurology (AAN); American Academy of Ophthalmology (AAO); American Academy of Otolaryngology-Head and Neck Surgery (AAOHNH); American Academy of Pediatrics (AAP); American Academy of Physical Medicine & Rehabilitation (AAPMR); American College of Cardiology (ACC); American College of Chest Physicians (ACCP); American College of Emergency Physicians (ACEP); American College of Medical Genetics (ACMG); American College of Obstetricians & Gynecologists (ACOG); American College of Occupational and Environmental Medicine (ACOEM); American College of Physicians (ACP); American College of Preventive Medicine (ACPM); American College of Radiology (ACR); American College of Rheumatology (ACR); American College of Surgeons (ACS); American Geriatrics Society (AGS); American Medical Informatics Association (AMIA); American Psychiatric Association (APA); American Society for Clinical Pathology (ASCP); American Society for Reproductive Medicine (ASRM); American Society for Radiation Oncology (ASTRO); American Society of Clinical Oncology (ASCO); American Society of Colon and Rectal Surgeons (ASCRS); American Society of Hematology (ASH); American Society of Plastic Surgeons (ASPS); American Urological Association (AUA); North American Spine Society (NASS); Society of Critical Care Medicine (SCCM); Society of Hospital Medicine (SHM); Society of Neurological Surgeons (SNS); Society of Nuclear Medicine (SNM); Society of Thoracic Surgeons (STS).

the Company's products or services. For purposes of this Code, Advertiser refers to a Company that purchases Advertising.

Business Transaction: A Business Transaction is an interaction between a Society and a Company in which a Company pays a fee to the Society in exchange for the Society's item, service, or product. Examples of Business Transactions include Company payment of fees associated with subscriptions to Society publications, Advertising in Society publications, registrations for Society meetings, and exhibit space rental.

Charitable Contribution: A Charitable Contribution is a gift, including an in-kind gift, given by a Company to a qualified tax-exempt organization (e.g., a Society or its affiliated Foundation) for use in furthering the organization's charitable purposes and in accordance with applicable tax rules and legal standards.

Clinical Practice Guideline: A Clinical Practice Guideline (or Guideline) is a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. As used in this Code, the term Clinical Practice Guideline also refers to medical technology assessments, clinical opinions, and other evidence-based clinical practice tools, as well as updates to existing Clinical Practice Guidelines ("Guideline Updates").⁵ Societies will determine whether Clinical Practice Guidelines applies to clinical performance measurers and safety standards developed by the Society.

Company: A Company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions⁶. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients. However, a Society may choose to adopt a broader definition of "Company" if doing so would better address the Society's interactions.

Continuing Medical Education (CME): (CME) consists of educational activities for which the learner may receive CME credit (e.g. American Medical Association (AMA) Physician's Recognition Award Credit, American Academy of Family Physicians (AAFP) Prescribed or Elective Credit, American Osteopathic Association (AOA) Credit – various categories) based on accreditation awarded to the continuing education provider by a recognized accrediting body (e.g., Accreditation Council for Continuing Medical Education (ACCME), AOA, AAFP). CME activities "serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession."⁷ For purposes of this Code, educational

⁵ Lohr KN, Field MJ: A provisional instrument for assessing clinical practice guidelines, in Field MJ, Lohr KN (eds): Guidelines for clinical practice: From development to use. Washington, D.C., National Academy Press, 1992, p 346.

⁶ See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. <http://www.adva-med.org/MemberPortal/About/code/>. Accessed May 4, 2009; Accreditation Council for Continuing Medical Education (ACCME): Definition of commercial interest. http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm. Accessed December 17, 2009.

⁷ Accreditation Council for Continuing Medical Education (ACCME): CME content. http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm. Accessed October 25, 2009; American Medical Association (AMA): The Physician Recognition Award and credit system. <http://www.ama-assn.org/ama1/pub/upload/mm/455/prra2006.pdf>. Accessed December 18, 2009.

activities for physicians and other health care providers that are not CME-accredited are considered Non-CME Educational/Informational Programs.

Corporate Sponsorship: A Corporate Sponsorship is an arrangement in which a Company, typically through its marketing department, provides monetary or in-kind support for a particular Society product, service, or event, and is then acknowledged in connection with the product, service or event. Corporate Sponsorships are distinct from Educational Grants, and do not constitute Commercial Support of CME. For purposes of this Code, Corporate Sponsor refers to a Company that provides a Corporate Sponsorship.

