CODE FOR INTERACTIONS WITH COMPANIES

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AAO-HNS/F Code for Interactions with Companies

I. Preamble

AAO-HNS/F and other medical specialty societies (Societies) play an important role in reaching out to health professionals, patients, and other groups. Our members guide biomedical research, discover new therapies, and engage in high quality medical practice. Societies offer educational opportunities that help translate scientific and medical progress into the efficient delivery of effective medical care. Societies develop resources that guide our members in advancing medical care. Societies provide a forum for presenting new skills and scientific developments.

A Company is defined as for-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. Additionally, a company includes a for-profit that provides good or services to physicians and/or their practice. This definition is not intended to include non-profit entities or entities through which physicians provide clinical services directly to patients. Referred to in this Code as “Companies,” also strive to help patients live longer and healthier lives. Companies invest resources to bring new drugs, devices and therapies out of the laboratory and to the patient while maximizing value for shareholders.

Members and patients count on Societies to be authoritative, independent voices in the world of science and medicine. Public confidence in our objectivity is critical to carrying out our mission. We know the public relies on us to minimize actual and perceived conflicts of interest. AAO-HNS/F must be sure its interactions with Companies meet high ethical standards. AAO-HNS/F interactions with Companies may include receiving charitable contributions, applying for grants in support of programmatic activities, and conducting a range of business transactions. In all of these interactions, the AAO-HNS/F is committed to acting with integrity and transparency.

AAO-HNS/F adopts this Code to reinforce the core principles that help us maintain actual and perceived independence. Adopting this Code helps to ensure that AAO-HNS/F’s interactions with Companies will be for the benefit of patients and members and for the improvement of care in the field of otolaryngology.

II. About the Code

In Spring 2009, at the request of the CEOs of the Council for Medical Specialty Societies (CMSS) member organizations, the CMSS Board of Directors charged the CMSS Task Force on Professionalism and Conflicts of Interest (“Task Force”) with developing and recommending a voluntary “code of conduct” for Medical Specialty Societies to “enhance professionalism and to disclose, manage, and resolve relationships with industry.” For nearly one year, Task Force representatives from more than 30...
Member Organizations worked collaboratively to draft a document in response to this charge. In the spring of 2010, the Task Force recommended the CMSS Code for Interactions with Companies to the CMSS Council for adoption. The Code was officially adopted by CMSS on April 17, 2010.

The purpose of the Code is to guide Societies, such as AAO-HNS/F, in the development of policies and procedures that safeguard the independence of their programs, policies, and advocacy positions. Because Societies can vary in their activities and corporate structures, these policies and procedures need not be uniform. Each Society that signs on to the Code is encouraged to adopt policies and procedures that are tailored to meet the individual organizational needs.

On May 2, 2011, after several in-depth discussions at the AAO-HNS/F Executive Committee and Board levels, including a Board-appointed task force, and after a thorough comparison of the CMSS Code to existing AAO-HNS/F policies, the AAO-HNS/F Boards of Directors approved our sign-on to the CMSS Code for Interaction with Companies.

The AAO-HNS/F Code is based on the CMSS Code and its Annotations and is adopted to the specific situations of AAO-HNS/F. Certain aspects of the AAO-HNS/F Code are more rigorous than the CMSS Code. Annually, AAO-HNS/F will affirm to CMSS that its Code continues to be adhered to.

The Code is divided into Principles and Annotations. The Principles state minimum expectations for AAO-HNS/F. The Principles are expected to remain relatively constant, and may be changed only by the AAO-HNS/F Boards of Directors. The Annotations, on the other hand, are provided when necessary to reflect current interpretation of a given Principle. An Annotation may explain the purpose of a Principle, or give examples of AAO-HNS/F policies and safeguards that are consistent with the Code. Annotations may be clarified periodically by AAO-HNS/F in response to questions or to changes in the landscape as highlighted by CMSS.

Questions about the AAO-HNS/F Code should be addressed to the AAO-HNS/F Executive Operations Staff. AAO-HNS/F will also monitor CMSS interpretations and update Annotations as necessary.

III. Definitions

AAO-HNS/F CME: AAO-HNS/F CME refers to CME programs that are planned by a AAO-HNS/F and for which the AAO-HNS/F, as an accredited CME provider, provides CME credit.

