

**Preferred Practice Patterns and Ophthalmic Technology Assessments:  
New Relationship with Industry Procedures – June 2010  
Revised April 2011**

**Introduction:**

On April 17, 2010, the Council of Medical Specialty Societies (CMSS) adopted a Code for Interactions with Companies.<sup>1</sup> The American Academy of Ophthalmology (the Academy), a member of CMSS, was one of the original signatories. The Code was subsequently revised in March 2011.

Although a code for medical organizations, not for individual physicians, it will have an effect on the functioning of “clinical guidelines committees,” which at the Academy means its Preferred Practice Pattern (PPP) committees and Ophthalmic Technology Assessment (OTA) committees. As a result, the Academy’s Board of Trustees approved the procedures below.

**New Relationship with Industry Procedures for Preferred Practice Patterns and Ophthalmic Technology Assessments:** (The following procedures follow the provisions in the CMSS Code pertaining to Clinical Practice Guidelines. Definitions appear on page 4.)

1. The Academy will base its PPPs and OTAs on scientific evidence, with published criteria for the rating of scientific evidence. (*Code Ref. 7.1 Societies will base Clinical Practice Guidelines on scientific evidence.*)
2. The Academy will follow a transparent guideline development process that is not subject to Company influence. For PPPs, OTAs, and updates published after adoption of the Code, the Academy will publish a description of its PPP and OTA development process, including the process for identifying and managing Financial Relationships with Industry on the Academy website. (*Code Ref 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.*)
3. The Academy will not permit direct Company support of the development of PPPs and OTAs. Company support of the overall mission-based activities of the Academy is not considered direct support of Guideline development. (*Code Ref 7.3: Societies will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates.*)
4. The Academy will not permit direct Company support of the initial printing, publication and distribution of PPPs or OTAs. The Academy will accept Company support for the Academy’s further distribution (broader dissemination of printed documents to various audiences, e.g.,

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<sup>1</sup> Council of Medical Specialty Societies. Code for Interactions with Societies. Available at: [www.cmss.org/codeforinteractions.aspx](http://www.cmss.org/codeforinteractions.aspx).

residents, physicians, international societies, etc.) of the PPPs or OTAs, translations or repurposing of the PPP and OTA content. In these circumstances, the Academy will require a written statement with the materials, acknowledging the Company's role and describing the independent nature of the Academy's PPP and OTA development process. (*Code Ref 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.*)

5. The Academy will require all PPP and OTA panel members to disclose relevant relationships prior to panel deliberations and to update their disclosure throughout the PPP and OTA development process. (*Code Ref 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.*)
6. The Academy PPP and OTA chairs and staff will determine whether an individual panel member's disclosed relationships constitute a Financial Relationship with Industry that is relevant to the subject matter of the PPP or OTA. If an individual is determined to have a Financial Relationship with Industry, then he/she will not be able to draft the text section directly related to their Financial Relationship with Industry, and will be recused from voting on panel recommendations directly related to his/her Financial Relationship with Industry. (*Code Ref 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.*)
7. For the PPPs and OTAs, a majority of panel members would need to be free of Financial Relationships with Industry relevant to the subject matter of the PPP or OTA. The Panel is made up of two groups: one group (writing) would be primarily charged with writing of the guideline or assessment and have meetings to facilitate the writing, and one group (review) would be primarily charged with reviewing and modifying the guideline or assessment to assure scientific objectivity and the absence of commercial bias, and would meet only via conference call. If there are any issues of disagreement between the writing group and the review group, the Secretary of Quality of Care will adjudicate. Selection of members for the writing group would be based on qualifications and standing in the field. If there were two equivalent individual experts in the field being considered, but one had a Financial Relationship with Industry and one did not have a Financial Relationship with Industry, the one without a Financial Relationship with Industry would be preferred. Selection of members for the review group would be based on qualifications and the absence of a Financial Relationship with Industry. (*Code Ref 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.*)
8. The Chair, or at least one Co-Chair of two Co-Chairs, of the PPP or OTA Panel would need to be free of a Financial Relationship with Industry and would be asked to remain free of a Financial Relationship with Industry for one year following publication of the PPP or OTA. The overall

Chair of the OTAs and Chair of the PPPs would not be required to be free of relationships with industry (this is not required in the CMSS Code). *(Code Ref 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.)*

9. The Academy would continue to subject the PPPs and OTAs to multiple levels of review, including rigorous peer-review by a range of experts to ensure that a balance of perspectives has been considered. (PPPs – subspecialty societies, state societies, specialized interest societies, Board of Trustees, other experts in the field, other medical specialty societies as indicated; OTAs – subspecialty societies, Board of Trustees, other experts in the field). The Academy will not select reviewers who are individuals employed by or engaged to represent a Company. *(Code Ref 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.)*
10. The Academy Board of Trustees reviews and approves all PPPs and OTAs before submission for publication. *(Code Ref 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.)*
11. The OTAs will be subject to editorial review by the Ophthalmology Journal. The PPPs are published online. *(Code Ref 7.11: Guideline manuscripts will be subject to independent editorial review by a journal or other publication where they are first published.)*
12. The Academy will publish the PPP and OTA panel members' disclosure information about Financial Relationships with Industry along with the documents and identify abstentions from voting on the Academy website. (This information is published with the PPPs and the last page of the OTA article as per Ophthalmology Journal conventions.) *(Code Ref 7.1: Societies will publish Guideline development panel members' disclosure information in connection with each Guideline and may choose to identify abstentions from voting.)*
13. The Academy would request that all reviewers not officially part of the PPP or OTA panel disclose financial or other substantive relationships that may constitute Financial Relationships with Industry. Any reviewer who refused to disclose these relationships would not have his/her comments considered by the panel. *(Code Ref 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.)*
14. The Academy will recommend that PPP and OTA panel members decline offers from affected Companies to speak about the PPP or OTA on behalf of the Company for a reasonable period after publication. *(Code Ref 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.)*

15. The Academy will discourage PPP or OTA members and will not permit staff to discuss a PPP or OTA's development with Company employees or representatives. The Academy will not accept unpublished data from Companies for the PPP and OTA development. The Academy will not permit Companies to review PPPs and OTAs in draft form. (*Code Ref 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.*)

### **Definitions:**

The following terms are defined in the CMSS Code:

**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"). 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. 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.

**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.

### Additional Clarification from Principle 1.4

Under Principle 1.4, Key Society Leaders 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

This definition is for the setting of the PPPs and OTAs:

**Financial Relationship with Industry:** A Financial Relationship with Industry is a Direct Financial Relationship (as defined by the Code for Interactions with Companies) that is relevant to the subject matter of the PPP or OTA. . This may or may not constitute a substantive conflict of interest. Research grants are not considered a Financial Relationship with Industry when the funds are controlled by the institution/practice.

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