Direct Financial Relationship⁸: A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual's services or expertise. As used in this Code, the term Direct Financial Relationship does not mean stock ownership or intellectual property licensing arrangements. See Principle 1.4 for additional clarification of the meaning of Direct Financial Relationship.

Educational Grant: An Educational Grant is a sum awarded by a Company, typically through its grants office, for the specific purpose of supporting an educational or scientific activity offered by the Society. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as "Commercial Support" of CME⁹. An Educational Grant may also be "in-kind."

Key Society Leaders: At a minimum, and for purposes of this Code, the Key Society Leaders are officers at the Presidential-level (e.g., the President, the President-Elect, and the Immediate Past President as applicable), the Secretary-Treasurer level (e.g., Secretary-Treasurer and Assistant Secretary-Treasurer), the chief executive officer of a Society's membership organization, and the Editor(s) -in-Chief of Society Journal(s).¹⁰

Medical Specialty Society: A Medical Specialty Society (or Society) is a non-profit organization whose membership includes predominantly physicians who practice in a specific medical specialty or sub-specialty that seeks to further the medical specialty, to advance the interests and education of individuals engaged in the specialty, to improve patient care, and to provide information for patients and the general public. Societies may have different corporate structures and encompass several affiliated legal entities. If a function described in the Code is carried out by an entity other than a

⁸ Definition: A Direct Financial Relationship is a compensated relationship held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report. Key Society Leaders (including the President, President-Elect, Immediate Past President, the Secretary-Treasurer, Assistant Secretary-Treasurer, the chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s)) may provide uncompensated service to for-profit health care products companies ("Companies") and accept reasonable travel reimbursement in connection with those services. Key Society Leaders may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual. Exception may be made in certain circumstances for provision of consultant or investigator expertise related to protocol development and/or safety monitoring or any other consulting work related to one's own past, current or potential research studies as long as the activities are not related to marketing or promotional efforts. In this event, the Secretary-Treasurer must be provided with background information and approval must be provided in advance for an exception to the policy. In these circumstances, compensation to the individual may not exceed \$10,000/company/year. Verifying 1099 forms must be submitted to the Secretary-Treasurer when received. This exception may not be applied to the President, who shall remain free from any and all direct financial relationships during his/her term of office.

⁹ Accreditation Council for Continuing Medical Education (ACCME): Standards for commercial support.

http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf. Accessed December 17, 2009.

¹⁰ See definition of Society Journal

Society's membership organization (e.g., by an affiliated Foundation), Code provisions dealing with that function apply to the other entity to the extent the membership organization controls that entity. Each Society should decide independently how best to comply with the Code in light of its corporate structure.

Non-CME Informational/Educational Program: A Non-CME Informational/Educational Program is a program offered by a Society, Company or other third party that provides educational or promotional information and does not offer CME credit.

Research Grant: A Research Grant is an award that is given by a Society to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide Societies with programmatic support (e.g., an Educational Grant or Charitable Contribution) designated for the specific purpose of funding Research Grants.

Satellite CME Symposium: A Satellite CME Symposium is a Company-supported CME program held as an adjunct to a Society meeting where CME credit for the Symposium is provided by a third party CME provider, and for which the Society receives a fee.

Society CME: Society CME refers to CME programs that are planned by a Society and for which the Society, as an accredited CME provider, provides CME credit.

Society Journal: A Society Journal is a peer-reviewed scientific journal published by a Society or by a publisher on a Society's behalf.

IV. Principles for Interaction

1. Independence

- 1.1.** Societies will commit that their educational activities, scientific programs, products, services and advocacy positions are independent of Company influence, and will develop and adopt policies and procedures that foster independence.

Annotation: These policies need not be uniform; rather, each Society's policies can be tailored to fit its individual organizational needs. Societies should make these policies available to the public (See Principle 2.1). If a Society collaborates with a Company on a project or utilizes a Company's product or service, there will be an arms-length business relationship between the Society and the Company. The Society will apply its independent judgment to the arrangement and will not allow the Company to control content or project decisions.

- 1.2.** Societies will separate their efforts to seek Educational Grants, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from their programmatic decisions.

