

Guidance Document for Service on the AAOS Board of Directors, as Council/ Chairs, as Editors-in-Chief of JAAOS, JAAOS Research/Global, AAOS Now, OrthoInfo, and as Members of the Executive Leadership Team (ELT) Overview

Following is a summary of the provisions from the Guidance Document for Service on the AAOS Board of Directors, as Council Chairs, as Editors-in-Chief of *JAAOS*, *JAAOS Research/Global*, *AAOS Now*, *OrthoInfo* ("governance positions") and as Members of the Executive Leadership Team (ELT) [Guidance Document]. The overview is intended to provide a quick synopsis of the guidelines relating to potential conflicts of interest.

1. Employment/Consulting/Product Development – Commercial Orthopaedic Companies

- A. Employment Commercial orthopaedic companies
 - Terminate existing employment arrangements
 - Agree to not enter into any new employment arrangements during the time of service for AAOS
- B. Consulting Commercial orthopaedic companies
 - Terminate existing consulting arrangements (whether paid/unpaid)
 - Agree to not to enter into any new consulting arrangements (whether paid/unpaid) during the time of service for AAOS
- C. Product Development (Design Team/Royalty-base contract) Commercial Orthopaedic Company
 - Maintain product development/design team activities with commercial orthopaedic companies
 - New product development/design team activities permissible
 - Relationship must be disclosed in advance and a Plan for Active Management developed/approved
 - Intellectual Property or royalty arrangement is based on a verifiable transfer of IP
 - No per diem or consulting fees is permissible
 - Reimbursement of actual expenses is appropriate
- D. Research -Commercial Orthopaedic Company
 - Existing and new research arrangements permissible in accordance with AAOS Standards of Professionalism on Research and Academic Responsibilities and AAOS Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships
 - If serving as an investigator in a clinical trial, requires relationship to be disclosed and an approved Plan for Active Management developed
 - Individual may not use his/her title or affiliation with AAOS to market or promote intellectual property developed under the research agreement

Guidance Document – AAOS Board of Directors, Council Chairs and others

2. Employment or Consulting Arrangements with Other Health Care Entities

- Existing and new employment or consulting arrangement permissible in accordance with the AAOS Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships
- Relationship must be disclosed in advanced and a Plan for Active Management developed/approved
- Intellectual Property or royalty arrangement is based on a verifiable transfer of IP
- Individual may not use his/her title or affiliation with AAOS to market or promote intellectual property developed under the agreement

3. Board of Directors or Committees of Other Orthopaedic or Medical Organizations

- Resign from current leadership/Board positions, committees or advisory groups of other national or international orthopaedic organizations or national or state medical societies
- Agree to not begin new leadership/Board/Committee service during the time of AAOS service

4. Speakers' Bureaus or Honoraria for Speaking

- Terminate service on speakers' bureaus of any commercial orthopaedic company or other health care entity
- Agree to not accept new responsibilities with speakers' bureaus during the time of AAOS service
- Speaking at educational programs sponsored by a commercial orthopaedic company or other health care entity is permissible provided no honorarium is accepted

5. Orthopaedic Publications; Textbook Exception

A. Publications

- Resign as editor, deputy, associate, section or topic editor or editorial board during time of AAOS service (AAOS editors-in-chief maintain their AAOS role)
- Serving as a reviewer on editorial boards is permissible
- Relationship must be disclosed in advance and a Plan for Active Management developed/approved

B. Textbook Exception

- Existing and new textbook projects are permissible for those serving as editor, co-editor, or contributor
- Relationship must be disclosed in advance and a Plan for Active Management developed/approved

6. AAOS Volunteer Positions

- Resign from AAOS volunteer positions solicited through the Committee Appointment Program (CAP) process during the time of AAOS service
- Liaison positions to non-orthopaedic/other organizations or government entities are permissible
- Relationship must be disclosed in advance and a Plan for Active Management developed/approved

