

Academy Update February 2022

James C. Denny III, MD
EVP/CEO



Advocacy: Areas of Focus

- Federal Legislation
 - MC expansion
 - Pre-authorization
 - Telehealth
- State Legislation
 - Scope
- Regulatory
 - FDA OTC regs
 - NSA regs

Federal Legislative and Regulatory Agenda

- Championing Fair Medicare Reimbursement
- Scope of Practice
- Prior Authorization Reform
- Reducing Regulatory Burdens to Quality Improvement Activities
- **Surprise Billing regulations (amicus brief)**
- **FDA OTC Hearing aid proposed regulations**
- **ELIMINATING BUDGET NEUTRALITY**
- **ADEQUATELY FUNDING HEALTHCARE**

FDA Proposed OTC HA Regulations

- Guidance entitled “Conditions for Sale for Air-Conduction Hearing Aids” that we do not intend to enforce the medical evaluation, waiver, or recordkeeping
- All non-OTC hearing aids will be prescription devices and would be subject to the labeling requirements
- OTC labeling
 - A conspicuous warning that the device is not for users younger than 18 years old;
 - The symptoms of perceived mild-to-moderate hearing loss;
 - Considerations for seeking a consultation with a hearing healthcare professional; and
 - Red flag conditions: warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician (preferably an ear specialist)

We are not proposing to require that manufacturers accept returns under these proposed Federal regulations.

FDA OTC Proposed Rule Comments

- FDA provide resources for patients identifying where free, online hearing exams are available to help determine whether OTC hearing aids may be appropriate. We also feel it would be beneficial for the FDA to support this type of testing on the agency's website.
- Labeling requirements be written in as simple and concise a manner as possible, in language that is readily understandable by potential consumers.
- Additional detail be included in the labeling requirements addressing maximum device output level.
- Add links to websites where one can obtain non-promotional information about hearing loss that includes possible treatments, both medical and through amplification. Links to websites where potential consumers can perform a self-hearing test should be added to any informational websites.
- The AAO-HNS disagrees with the FDA on this point and recommends a requirement that consumers be permitted to return OTC hearing aids.

FDA OTC Proposed Rule Comments

- The AAO-HNS recommends a maximum depth of insertion for males of 9 mm and 7.5 mm for females.
- The AAO-HNS strongly supports prohibiting sales to children under age eighteen and recommends that the FDA require sellers institute a verification process to ensure that OTC hearing aids are only purchased for adults aged eighteen and up.
- The AAO-HNS feels that this maximum is too high, and instead recommends that the output maximum should be no greater than 110 dB (dB) in sound pressure level (SPL).
- The AAO-HNS believes that these devices should have a maximum twenty-five dB gain limitation.
- The AAO-HNS supports the requirement for an evaluation unless it is waived by an adult.
- The AAO-HNS recommends that the certification requirement that the device will not be used for a patient under 18 be one of the conditions for sale of an OTC hearing aid.

Advocacy: Private Payer

- Experimental/investigational
- New technology coverage
- 25 – modifier
- Fallout NSA regulation
- Value based strategies
- CPT issues

AAO-HNS Payer Services: Combatting Denials

Background

- Health Policy Advocacy Team advocates to impact detrimental medical coverage gaps
- Multidisciplinary collaboration between:
 - Physician Payment Policy (3P) Workgroup
 - Academy leaders and clinical experts
 - Multiple private payers
 - Academy Committees

Examples of Coverage Topics

- Obstructive Sleep Apnea Treatment Services
- Eustachian Tube Balloon Dilation
- Cochlear Implants
- Implantable Hearing Aids
- Steroid-eluting Stents
- Functional Endoscopic Sinus Surgery
- Post-Op Sinus Endoscopy and/or Debridement Procedures
- Minimally Invasive Treatment of the Posterior Nasal Nerve to Treat Rhinitis



Specialty Collaboration with Payers

- Common Standards Across Payers
 - Common tests/procedures
 - Limit pre-authorizations
 - All patients get treatment based on disease, not insurance
 - AAOA, ANS, AOS, ARS currently



Guidance Document for Insurers

Radiographic Guidance for Consideration for Endoscopic Sinus Surgery and

Balloon Sinus Ostial Dilation

Background:

Chronic rhinosinusitis (CRS) is a common problem that causes considerable quality of life issues in certain patients. Initial treatment revolves around aggressive medical management including irrigations, oral medications including antibiotics and steroids, topical medications and environmental modification. In those patients where this strategy fails, Endoscopic Sinus Surgery (ESS) and Balloon Sinus Ostial Dilation (BSOD) have proven valuable for selected patients where imaging and physical examination reflect ongoing disease.