Annotation: The initial step in program development is the independent assessment by a Society that a program is needed (e.g., to address gaps in care or knowledge). Once a Society determines that a program is needed, it is permissible to assess the availability of funds.

- 1.3.** Societies will identify the high-level group responsible for guiding Society interactions with Companies.

Annotation: A Society may assign the responsibility of monitoring and guiding Society-level interactions with companies to an existing group, such as its Board of Directors (or a subcommittee of the Board), Ethics Committee, or Conflict of Interest Committee, or to a new group created for this purpose.

- 1.4.** No Key Society Leader, defined for purposes of this Code as the Presidential-level of a Society's membership organization (e.g., the President, President-Elect, and Immediate Past President as applicable), the Secretary-Treasurer level (e.g., Secretary-Treasurer and Assistant Secretary-Treasurer) the chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s), may have Direct Financial Relationships¹¹ with Companies during his or her term of service.

With the Academy's adoption of the Code for Interactions with Companies, the successful officer candidates will be required to divest themselves during their entire term in office of any direct financial relationships with for-profit companies that manufacture or sell health care products or services.

Annotation: Each Society may set a reasonable period after election or appointment for Key Society Leaders to terminate any Direct Financial Relationships. A Society may permit Key Society Leaders who are elected or appointed prior to the time the Society signs on to the Code to maintain existing Direct Financial Relationships with Companies for the duration of their terms. These relationships should be disclosed and managed in accordance with Principles 2.3 and 2.4.

Under Principle 1.4, a Key Society Leader may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services. A Key Society Leaders may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual. A Key Society Leaders may receive wages or other compensation from a Company in exchange for providing or overseeing the provision of health services to Company personnel. A Key Society Leader may accept reasonable compensation for serving on an independent data safety monitoring board in a Company study. A Key Society Leader may own stock or stock options in a Company. A Key Society Leader may receive royalties or similar fees relating to patents or other intellectual property. While permitted under Principle 1.4, all such relationships should nevertheless be disclosed and managed in accordance with Principles 2.3 and 2.4.

¹¹ Definition: A Direct Financial Relationship is a compensated relationship held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report. Key Society Leaders (including the President, President-Elect, Immediate Past President, the Secretary-Treasurer, Assistant Secretary-Treasurer, the chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s) may provide uncompensated service to for-profit health care products companies ("Companies") and accept reasonable travel reimbursement in connection with those services. Key Society Leaders may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual. Exception may be made in certain circumstances for provision of consultant or investigator expertise related to protocol development and/or safety monitoring or any other consulting work related to one's own past, current or potential research studies as long as the activities are not related to marketing or promotional efforts. In this event, the Secretary-Treasurer must be provided with background information and approval must be provided in advance for an exception to the policy. In these circumstances, compensation to the individual may not exceed \$10,000/company/year. Verifying 1099 forms must be submitted to the Secretary-Treasurer when received. This exception may not be applied to the President, who shall remain free from any and all direct financial relationships during his/her term of office.

If a Key Society Leader receives stock or stock options from a Company as wages, consulting fees, honoraria, or other compensation (other than permitted payments as described in the prior paragraph), this is considered a Direct Financial Relationship. If a Key Society Leader directs a Company honorarium or other fee to the Society, a charity, or another entity, this is considered a Direct Financial Relationship. See the definition of “Direct Financial Relationship” for additional information relating to Principle 1.4. See Principles 5.2.5 and 5.4.4 for additional limitations on the relationships of Key Society Leaders.

- 1.5.** Societies will use written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of Research Grants.

Annotation: Good business practices require that funds accepted from Companies be associated with written agreements that specify what the funds are for, the amount given, and the separate roles of the Company and the Society. Such agreements show that a transaction is “arms length,” establish clear parameters for the use of funds, and affirm the independence of the Society. To help Societies comply with this Principle, CMSS will develop customizable agreement templates or standard clauses to serve as a model for Societies’ written agreements. Societies may choose to use these templates or create their own agreements independently.

2. Transparency

- 2.1.** Societies will make their conflict of interest policies and/or forms available to their members and the public.

Annotation: Transparency is a key element in fostering confidence in Societies’ independence. Societies should make disclosure forms and policies adopted under Principle 1.1 of this Code available to the public. Societies may choose to make internal conflict of interest management procedures publicly available as well.

