



American College of Foot and Ankle Surgeons®

Code for Interaction with Companies

Revised by the Board of Directors on October 23, 2015

The Council of Medical Specialty Societies (CMSS) “Code for Interactions with Companies” was first published in 2011 to foster high ethical standards of medical specialty societies in their relationships with companies. The code recognizes:

- Medical Specialty Societies play an important role in reaching out to health professionals, patients, and other groups. Societies 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, 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 conflicts of interest.
- Societies’ interactions with Companies may include receiving charitable contributions, applying for grants in support of programmatic activities, and conducting a range of business transactions. In all of these interactions, Societies should be committed to acting with integrity and transparency.

Although ACFAS is not a member of CMSS due to its membership criteria, the ACFAS Board of Directors has adopted relevant principles of the CMSS Code to help the College maintain actual and perceived independence. Adopting relevant portions of the Code is intended to ensure the College’s interactions with companies will be for the benefit of patients, members, and for the improvement of care in foot and ankle surgery. ACFAS acknowledges the Council’s leadership in developing its Code for the benefit of the public and all medical societies, regardless of each society’s respective membership criteria.

Definitions

The following terms are defined for purposes of this Code. Some of these terms refer to types of interactions in which ACFAS 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 ACFAS 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 ACFAS and a Company in which a Company pays a fee to the College in exchange for the Society's item, service, or product. Examples of Business Transactions include Company payment of fees associated with subscriptions to College publications, advertising in College publications, registrations for College 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., ACFAS) for use in furthering the organization's charitable purposes and in accordance with applicable tax rules and legal standards.
- **Clinical Practice Guideline (CPG) or Clinical Consensus Statement (CCS):** A CPG or CCS 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 CPG or CCS also refers to medical technology assessments, clinical opinions, and other evidence-based clinical practice tools. ACFAS will determine whether the term CPG or CCS 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. 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, ACFAS may choose to adopt a broader definition of "Company" if doing so would better address the College'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., Council on Podiatric Medical Education (CPME)).
- 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 College 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.
- **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 College. Educational Grants awarded by a Company to support a CME activity are referred to in Council of Podiatric Medical Education (CPME) standards. An Educational Grant may also be "in-kind."
- **Key College Leaders:** At a minimum, and for purposes of this Code, the Key College Leaders are Board of Directors, Executive Committee, committee chairs, Division Presidents Council, *Journal of Foot & Ankle Surgery* Editor and Section Editors, and all members of the Council of Journal Management.
- **Non-CME Informational/Educational Program:** A Non-CME Informational/Educational Program is a program offered by the College, 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 given by the College to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide the College 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 Medical Society meeting where CME credit for the Symposium is provided by a third party CME provider, and for which the Medical Society receives a fee. **Note:** ACFAS does not allow any CME to be provided at any corporate-sponsored event during College events regardless of CME accreditation
- **Society or College CME:** Society or College CME refers to CME programs planned by a Society or ACFAS, and for which the Society or ACFAS, 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. (e.g., *Journal of Foot & Ankle Surgery*).

Section 1 - Independence

- 1.1 The College will commit that its 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.
- 1.2 The College will separate its efforts to seek Educational Grants, Research Grants, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from its programmatic decisions.
- 1.3 The Board of Directors will identify the high-level group responsible for guiding College interactions with Companies.
- 1.5 The College will use written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of Research Grants.

Section 2 - Transparency

- 2.1 The College will make its conflict of interest policies and/or forms available to its members and the public.
- 2.2 The College will disclose Company support (at a minimum Educational Grants, Corporate Sponsorships, Charitable Contributions, and support of Research Grants), making this information available to its members and the public.
- 2.3 The College will adopt written disclosure policies for Key College Leaders, Board members, committee members and others who serve on behalf of the College, and will use the disclosed information to manage conflicts of interest in decision-making. The College will require volunteers to update disclosure information at least annually and when material changes occur.
- 2.4 The College will disclose all financial and uncompensated relationships that Key College Leaders and members of the Board of Directors of the College's membership organization have with Companies, making this information available to its members and the public.

Section 3 – Accepting Charitable Contributions

- 3.1. The College will control the use of charitable contributions in a manner that is aligned with the College's tax-exempt purpose, mission, and business plans.
- 3.2. The College will decline charitable contributions where the Company expects to influence College programs or advocacy positions, or where Company restrictions would influence

College programs or advocacy positions in a manner that is not aligned with the College’s mission.

3.3. The College 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.

3.5. The College will adopt policies for consistent and appropriate recognition of donors.

Section 4 – Accepting Corporate Sponsorships

4.1. The College will only accept corporate sponsorships of an item or program if the item or program is aligned with the College’s tax-exempt purpose, mission, and business plans.

4.2. The College will make reasonable efforts to seek multiple corporate sponsorships for sponsored items or programs. Sources outside the for-profit healthcare sector are acceptable.

4.3. The College will be in the placement of names or logos of Companies or products on College-distributed, non-educational “giveaway” items (e.g., bags, highlighters, notebooks, luggage tags, etc.) that Companies are not permitted to give directly to healthcare professionals under generally accepted standards for ethical interactions (i.e., PhRMA Code, AdvaMed Code). Specifically: 1) No names/logos will appear on identification badges, lanyards, etc.; 2) no single company advertising will appear near or inside educational meeting space, and 3) recognition house ads or signage will appear sparingly and include all sponsors, etc.

4.4. If accepting Corporate Sponsorship of a data registry, the College will prohibit Corporate Sponsors from participating in the direct management of the registry (e.g., deciding to sell, disclose, or publish data; serve on committees; have special access to data).

