INDUSTRY RELATIONSHIPS
STANDARDS OF PROFESSIONALISM

Orthopaedic Surgeon-Industry Relationships

Adopted April 18, 2007; Proposed revisions will be voted on by the Fellowship after the 2012 Annual Meeting.

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 Relationship 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.
Opinions on Ethics and Professionalism

The Orthopaedic Surgeon's Relationship with Industry

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

Under what, if any, circumstances is it appropriate for orthopaedic surgeons to accept gifts or other financial support from industry, including pharmaceutical, biomaterial or device manufacturers?

Applicable provision of the Principles of Medical Ethics and Professionalism in Orthopaedic Surgery

"I. Physician-Patient Relationship. 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. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect."

Applicable provisions of the 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."

"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."

"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 relevant continuing medical educational activities."
Other references:

American Medical Association, Section 8.061 (Gifts to Physicians from Industry) of the Current Opinions of the Council on Ethical and Judicial Affairs.


Discussion

Orthopaedic surgeons have long recognized the importance of continuing medical education in maintaining their professional skills. Both orthopaedists-in-training and practicing orthopaedic surgeons attend and participate in numerous continuing medical educational programs and seminars. Industry, including pharmaceutical, biomaterial and device manufacturers, has generously supported many of these beneficial programs.

For several years, there has been concern about industry making gifts to physicians. Some of these gifts that reflect customary marketing practices of industry may not be consistent with basic principles of medical ethics. The line is sometimes blurred between industry's providing funds for an actual continuing medical educational experience and providing funds to promote the use or purchase of a particular pharmaceutical, biomaterial or piece of orthopaedic equipment.

Generally, the American Academy of Orthopaedic Surgeons (AAOS) believes that it is acceptable for industry to provide financial and other support to orthopaedic surgeons if such support has significant educational value and has the purpose of improving patient care. All dealings between orthopaedic surgeons and industry should benefit the patient and be able to withstand public scrutiny.

Guidelines

To avoid acceptance of inappropriate gifts or other financial support, the AAOS recommends that orthopaedic surgeons observe the following guidelines:

1. Benefit to Patients.

   The patient's best interest is paramount. Therefore, it is of utmost importance that any gift or other financial support accepted by an orthopaedic surgeon should primarily entail a benefit to his or her patient. A gift of any kind from industry should in no way influence the orthopaedic surgeon in determining the most appropriate treatment for his or her patient. It is only by strict adherence to this principle that the orthopaedic surgeon may maintain the patient’s trust.

2. Gifts With Conditions Attached.

   Orthopaedic surgeons should not accept gifts or other financial support with conditions attached. No gifts (including goods, meals, accommodations, meeting registrations, travel, etc. to attend educational meetings or learning new skills under the tutelage of an expert) should be accepted with the explicit or implicit requirement that the orthopaedic surgeon use the products or services provided by that particular industry.
3. **Social Functions.**

Although the AAOS is generally opposed to social events sponsored by industry, social functions supported by industry in combination with significant continuing medical education events are acceptable. However, social functions supported by industry (e.g. dinners, tickets to sporting events or theater, golf outings, etc.) where there is no educational element should not be offered to nor accepted by orthopaedic surgeons.

4. **Cash Gifts.**

Cash gifts from industry to orthopaedic surgeons must not be offered nor accepted.

5. **Continuing Medical Education (CME) Events.**

   A. **Subsidies.**

   Subsidies by industry to underwrite the costs of educational events where CME credits are provided can contribute to the improvement of patient care and are acceptable. A corporate subsidy received by the conference’s sponsor is appropriate and acceptable so long as such support is publicly acknowledged and the location, curriculum, faculty, and educational methods of the conference or meeting are determined solely by the organization sponsoring the educational course, not industry. Industry reimbursement, whether direct or indirect, for an orthopaedic surgeon to attend an educational event is not appropriate.

   B. **Faculty Expenses and Honoraria for Continuing Medical Education Activities.**

   It is appropriate for faculty at educational events where CME credits are provided to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging and meal expenses from the conference’s sponsor.

6. **Other Educational Events.**

Educational events sponsored by industry may be of educational value and improve patient care. Orthopaedic surgeons are responsible for insuring that decisions to accept subsidies from industry are in the best interest of their patients. The AAOS believes a potential conflict of interest exists when an orthopaedic surgeon receives such subsidies.