- 2.2.** Societies will disclose Company support (at a minimum Educational Grants, Corporate Sponsorships, Charitable Contributions, and support of Research Grants), making this information available to their members and the public.

Annotation: With the support of CMSS, Societies will work together, along with other appropriate stakeholders, to develop a consistent template for disclosure of Company support received by a Society. Generally, disclosure fields should include the name of the Company, the category of support (e.g., Educational Grant, Corporate Sponsorship, Charitable Contribution), the time period of the support, and the dollar amount or range. Some Societies may also decide to disclose information related to Business Transactions, support from donors outside of the for-profit healthcare sector, support from non-profit organizations, and support from individual donors.

- 2.3.** Societies will adopt written disclosure policies for Key Society Leaders, Board members, committee members and others who serve on behalf of the Society, and will use the disclosed information to manage conflicts of interest in decision-making. Societies will require volunteers to update disclosure information at least annually and when material changes occur.

CMSS will support and participate in efforts to arrive at a consistent scope and format for individual disclosure across multiple organizations and activities.

Societies can manage conflicts of interest in a variety of ways. In some cases, disclosure is sufficient. Additional conflict of interest management mechanisms such as recusal, peer review, and CME session audits may be appropriate. Societies should select conflict of interest management mechanisms that are appropriate for the activity and type of relationship under consideration.

- 2.4.** Societies will disclose all financial and uncompensated relationships that Key Society Leaders and members of the Board of Directors of the Society's membership organization have with Companies, making this information available to their members and the public.
Annotation: With the support of CMSS, Societies will work together, along with other appropriate stakeholders, to develop a consistent template for disclosure of these relationships. Generally, disclosure fields should include employment, consulting or advisory arrangements, stock ownership, honoraria, research funding paid to an individual's institution or practice, expert testimony, and gifts. A Society is not required to disclose the relationships of Board members elected prior to the time the Society signs on to the Code.

3. Accepting Charitable Contributions

- 3.1.** Societies will control the use of Charitable Contributions in a manner that is aligned with the Society's strategic plan and mission.¹²
- 3.2.** Societies will decline Charitable Contributions where the Company expects to influence Society programs or advocacy positions, or where Company restrictions would influence Society programs or advocacy positions in a manner that is not aligned with the Society's mission.
- 3.3.** Societies will adhere to applicable tax rules and legal standards for acceptance of Charitable Contributions and management of institutional funds.
- 3.4.** Reasonable restrictions on the purposes for which Charitable Contributions will be used are acceptable, as are reasonable requirements for reporting on the uses of the donated funds.

Annotation: For example, it is appropriate for Charitable Contributions to be designated to support a broad section of a Society's mission (e.g., general research, research in a particular disease area, or patient information). It is also appropriate for Charitable Contributions to be designated to support a specific Society program (e.g., a research award or fellowship), as long as the donor is not permitted to influence or control the program (e.g., selecting award recipients or determining research topics).

- 3.5.** Societies will adopt policies for consistent and appropriate recognition of donors.

Annotation: Donor recognition is a universal part of fundraising and should be conducted with appropriate limitations. For example, donors can be recognized in print materials, in private or public ceremonies, and with banners or other visible displays. Recognition should not be provided in a manner that implies donor influence over Society programs or advocacy positions (See Principle 1.1).

¹² See Definition of Society for discussion of the role of affiliated foundations.

4. Accepting Corporate Sponsorships

- 4.1. Societies will only accept Corporate Sponsorship of an item or program if the item or program is aligned with the Society's strategic plan and mission.
- 4.2. Societies will make reasonable efforts to seek multiple Corporate Sponsors for sponsored items or programs.

Annotation: In addition to or instead of seeking multiple Corporate Sponsors for sponsored items or products, Societies may seek support from sources outside of the for-profit healthcare sector.

- 4.3. Societies will not place the names or logos of Companies or products on Society distributed, non-educational "reminder" items (e.g., tote bags, lanyards, highlighters, notebooks, and luggage tags) that Companies are not permitted to give directly to healthcare professionals under generally accepted standards for ethical interactions (i.e., PhRMA Code, AdvaMed Code).

Annotation: The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals do not permit Companies to give promotional, non-educational "reminder" items directly to healthcare professionals.¹³ In support of these standards, Societies should not permit the placement of Company names or logos on Society distributed reminder items.