Section 5 - College Meetings

5.1 - College Educational and Informational Programs

5.1.1. When providing CME, the College will comply with CPME standards, including by adopting policies and procedures designed to identify and manage conflicts of interest in Company-supported College CME programs.

5.1.2. In providing College CME, the College will seek support from multiple companies when presenting product-specific topics.

5.1.3. The College will make reasonable efforts to achieve a balanced portfolio of support for each College CME program.

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

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

5.1.6. The College will not solicit Companies' suggestions about program topics, speakers, or content.

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

5.1.8. The College 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. The College will clearly distinguish its Non-CME Informational/Educational Programs from College CME.

5.1.10. Incoming and outgoing board officers, board directors, and members of the Annual Scientific Conference Committee may not participate as leaders or presenters in Company promotional/ marketing events three days prior, during, or three days after the official dates of the Annual Scientific Conference.

5.2. - CME-Accredited Satellite Symposium

Note: ACFAS does not allow any CME to be provided at any corporate-sponsored event during College events regardless of CME accreditation.

5.2.1. The College will require Satellite CME Symposia to undergo an application and election process.

5.2.2. The College will require Satellite CME Symposia to comply with CPME standards.

5.2.3. The College will ensure that Satellite CME Symposia are clearly distinguished from College CME in College meeting programs and promotional materials.

5.2.4. The College will require third-party organizers of Satellite CME Symposia to use appropriate disclaimers to distinguish the Symposia from College CME programs in Symposia advertising and program materials.

5.3. - Company Informational/Education Programs

5.3.1. The College will require Company Informational/Educational Programs to be clearly distinguished from CME.

5.4. – Exhibits

5.4.1. The College 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.

5.4.2. The College will only permit exhibitor giveaways that are educational and modest in value.

5.4.3. The College will make reasonable efforts to place exhibit booths out of attendees' obligate path to College CME sessions.

Section 6 – Awarding of Research Grants

6.1. The College will not permit Companies to select (or influence the selection of) recipients of research grants.

6.2. The College will appoint an independent committee(s) to select recipients of research grants.

6.3. The College will not require recipients of research grants to meet with Company supporters.

6.4. The College will not permit Companies that support research grants to receive intellectual property rights or royalties arising out of the grant-funded research.

6.5. The College will not permit Companies that support research grants to control or influence manuscripts that arise from the grant-funded research.

6.6. If the College receives programmatic support (e.g., an educational grant or charitable contribution) from a Company to support the College's own research, the College will disclose the Company support. The College will act independently in the selection of research topics and the conduct of the research itself.

Section 7 – Clinical Consensus Statements

- 7.1. The College will base Clinical Consensus Statements on scientific evidence.
- 7.2. The College will follow a transparent Statement development process that is not subject to Company influence.
- 7.3. The College will not permit direct Company support of the development of Statements. Company support of the overall mission-based activities of the College is not considered direct support.
- 7.4. The College will not permit direct Company support of the initial printing, publication, and distribution of Statements. After initial development, printing, and distribution is complete, it is permissible for the College to accept Company support for the College's further distribution of Statements, translation, or repurposing of Statement content.
- 7.5. The College will require all Statement development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Statement development process.
- 7.6. The College will develop procedures for determining whether financial or other relationships between Statement development panel members and Companies constitute conflicts of interest relevant to the subject matter of the Statement, as well as management strategies that minimize the risk of actual and perceived bias if panel members have conflicts (e.g., not allowing panel members from drafting text or voting on recommendations).
- 7.7. The College will require that a majority of Statement development panel members are free of conflicts of interest relevant to the subject matter of the Statement.
- 7.8. The College 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 Statement, and to remain free of such conflicts of interest for at least one year after Statement publication.
- 7.9. The College will require that Statement recommendations be subject to peer-review by a range of experts. The College will not select as reviewers individuals employed by or engaged to represent a Company.
- 7.10. The College's Statement recommendations will be reviewed and approved before submission for publication by at least one body beyond the Statement development panel, such as a committee or the Board of Directors.
- 7.11. Statement manuscripts will be subject to independent editorial review by a journal or other publication where they are first published.

7.12. The College will publish Statement development panel members' disclosure information in connection with each Statement and may choose to identify abstentions from voting.

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

7.14. The College will recommend that Statement development panel members decline offers from affected Companies to speak about the Statement on behalf of the Company for a reasonable period after publication.

7.15. The College will not permit Statement development panel members or staff to discuss a Statement's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Statements in draft form.

Section 8 - ACFAS Journals

8.1. College Journals will maintain editorial independence from the College and from Advertisers.

8.2. College Journals will require all authors to disclose financial and other relationships with Companies. Authors' disclosure information will be considered by Journal editors in evaluating an article for publication. If the article is published, the College's Journal will publish the author's disclosure information with the article. The "look-back" period for disclosure should be at least one year. The Council for Journal Management and Journal editor will adopt policies governing the scope and format of disclosure, including consistent disclosure categories.

8.3. College Journals will require editors and reviewers to disclose financial and other relationships with Companies.

8.4. The Editor-in-Chief of each 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.

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

Section 9 – Standards for Advertising

9.1. The College will adopt written policies that set standards for advertising (e.g., advertising should be easily distinguishable from editorial content; advertising should not be designed to look like scientific articles; etc.).

Section 10 – Standards for Licensing

10.1. The College 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 College trademarks to imply College endorsement of Company products or services.

For more information visit www.acfas.org/conflicts

American College of Foot and Ankle Surgeons

8725 West Higgins Road, Suite 555

Chicago, IL 60631

T 773-693-9300 F 773-693-9304

info@acfas.org

Code Revisions History

Sections 1, 2, and 5 – Adopted October 2014

Sections 3, 4, 6, 7, 8, 9, and 10 – Adopted July 2015

Section 5.1.10 – Revised October 2015