Guidance Document – AAOS Board of Directors, Council Chairs and others

7. Compensation for AAOS Services

- Discontinue compensation for AAOS services (i.e. editorial services) during time of AAOS service
- Agree to not provide services to the AAOS for which compensation would normally be provided

8. Simultaneous AAOS Governance Positions

 Individuals may not serve simultaneously in two AAOS governance positions, be they voting or non-voting

9. Expert Witness Testimony

- Individuals may act as expert witness for services retained prior to service on the Board
- Individuals may provide opinions of fact on behalf of their patients, serve as an expert witness in matters unrelated to medical liability cases and/or testify on behalf of AAOS
- Relationship must be disclosed in advance and a Plan for Active Management developed/approved
- Clarify that any expert opinions are the individual's personal opinion and is not the position of the AAOS
- Expert opinions provided must be consistent with the AAOS Standards of Professionalism on Orthopaedic Expert Opinion and Testimony
- Other than the instances outlined above, no new expert witness work assignments may be taken during time of AAOS service

Specific details, including definitions and guidelines, relating to each section above are provided below.

Guidance Document – AAOS Board of Directors, Council Chairs and others



Guidance Document for Service on the AAOS Board of Directors, as Council Chairs, Editors-in-Chief of JAAOS, JAAOS Research/Global, AAOS Now, OrthoInfo, and as Members of the Executive Leadership Team (ELT)

The Board of Directors of the American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons ("AAOS") has approved this Guidance Document to apply to members serving on or interested in serving as officers or members of the AAOS Board of Directors, or as Council Chairs, Editors-in-Chief of *JAAOS*, *JAAOS Research/Global*, *AAOS Now*, and OrthoInfo ("governance positions"). It also applies, where applicable, to members of the AAOS Executive Leadership Team ("ELT").

Based on this Guidance Document, the Committee on Ethics and Outside Interests shall develop Plans for Active Management ("PAMs") for applicants for governance positions as well as for individuals whose disclosures have changed during their tenure in a governance position. This Guidance Document shall apply to relationships or activities once an individual has been elected or appointed to a governance position and for as long as that person is serving in the same governance position. If an individual is elected to a different governance position or is reappointed (i.e., reappointment of Council Chairs), the Guidance Document in effect at the time of the re-election or reappointment shall apply.

This Guidance Document shall be shared with nominees for service on the AAOS Board of Directors, candidates to serve as Council Chairs and in governance positions; and with the AAOS, Board of Councilors (BOC) and Board of Specialty Societies (BOS) Nominating Committees.

1. <u>Employment, Consulting, Product Development (Design Team/Royalty-based Contracts) and Research Arrangements with a Commercial Orthopaedic Company</u>

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

A. Definitions

- Commercial Orthopaedic Company shall be defined as a for-profit company that develops, produces, manufactures and/or markets orthopaedic products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate musculoskeletal conditions. Commercial orthopaedic companies may include but are not limited to those companies that exhibit at the AAOS Annual Meeting with a rating of "1" (defined as "products and services exclusively related to orthopaedics") or ".75" (defined as "products or services related to surgical disciplines").
- 2. Employment shall be defined as a relationship between two parties, usually based on contract, where the employee contributes labor and expertise to an endeavor of an employer and is usually hired to perform specific duties. An employee is a person who is hired to provide services to a company on a regular basis in exchange for compensation and may be retained full or part-time. An employed individual receives a W-2 form from the employer for tax purposes. An example would be an orthopaedic surgeon who serves as a medical director of a commercial orthopaedic company.

