



# **POLICY PERSPECTIVES AND UPDATES FOR THE Hearing Healthcare Professional**

Presented by:  
International Hearing Society



# Medicare Coverage of Hearing Aids

***In the 117<sup>th</sup>  
Congress  
(2021-2022)***

## Current political status:

- Democrats in power in the White House, U.S. House of Representatives, and U.S. Senate, through 2022. No guarantee of maintaining House or Senate majority in 2023.
- Medicare expansion to cover hearing has been identified as a top priority for several key Congressional leaders.
- IHS is presently taking all necessary steps to advocate for appropriate and fair policies (lobbying, coalitions, etc.).
- The primary vehicle is the “budget reconciliation” bill, which requires only a simple majority vote in the Senate.
- The budget bill will fund the 2022 FY Federal Budget.



# Medicare Coverage of Hearing Aids

## IHS' Policy Goals

### What would the House bill do?

Would newly authorize coverage for hearing aids and related tests. Hearing aids would be defined as prosthetic devices, and be available to Part B beneficiaries who have moderately severe to profound hearing loss, one per ear every 5 years, beginning in 2023.

In the original bill, hearing aid specialists were not included as providers.

### What has IHS accomplished?

In the House-passed bill, hearing aid specialists are included as Medicare providers of hearing assessments and can provide the direct order for a hearing aid.

IHS is still actively engaged in discussions to refine and improve the language with Senate staff.

# Medicare Coverage of Hearing Aids

*Past,  
Present,  
and Future*

- Next up, the Senate will consider its reconciliation bill language, which is expected to differ from the House reconciliation bill language.
- The two chambers will need to agree and pass the same language.
- The bill then goes to the President for signature.
- The Senate Majority Leader is targeting a Senate vote before Christmas, but this timeline may slide.
- IF Medicare expansion passes, many of the details will be decided by the Centers for Medicare and Medicaid Services. IHS will also be very involved in this process, and will ensure IHS members receive useful information about Medicare participation. It will be up to businesses to decide whether they want to participate.


# For more information



# Start here

[bit.ly/IHSMedicare](https://bit.ly/IHSMedicare)

- Action alerts
- Bills
- IHS updates
- Relevant news



# OVER THE COUNTER HEARING AIDS




## *Proposed Rules and Timing*

### Key Dates:

- FDA released proposed rules on October 20, 2021.
- Comments are due January 18, 2022.

### The Subjects of the Rules:

- Adds new classification of Over the Counter Hearing Aids, and includes labeling, specifications, intended use, preemption details, and more.
- Changes the rules governing traditional hearing aids, to be called “prescription hearing aids,” removes the physician clearance/waiver requirement for all ages, heavily reliance on labeling.



# OVER THE COUNTER HEARING AIDS



## *Proposed Rules and Timing*

IHS performed a detailed analysis of the proposal, for which we have several areas of concern and recommendations.

IHS is:

- Developing and will be submitting comments
- Providing guidance to members and other stakeholders on drafting comments
- Meeting with state licensing boards upon request to encourage them to comment on issues of concern
- Working with other national organizations to coordinate comments as appropriate



# OVER THE COUNTER HEARING AIDS



***Take action!***

We need **YOU** to submit comments when the comment period opens!

- Federal agencies, including FDA, need input from stakeholders and subject matter experts. This is obtained during the comment period.
- The FDA reviews each comment submitted and must respond to comments in their final rulemaking documentation.
- FDA looks for data, science, and reasoning in making its determinations.
- The more comments in favor of our positioning, the more attention our recommendations will receive.
- Form letters have less impact than individualized, personal comments.
- Consumers, consumer electronics, and others will advocate for their own positions, which will likely be different from ours (at least in part).



# Access Information

Learn about commenting and access talking points here:  
<https://bit.ly/IHSOTCWebpage>

## IHS Advocacy

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*IHS leaders with U.S. Congressman David McKinley (R-WV), Co-Chair of the Congressional Hearing Health Caucus*

## Direct to Consumer & Over the Counter Hearing Aids

[IHS Policy](#)  
[National Policy Updates](#)  
[Take Action](#)

### IHS Policy

The purchase of hearing aids direct by consumer using the internet, in-person, without the involvement of a licensed and trained hearing healthcare professional, compromises outcomes and places consumers at risk of missed, and sometimes serious, medical pathology, or being improperly and/or inappropriately fitted with hearing devices. IHS strongly urges anyone who suspects they may have hearing loss to see a licensed professional - a hearing aid specialist or audiologist - to determine whether hearing aids can help or medical intervention may be necessary. IHS encourages providers and the public to review its best practices and position statement for further information.

