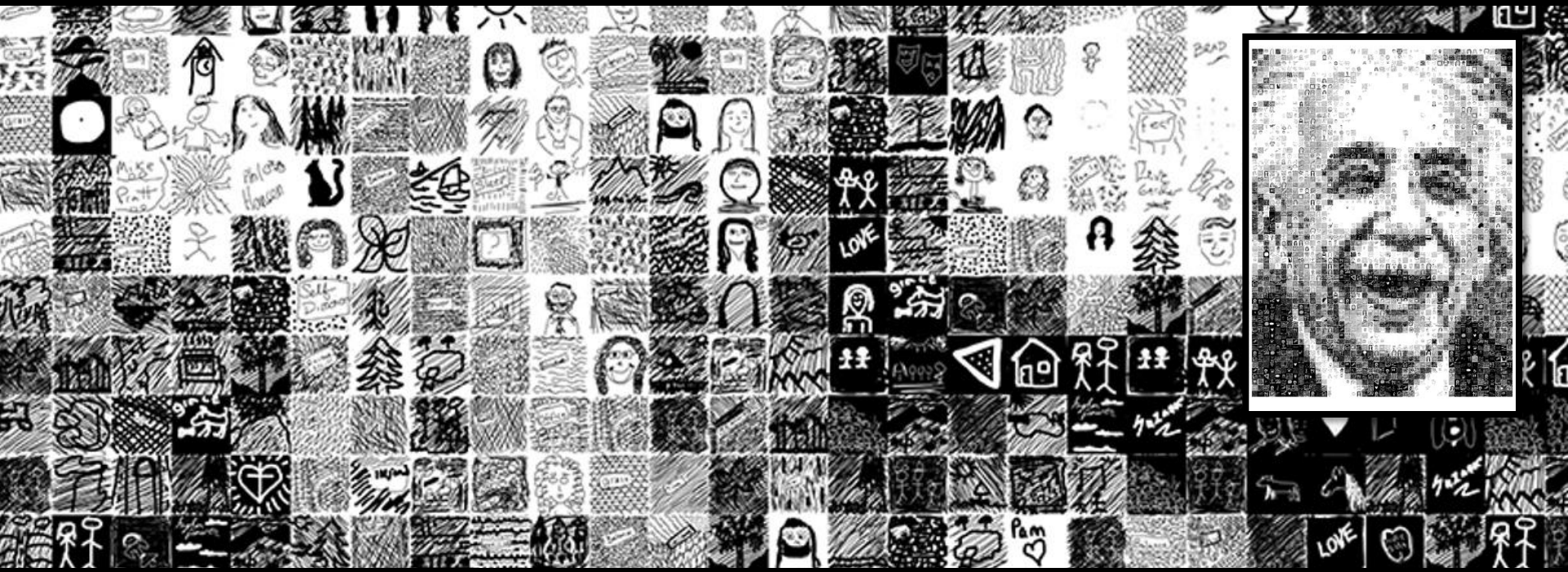


# Harnessing the Power of the IHS Community

## 2022 POLICY UPDATES AND RESOURCES



# IHS' Community-Based Focus

- International recognition of the value of hearing aid professionals/specialists
- Federal & state advocacy, education, and guidance on potential changes to the hearing aid delivery system
- Maintaining robust training and professional development standards, resources, and events
- Providing tools and advocacy for greater managed care participation, success, and compliance
- Creating connections between members for meaningful collaboration and sharing
- (And more!)

# Current State in Brief

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- Research points to the value of hearing healthcare, and consumers are becoming more aware.
- Hearing loss treatment is in the national and global spotlight.
- The demand for hearing healthcare services/professionals is strong.
- The development and application of practice standards and compliance are critically important.
- Entry of OTC hearing aids to the market.
- Medicare expansion, if passed, will affect your patients and business.



# IHS Advocacy: Medicare

## Current political status:

- Democrats in power of White House and Congress through 2022. There will be a split government in 2023 as the Republicans have taken control of the U.S. House of Representatives.
- Medicare expansion to cover hearing has been identified as a top priority for several Congressional Democratic leaders.
- IHS has been working on this issue for 2.5 years to advocate for appropriate and fair policies (lobbying, coalitions, etc.).
- The primary vehicle for passing Medicare expansion in the current session of Congress would have been the FY2022 budget reconciliation bill. However, with the Democrats only having a simple majority of 50 votes and the tiebreaker, they were unable to include Medicare expansion in the approved package. Senator Sanders (I-VT) offered up an amendment which would have expanded Medicare access to include dental, vision, and hearing, however the measure was ultimately defeated 3-97.
- IHS will continue to monitor this issue for the remainder of the current session of Congress.