- 4.4. If accepting Corporate Sponsorship of data registries, Societies will prohibit Corporate Sponsors from participating in the direct management of the registry.

Annotation: Corporate Supporters should not be involved in decisions to sell or otherwise disclose or publish registry data. Representatives of Corporate Supporters should not be permitted to serve on registry steering groups. Corporate Supporters should not receive special access to registry data.

5. Society Meetings

5.1. Society Educational and Informational Programs

- 5.1.1. When providing Society CME, Societies will comply with ACCME Standards for Commercial Support, including by adopting policies and procedures designed to identify and manage conflicts of interest in Company-supported Society CME programs.

Annotation: Societies should adopt policies and procedures for managing the relationships of individuals who plan, carry out, or contribute to the content of Society CME activities. Adopting and rigorously enforcing these policies precludes Company influence over Society CME content.

¹³ See Pharmaceutical Research and Manufacturers of America (PhRMA): Code on interactions with healthcare professionals. <http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf>. Accessed March 9, 2010; Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with healthcare professionals. <http://www.advamed.org/MemberPortal/About/code/>. Accessed May 4, 2009.

- 5.1.2.** In providing Society CME, Societies will not seek support for product-specific topics.

Annotation: Where the purpose of a Society CME session is to demonstrate or train learners in the safe and effective use of a particular drug, device, service or therapy, Societies may accept in-kind support from Companies that develop, produce, market, or distribute that drug, device, service or therapy. In accordance with ACCME Standards, a Society may accept in-kind support from a single Company when other equal by competing products or services are not available for inclusion.

- 5.1.3.** Societies will make reasonable efforts to achieve a balanced portfolio of support for each Society CME program.

Annotation: Societies will make reasonable efforts to seek multiple sources of support for Society CME programs, including support from Companies, support from organizations outside the for-profit healthcare sector, and tuition from learners.

- 5.1.4.** Societies will retain control over the use of Educational Grants and implement safeguards designed to ensure that educational programs are non-promotional and free from commercial influence and bias.

- 5.1.5.** Societies will appoint their own planning committees to select the objectives, content, faculty, and format of educational activities in a manner that is consistent with their organizational missions.

- 5.1.6.** Societies will not solicit supporters' suggestions about program topics, speakers, or content.

Annotation: This restriction would not prevent Societies from assessing the availability of funds for a program in accordance with Principle 1.2.

- 5.1.7.** Societies will prohibit presenters from using Company-controlled presentation materials, and from using slides with Company logos.

- 5.1.8.** Societies will require presenters in Society CME programs to give a balanced view of therapeutic options, and will encourage presenters to use generic names in place of product trade names.

- 5.1.9.** Societies will clearly distinguish their Non-CME Informational/Educational Programs from Society CME.

5.2. CME Accredited Satellite Symposia

- 5.2.1.** Societies will require Satellite CME Symposia¹⁴ to undergo an application and selection process.
- 5.2.2.** Societies will require Satellite CME Symposia to comply with ACCME Standards.

Annotation: Societies can best implement Principle 5.2.2 by requiring written agreements with third party CME providers. Written agreements should also include consequences for non-compliance.

To minimize the potential for bias in Satellite CME Symposia, Societies may also consider the following best practices:

- 1. Requiring presentations to be evidence-based;*
 - 2. Requiring peer review of slide presentations in advance;*
 - 3. Prohibiting presenters who disclose unmanageable conflicts from making practice recommendations. These presenters may present on general topics only (e.g., pathophysiology, research data). An additional speaker without unmanageable conflicts may be added to the program to make practice recommendations instead.*
 - 4. Requiring presentations to be monitored by reviewers trained to recognize bias.*
- 5.2.3.** Societies will ensure that Satellite CME Symposia are clearly distinguished from Society CME in Society meeting programs and promotional materials.
- 5.2.4.** Societies will require third party organizers of Satellite CME Symposia to use appropriate disclaimers to distinguish the Symposia from Society CME programs in Symposia advertising and program materials.
- 5.2.5.** Societies will not permit Key Society Leaders to participate in Satellite CME Symposia as faculty members, presenters, chairs, consultants, or in any other role besides that of a learner who receives no honoraria or reimbursement.

