

# No Surprises Act: What You Need to Know

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James C. Denneny III, MD



# High Income Countries Key Comparisons 2013-2016

- Physicians/1000 population: US 2.6 (#8), Mean 3.3
- Primary care %: US 43(#8), Mean 43
- Specialists %: US 57 (#3), Mean 57
- Pay generalist physician: US \$218k (#1), Mean \$133K
- Pay specialist physician: US \$316k (#1), Mean \$182k
- Pay nurses: US \$74k (#1), Mean \$52k
- Pay non-health worker: US \$60k (#1), Mean \$49k
- Ratio generalist/mean wage: US 3.6 (#1), Mean 2.7
- Ratio specialist/mean wage: US 5.3 (#1), Mean 3.7

Papanicolas, Woskie, Jha. Health Care Spending in the United States and Other High-Income Countries. *JAMA*. 2018; 319(10): 1024-1038.

# NSA: What Does it Do?

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The federal NSA prohibits out-of-network healthcare providers and facilities from balance billing commercially insured patients, in certain circumstances. The NSA and its implementing regulations set a method for determining the patient cost-sharing for these out-of-network situations, and when state law does not establish a provider payment methodology, the NSA establishes an independent dispute resolution (IDR) arbitration system to establish provider payment.

# What Situations Does Apply To:

- **Out-of-network emergency services** provided at a hospital emergency department or independent freestanding emergency department or by air ambulance (not ground)
- **Nonemergency care** rendered by **out-of-network providers** at an in-network hospital or ASC unless the patient is consented to be treated by an out-of-network provider and be balanced billed
- Nonemergency services at in-network facilities
- Emergency services and post-stabilization care at hospitals or freestanding emergency departments
- Good Faith estimates (GFEs) for self-pay and uninsured patients

# NSA: Additional Requirements

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- Provider and facility disclosure requirements
  - Posted on website and delivered to patients
- GFEs for insured patients when regulations set
  - Uninsured already required as of January 1, 2022
- Health plan directory updates
  - Every ninety days
- Continuity of care
  - Up to ninety days

# Nonemergency Services: In-network Facilities Basic Rule

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If an out-of-network provider treats a patient covered by commercial health coverage at any in-network facilities, the provider may collect only the in-network cost-sharing amount from the patient and may not balance bill, unless the provider has furnished advance notice to the patient and obtained the patient's written consent to balance bill (for those providers and services where the rules permit the patient to give consent to be balance billed).

# Nonemergency Services: In-network Facilities

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- Hospital
- Hospital outpatient departments
- Ambulatory Surgery Centers
- All locations subject to basic rule

