

STANDARDS OF PROFESSIONALISM

Orthopaedic Surgeon-Industry Relationships

Adopted April 18, 2007; Amended April 23, 2012

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

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 (CME) programs, seminars, and professional meetings. Often, these professional functions are sponsored by the manufacturers of medical devices, biologics, drugs and other items use in the care of the patient (Product). These businesses play an important role in the support of CME events and the development of new technologies. This collaborative effort ensures that patients have the best 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.

A potential 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. Disclosure of a conflict of interest is required in communications to patients, the public and colleagues. 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.

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 Orthopaedic Surgeon - Industry Relationships 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.

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 products or 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 shall comply with all relevant federal and state conflict of interest and fraud and abuse laws.

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 product. Fair market 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 non-monetary items which benefit patients or serve an educational function and which have a fair market value of less than \$100.
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 product 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:
 - That there is an actual need for the service;
 - That the provision of the service will be verified;
 - That the compensation for services provided by the orthopaedic surgeon is based on fair market value;
 - That the compensation for services provided by the orthopaedic surgeon is not based on the volume or value of business he or she generates; and
 - That reimbursement for reasonable and actual expenses, such as modest meals, travel and lodging, incurred by the orthopaedic surgeon is based on appropriate need and accurate documentation.
11. An orthopaedic surgeon shall consult at only those meetings that are conducted in clinical, educational, or conference settings conducive to the effective exchange of basic science and/or clinical 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. The industry entity funding the grant shall have no influence in the selection of the individual recipients. *Bona fide* faculty members at a CME event may accept industry-supported reasonable honoraria, travel expenses, lodging and modest 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 the presentation of *bona fide* scientific, educational or business information 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 product must disclose any financial interest in that procedure or product 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 product, shall disclose any financial interest in that procedure or product if he or she or any institution with which he or she is connected has received anything of value from its inventor, manufacturer, or distributor.
17. An orthopaedic surgeon who is an investigator shall make his or her best efforts to ensure at the completion of an industry-sponsored 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.