

## STANDARDS OF PROFESSIONALISM

### ORTHOPAEDIST-INDUSTRY CONFLICTS OF INTEREST

**These Standards of Professionalism (SOPs) on Orthopaedist-Industry Conflicts of Interest take effect on April 18, 2007. Enforcement of these SOPs begins with acts occurring on or after January 1, 2008.**

The primary focus of the orthopaedic profession is care of the patient. As part of their lifetime commitment to patients, orthopaedic surgeons must maintain specialized knowledge and skills through participation in continuing medical education programs, seminars, and professional meetings. Often, these professional functions are sponsored by the community of medical device manufacturers, pharmaceutical companies, and other businesses who play an important role supporting continuing medical education (CME) events and the development of new technologies that contribute to the on-going patient-physician relationship. This collaborative effort ensures that patients have the best surgical outcomes through the invention and testing of new technology, research and evaluation of existing technology, and continued education of orthopaedic surgeons.

Cooperative relationships between orthopaedic surgeons and industry benefit patients. Orthopaedic surgeons are best qualified to provide innovative ideas and feedback, conduct research trials, serve on scientific advisory boards, and serve as faculty to teach the use of new technology. Orthopaedic surgeons, in an effort to improve patient care, rely on industry to bring their creative ideas to fruition. A collaborative relationship between orthopaedic surgeons and industry is necessary to improve patient care, but must be carefully scrutinized to avoid pitfalls of improper inducements, whether real or perceived.

Orthopaedic surgeons must be mindful of potential conflicts of interest with patient care in pursuing academic and commercial ventures. A conflict of interest exists when professional judgment concerning the well being of the patient has a reasonable chance of being influenced by other interests of the physician. The self-interest of the physician may be financial in nature. The competing interests may involve fame and notoriety for the physician or time for the physician or the physician's family. When such conflicts exist, there is concern that care decisions may not be in the best interests of the patient. Disclosure of a conflict of interest is required in communications to patients, the public and colleagues. The benefit to the patient must be the primary goal and must not be compromised. Orthopaedic surgeons, like all physicians, have an ethical obligation to present themselves and the services they provide to patients in a clear and accurate manner.

When faced with a potential conflict of interest that cannot be resolved, an orthopaedic surgeon should consult with colleagues or an institutional ethics committee to determine whether there is an actual or potential conflict of interest and how to address it.

For purposes of these Standards of Professionalism, “industry” includes pharmaceutical, biomaterial, and device manufacturers.

For purposes of these Standards of Professionalism, “CME events” refer to educational events that meet the requirements of and have been approved by the Accreditation Council for Continuing Medical Education (ACCME). Further, it is understood that attendance at a CME event shall mean that the orthopaedic surgeon is attending and is not an instructor at that CME event.

For purposes of these Standards of Professionalism, a conflict of interest occurs when an orthopaedic surgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the orthopaedic surgeon’s obligation to act in the best interest of the patient.

A “financial interest,” “financial arrangement,” “financial inducement” or “financial support” includes, but is not limited to:

- Compensation from employment;
- Paid consultancy, advisory board service, etc.;
- Stock ownership or options;
- Intellectual property rights (patents, copyrights, trademarks, licensing agreements, and royalty arrangements);
- Paid expert testimony;
- Honoraria, speakers’ fees;
- Gifts;
- Travel; and
- Meals and hospitality

A “positional interest” occurs when an orthopaedic surgeon or family member is an officer, director, trustee, editorial board member, consultant, or employee of a company with which the orthopaedic surgeon has or is considering a transaction or arrangement.

Some states have enacted legislation regarding relationships between physicians and industry. When the law supersedes these Standards of Professionalism, AAOS Fellows and Members are expected to follow the law.

These Standards of Professionalism draw from the aspirational *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* that appears in bold italics. The statements that follow the **aspirational** Code establish the **mandatory** minimum standards of acceptable conduct for orthopaedic surgeons when engaged in relationships with industry. Violations of these minimum standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

The Standards of Professionalism on Orthopaedist-Industry Conflicts of Interest apply to all AAOS Fellows and Members. Only an AAOS Fellow or Member may file complaints of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

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**Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I.A.:**

*The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns.*

**Mandatory Standards:**

1. An orthopaedic surgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount.
2. An orthopaedic surgeon shall prescribe drugs, devices, and other treatments primarily on the basis of medical considerations and patient needs, regardless of any direct or indirect interests in or benefit from industry.

**Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, II. C.:**

*The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct.*

**Mandatory Standard**

3. An orthopaedic surgeon convicted of violating federal or state conflict of interest laws or regulations shall be subject to discipline under the AAOS Professional Compliance Program.

**Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.A.:**

*The practice of medicine inherently presents potential conflicts of interest. When a conflict of interest arises, it must be resolved in the best interest of the patient. The orthopaedic surgeon should exercise all reasonable alternatives to ensure that the most appropriate care is provided to the patient. If the conflict of interest cannot be*

*resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the relationship.*

Mandatory Standards

4. An orthopaedic surgeon shall, when treating a patient, resolve conflicts of interest in accordance with the best interest of the patient, respecting a patient's autonomy to make health care decisions.
5. An orthopaedic surgeon shall notify the patient of his or her intention to withdraw from the patient-physician relationship, in a manner consistent with state law, if a conflict of interest cannot be resolved in the best interest of the patient.

**Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.C.:**

*When an orthopaedic surgeon receives anything of significant value from industry, a potential conflict exists which should be disclosed to the patient. When an orthopaedic surgeon receives inventor royalties from industry, the orthopaedic surgeon should disclose this fact to the patient if such royalties relate to the patient's treatment. It is unethical for an orthopaedic surgeon to receive compensation of any kind from industry for using a particular device or medication. Reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable.*

Mandatory Standards:

6. An orthopaedic surgeon shall decline subsidies or other financial support from industry, except that an orthopaedic surgeon may accept gifts having a fair market value of less than \$100, medical textbooks, or patient educational materials.
7. An orthopaedic surgeon who has influence in selecting a particular product or service for an entity shall disclose any relationship with industry to colleagues, the institution and other affected entities.
8. An orthopaedic surgeon shall disclose to the patient any financial arrangements with industry that relate to the patient's treatment, including the receipt of inventor royalties, stock options or paid consulting arrangements with industry.
9. An orthopaedic surgeon shall accept no direct financial inducements from industry for utilizing a particular implant or for switching from one manufacturer's product to another.
10. An orthopaedic surgeon shall enter into consulting agreements with industry only when such arrangements are established in advance and in writing to include evidence of the following:

- Documentation of an actual need for the service;
- Proof that the service was provided;
- Evidence that physician reimbursement for consulting services is consistent with fair market value; and
- Not based on the volume or value of business he or she generates.

11. An orthopaedic surgeon shall participate in or consult at only those meetings that are conducted in clinical, educational, or conference settings conducive to the effective exchange of information.

**Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, IV.A.:**

*The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in continuing medical educational activities.*

Mandatory Standards:

12. An orthopaedic surgeon shall accept no financial support from industry to attend industry-related social functions where there is no educational element.

13. An orthopaedic surgeon who is attending a CME event shall accept no industry financial support for attendance at a CME event. Residents and orthopaedists-in-training may accept an industry grant to attend a CME event if they are selected by their training institution or CME sponsor and the payment is made by the training program or CME sponsor. *Bona fide* faculty members at a CME event may accept industry-supported reasonable honoraria, travel expenses, lodging and meals from the conference sponsors.

14. An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept only tuition, travel and modest hospitality, including meals and receptions; the time and focus of the event must be for education or training.

15. An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept no financial support for meals, hospitality, travel, or other expenses for his or her guests or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

**Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.D.:**

*An orthopaedic surgeon reporting on clinical research or experience with a given procedure or device must disclose any financial interest in that procedure or device if the orthopaedic surgeon or any institution with which that orthopaedic surgeon is connected has received anything of value from its inventor or manufacturer.*

### Mandatory Standards

16. An orthopaedic surgeon, when reporting on clinical research or experience with a given procedure or device, shall disclose any financial interest in that procedure or device if he or she or any institution with which he or she is connected has received anything of value from its inventor or manufacturer.
  
17. An orthopaedic surgeon who is the principal investigator shall make his or her best efforts to ensure at the completion of the study that relevant research results are reported and reported truthfully and honestly with no bias or influence from funding sources, regardless of positive or negative findings.