AAO-HNS/F Journal: Otolaryngology—Head and Neck Surgery is a peer-reviewed scientific journal published by AAO-HNS/F or by a publisher on AAO-HNS/F’s behalf.

Advertising: Advertising is a Business Transaction in which a Company pays a fee to AAO-HNS/F in exchange for the AAO-HNS/F’s publication of a promotional announcement that highlights the Company
or the Company’s products or services. For purposes of this Code, Advertiser refers to a Company that purchases Advertising.

**Business Transaction:** A Business Transaction is an interaction between AAO-HNS/F and a Company in which a Company pays a fee to AAO-HNS/F in exchange for the AAO-HNS/F’s item, service, or product. Examples of Business Transactions include Company payment of fees associated with subscriptions to AAO-HNS/F publications, advertising in AAO-HNS/F publications, registrations for AAO-HNS/F meetings, and exhibit space rental.

**Charitable Contribution:** A Charitable Contribution is a gift, including an in-kind gift, given by a Company to a qualified tax-exempt organization (i.e. the AAO-HNS/F) for use in furthering the organization’s charitable purposes and in accordance with applicable tax rules and legal standards.

**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”).

**Company (used interchangeably with commercial interest):** 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/or alleviate health conditions. Additionally, a company includes a for-profit that provides goods or services to physicians and/or their practice. This definition is not intended to include non-profit entities or entities through which physicians provide clinical services directly to patients.

**Continuing Medical Education (CME):** Continuing Medical Education (CME) consists of educational activities for which the attendee may receive CME credit (American Medical Association (AMA) Physician’s Recognition Award Credit, American Academy of Family Physicians (AAFP) Prescribed or Elective Credit, American Osteopathic Association (AOA) Credit – various categories) based on accreditation awarded to the provider by a recognized accrediting body (e.g., Accreditation Council for Continuing Medical Education (ACCMCE), AOA, AAFP). CME activities “serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.” For purposes of this Code, educational activities for physicians that are not CME-accredited are considered Non-CME Educational/Informational Programs.

**Corporate Sponsorship:** A Corporate Sponsorship is an arrangement in which a Company, typically through its marketing department, provides monetary or in-kind support for a particular AAO-HNS/F product, service, or event, and is then acknowledged in connection with the product, service or event.
Corporate Sponsorships are distinct from Educational Grants, and do not constitute Commercial Support of CME. For purposes of this Code, Corporate Sponsor refers to a Company that provides a Corporate Sponsorship.

**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 arrangement.

**Educational Grant:** An Educational Grant is a sum awarded by a Company, typically through its grants office, for the specific purpose of supporting an educational or scientific activity offered by the AAO-HNS/F. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as “Commercial Support” of CME. An Educational Grant may also be “in-kind.”

**Elected Officers:** For purposes of this code in accordance with the AAO-HNS/F Bylaws, Elected Officers are defined as the President, President-Elect, Secretary-Treasurer, and Executive Vice President/CEO.

**Key AAO-HNS/F Leaders:** At a minimum, and for purposes of this Code, the Key AAO-HNS/F Leaders are defined as all AAO-HNS/F Elected Officers and Boards of Directors, and the Editor-in-Chief of *Otolaryngology—Head and Neck Surgery*.

**Medical Specialty Society:** A Medical Specialty Society (or Society) is a non-profit organization whose membership includes predominantly physicians who practice in a specific medical specialty or sub-specialty that seeks to further the medical specialty, to advance the interests and education of individuals engaged in the specialty, to improve patient care, and to provide information for patients and the general public. Societies may have different corporate structures and encompass several affiliated legal entities. If a function described in the Code is carried out by an entity other than a Society’s membership organization (e.g., by an affiliated Foundation), this Code applies to the extent the membership organization controls that entity. Each Society should decide independently how best to comply with the Code in light of its corporate structure.

**Non-CME Informational/Educational Program:** A Non-CME Informational/Educational Program is a program offered by AAO-HNS/F, Company, or other third party that provides educational or promotional information and does not offer CME credit.