Special circumstances may arise in which orthopaedic surgeons may be required to learn new surgical techniques demonstrated by an expert in the field in his/her institution or to review new implants or other devices on-site. On-site education provides the added benefit of educating a larger number of attendees per session and offers important insights into the function of ancillary staff and institutional protocols. In these circumstances, reimbursement for expenses may be appropriate.

Reimbursement should be limited to expenses that are strictly necessary and able to withstand public scrutiny. In no case should honoraria or reimbursement for time off to attend the course be offered or accepted. In addition, attending the course and learning
the technique must not require or imply that the orthopaedic surgeon must subsequently use that technique.

7. Scholarships for Orthopaedic Surgeons-in-Training.

Scholarships or other special funds from industry to permit orthopaedic surgeons-in-training to attend continuing medical education conferences are appropriate as long as the selection of students, residents or fellows who will receive the funds is made by the orthopaedist-in-training’s program director.

8. Consultant Expenses and Honoraria.

It is appropriate for consultants to industry who provide genuine services as faculty in educational events to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token consulting or advisory arrangements, such as passive attendance at a meeting or being named to an advisory board for simply discussing a device without making any real contribution to product development or analysis, cannot be used to justify compensating orthopaedic surgeons for their time, travel, lodging or other out-of-pocket expenses.

9. Other Consulting Arrangements.

A symbiotic relationship exists between orthopaedic surgeons and industry. Orthopaedic surgeons are best qualified to provide innovative ideas and feedback, conduct research trials, serve on scientific advisory boards, and to 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.

It is appropriate for consultants to industry who provide genuine services to receive reasonable compensation for their services. Such arrangements should be established in advance and in writing to include evidence of the following: 1.) Documentation of an actual need for the service. 2.) Proof that the service was provided; and 3.) Evidence that physician reimbursement for consulting services should be equal to fair market value.

Examples of inappropriate relationships between orthopaedic surgeons and industry include, but are not limited to: 1.) Receiving a consultant fee for simply attending a meeting; 2.) Receiving remuneration for using a particular implant; and 3.) Receiving consultant fees or other financial inducement for switching from one manufacturer’s product to another.

Proper collaborative relationships between orthopaedic surgeons and industry are critical for advancement and improvement in patient care. Such relationships allow industry to fulfill their goals to improve patient care and increase patient access to new products and also are beneficial to orthopaedic surgeons and their patients. Orthopaedic surgeons must continually strive to improve patient care through the development of new advances and methodology.
Orthopaedic surgeons should never lose sight of their primary ethical responsibility to provide competent, compassionate patient care, maintaining professionalism and objectivity at all times.


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Position Statement

Alignment of Physician and Facility Payment and Incentives

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The United States healthcare system currently faces numerous challenges. The cost of delivering medical care in the U.S. is growing at twice the rate of inflation and totaled 16 percent of the Gross Domestic Product (GDP) in 2006.\textsuperscript{1} If left unchecked, healthcare is projected to rise to 20 percent of the GDP by 2016.\textsuperscript{2} Current methods of physician reimbursement by government programs and private insurance offer little incentive to help control the cost of delivering care. Furthermore, variation in practice patterns and eroding public confidence in the quality of healthcare delivery in the U.S. has become recognized as major threats to our healthcare system. Faced with these daunting challenges, alignment of physician and facility payment incentives has caught the interest of federal policymakers and many other stakeholders, who are searching for ways to stimulate savings and improve operational and financial performance. “Episode of care” bundled payment initiatives and gainsharing arrangements with physicians are common examples of ways to align facility and provider incentives.