Guidance Document – AAOS Board of Directors, Council Chairs and others Last Updated: 2/24/2020

- 3. Consulting shall be defined as a contractual or non-contractual arrangement, paid or unpaid, in which an orthopaedic surgeon provides professional expertise to a commercial orthopaedic company. A paid consultant receives a 1099-MISC from the company for tax purposes. An example would be an orthopaedic surgeon who serves on the scientific advisory board of a commercial orthopaedic company.
- 4. Product Development (Design Team/Royalty-based contracts) shall be defined as a relationship between an orthopaedic surgeon and a commercial orthopaedic company in which the orthopaedic surgeon uses his or her professional expertise, often in conjunction with others, to develop devices or other products that company might commercialize in the future, with the possibility of compensation (e.g., royalties, licensing fees or other forms of compensation) in return for a verifiable transfer of the orthopaedic surgeon's intellectual property interest and/or know how.

Clinical and Basic Research –

- a. Clinical research shall be defined as any research that assigns human participants or groups of participants to one or more health-related interventions to evaluate the effects on health outcomes.
- b. Basic research shall be defined as a systematic study directed toward greater knowledge or understanding of a fundamental aspect of a given issue. Basic research is carried out typically without a specific goal or product in mind. In addition, basic research by definition does not include the use of human subjects.
- c. Clinical research and basic research are typically conducted by a Principal Investigator, with or without co-investigators. Typically, at institutions such as universities, there is also oversight provided by Institutional Review Boards, research committees and academic departments.

B. General Statement

Consistent with the guidelines noted below, an individual in an AAOS governance position may have the skills, temperament, training and interest to participate in product development or conduct research for the advancement of medical science and the improvement of patient care. With the prior approval of AAOS through an agreed upon Plan for Active Management (PAM), an individual in an AAOS governance position may enter into or continue product development activities or musculoskeletal research. In this way, AAOS can balance the interest of the individual and the organization ensuring that the given individual is in a position to carry out his or her AAOS duties.

C. Guidelines

- 1. Employment The individual in an AAOS governance position will terminate existing employment arrangements and agree not to enter into any new employment relationship (whether compensated or not) with a commercial orthopaedic company during the time of service for AAOS.
- Consulting The individual in an AAOS governance position will terminate consulting arrangements and agree not to enter into any new consulting relationship (whether compensated or not) with a commercial orthopaedic company during the time of service for AAOS.
- 3. Product Development (Design Team/Royalty-based contracts) -
 - The individual in an AAOS governance position may maintain and/or begin his or her product development/design team activities with the commercial orthopaedic company, provided that
 - i. In the case of maintaining the relationship, it has been disclosed to AAOS prior to assuming any governance position; in the case of a new relationship, it has been disclosed to the AAOS prior to entering into the new relationship;
 - ii. A PAM has been agreed to that details this relationship; and
 - iii. The intellectual property or royalty arrangement is based on a verifiable transfer of intellectual property and know-how (e.g., patents, copyrights, royalty, and licensing agreements).

This product development/design team relationship shall be managed per Protocol.

- b. The individual in an AAOS governance position will neither request nor accept any per diem or consulting fees from the commercial orthopaedic company if he or she is participating under a product development/design team arrangement. The payment by the commercial orthopaedic company for the individual's reasonable and actual expenses is appropriate.
- c. The individual in an AAOS governance position agrees that he or she will not use his or her title or affiliation with AAOS to market or otherwise promote any intellectual property developed under a product development/design team arrangement. In addition, in this situation, the individual will make a reasonable effort to ensure that statements made by others, including by the commercial orthopaedic company, do not reference his or her affiliation with AAOS in connection with the relationship or the intellectual property developed.

4. Research -

- a. All existing and new research arrangements by an individual in an AAOS governance position with a commercial orthopaedic company shall be in accordance with the current version of the AAOS Standards of Professionalism on Research and Academic Responsibilities and the AAOS Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships.
- b. If the individual in the AAOS governance position is an investigator in a clinical trial, this relationship shall be disclosed whenever the topic of the clinical trial is discussed in the governance setting.
- c. The individual in an AAOS governance position agrees that he or she will not use his or her title or affiliation with AAOS to market or otherwise promote any intellectual property developed under a research agreement with a commercial orthopaedic company. In addition, in this situation, the individual will make a reasonable effort to ensure that statements made by others, including by the commercial orthopaedic company, do not reference his or her affiliation with AAOS in connection with the relationship or the intellectual property developed.