**Research Grant:** A Research Grant is an award that is given by AAO-HNS/F to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide AAO-HNS/F with
programmatic support (e.g., an Educational Grant or Charitable Contribution) designated for the specific purpose of funding Research Grants.

**Satellite Symposium:** A Satellite Symposium is a Company-supported program held as an adjunct to an AAO-HNS/F meeting. When CME credit for the Symposium is provided, credit is provided by a third party accredited provider, and for which AAO-HNS/F receives a fee.
IV. Principles for Interaction

1. Independence

1.1. All AAO-HNS/F educational activities, scientific programs, products, services and advocacy positions are independent of Company influence, and the AAO-HNS/F has policies and procedures that foster independence.

1.2. AAO-HNS/F separates its efforts to seek Educational Grants, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from its programmatic decisions.

1.3. AAO-HNS/F Ethics Committee under the direction of the AAO-HNS/F Boards of Directors is responsible for guiding the Academy’s interactions with Companies.

1.4. Key AAO-HNS/F Leaders may not have Direct Financial Relationships with Companies during his or her term of service. Key AAO-HNS/F Leaders may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services. Key AAO-HNS/F Leaders may accept research support as long as grant money is paid to the institution or practice where the research is conducted, not to the individual. Research support, uncompensated services, and other permitted relationships are required to be disclosed.

Annotation: Key AAO-HNS/F Leaders may receive wages or other compensation from a Company in exchange for providing or overseeing the provision of health services to Company personnel. Key AAO-HNS/F Leaders may accept reasonable compensation for serving on an independent data safety monitoring board in a Company study. Key AAO-HNS/F Leaders may own stock or stock options in a Company. Key AAO-HNS/F Leaders 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.

If a Key AAO-HNS/F Leader receives stock or stock options from a Company as wages, consulting fees, honoraria, or other compensation (other than the permitted payments as described in the prior paragraph), this is considered a Direct Financial Relationship. If a Key AAO-HNS/F Leader directs a Company honorarium, other fee or compensation (other than the permitted payments as described in the prior paragraph), to AAO-HNS/F, a charity, their practice or another entity, this is also considered a Direct Financial Relationship.

1.5. AAO-HNS/F establishes written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of Research Grants.

Annotation: The written agreements should specify what the funds are for, the amount given, and the separate roles of the Company and AAO-HNS/F. Such agreements will show that a transaction is “arms length,” establish clear parameters for the use of funds, and affirm the independence of AAO-HNS/F.
2. Transparency

2.1. AAO-HNS/F requires its conflict of interest policies and/or forms be made available to its members and the public.

Annotation: Transparency is a key element in fostering confidence and independence.

2.2. AAO-HNS/F discloses Company support (at a minimum Educational Grants, Corporate Sponsorships, Charitable Contributions, and support of Research Grants), making this information available to its members and the public.

Annotation: Generally, disclosure fields should include the name of the Company, the category of support (e.g., Educational Grant, Corporate Sponsorship, Charitable Contribution), the time period of the support, and the dollar amount or range.

2.3. AAO-HNS/F requires written disclosure policies, which require disclosures of all financial and uncompensated relationships with Companies, for Key AAO-HNS/F Leaders and others who serve on behalf of the AAO-HNS/F. The Academy Ethics Committee uses the disclosed information to manage conflicts of interest in decision-making. AAO-HNS/F requires all volunteers to update disclosure information at least annually and when material changes occur.

Annotation: Additional conflict of interest management mechanisms such as recusal, peer review, and CME session audits may be appropriate. AAO-HNS/F will select conflict of interest management mechanisms that are appropriate for the activity and type of relationship under consideration. Generally, disclosure fields should include employment, consulting or advisory arrangements, stock ownership, honoraria, research funding paid to an individual's institution or practice, expert testimony, and gifts.

3. Accepting Charitable Contributions

3.1. AAO-HNS/F controls the use of Charitable Contributions in a manner that is aligned with the AAO-HNS/F strategic plan and mission.

3.2. AAO-HNS/F declines Charitable Contributions if the donor expresses a desire to influence AAO-HNS/F programs or advocacy positions, or where donor restrictions would influence AAO-HNS/F programs or advocacy positions.