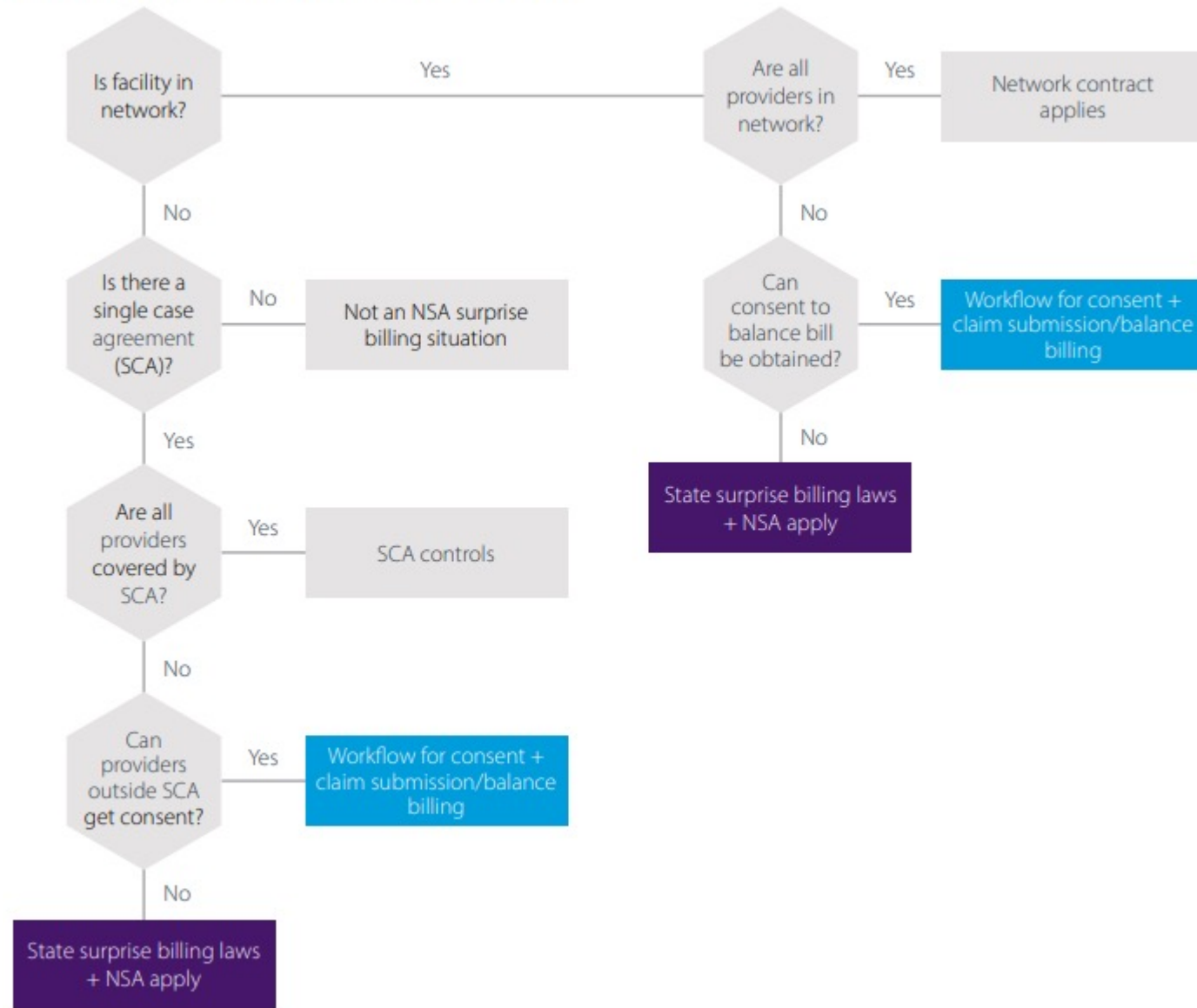
# Nonemergency Service: Out-of-Network Provider Payment

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- State surprise billing law, if exists and applies to patient's plan or service
- If no state law or if law are not applicable to patient's plan or service
  - Federal Independent Dispute Resolution (IDR) process can be used to determine payment
  - No prohibition from reaching independent agreement between provider (s) and patient



FIGURE 1. NONEMERGENCY SERVICES NSA DECISION TREE



# Consent to Balance Bill

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- Out-of-network provider at in-network facility must get permission to balance bill
  - Nonparticipating providers must use HHS "consent to balance bill" form [www.cms.gov/files/document/standard-noticeconsent-forms-nonparticipatingproviders-emergency-facilitiesregarding-consumer.pdf](http://www.cms.gov/files/document/standard-noticeconsent-forms-nonparticipatingproviders-emergency-facilitiesregarding-consumer.pdf).
  - Can use state form that satisfies federal requirements

# Prohibitions to Balance Billing: Nonemergency Situations

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- Out-of-network provider performing the following services at an in-network hospital or ASC will always be limited to collecting the in-network cost-sharing in **may not balance bill** for items and services listed below:
  - Emergency medicine, anesthesiology, pathology, radiology and neonatology provided by physician or non-physician practitioner
  - Assistant surgeons, hospitalists and intensivists
  - Diagnostic services including radiology and laboratory services
  - Nonparticipating provider if there is no participating provider at facility available

# Prohibitions to Balance Billing: Nonemergency Situations

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- Out-of-network provider performing the following services at an in-network hospital or ASC will always be limited to collecting the in-network cost-sharing in **may not balance bill** for items and services listed below:
  - Items or services furnished as a result of **unforeseen**, **urgent** medical needs that arise at the time an item or services furnished, **regardless** of whether the provider **previously obtained consent** to balance bill

# Balance Billing Compliance Details

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- If appointment >72h, notice/consent to pt >72h in advance
- If appointment <72h, notice/consent to pt same day at least 3h in advance
- Notice must include estimate of charges
- Pt may revoke consent prior to receiving service
- Provider must furnish the notice and consent in any of the **fifteen** most commonly spoken **languages** in the provider's region and must provide an **interpreter** if the patient speaks a different language.