2. Employment or Consulting Arrangements with Other Health Care Entities

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

A. Definition

1. "Other health care entities" shall be defined to include companies other than commercial orthopaedic companies, not-for-profit organizations, and units of the U.S., state or local government that provide, govern or oversee health care services. Other health care entities may include but are not limited to those companies that exhibit at the AAOS Annual Meeting with a rating of less than ".75" or which do not exhibit at all. These include by way of example health insurance companies, hospitals and hospital systems, organizations that provide, regulate or finance healthcare services, and units of the federal, state or local government that provide, govern or oversee health care services.

B. General Statements

- 1. The individual in an AAOS governance position may maintain and/or begin his or her relationship with a health care entity, provided that
 - a. In the case of maintaining the relationship, it has been disclosed to AAOS prior to assuming any governance position; in the case of a new relationship, it has been disclosed to the AAOS prior to entering into the new relationship;

- b. A PAM has been agreed to that details this relationship; and
- c. If there is an intellectual property or royalty arrangement with the health care entity, it should be based on a verifiable transfer of intellectual property (e.g., patents, copyrights, royalty, and licensing agreements).

This relationship shall be managed per Protocol.

- 2. All existing and new arrangements by an individual in an AAOS governance position with a health care entity shall be in accordance, as applicable, with the current version of the AAOS Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships.
- 3. The individual in an AAOS governance position agrees that he or she will not use his or her title or affiliation with AAOS to market or otherwise promote the intellectual property developed under this arrangement with a health care entity. In addition, in this situation, the individual will make a reasonable effort to ensure that statements made by others, including by the health care entity, do not reference his or her affiliation with AAOS in connection with the relationship or the intellectual property developed.

C. Guidelines

- 1. Employment With the prior approval of AAOS through an agreed upon PAM, the individual in an AAOS governance position may continue existing employment arrangements and enter into a new employment relationship (whether compensated or not) with a health care entity during the time of service for AAOS.
- 2. Consulting With the prior approval of AAOS through an agreed upon PAM, the individual in an AAOS governance position may continue consulting arrangements and enter into a new consulting relationship (whether compensated or not) with a health care entity during the time of service for AAOS.

3. Board of Directors or Committees of Other Orthopaedic or Medical Organizations

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

A. A Board Member, Council Chair, governance position or member of the ELT should agree that he or she will not serve on the Board of Directors, the Leadership Line¹ or committees or advisory groups of any other national or international orthopaedic organization or of a national or state medical society while he or she is in office*. [See Appendix A]

¹ The Leadership Line includes those individuals in the Presidential Line, including those who maintain a position on the Board of Directors *after* they serve as President (e.g., Second Vice President, First Vice President, President, Immediate Past President).

^{*} For positions with smaller societies or that are more difficult to fill due to expertise, Board Members, Council Chairs, governance positions and members of the ELT have the opportunity to request an exemption from the Committee on Ethics and Outside Interests for an exception to this rule.

4. Speakers' Bureaus or Honoraria for Speaking

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

A. <u>Definitions</u>

- 1. Speakers Bureau shall be defined as marketing program by a commercial orthopaedic company or other health care entity in which a physician is recruited, trained and delivers information developed by the company about the company's products to physicians or others in exchange for a fee. Although usually presented as educational, the events conducted by a speakers bureau may influence purchase decisions that are not based on the suitability and effectiveness of the product but rather on the prestige and persuasiveness of the speaker.
- 2. Honorarium shall be defined as a payment in recognition of an act or professional service.