3.3. AAO-HNS/F adheres to applicable tax rules and legal standards for acceptance of Charitable Contributions and management of institutional funds.
3.4. Reasonable restrictions on the purposes for which Charitable Contributions will be used are acceptable, as are reasonable requirements for reporting on the uses of the donated funds.

Annotation: For example, it is appropriate for Charitable Contributions to be designated to support a broad section of AAO-HNS/F mission (e.g., general research, research in a particular disease area, or patient information). It is also appropriate for Charitable Contributions to be designated to support a specific AAO-HNS/F program (e.g., a research award or fellowship), as long as the donor is not permitted to influence or control the program (e.g., selecting award recipients or determining research topics).

3.5. AAO-HNS/F adheres to strict policies for consistent and appropriate recognition of donors.

Annotation: Donor recognition is a universal part of fundraising and should be conducted with appropriate limitations. For example, donors can be recognized in print materials, in private or public ceremonies, and with banners or other visible displays. Recognition will not be provided in a manner that implies donor influence over AAO-HNS/F programs or advocacy positions.

4. Accepting Corporate Sponsorships

4.1. AAO-HNS/F reserves the right to only accept Corporate Sponsorship of an item or program if the item or program is aligned with the AAO-HNS/F’s strategic plan and mission.

4.2. AAO-HNS/F makes reasonable efforts to seek multiple Corporate Sponsors for sponsored items or programs.

Annotation: In addition to or instead of seeking multiple Corporate Sponsors for sponsored items or products, AAO-HNS/F may seek support from sources outside of the for-profit healthcare sector.

4.3. AAO-HNS/F prohibits the names or logos of Companies or products on AAO-HNS/F distributed, non-educational “reminder” items (e.g., tote bags, lanyards, highlighters, notebooks, and luggage tags) that Companies are not permitted to give directly to healthcare professionals under generally accepted standards for ethical interactions (i.e., PhRMA Code, AdvaMed Code).

Annotation: The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals do not permit Companies to give promotional, non-educational “reminder” items directly to healthcare professionals. In support of these standards, AAO-HNS/F does not permit the placement of Company names or logos on AAO-HNS/F distributed reminder items.
4.4. AAO-HNS will only accept data that complies with AAO-HNS data integrity standards.

If accepting Corporate Sponsorship of data registries, Societies will prohibit Corporate Sponsors from participating in the direct management of the registry unless the data registry is in part operating as a public/private medical society, device/drug manufacturer and government partnership or for the purpose of meeting regulatory FDA objectives of device/drug surveillance and patient safety.

*Annotation: Company representatives will not be involved in decisions to sell or otherwise disclose or publish registry data, and should not be permitted to serve on registry steering groups. Companies that contribute data or provide Corporate Sponsorship for data registries will not receive special access to registry data.*

5. Foundation Meeting & Live Education

5.1. Educational Grants and Society CME

5.1.1. When providing AAO-HNS/F CME, AAO-HNS/F complies with ACCME Standards for Commercial Support by adopting policies and procedures designed to identify and manage conflicts of interest in Company-supported AAO-HNS/F CME programs.

*Annotation: Adopting and rigorously enforcing these policies precludes Company influence over AAO-HNS/F CME content.*

5.1.2. In providing AAO-HNS/F CME, AAO-HNS/F will not seek support for product-specific topics.

*Annotation: Where the purpose of an AAO-HNS/F CME session is to demonstrate or train attendees in the safe and effective use of a particular drug, device, service or therapy, AAO-HNS/F may accept in-kind support from Companies that develop, produce, market, or distribute that drug, device, service or therapy. In accordance with ACCME Standards, AAO-HNS/F may accept in-kind support from a single Company when other equal but competing products or services are not available for inclusion.*

5.1.3. AAO-HNS/F demonstrates a reasonable effort to achieve a balanced portfolio of support for each AAO-HNS/F CME program.

*Annotation: AAO-HNS/F will make reasonable efforts to seek multiple sources of support for AAO-HNS/F CME programs, including support from Companies, support from organizations outside the for-profit healthcare sector, and tuition from attendees.*
5.1.4. AAO-HNS/F retains control over the use of Educational Grants and implementation of safeguards designed to ensure that educational programs are non-promotional and free from commercial influence and bias.