ESS and/or BSOD are medically necessary for the treatment of sinusitis, polyposis, cerebrospinal fluid leakage, or a sinus mass when any one of the following radiographic features is present:

1. Irregular, expansile, or erosive sinonasal or skull base mass/opacification; or
2. Skull base defect causing cerebrospinal fluid leakage or meningocele/encephalocele; or
3. Complication of acute or chronic rhinosinusitis; or
4. Anatomic variant leading to radiographically documented recurrent acute rhinosinusitis with evidence of inflammation; or
5. Complete, near complete, or partial opacification of any of the sinus(es); or
6. Obstruction of sinus outflow tracts (e.g., ostiomeatal complex, sphenoethmoidal recess, nasofrontal outflow tract) with evidence of inflammation; or
7. Air-fluid level of any of the sinus(es); or
8. Hyperostosis or sclerotic bony changes with evidence of inflammation; or
9. Presence of sinus and/or nasal polyps

Cochlear Implant Symposium

- FDA reaching out in collaboration
- Future direction of technology/research
- Incorporating RWE through registries
- Core data set identification
- Align clinical studies between FDA/payers
- Get new technology to patients sooner

Future of Meetings Task Force

Created by President Bradford, Chaired by President-elect Yaremchuk

- Review Academy and Foundation meetings
- Effect of virtual technology
- Value of face-to-face meeting for community, mentoring, socialization
- Annual Meeting and OTO Experience
- Spring Leadership meeting
- CORE
- GTF
- Committees
- Cost/revenue
- Technology needed

Task Force for Socioeconomic/ Workforce Surveys

- Need accurate assessment of current and future workforce
 - Needs assessment
 - Current situation
 - Future needs
- Will pair with comprehensive socioeconomic survey
 - Partner with ASCENT
- Longitudinal studies
- Advocacy and Training planning needs

AASM OSA Awareness Grant

- Five-year NIH grant
- AAO-HNS asked to participate
- Three workgroups
 - Public Awareness and Communications
 - Provider Education
 - Tool Development and Surveillance
- One of several recent collaborative projects with AASM

Business of Medicine

- Advocacy
 - Legislative, regulatory, private payer
- Collaborations
 - Intraspecialty, house of medicine, industry payers
- Information and analysis
 - Internal, external, paid consultants
- Member participation
 - Time, expertise, funding

Private Practice Study Group

- Approved by BOD EC summer 2021
- Extraordinary activity since then
- Over 500 participants ENT Connect
- Produces practice related webinars
- Multiple presentations at upcoming AM in Philadelphia
- Already developing leaders for future
- Congratulations to Drs. Dubin and Mitskavich for their leadership and Dr. Brown for shepherding the formation of PPSG

Private Practice Study Group

The PPSG, which will have its own ENT Connect community, will work in collaboration with the Academy's 3P Workgroup and Advocacy team to gather payer policy information and concerns necessary for successful advocacy, report on innovative practice strategies and solutions, and advise the Board of Directors on its constituents' needs. Equally as important, it will give a large number of private practitioners a strong voice and a community through which they can take an active role in advocacy efforts. Concurrently, the PPSG will provide a pipeline to develop new Academy leaders from the private practice community who will develop expertise in the socioeconomic and health policy arenas. The PPSG will also provide valuable information and mentorship to our trainees and young physicians about the merits and joys of a career in private practice. In addition to sharing experiences and successes, the community will increase the visibility and value of private practice medicine with the goal of working to preserve and promote this practice model for future otolaryngologists.

Private Practice Study Group

- Advise BOD on constituent's needs
- Collaborate with Advocacy team and 3P on payer policy
- Share innovative practice strategies and solutions
- Create Private Practice Leadership pipeline
- Mentor young physicians and residents on PP careers
- Preserve and promote practice model



PPSG

PRIVATE
PRACTICE
STUDY GROUP



PPSG

PRIVATE
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Political Action Committee



