



# CODE FOR INTERACTIONS WITH COMPANIES

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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,<sup>1</sup> 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 actual and perceived

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<sup>1</sup> See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. <http://www.advamed.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](http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm). Accessed December 17, 2009.

conflicts of interest. SAEM and the SAEM Foundation must be sure its interactions with Companies meet high ethical standards.<sup>2</sup>

Societies' interactions with Companies may include receiving charitable contributions, applying for grants in support of programmatic activities, and conducting a range of business transactions.<sup>3</sup> 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.

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

<sup>3</sup> This Code does not address a Society's interactions with non-profit entities or entities outside of the healthcare sector.

## **II. About the Code**

SAEM and the SAEM Foundation are 501(c)(3) non-profit organizations committed to improving the emergency care of patients through scientific discovery; enhancing research capabilities in emergency medicine; and helping emergency physicians develop the skills to become successful investigators. In May 2015, the SAEM Board of Directors and the SAEM Foundation Board of Trustees requested a policy to guide their relationships with industry. With the exception of physician contract management groups, the SAEMF Boards of Directors and Trustees supports the forming relationships with for-profit companies.

The purpose of the Code is to guide the SAEM Board of Directors, SAEM Foundation Board of Trustees, and staff in determining which company relationships are acceptable to enter.

### III. Definitions

*The following terms are defined for purposes of this Code. 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 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.<sup>4</sup> 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"). Societies will determine whether the term Clinical Practice Guidelines applies to clinical performance measures 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 conditions.<sup>5</sup> 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

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<sup>4</sup> 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.

<sup>5</sup> See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. <http://www.advamed.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](http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm). Accessed December 17, 2009.

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 based on accreditation awarded to the continuing education provider by a recognized accrediting body (e.g., Accreditation Council for Continuing Medical Education (ACCME)). 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.”<sup>6</sup> For purposes of this Code, educational 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 Relationship:** 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 or 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 CME.<sup>7</sup> 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-Elect, the President, and the Immediate Past President as applicable) of a Society’s membership organization, the

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<sup>6</sup> Accreditation Council for Continuing Medical Education (ACCME): CME content. [http://www.acme.org/index.cfm/fa/Policy.policy/Policy\\_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm](http://www.acme.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/pr2006.pdf>. Accessed December 18, 2009.

<sup>7</sup> Accreditation Council for Continuing Medical Education (ACCME): Standards for commercial support. [http://www.acme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-8725-80a1504e520c\\_uploaddocument.pdf](http://www.acme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf). Accessed December 17, 2009.

chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s).<sup>8</sup>

**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 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.

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<sup>8</sup> See definition of Society Journal.

## **IV. Principles for Interaction**

### **1. Independence**

1.1. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation will identify the high-level group responsible for guiding 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 officers of a Society's membership organization (e.g., the President, President-Elect, and Immediate Past President as applicable), the chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s), may have Direct Financial Relationships with Companies during his or her term of service.

*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 Leader 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 Leader 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.*

*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. SAEM and SAEM Foundation 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.*

## **2. Transparency**

2.1. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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: 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. SAEM and SAEM Foundation 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. SAEM and SAEMF will require volunteers to update disclosure information at least annually and when material changes occur.

*Annotation: 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. 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.*

*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. SAEM and SAEMF will control the use of Charitable Contributions in a manner that is aligned with the organizations' strategic plans and missions.<sup>9</sup>

3.2. SAEM and SAEMF will decline Charitable Contributions where the Company expects to influence organizational programs or advocacy positions, or where Company restrictions would influence organization programs or advocacy positions in a manner that is not aligned with the organizations' missions.

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<sup>9</sup> See Definition of Society for discussion of the role of affiliated foundations.

3.3. SAEM and SAEMF 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. SAEM and SAEMF 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).*

#### **4. Accepting Corporate Sponsorships**

4.1. SAEM and SAEMF will only accept Corporate Sponsorship of an item or program if the item or program is aligned with the organizations' strategic plans and missions.

4.2. SAEM and SAEMF 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. SAEM and SAEMF 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.<sup>10</sup> 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, SAEM and SAEM Foundation 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, SAEM and SAEM Foundation 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.*

5.1.2. In providing Society CME, SAEM and SAEM Foundation will not seek support for product-specific topics.

*Annotation: Where the purpose of a Society CME session is to demonstrate or train attendees 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 but competing products or services are not available for inclusion.*

5.1.3. SAEM and SAEM Foundation will make reasonable efforts to achieve a balanced portfolio of support for each Society CME program.

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<sup>10</sup> 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 health care professionals. <http://www.advamed.org/MemberPortal/About/code/>. Accessed May 4, 2009.

*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 attendees.*

5.1.4. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation will not solicit Companies' 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. SAEM and SAEM Foundation will prohibit presenters from using Company-controlled presentation materials, and from using slides with Company logos.

5.1.8. SAEM and SAEM Foundation will require presenters 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. SAEM and SAEM Foundation will clearly distinguish their Non-CME Informational/Educational Programs from Society CME.

## 5.2. CME-Accredited Satellite Symposia

5.2.1. SAEM and SAEM Foundation will require Satellite CME Symposia<sup>11</sup> to undergo an application and selection process.

5.2.2. SAEM and SAEM Foundation 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:*

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<sup>11</sup> 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.

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. SAEM and SAEM Foundation will ensure that Satellite CME Symposia are clearly distinguished from Society CME in Society meeting programs and promotional materials.

5.2.4. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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 an attendee 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. SAEM and SAEM Foundation 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, attendees of Non-CME Informational/Educational Programs should be able to easily ascertain that the Programs are not CME accredited.*

### 5.4. Exhibits

5.4.1. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation will make reasonable efforts to place exhibit booths out of attendees' 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. SAEM and SAEM Foundation will not permit Companies to select (or influence the selection of) recipients of Research Grants.

6.2. SAEM and SAEM Foundation will appoint independent committees to select recipients of Research Grants based on peer review of grant applications.

6.3. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation will not permit Companies that support Research Grants to receive intellectual property rights or royalties arising out of the grant-funded research.

6.5. SAEM and SAEM Foundation will not permit Companies that support Research Grants to control or influence manuscripts that arise from the grant-funded research.

6.6. If a SAEM or SAEM Foundation receives programmatic support (e.g., an Educational Grant or Charitable Contribution) from a Company to support the organization's own research, the organization will disclose the Company support. The organization will act independently in the selection of research topics and the conduct of the research itself.

## **7. Clinical Practice Guidelines**

7.1. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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, SAEM and SAEM Foundation will publish a description of their Guideline development process, including their process for identifying and managing conflicts of interest, in Society Journals or on organization 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. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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 SAEM and SAEM Foundation to accept Company support for the 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. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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. SAEM and SAEM Foundation 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.<sup>12</sup> Societies may permit public or member comment on draft Guidelines as a part of the Society's published Guideline development process*

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.

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<sup>12</sup> 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.

*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.*

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, except if a Society permits public or member comment on draft Guidelines as a part of the Society's published Guideline development process.

## **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).<sup>13</sup>*

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.*

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<sup>13</sup> 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](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.

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.<sup>14</sup>*

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

## **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.

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<sup>14</sup> 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](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.