5.1.5. The Foundation Program Advisory Committee and Instruction Course Committee, in conjunction with the Education Steering Committee under the direction of the AAO-HNS/F Boards of Directors, are responsible for the selection of objectives, content, faculty, and format of educational activities in a manner that is consistent with the organizational mission.

5.1.6. AAO-HNS/F prohibits the solicitation of and does not accept or consider Companies’ suggestions about program topics, speakers, or content.

Annotation: This restriction would not prevent AAO-HNS/F from assessing the availability of funds for a program in accordance with Principle 1.2.

5.1.7. AAO-HNS/F prohibits presenters in AAO-HNS/F CME programs from using Company-controlled presentation materials, and from using slides with Company logos.

5.1.8. AAO-HNS/F requires presenters in AAO-HNS/F CME programs to give a balanced view of therapeutic options, and requires presenters to use generic names in place of product trade names.

Annotation: AAO-HNS/F may accept in-kind support from Companies that develop, produce, market, or distribute that drug, device, service or therapy. In accordance with ACCME Standards, AAO-HNS/F may accept in-kind support from a single Company when other equal but competing products or services are not available for inclusion.

5.1.9. AAO-HNS/F clearly distinguishes Non-CME Informational/Education Programs from AAO-HNS/F CME.

5.2. Satellite Symposia

5.2.1. AAO-HNS/F adheres to a strict application and selection process for all Satellite Symposia.

5.2.2. AAO-HNS/F requires Satellite Symposia to comply with ACCME Standards when CME is offered by a third-party accredited provider.

Annotation: AAO-HNS/F will use written agreements with third party CME providers. Written agreements should also include consequences for non-compliance.
5.2.3. AAO-HNS/F clearly distinguishes between AAO-HNS/F CME and Satellite Symposia in its meeting programs and promotional materials.

5.2.4. AAO-HNS/F requires third party organizers of Satellite Symposia to use appropriate disclaimers to distinguish the Symposia from AAO-HNS/F CME programs in Symposia advertising and program materials.

5.2.5. AAO-HNS/F does not permit Key AAO-HNS/F Leaders to participate in Satellite Symposia as faculty members, presenters, chairs, consultants, or in any other role besides that of an attendee who receives no honoraria or reimbursement.

5.3. Company Informational/ Educational Programs

5.3.1. AAO-HNS/F requires Non-CME Informational/Educational Programs to be clearly distinguished from AAO-HNS/F CME.

Annotation: Through the Company’s use of appropriate disclaimers in advertising and informational materials, attendees of Non-CME Informational/Educational Programs should be able to easily ascertain that the Programs are not AAO-HNS/F CME accredited.

5.4. Exhibits

5.4.1. AAO-HNS/F maintains policies and procedures that govern the nature of exhibits and the conduct of exhibitors, including requiring exhibitors to comply with applicable laws, regulations, and guidance.

Annotation: AAO-HNS/F policies can place limits on exhibits and exhibitor conduct (e.g., booth décor, size, and activities) to ensure that the tone of the exhibit hall is professional in nature. Policies should be provided to exhibitors and made available to others upon request.

5.4.2. AAO-HNS/F only permits Company exhibitor giveaways that are educational and modest in value as defined by the Exhibitor Guidelines.

Annotation: The requirement that Company giveaways be educational (for physicians or patients) and modest in value originates in the standards for ethical interactions set out by AMA, PhRMA, and Advamed. AAO-HNS/F has extended this policy to all exhibitors even though not required by CMSS.

5.4.3. AAO-HNS/F makes reasonable efforts to place exhibit booths out of attendees’ obligatory path to AAO-HNS/F CME sessions.
5.4.4. Elected Officers are not permitted to participate as leaders or presenters in Company promotional/marketing events held in exhibit space.

Annotation: Participation of AAO-HNS/F elected officers in Company promotional or marketing events has the potential to create the perception that AAO-HNS/F endorses a particular Company or product. In order to avoid this perception, AAO-HNS/F prohibits its elected officers from participating as leaders or presenters.

6. Awarding of Research Grants

6.1. AAO-HNS/F does not permit Companies to select (or influence the selection of) recipients of Research Grants.

6.2. AAO-HNS/F has charged the Centralized Otolaryngology Research Efforts (CORE) to select recipients of Research Grants based on peer review of grant applications.