[IHS Best Practices for Fitting and Dispensing Hearing Aids](#)  
[IHS Position Statement on Direct to Consumer Sales](#)

### National Policy Updates

In recent years, several workgroups and policymakers have taken steps to establish an over-the-counter hearing aid classification in order to meet the needs of individuals who require this approach to obtain hearing assistance. These efforts led to the passage of a new law in 2017, contained

## Related Resources

### IHS Resources

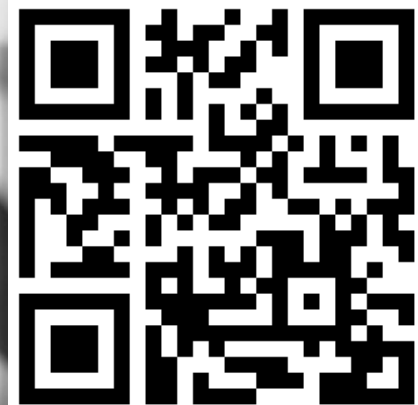
[IHS, AAA, ADA, ASHA Consensus Paper "Regulatory Recommendations for OTC Hearing Aids: Safety and Effectiveness"](#)  
[Joint Statement on Direct-to-Consumer Sales and Consumer-Administered Hearing Testing](#)  
[IHS Webinar: OTC Hearing Aids and PSAPS: Implications of the PCAST and NAS Reports](#) (6/28/16)

### Federal/Agency Resources

Congress: [PL 115-52, FDA Reauthorization Act - Containing 2017 Over the Counter Hearing Aid Act](#)  
[FDA: Guidance on Personal Sound Amplifiers](#)  
[FDA: How to Get Hearing Aids](#)  
[FDA: Letter to Industry re: OTC hearing aids](#) (7/24/18)  
[FDA: Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids](#) (12/12/16)  
[FDA Workshop: "Streamlining Good Manufacturing Practices for Hearing Aids"](#) (4/21/16)  
[FTC: U.S. Federal Trade Commission April 2017 workshop: "Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care"](#)  
NASEM: June 2016 National Academy of Sciences, Engineering and Medicine Report on Hearing Care: [Summary and Full Report](#)

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work relies on  
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**[bit.ly/2021IHSDonation](https://bit.ly/2021IHSDonation)** via **[ihsinfo.org](https://ihsinfo.org)** or  
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The image shows a large, well-lit conference hall filled with people seated at round tables. In the background, a stage features a large presentation screen displaying logos for Starkey, WIDEX, BDU, PHONAK, signia, and oticon. The room has high ceilings with recessed lighting and large windows on the right side. A blue semi-transparent banner is overlaid across the lower half of the image, containing the text 'BUSINESS TOOLS & PROFESSIONAL DEVELOPMENT' in white, bold, sans-serif capital letters.

# BUSINESS TOOLS & PROFESSIONAL DEVELOPMENT



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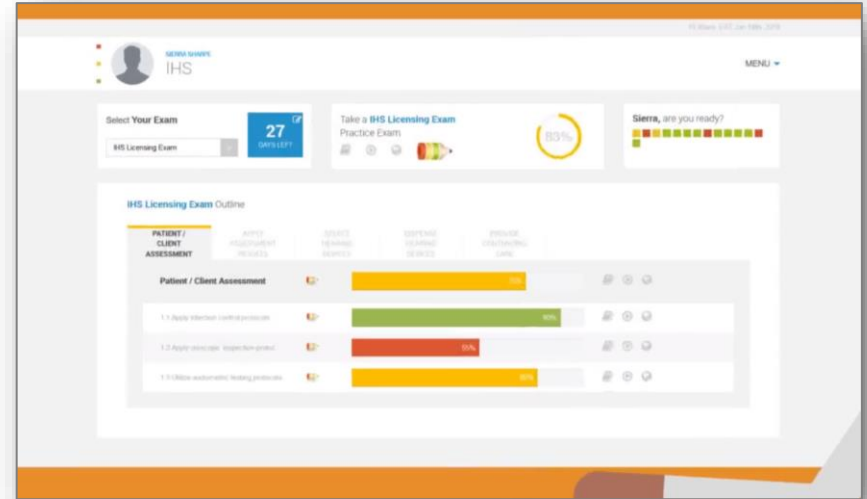