# Notifying Health Plan/Patient of Balance Billing

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- Identify provider as out-of-network to that health plan
- Visit/service occurred at an in-network facility
- Provide a **copy of signed consent** to bill at patient's out-of-network rate
- If billing patient directly, the requirement is satisfied by including a copy of the signed consent with the bill
- Consent document must be retained by either provider or facility

# Emergency Services and Post-Stabilization Care at Hospitals or Freestanding EDs

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- Out-of-network emergency services at hospital ED or independent ED
  - Facilities and providers may charge only the applicable in-network cost-share
  - Applies to same visit post-stabilization care (some exceptions allowed)
- Post-stabilization care
  - Observation, inpatient or outpatient care as part of the ER visit
  - Takes place in any department of the hospital that provided initial evaluation stabilization

# Post-Stabilization Care

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If the patient has not been given the opportunity to **consent** to **treatment** by an **out-of-network** or facility for post-stabilization care, the provider or facility are limited to charging the patient the **in-network cost-sharing** amount. The out-of-network payment by the health plan is subject to state law or the federal IDR process.



# Rules for OON Facility or Provider to Seek Consent for Post-Stabilization Care at OON Rates

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- Patient able to travel to a network provider using nonemergency medical transportation or nonmedical transportation
- OON provides patient written notice and the patient consents to out of network post-stabilization care
- Patient or authorized representative is in condition to receive the notice and provide informed consent
- The provider or facility satisfies any additional requirements under state law

# Good Faith Estimates for Uninsured or Self-pay Patients

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Under the NSA, uninsured patients and commercially insured patients who choose not to use their benefits are entitled to a good faith estimate (GFE) of charges from providers before schedule services. If the actual charges by a particular provider facility exceed the GFE the amount by more than \$400, the patient is entitled to dispute the charges under the arbitration process. Responsibilities for the GFE vary depending on whether they serve as a “convening provider” or a “co-healthcare provider”. The NSA also requires that GFEs be available for insured patients at a later time.

# Convening Provider Responsibilities

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- Convening provider/facility is required to inquire whether a patient is covered under commercial health insurance, Medicare, Medicaid or the FEHBP and if covered, do they plan to use the insurance.
- The convening provider/facility is then required to inform the uninsured and self-pay patients of the availability of the GFE.
- The notice of availability of the GFE must be posted on the provider/facility website, office and on site where scheduling is done.
- Convening provider/facility is required to request estimates from each co-provider/facility within one business day of a service being scheduled (this is not required for 2022 calendar year).

# Co-Providers Responsibilities

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- Provide GFE information in one business day of request from a convening provider/facility
- Must update estimate if they anticipate any changes to the scope of services after submitted
- Provide itemized list of services to be provided with diagnosis and procedure codes as well as name of and identifying information for each provider/facility
- Disclaimer that the estimate is not a contract
- If contracted directly by patient, co-providers become convening providers

# Dispute Resolution

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- Uninsured or self-pay patient may dispute any bill that exceeds by more than \$400 the amount listed for the provider or facility in the GFE
- Patient submits “initiation notice” to HHS. HHS refers the notice to the state, if the state has adopted its own process. The dispute resolution entity will then notify the provider or facility if the dispute is eligible for resolution.
- The provider then has ten days to provide a copy of the disputed GF the with Bill and any documentation.
- Collection process suspended once filed

# Independent Dispute Resolution: As Negotiated

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- Medical community fought for patient protections during negotiations
- Goal was level playing field with patients not involved
  - Starting point, median in-network rate
  - Additional factors would be considered in determining payment
- Initial payment would be made in a timely fashion
  - Based on qualifying payment amount
  - Tolerable administrative additions
- Benefit out-of-network and uninsured patients

# Independent Dispute Resolution: What We Got

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- Qualifying payment amount (QPA) based on “Median in-network rate” now de facto payment
- Other factors no longer building blocks, but rebuttable facts
- Calculation of median in-network rate questionable
  - Estimates range from **15 – 30% decline**
- Good faith estimates required
  - If > \$400 difference can go to IDR
- Process opens the door for significant decline in reimbursement
  - Already seen in NC
  - Downcoding claims

# Danger of NSA as Administered

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- Exceptional administrative burden requirements
  - Uninsured, self pay “Good Faith Estimate” (GFE)
    - Twelve categories, > 100 items
  - Estimate that is > \$400 low subject to IDR
  - Discriminates against independent practitioners
- Allowed downcoding
- Independent Resolution Process (IDR)
  - Qualifying Payment Amount (QPA)
    - Calculation
    - De facto payment



# Texas Medical Assoc and AMA/AHA Filed Separate Lawsuits

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- Suits address determination of QPA only
- Specifically, it's role as the de facto value for payment unless proven otherwise
- Several amicus briefs started supporting TMA and AMA/AHA suits
- Academy joined with group led by Neurosurgery in an amicus brief

# TMA Response

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- “The decision will guard against health insurer business practices that give patients fewer choices of affordable in-network physicians and threaten the sustainability of physician practices,” Diana Fite, the immediate past president of the Texas Medical Association, said in a statement.