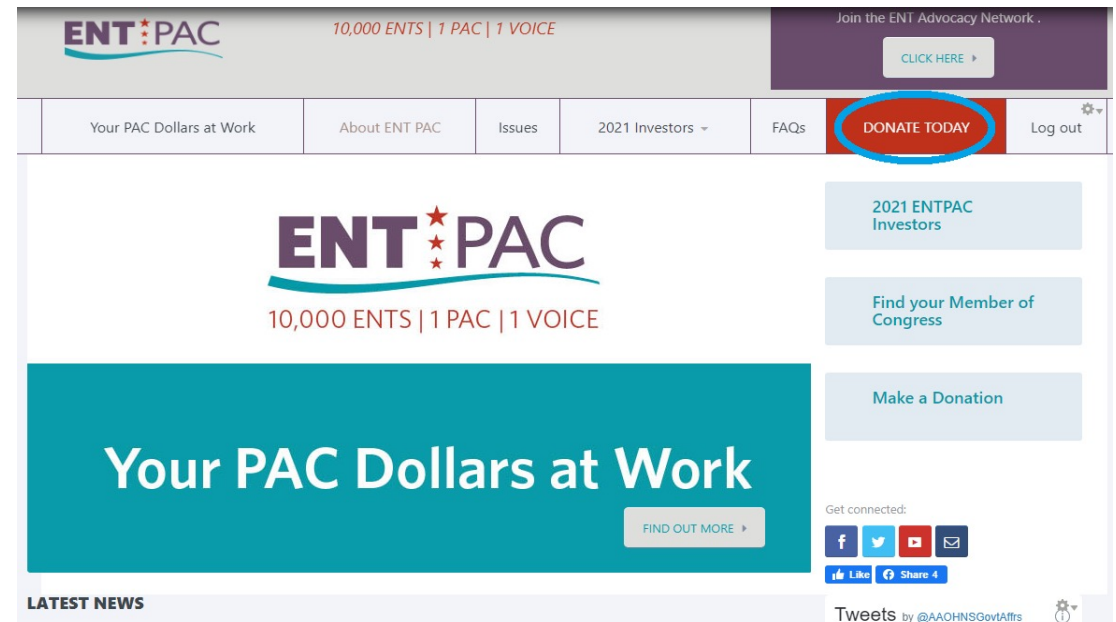
- ENT PAC is the **non-partisan, issue-driven** political action committee of the AAO-HNS, established in 1995 to advance and protect the interests of the specialty on Capitol Hill.
 - Enhances AAO-HNS visibility and voice with federal legislators by allowing a “seat at the table.”
 - **Helps build awareness about the specialty with Members of Congress.**
- The stronger our PAC, the stronger our collective voice on our federal legislative priorities.
- Reminder: AAO-HNS membership dues cannot be used for political purposes.
- Visit **www.entpac.org** (log in with your AAO-HNS ID and password) to access the latest list of Investors and contributions.

How Do I Donate?

Visit **ENTPAC.org** and in the upper right-hand corner click **“DONATE NOW”!**

Questions? Please contact ENT PAC staff at ENTPAC@ENTNET.ORG

Contributions to ENT PAC are not deductible as charitable contributions for federal income tax purposes. Contributions are voluntary, and all members of the American Academy of Otolaryngology-Head and Neck Surgery have the right to refuse to contribute without reprisal. Federal law prohibits ENT PAC from accepting contributions from foreign nationals. By law, if your contributions are made using a personal check or credit card, ENT PAC may use your contribution only to support candidates in federal elections. All corporate contributions to ENT PAC will be used for educational and administrative fees of ENT PAC, and other activities permissible under federal law. Federal law requires ENT PAC to use its best efforts to collect and report the name, mailing address, occupation, and the name of the employer of individuals whose contributions exceed \$200 in a calendar year.



High Priority Projects

- Transition to new Journal publisher
- Gender pay parity
- Pan American Congress
- Office based reimbursement
- Innovative practice models
- Implement meetings strategy
- Payer projects
- Academic-private practice partnership for residents

Annual Meeting and OTO Experience

- 126th Annual Meeting in Philadelphia, Pennsylvania
- In-person with streaming virtual component
- Upgraded app
- Committee meetings at AM resume
- Attendance likely to take several years to recover
 - Especially International
- Combined President's reception
- Number of program upgrades

Save the Date!



FORWARD TOGETHER

AAO-HNSF 2022
ANNUAL MEETING & OTO EXPERIENCE
SEPTEMBER 10-14  PHILADELPHIA, PA

- Connect with Medical Minds from Around the World
- Stay Up to Date with Groundbreaking Research and Best Practices
- Discover the Latest Advancements in Medial Products and Services at the OTO Experience

XXXVII

Pan American Congress of Otolaryngology- Head and Neck Surgery

June 25-27, 2022 | Orlando, FL, USA



We Are One





"FELLOW PHYSICIANS: I have called you here to organize an ophthalmological, otological, laryngological association. The little acorn I plant here today will never satisfy me until like an oak, it grows and spreads all over ..."
Hal Foster, MD, opening remarks to the approximately 50 attendees of the first meeting, April 9 and 10, 1896



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WE ARE ONE TWENTY-FIVE

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