6.3. AAO-HNS/F does not require recipients of Research Grants to meet with Company supporters.

Annotation: An individual, institution or practice that receives a Research Grant may publicly acknowledge the Company that supported his or her Research Grant, if known. Research Grant recipients may be required to disclose known Company support in connection with the presentation or publication of grant-funded research.

6.4. AAO-HNS/F does not permit Companies that support Research Grants to receive intellectual property rights or royalties arising out of the grant-funded research.

6.5. AAO-HNS/F does not permit Companies that support Research Grants to control or influence manuscripts that arise from the grant-funded research.

6.6. If the AAO-HNS/F receives programmatic support (e.g., an Educational Grant or Charitable Contribution) from a Company to support its own research, the AAO-HNS/F must disclose the Company support. The AAO-HNS/F acts independently in the selection of research topics and the conduct of the research itself.

7. Clinical Practice Guidelines

7.1. AAO-HNS/F bases Clinical Practice Guidelines on scientific evidence.
Annotation: AAO-HNS/F develops and publishes Clinical Practice Guidelines, medical technology assessments, and other clinical practice opinions in order to meet members’ needs for tools that help improve the quality and effectiveness of patient care. The credibility and authority of AAO-HNS/F Guidelines depends on a common understanding that Guidelines are developed through a rigorous independent process, based on the best available scientific evidence. AAO-HNS/F may refer to published criteria for rating studies and other evidence, or may use another recognized means of characterizing the strength of medical evidence.

7.2. AAO-HNS/F adheres to strict and transparent Guideline development processes that are free from Company influence. AAO-HNS/F has published a description of its Guideline development process, including the process for identifying and managing conflicts of interest, in *Otolaryngology—Head and Neck Surgery* and on the AAO-HNS/F website.

Annotation: Healthcare providers, payors, and patients regard AAO-HNS/F Clinical Practice Guidelines as an important source of information from experts in the field. AAO-HNS/F therefore takes steps to ensure that Guidelines are free from commercial bias and Company influence.

7.3. AAO-HNS/F prohibits direct Company support of the development of specific Clinical Practice Guidelines or Guideline Updates.

Annotation: AAO-HNS/F will not accept Corporate Sponsorship, Educational Grants, Charitable Contributions, support of Research Grants, or any other direct Company support of Guideline development activities. Company support of the overall mission based activities of a AAO-HNS/F is not considered direct support of Guideline development.

7.4. AAO-HNS/F prohibits 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 AAO-HNS/F to accept Company support for the further distribution of the Guideline or Guideline Update, translation of the Guideline or Guideline Update, or repurposing of the Guideline content.

Annotation: After initial development, printing, publication, and distribution of a Guideline or Guideline Update is complete, it is permissible for AAO-HNS/F to engage in Business Transactions where Companies purchase Guideline reprints or license Guideline content for translation or repurposing. AAO-HNS/F may choose to require a written statement with the purchased or licensed material, acknowledging the Company’s role and describing the independent nature of the AAO-HNS/F’s Guideline development process.
7.5. AAO-HNS/F requires all Guideline Development Task Force (GDTF) and work group participants and appointed reviewers to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Guideline development process.

7.6. AAO-HNS/F Ethics Committee follows strict procedures for determining whether financial or other relationships between guideline panelists 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.

7.7. AAO-HNS/F requires that a majority of guideline panel members are free of conflicts of interest relevant to the subject matter of the Guideline.

Annotation: If the GDTF members and chairs have conflicts of interest at the time of adoption of the Code, AAO-HNS/F may permit these individuals to remain actively involved in drafting the Guideline. However, each panel for which this exception is made must meet the requirements of this principle by the time of the next Guideline Update. For the minority of panel members who are not free of conflicts, AAO- HNS/F will apply procedures for disclosure and conflict of interest management developed in accordance with Principles 7.5 and 7.6.

7.8. AAO-HNS/F requires guideline 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.

Annotation: In addition to minimizing potential conflicts, remaining free of conflicts of interest helps to ensure that a panel chair remains eligible to participate in subsequent Guideline Updates.