# AHIP Response

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America's Health Insurance Plans, the leading lobbying group for insurers responded through their president, Matt Eyels, stating "providers are doing everything they can to protect their profits."

"It is unconscionable for providers to fight to weaken protections for patients who deserve to be protected from surprise medical bills and to exploit the arbitration process to pad their bottom lines," he added.

# Coalition Against Surprise Medical Billing

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- The Coalition Against Surprise Medical Billing — a bloc of insurers and employer groups that often partners with patient groups — echoed the AHIP sentiment, saying the decision “hurts patients by making health care more expensive and benefits private-equity and out-of-network providers, whose court challenges demonstrate they care more about protecting their own profits.”

# Academy Update February 2022

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James C. Denny III, MD  
EVP/CEO

# Advocacy: Areas of Focus

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

# Federal Legislative and Regulatory Agenda

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- 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

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- 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

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- 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

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- 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*

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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



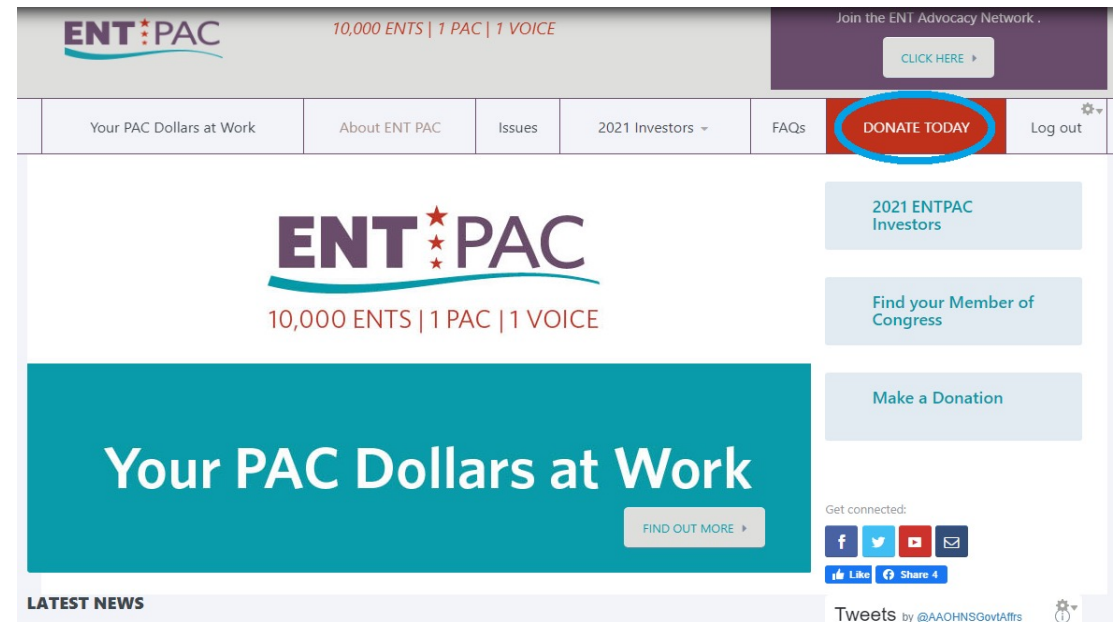
- ENT PAC is the **non-partisan, issue-driven** political action committee of the AAO-HNS, established in 1995 to advance and protect the interests of the specialty on Capitol Hill.
  - Enhances AAO-HNS visibility and voice with federal legislators by allowing a “seat at the table.”
  - **Helps build 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](http://www.entpac.org)** (log in with your AAO-HNS ID and password) to access the latest list of Investors and contributions.

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Questions? Please contact ENT PAC staff at [ENTPAC@ENTNET.ORG](mailto:ENTPAC@ENTNET.ORG)

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# High Priority Projects

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- 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

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- 126<sup>th</sup> 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
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# 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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## LEGACY of EXCELLENCE



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