Annotation: See Principle 1.4 for additional limitations on the relationships of Key Society Leaders.

5.3. Company Informational/Educational Programs

- 5.3.1.** Societies will require Company Informational/Educational Programs to be clearly distinguished from CME.

Annotation: Through the Company's use of appropriate disclaimers in advertising and informational materials, learners of Non-CME Informational/Educational Programs should be able to easily ascertain that the Programs are not CME accredited.

¹⁴ See Definition of Satellite CME Symposium. Based on the definition of Satellite CME Symposium, Section 5.2 of the Code does not apply to programs that are held adjunct to Society meetings but (1) are not Company supported; (2) are not CME accredited; or (3) for which Societies do not receive a fee

5.4. Exhibits

- 5.4.1.** Societies will adopt written policies that govern the nature of exhibits and the conduct of exhibitors, including by requiring exhibitors to comply with applicable laws, regulations, and guidance.

Annotation: Society policies can place limits on exhibits and exhibitor conduct (e.g., booth décor, size, and activities) to ensure that the tone of the exhibit hall is professional in nature. Policies should be provided to exhibitors and made available to others upon request.

- 5.4.2.** Societies will only permit exhibitor giveaways that are educational and modest in value.

Annotation: The requirement that Company giveaways be educational (for physicians or patients) and modest in value originates in the standards for ethical interactions set out by AMA, PhRMA, and AdvaMed. The educational giveaway requirement stated in Principle 5.4.2 applies equally to Companies that have signed on to the PhRMA or AdvaMed Codes and those that have not. This approach allows Societies to place all Company exhibitors on an even playing field. Principle 5.4.2 does not apply to non-profit exhibitors or to exhibitors outside of the healthcare sector. However, Societies may apply these requirements more broadly at their individual discretion.

- 5.4.3.** Societies will make reasonable efforts to place exhibit booths out of learners' obligate path to Society CME sessions.

- 5.4.4.** Key Society Leaders may not participate as leaders or presenters in Company promotional/marketing events held in exhibit space.

Annotation: Participation of Key Society Leaders in Company promotional or marketing events has the potential to create the perception that the Society endorses a particular Company or product. In order to avoid this perception, Societies should prohibit Key Society Leaders from participating as leaders or presenters, and may consider extending this restriction to the entire Board of Directors. See Principle 1.4 for additional limitations on the relationships of Key Society Leaders.

6. Awarding of Research Grants

- 6.1.** Societies will not permit Companies to select (or influence the selection of) recipients of Research Grants.
- 6.2.** Societies will appoint independent committees to select recipients of Research Grants based on peer review of grant applications.
- 6.3.** Societies will not require recipients of Research Grants to meet with Company supporters.

Annotation: An individual, institution or practice that receives a Research Grant may publicly acknowledge the Company that supported his or her Research Grant, if known.

Research Grant recipients may be required to disclose known Company support in connection with the presentation or publication of grant-funded research.

- 6.4.** Societies will not permit Companies that support Research Grants to receive intellectual property rights or royalties arising out of the grant-funded research.
- 6.5.** Societies will not permit Companies that support Research Grants to control or influence manuscripts that arise from the grant-funded research.
- 6.6.** If a Society receives programmatic support (e.g., an Educational Grant or Charitable Contribution) from a Company to support the Society's own research, the Society will disclose the Company support. The Society will act independently in the selection of research topics and the conduct of the research itself.

7. Clinical Practice Guidelines

- 7.1.** Societies will base Clinical Practice Guidelines on scientific evidence.

Annotation: Many Societies develop and publish Clinical Practice Guidelines, medical technology assessments, and other clinical practice opinions in order to meet their members' needs for tools that help improve the quality and effectiveness of patient care. The credibility and authority of Society Guidelines depends on a common understanding that Guidelines are developed through a rigorous independent process, based on the best available scientific evidence. Societies may refer to published criteria for rating studies and other evidence, or may use another recognized means of characterizing the strength of medical evidence.

The definition of Clinical Practice Guidelines in this Code includes "other clinical practice tools." Some Societies develop and publish measures or standards for quality, safety, or other types of performance. Performance measures may apply to clinical care, research or other professional activities. To underscore the credibility of its performance measures, a Society may choose to treat them as Clinical Practice Guidelines for purposes of this Code, applying the standards for independence and transparency set out in this Principle 7.