7.9. AAO-HNS/F requires that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts and an open public comment period. AAO-HNS/F prohibits the selection of reviewers who are employed by or engaged to represent a Company.

Annotation: As part of the AAO-HNS/F published Guideline development process, AAO-HNS/F will seek critical feedback on draft Guidelines from independent reviewers. These may include subject matter experts, healthcare practitioners, biostatisticians, and patient representatives, among others.

7.10. AAO-HNS/F’s Guideline recommendations are reviewed and approved before submission for publication by at least one AAO-HNS/F body beyond the Guideline development panel, such as a committee or the AAO-HNS/F Boards of Directors.
7.11. Guideline manuscripts are subject to independent editorial review by a journal or other publication where they are first published.

Annotation: Editorial review provides an additional safeguard independent of AAO-HNS/F’s Guideline development and approval process.

7.12. AAO-HNS/F publishes Guideline work group members’ disclosure information adjacent to each Guideline and will identify abstentions from voting.

7.13. AAO-HNS/F requires all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline work group, to disclose financial or other substantive relationships that may constitute conflicts of interest.

Annotation: To identify and manage conflicts of interest among contributors, advisors, and reviewers, AAO-HNS/F will follow similar procedures as those applied to the GDTF. When AAO-HNS/F is collaborating with or seeking input from outside organizations on guideline development should investigate the conflict of interest standards of those organizations.

7.14. AAO-HNS/F recommends that Guideline work group members decline offers from affected Companies to speak about the Guideline on behalf of the Company for a reasonable period after publication.

Annotation: A period of at least one year is recommended. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the Guideline.

7.15. AAO-HNS/F does not permit Guideline work group 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.

8. AAO-HNS/F Journals

8.1. The AAO-HNSF journal, Otolaryngology-Head and Neck Surgery (the Journal), maintains editorial independence.

Annotation: In general, a firewall separates the editorial policies and decisions of the Journal from AAO-HNS/F governance and operations. Editorial independence should be consistent with accepted standards for medical publishing, such as those established by the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors (WAME).
8.2. Otolaryngology-Head and Neck Surgery requires all authors to disclose financial and other relationships with Companies.

Annotation: Authors’ disclosure information will be considered by AAO-HNS/F Journal editors in evaluating an article for publication. If the article is published, the Journal will publish the authors’ disclosure information with the article or issue. The “look-back” period for disclosure should be at least one year. The Journal will adopt policies governing the scope and format of disclosure, including consistent disclosure categories.

8.3. The Otolaryngology-Head and Neck Surgery requires editors and reviewers to disclose financial and other relationships with Companies.

Annotation: The Journal will publish its editors’ disclosure information on its website.

8.4. The Editor-in-Chief of Otolaryngology-Head and Neck Surgery has the ultimate responsibility for determining when a conflict of interest should disqualify an editor or reviewer from reviewing a manuscript, according to established policies.

Annotation: When establishing these policies, The Journal will consult accepted standards for medical publishing, such as those established by ICMJE and WAME.

8.5. Otolaryngology-Head and Neck Surgery policy prohibits the submission of “ghost-written” manuscripts prepared by or on behalf of Companies.

9. Standards for Advertising

9.1. AAO-HNS/F has and maintains written policies that set standards for Advertising.

Annotation: Advertising in all AAO-HNS/F publications is easily distinguishable from editorial content (e.g., through labels and color-coding). Advertising is designed not to look like scientific articles. In the Journal, the placement of Advertising adjacent to articles or editorial content discussing the Company or product that is the subject of the ad should be prohibited. Advertising in Society Journals should subject to review by the Editor-in-Chief and overseen by AAO-HNS/F. Society Journals and other Society publications that publish Advertising for CME activities or provide activities through which readers can earn CME credits should also comply with ACCME requirements for Advertising set out in the Standards for Commercial Support.
10. Standards for Licensing

10.1. AAO-HNS/F adheres to written standards for licensing that are intended to prevent misuse, unintended use, and modification of licensed materials, prohibits modification of licensed materials in a way that would change their meaning, and prohibits use of AAO-HNS/F trademarks to imply unwarranted AAO-HNS/F endorsement of Company products or services.