## Licensure Preparation Tools



The first and only official PREP tool available for the International Licensing Examination (ILE).  
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[ihsinfo.org/testprep](https://ihsinfo.org/testprep)

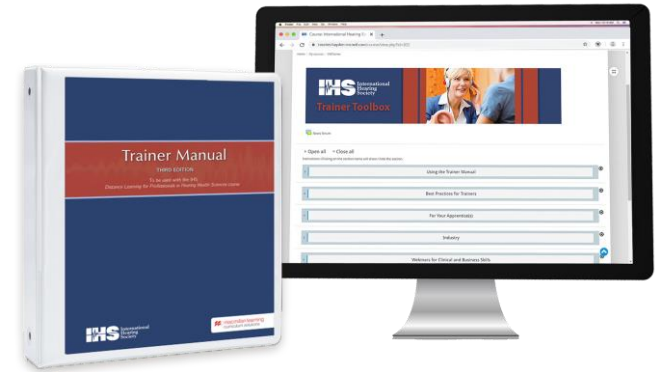


## Licensure Preparation Tools 3<sup>rd</sup>. Ed. Trainer Manual & Trainer Toolbox

This **Total Training Solution** is a companion to the **Distance Learning for Professionals in Hearing Health Sciences** course!

Trainer Toolbox resources include:

- ✓ Best practices for recruiting and hiring, leadership and management, and skills for mentoring
- ✓ IHS Clinical Practice Guidelines and policy statements
- ✓ Key links to industry news
- ✓ Helpful tools to share with your apprentice(s)
- ✓ Webinars for clinical and business skills



Visit  
[ihsinfo.org/trainermanual](https://ihsinfo.org/trainermanual)



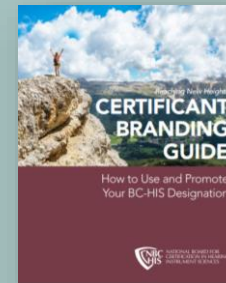
# Professional Development

## Why Get Board Certified?

- ✓ Increase confidence, recognition, and client awareness
- ✓ Enhance career advancement and earning potential
- ✓ Demonstrate the commitment to excellence and the desire to excel beyond normal requirements
- ✓ Distinguish yourself and your practice, including amidst non-certified peers and DTC retailers



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## Business Tools and Resources



AMERICAN COCHLEAR IMPLANT ALLIANCE

### **Free for one year: membership to the American Cochlear Implant Alliance**

**IHS members may enjoy a complimentary one-year membership** to the ACI Alliance. Affiliation with ACI Alliance elevates you as a knowledgeable resource amongst your clients and community. No matter which country you reside in, you receive access to resources that expand your network and knowledge about cochlear implants, and allow you to better serve clients by making cochlear implant (CI) referrals when appropriate. Sign up today!

**Use code **IHS** to receive one year of  
FREE Membership**

*(subject to 2021 IHS Membership verification)*



**[bit.ly/ACIAllianceSignup](https://bit.ly/ACIAllianceSignup)**





## Business Standards and Compliance *Compliance Plan Development Guide*

**Exclusively for IHS members**, the Compliance Plan Development Guide offers the small hearing aid business a simple step-by-step outline for developing a compliance plan, tips to increase its effectiveness, and a sample plan for reference. If you don't yet have a compliance plan or want to refine your existing one, **this FREE resource can help you get started.**

**Effective use of a compliance plan contributes to:**

- Minimizing organizational and individual risk
- Avoiding serious sanctions through plan implementation and observance
- Preventing and detecting unethical/illegal conduct
- Establishing a uniform process and procedures for staff and business associates to follow



The IHS Compliance Plan Development Guide is available for FREE download on the [IHS member website](#), under Resources.

# Not an IHS member yet?

*Don't delay. JOIN NOW!*

***ihinfo.org***

PROUD MEMBER



**International  
Hearing  
Society**

Already a member? Thank you for your support and membership in IHS!

Questions? Contact IHS at 734-522-7200 or [interact@ihinfo.org](mailto:interact@ihinfo.org)