- 7.2.** Societies will follow a transparent Guideline development process that is not subject to Company influence. For Guidelines and Guideline Updates published after adoption of the Code, Societies will publish a description of their Guideline development process, including their process for identifying and managing conflicts of interest, in Society Journals or on Society websites.

Annotation: Healthcare providers, payors, and patients regard Society Clinical Practice Guidelines as an important source of information from experts in the field. Societies must therefore take steps to ensure that Guidelines are free from commercial bias and Company influence.

- 7.3.** Societies will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates.

Annotation: Societies will not accept Corporate Sponsorship, Educational Grants, Charitable Contributions, support of Research Grants, or any other direct Company support of Guideline development activities. Company support of the overall mission-based activities of a Society is not considered direct support of Guideline development.

- 7.4.** Societies will not permit direct Company support for the initial printing, publication, and distribution of Clinical Practice Guidelines or Guideline Updates. After initial development, printing, publication and distribution is complete, it is permissible for Societies to accept Company support for the Society's further distribution of the Guideline or Guideline Update, translation of the Guideline or Guideline Update, or repurposing of the Guideline content.

Annotation: After initial development, printing, publication, and distribution of a Guideline or Guideline Update is complete; it is permissible for a Society to engage in Business Transactions where Companies purchase Guideline reprints or license Guideline content for translation or repurposing. A Society may choose to require a written statement with the purchased or licensed material, acknowledging the Company's role and describing the independent nature of the Society's Guideline development process.

- 7.5.** Societies will require all Guideline development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Guideline development process.
- 7.6.** Societies will develop procedures for determining whether financial or other relationships between Guideline development panel members and Companies constitute conflicts of interest relevant to the subject matter of the guideline, as well as management strategies that minimize the risk of actual and perceived bias if panel members do have conflicts.

Annotation: For example, Societies may decide not to permit panel members with conflicts of interest to draft text or vote on panel recommendations.

- 7.7.** Societies will require that a majority of Guideline development panel members are free of conflicts of interest relevant to the subject matter of the Guideline.

Annotation: If Guideline development panel members and chairs (see Principle 7.8) have conflicts of interest at the time of adoption of the Code, a Society may permit these individuals to remain actively involved in drafting the Guideline. However, each panel for which this exception is made must meet the requirements of Principle 7.7 by the time of the next Guideline Update. For the minority of panel members who are not free of conflicts, Societies will apply procedures for disclosure and conflict of interest management developed in accordance with Principles 7.5 and 7.6.

- 7.8.** Societies will require the panel chair (or at least one chair if there are co-chairs) to be free of conflicts of interest relevant to the subject matter of the Guideline, and to remain free of such conflicts of interest for at least one year after Guideline publication.

Annotation: In addition to minimizing potential conflicts, remaining free of conflicts of interest helps to ensure that a panel chair remains eligible to participate in subsequent Guideline Updates.

- 7.9.** Societies will require that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts. Societies will not select as reviewers individuals employed by or engaged to represent a Company.

Annotation: As part of their published Guideline development processes, Societies will seek critical feedback on draft Guidelines from independent reviewers. These may include subject matter experts, healthcare practitioners, biostatisticians, and patient representatives, among others.¹⁵

- 7.10.** Societies' Guideline recommendations will be reviewed and approved before submission for publication by at least one Society body beyond the Guideline development panel, such as a committee or the Board of Directors.

- 7.11.** Guideline manuscripts will be subject to independent editorial review by a journal or other publication where they are first published.

Annotation: Editorial review provides an additional safeguard independent of a Society's Guideline development and approval process.

- 7.12.** Societies will publish Guideline development panel members' disclosure information in connection with each Guideline and may choose to identify abstentions from voting.

- 7.13.** Societies will require all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline development panel, to disclose financial or other substantive relationships that may constitute conflicts of interest.

Annotation: To identify and manage conflicts of interest among contributors, advisors, and reviewers, Societies should follow similar procedures as those applied to the Guideline development panel. Societies collaborating with or seeking input from outside organizations on guideline development should investigate the conflict of interest standards of those organizations.

- 7.14.** Societies will recommend that Guideline development panel members decline offers from affected Companies to speak about the Guideline on behalf of the Company for a reasonable period after publication.