*The American Association of Orthopaedic Surgeons (AAOS) supports efforts of all stakeholders to develop and evaluate payment methodologies that will incentivize coordination of care among providers (including physicians and hospitals) and help curb healthcare inflation. As the demand for musculoskeletal care increases with a more active society and an aging population, it is incumbent on orthopaedic surgeons to participate in the discussions and to take a lead role in the development and deployment of such programs.*

Currently, hospitals are paid under a Diagnosis Related Groups (DRG)-based prospective payment system which adjusts for severity and resource use in the discharge diagnosis. Physicians have traditionally been separately paid under a fee-for-service schedule without incentives to control volume or cost. The Centers for Medicare and Medicaid Services (CMS), along with multiple other stakeholders, believe that there are savings to be realized if the hospital and the physicians are paid and incentivized by the same methodology. With a single payment issued for the entire episode of care, interested parties hope to align the incentives of the facility and all involved providers, resulting in more efficient delivery of care and better compliance with standards and reporting requirements.
As traditionally defined, an “episode of care” bundled payment is a single payment made to all providers – physicians, facilities, laboratories, and all other health care professionals – for the entire episode of care provided to the patient. Episode of care payment programs may include a physician incentive or gainsharing component. Gainsharing refers to an arrangement between a physician and a hospital to share in the cost savings that result from specific actions to improve the efficiency of care delivery. Gainsharing programs may also be established independent of bundled payment programs.

Episode of care, or bundled, payment methodologies and gainsharing arrangements may carry unintended consequences. One possible consequence is deliberate deselecting of complex or risky patients. The patient must be the focal point of any initiative and therefore the system must not create incentives to treat healthier patients and limit access to sicker patients. Additionally, because a bundled payment would include a specific time period defining the episode of care, a workable and reasonable re-admission policy would be an essential piece to such initiatives. The system should not create incentives for patient diversion when a discharged patient in need of re-admission is sent to a different facility or provider. Developing a coherent risk adjustment policy is the primary method for preventing the practice of deselecting patients and addressing the readmission issues with this method of payment.

The AAOS believes risk adjustment is an indispensable component of a successful episode of care or bundled payment initiative and policy. Risk adjustment is important because unpredictable and unavoidable outcomes can occur even in the presence of evidence-based practice. Episodes of care must be risk-adjusted for patient demographics, co-morbidities, and severity of illness and procedure-specific characteristics that account for the differences that contribute to outcome and costs of treatment.

**Protecting Patient Access to Quality Care**

The AAOS embraces change that improves quality and lowers cost, but the patient must be the primary focus of all initiatives. Orthopaedic surgeons need to be knowledgeable about how their medical decisions affect costs, while ensuring that they are able to make proper choices in the best interest of patients, consistent with the best available evidence. Orthopaedic surgeons should continuously work to improve the quality and cost-efficiency of patients’ outcomes, regardless of any financial benefit. A facility’s attempt to control costs and maintain clinical programs should also not interfere with the surgeon’s goal of providing the highest quality care and serving the patient’s best interest. As part of a collaborative effort, orthopaedic surgeons within a facility should participate in the development of cost-containment strategies as long as patient care is never compromised and the proper safeguards are in place.

Necessary Safeguards for Patient Focused Care:

- The patient must be the primary focus of all initiatives.
- The patient should be empowered to be a fully participating stakeholder in their healthcare process.
- The patient’s access to quality care must always be a priority over cost savings.
- The physician must be the patient’s primary advocate for their unique medical needs.
- All stakeholders must disclose potential conflicts of interest when providing patient care.
- All stakeholders must not be incentivized to limit care or provide unnecessary care.
- Patients must maintain access to a variety of necessary providers and facilities.
Protecting and Facilitating Provider Alignment

The AAOS believes safeguards must be in place to protect the practice of medicine and the financial interests of all parties. The AAOS believes patient access to quality care, dependent on the alignment of all providers in the treatment of the patient, requires trust and collaboration. The incentives and influence should facilitate an environment in which all stakeholders can efficiently improve quality.

Necessary Safeguards to Ensure Provider Equity:

- The burden to affect cost savings must be on all providers and stakeholders.
- The process must be transparent so that all financial incentives and any revisions are known by all stakeholders.
- The initiative must align providers to collaboratively work together.
- All stakeholders must be represented when developing initiatives to align payment and incentives.
- The payment must be agreed upon prior to delivering care.
- All stakeholders must be represented when creating a method of distribution for payment.
- The compensation for work must be fair and reasonable for all providers.
- Payment must be risk adjusted for patient and procedure specific characteristics.
- The implementation must be equitable for all patients and providers.
- One provider must not have control over another provider.
- Competition must be maintained in the health care system.
- A physician must have the autonomy to provide care that addresses each patient’s unique medical needs.

References:


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