# IHS Advocacy: Medicare

- Original Congressional proposal covered hearing aids for Medicare Part B beneficiaries with severe to profound HL every five years provided by audiologists or physicians.
- IHS advocacy focused on:
  1. Hearing aid specialists be added to the list of Medicare providers to provide hearing evaluations and hearing aid dispensing services
  2. Coverage to include both hearing aids and hearing aid dispensing services, including those services consistent with the standard of care
  3. Hearing aids be defined as prosthetic devices; to meet the need of the individual; and beneficiaries be granted the ability to “top up”
  4. Beneficiaries be able to access hearing aid specialists and audiologists directly for hearing aid services

# IHS Advocacy: Medicare

## What did IHS Advocacy accomplish?

In the **House-Passed Bill** (11/2021):

- Hearing aid specialists added as Medicare Practitioners, authorized to provide assessment services and order hearing aids as primary points of entry for beneficiaries.

(Bill expanded to cover those with moderately severe HL beginning January 1, 2023.)

In the **Senate Finance Bill** (pending):

- Hearing aid specialists added as Medicare Practitioners and Suppliers, authorized to provide hearing aid evaluation services and order and deliver hearing aids and related services, as primary points of entry for beneficiaries.

(Bill also covers those with moderately severe HL beginning January 1, 2023.)

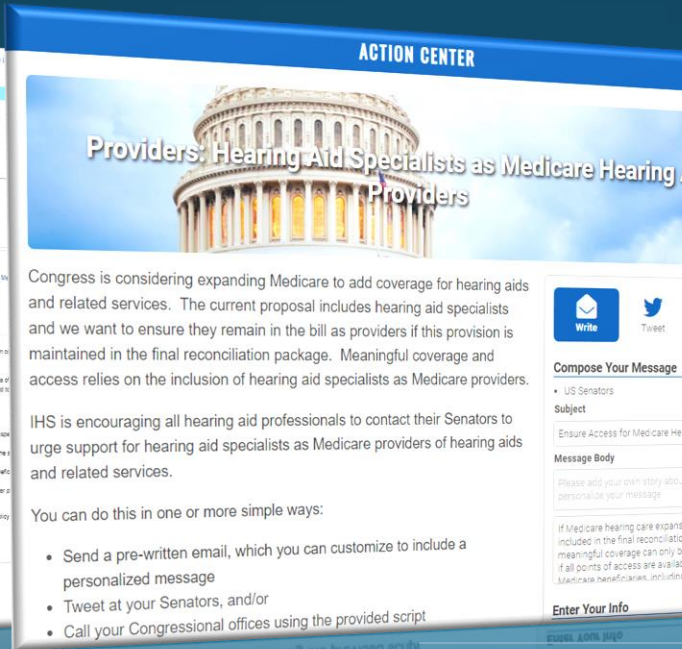
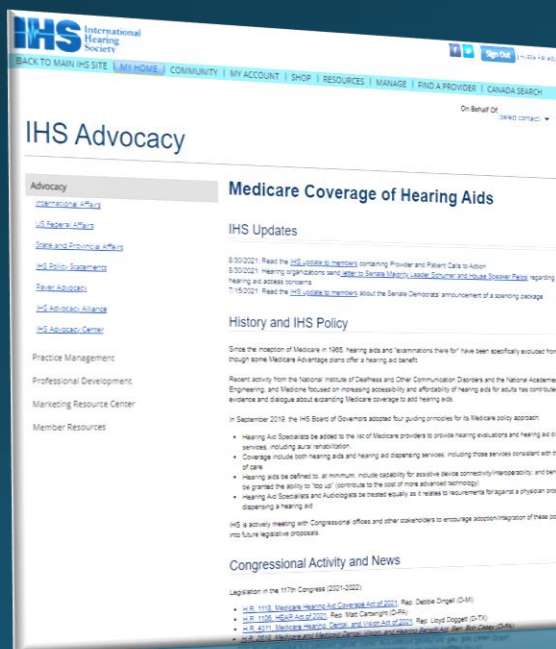
# IHS Advocacy: Medicare

Visit IHS' Federal Advocacy webpage for more or [bit.ly/IHSMedicare](https://bit.ly/IHSMedicare).

Stay Informed

Respond to Calls for Action

Spread the Word



WE are all about YOU 



# IHS Advocacy: OTC Hearing Aids

- On August 17, 2022, the U.S. Food and Drug Administration (FDA) released their final rules to establish a regulatory category for over-the-counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids.
- The move enables consumers 18 years of age and older who have perceived mild to moderate hearing loss to directly purchase OTC hearing aids from retailers.
- A license is not required to sell an OTC hearing aid. Licensed (and unlicensed) professionals may sell, service, market, dispense, or distribute) OTC hearing aids, and states may not enact restrictions or require a special licensing for these activities.



# IHS Advocacy: OTC Hearing Aids

- The FDA made several changes to the October 20, 2021, original proposed rule including:
  - lowering the maximum sound output to reduce the risk to hearing from over-amplification of sound (111-117 dB SPL)
  - revising the insertion depth limit in the ear canal (10 mm from the tympanic membrane)
  - requiring that all OTC hearing aids have a user-adjustable volume control
  - simplifying the phrasing throughout the required device labeling to ensure it is easily understood.