B. **Guidelines**

- 1. An individual in an AAOS governance position shall not serve on the speakers' bureau of any commercial orthopaedic company or other health care entity.
- 2. An individual in an AAOS governance position may speak at educational programs sponsored by a commercial orthopaedic company or other health care entity, provided he or she does not accept or receive an honorarium.
- 3. An individual in an AAOS governance position may speak at educational programs accredited by the Accreditation Council for Continuing Medical Education and receive honoraria as deemed appropriate by the program sponsor.

5. Orthopaedic Publications; Textbook Exception

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

A. Definition

 Textbook – shall be defined as a reference book used by students and professionals as a standard source of information about a particular branch of study, e.g., orthopaedic surgery.

B. Guidelines

- 1. An individual in an AAOS governance position will not enter into and shall withdraw from serving as the Editor, or as Deputy, Associate, Section or Topic Editor or on the paid or unpaid editorial panel of any print or electronic orthopaedic publications, except textbooks. (AAOS editors-in-chief maintain their AAOS role.)
- 2. An individual in an AAOS governance position may maintain on-going or begin new textbook projects serving as author, editor, co-editor, or contributor, provided that
 - a. In the case of maintaining the relationship, it has been disclosed to AAOS prior to assuming any governance position; in the case of a new relationship, it has been disclosed to the AAOS prior to entering into the new relationship;
 - b. A PAM has been agreed to that details this relationship; and
 - c. If there is an intellectual property or royalty arrangement with the publisher, it should be based on a verifiable transfer of intellectual property (e.g., copyrights, royalty, and licensing agreements).

This relationship shall be managed per Protocol.

The intent of this guideline is to avoid conflicts of interest without unfairly disrupting the academic work of the individual in an AAOS governance position.

- 3. It is acceptable for an individual in an AAOS governance position to serve as an *ex officio* member of an editorial board because of his or her specific position at AAOS. For example, it is appropriate for a Council Chair to serve on the *AAOS Now* editorial board because of his or her position as a Council Chair.
- 4. It is acceptable for an individual in an AAOS governance position to be reviewers of articles for AAOS and non-AAOS orthopaedic publications.

6. AAOS Volunteer Positions

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

An individual in an AAOS governance position must resign from any AAOS volunteer position for which applications are solicited through the Committee Appointment Program (CAP) process. This allows these positions to be filled by other AAOS volunteers. Positions to which the individual is directly elected by Fellowship (e.g., Membership Committee) or appointed by the President or Board of Directors are exempt from this guideline (e.g., service as Program Committee Chair, Instructional Courses Committee Chair, on the RUC, or on the AMA CPT Editorial Panel).

Guidance Document – AAOS Board of Directors, Council Chairs and others

An individual in an AAOS governance position may continue to serve and enter into new liaison roles to non-orthopaedic/other organizations or government entities provided the relationship is disclosed in advance. The relationships will be carefully managed if discussions occur at the Board level relating to the liaison positions or the organizations.

7. Compensation for AAOS Services

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

An individual in an AAOS governance position will not seek or accept compensation for services provided to AAOS while he or she serves on or with the Board of Directors and he or she will discontinue or not begin to provide services to the AAOS for which compensation would normally be provided (e.g., certain editorial services).

8. <u>Simultaneous AAOS Governance Positions</u>

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

A. **Guidelines**

- 1. Except in unusual circumstances as determined by the AAOS Board of Directors, an individual in an AAOS governance position may not serve simultaneously in two AAOS governance positions, be they voting or non-voting *ex officio* positions.
- 2. If a Member At Large on the AAOS Board of Directors or a Council Chair is also a member of the Board of Councilors (BOC) or representative to the Board of Specialty Societies (BOS), he or she should not serve as a member of the BOC or as a representative to the BOS while he or she serves on or with the Board of Directors or as a Council Chair.