Annotation: A period of at least one year is recommended. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the Guideline.

¹⁵ The AGREE Collaboration: Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Quality and Safety in Health Care* 2003; 12(1): 18-23.

- 7.15.** Societies will not permit Guideline development panel members or staff to discuss a Guideline's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Guidelines in draft form.

8. Society Journals

- 8.1.** A Society Journal will maintain editorial independence from the Society and from Advertisers.

Annotation: In general, a firewall separates the editorial decisions of a Society Journal from Society governance and operations. Editorial independence should be consistent with accepted standards for medical publishing, such as those established by the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors (WAME).¹⁶

- 8.2.** Society Journals will require all authors to disclose financial and other relationships with Companies.

Annotation: Authors' disclosure information will be considered by Society Journal editors in evaluating an article for publication. If the article is published, Society Journals will publish the authors' disclosure information with the article or issue. The "look-back" period for disclosure should be at least one year. Society Journals will adopt policies governing the scope and format of disclosure, including consistent disclosure categories.

- 8.3.** Society Journals will require editors and reviewers to disclose financial and other relationships with Companies.

Annotation: Each Society Journal will publish its editors' disclosure information on its website.

- 8.4.** The Editor-in-Chief of each Society Journal will have the ultimate responsibility for determining when a conflict of interest should disqualify an editor or reviewer from reviewing a manuscript, according to established policies.

Annotation: When establishing these policies, Society Journals may find it helpful to consult accepted standards for medical publishing, such as those established by ICMJE and WAME.¹⁷

- 8.5.** Society Journals will adopt policies prohibiting the submission of "ghost-written" manuscripts prepared by or on behalf of Companies.

¹⁶ International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals: Ethical considerations in the conduct and reporting of research: Editorship. http://www.icmje.org/ethical_2editor.html. Accessed October 20, 2009; World Association of Medical Editors: The responsibilities of medical editors. <http://www.wame.org/resources/policies#responsibilities>. Accessed October 20, 2009.

¹⁷ International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals: Ethical considerations in the conduct and reporting of research: Conflict of interest. http://www.icmje.org/ethical_4conflicts.html. Accessed March 8, 2010; World Association of Medical Editors: Conflict of interest in peer-reviewed medical journals. <http://www.wame.org/conflict-of-interest-in-peerreviewed-medical-journals>. Accessed March 9, 2010.

9. Standards for Advertising

9.1. Societies will adopt written policies that set standards for Advertising.

Annotation: Advertising in all Society publications should be easily distinguishable from editorial content (e.g., through labels and color-coding). Advertising should not be designed to look like scientific articles. In Society Journals, the placement of Advertising adjacent to articles or editorial content discussing the Company or product that is the subject of the ad should be prohibited. Advertising in Society Journals should subject to review by the Editor-in-Chief and overseen by the Society. Society Journals and other Society publications that publish Advertising for CME activities or provide activities through which readers can earn CME credits should also comply with ACCME requirements for Advertising set out in the Standards for Commercial Support.

10. Standards for Licensing

10.1. Societies will adopt written standards for licensing that are intended to prevent misuse, unintended use, and modification of licensed materials, prohibit modification of licensed materials in a way that would change their meaning, and prohibit use of Society trademarks to imply Society endorsement of Company products or services.

V. Adherence to the Code

Signing on to this Code is voluntary and is not a condition of continued membership in CMSS. Societies that sign on to the Code will be identified on the CMSS website. Societies that are not members of CMSS may also sign on to the Code and will be listed on the CMSS website as well.

Societies that sign on to the Code should adopt policies and procedures to guide Society-Company interactions in accordance with the Code. Societies will interpret and implement the Code in the context of their organizational structure and their policies and procedures.

Societies that sign on to the Code are encouraged to comply with as many Principles as possible at the time they sign on, and should set a reasonable timeframe for adopting the policies and procedures required to comply with any remaining Principles. At their individual discretion, Societies may choose to adopt policies that are more rigorous than the Code.

Societies should regularly evaluate their success in adhering to the Code. Societies will be encouraged to affirm annually to CMSS that they continue to adhere to the Code. Societies that affirm that they adhere to the Code will continue to be identified on the CMSS website. Any comments received by CMSS relating to a Society's adherence to the Code will be referred to the Society.