9. Orthopaedic Expert Witness Services

For all AAOS Board Members, Council Chairs, governance positions, and ELT

A. Definition

1. Expert Witness – shall be defined as an orthopaedic surgeon who provides "oral or written expert opinions, testimony or other services to attorneys, litigants, administrative agencies or the judiciary in the context of administrative, civil or criminal matters and include but are not limited to writing expert opinions, signing certificates or affidavits of merit, reviewing medical records, and providing sworn testimony."²

²Preamble, Standards of Professionalism on Orthopaedic Expert Opinion and Testimony (adopted 2005; amended 2010)

Guidance Document – AAOS Board of Directors, Council Chairs and others

2. For purposes of the Board Guidance, Expert Witness shall not include orthopaedic surgeons who provide opinions of fact on behalf of their patients in a Workers' Compensation matter or civil litigation or while testifying on behalf of the AAOS.

B. Guidelines

- If retained as an Expert Witness prior to being elected or appointed to the AAOS governance position, he or she may complete the service. An individual serving in an AAOS governance position will not accept new assignments as an Expert Witness during his/her term on the AAOS; however,
- 2. An individual in an AAOS governance position may participate in peer review processes conducted by a health care entity at which the such individual has privileges; and may serve as an Expert Witness in matters unrelated to medical liability matters.
- 3. An individual in an AAOS governance position serving as an Expert Witness in any capacity during his/her term of service with AAOS must:
 - Disclose such arrangement to AAOS prior to assuming an AAOS governance position and agree to a Plan for Active Management which adequately details the arrangement;
 - b. Ensure that the persons or entities retaining the individual's services are aware that any opinions or testimony are his/her own and not the opinion or position of the AAOS; and
 - c. Ensure that his/her opinions comply with the requirements of the AAOS Standards of Professionalism on Orthopaedic Expert Opinions and Testimony.

The intent of this guideline is to avoid the use of an individual's status within the AAOS governance to enhance an Expert Witness' credibility or influence the outcome of litigation or administrative processes; and to comply with the individual's duty of loyalty to the AAOS.

10. AAOS Additional Disclosure Requirements

For all AAOS Board Members, Council Chairs, and governance positions, and ELT:

An individual in an AAOS governance position will be required to participate in additional disclosure requirements mandated for Board members, Council Chairs and members of the Executive Team.

11. Management of Governance Conflicts of Interest

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

From time to time in the course of Board business, an individual in an AAOS governance position may become concerned that they or another participant in AAOS governance may have a conflict of interest regarding a particular issue. Pursuant to the *Protocol for the President to Use in Handling Potential Conflict of Interest Issues Before the AAOS Board of Directors*, these individuals should contact the President regarding these possible conflicts.

12. Exemptions to and Changes to this Board Guidance Document

For all AAOS Board Members, Council Chairs, governance positions, and ELT:

The Board shall have the sole discretion, with the advice of the Committee on Ethics and Outside Interests, to grant exemptions and make changes to this document as needed from time to time.

Individuals serving on or considered for positions on the AAOS Board of Directors or as Council Chairs or in governance positions, may request an appeal to the Committee on Ethics and Outside Interests and/or the AAOS Board of Directors on a specific recommendation developed as part of the Plan for Active Management process.

This Guidance Document is designed to be a living document and will be reviewed on a regular basis. It is not set in stone. This Guidance Document may not address every situation that may arise because AAOS is a complex organization and new issues are constantly being identified.

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Appendix a

Orthopaedic Organizations Identified in Paragraph 3 of the Guidance Document

These orthopaedic organizations identified in Paragraph 3 of the Guidance Document include but are not limited to:

- National orthopaedic specialty organizations;
- International orthopaedic organizations;
- Regional orthopaedic societies;
- State orthopaedic societies;
- National medical associations;
- State medical associations;
- American Joint Replacement Registry (AJRR);
- Association of Bone and Joint Surgeons (ABJS);
- American Orthopaedic Association (AOA);
- Canadian Orthopaedic Association (COA);
- American Board of Orthopaedic Surgery (ABOS); and
- Orthopaedic Research and Education Foundation (OREF)