# IHS Advocacy: OTC Hearing Aids

- Since the release of the rules, IHS has been working with a coalition of the Academy of Doctors of Audiology, American Academy of Audiology, American Speech-Language Hearing Association, Amplifon, Hearing Industries Association, and Hearing Loss Association of America to evaluate the potential effects of the rules and determine if additional action was necessary.
- Of particular concern was whether the FDA's approach and new rules, without clarification, could affect the delivery of hearing aids by licensed professionals, which the group agreed they could. These concerns centered around the use of the term "prescription hearing aids" and medical evaluation requirements, how the federal rules could be interpreted by states, and how state laws could be applied.

# IHS Advocacy: OTC Hearing Aids

- The coalition met with the FDA on September 23, 2022, to discuss these concerns. The agency agreed with the coalition that it was not the agency's intent to limit the abilities of hearing aid specialists and audiologists to dispense prescription hearing aids. On October 13, 2022, the FDA responded by issuing a "Dear State Official" clarifying that the final rule:
  - Does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting, and dispensing of these devices;
  - Does not require an additional professional to take actions (for example, does not in any way require a physician's involvement prior to fitting these devices); and
  - Does not require an examination of any kind to obtain a prescription hearing aid.

# IHS Advocacy: OTC Hearing Aids

- FDA intends to apply existing practices for monitoring the market and will take action, including enforcement as necessary and appropriate. Should stakeholders wish to call FDA's attention to potential concerns that we may not otherwise learn, including potential regulatory misconduct, they may file a report sometimes known as a trade complaint.
- Anyone may file a complaint, and FDA encourages people to include supporting and contact information for possible follow up questions. However, the reports can be anonymous. More information about the process is available on FDA's website: <https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct>.



# IHS Advocacy: OTC Hearing Aids

Read IHS' comments and access other information via [bit.ly/IHSOTCWebpage](https://bit.ly/IHSOTCWebpage).

**Details and Guidance from IHS on the FDA Proposed Rulemaking for Over-the-Counter Hearing Aids**

This document contains a summary of the proposed rulemaking. We encourage you to review each section of this document and develop comments for submission to the FDA.

**Your involvement in this process is very important: historic and critical moment in the hearing aid market.**

Note: In this document, we use the term "traditional hearing aid" today, as are commonly dispensed by licensed hearing aid professionals.

With questions on any of the information contained

[Background](#)  
[Summary of the Proposed Rules](#)  
[IHS Priorities for Public Comment](#)  
[Instructions on Submitting Comments to the FDA](#)

**Background**

In 2017 Congress passed H.R. 3, the Food and Drug Administration (FDA) in Section 709 to the U.S. Food and Drug Administration counter hearing aids" to be available and sold directly to professional, and stipulated certain safety and effective classification and supplemental regulations.

Prior to this action, in December 2016 the FDA released "Document: Conditions for Sale for Air-Conduction Hearing Aids." This non-binding guidance states state clearance requirement for adults, and the waiver and p

On October 20, 2021, the FDA released its proposed rulemaking changes to the approach for regulating track 801.420 and 21 CFR 801.421, which also align with the

**View the Proposed Rules**

The proposed rules and the FDA's explanation can be found in the main body of the page: <https://www.fda.gov/oc/otc-hearing-aids> downloaded: <https://www.fda.gov/oc/otc-hearing-aids> on Federal Register page 58177.

Released Dec 2021

100 Mackbeil Road, Suite 4 | Livonia, MI 48154 • P: 734.522.7200 F: 734.522.0000

**January 17, 2022**

The Honorable Janet Woodcock, MD, Acting Commissioner  
Food and Drug Administration  
Dockets Management Staff (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852  
Submitted via Regulations.gov

In Reference to: Docket No. FDA-2021-N-0555 for "Establishment of a New Category of Hearing Aids"

Dear Acting Commissioner Woodcock:

International Hearing Society (IHS) thanks the leadership and Administration (FDA) for its efforts to develop a new over the in accordance with the Food and Drug Administration Act of the complexity of developing such a regulatory addition, and necessary and appropriate revisions to the existing hearing aid 1977. We submit to you the following recommendations and believe align with the intentions of Congress, the agency, and reasonable, appropriate, and safe hearing aid treatment to the

Established in 1951, IHS represents hearing aid specialists in other hearing aid dispensing professionals (audiologists and) have a long history of delivering hearing healthcare to the put hearing assessments and delivering hearing aids and related aid specialists understand the unique needs of hearing aid users abilities, lifestyles, health status, and hearing degrees; and guiding the right solutions, counseling, and assisting them with success such as dexterity, applying proper techniques (like the communication status in social, vocational, and the acous hearing aid wearer. Hearing aid specialists are recognized by and state laws and programs, health plans, and can be direct hearing and manage hearing loss.

IHS' work is driven by its mission statement that states, "The highest standards of professional competency, business integrity, and security of... medical devices. FDA is responsible for health by helping to speed innovations that make medical products affordable and by helping the public get the accurate, science-based medical products and foods to maintain and improve their health."

Likewise, the guiding principles of the FDA are outlined in its "The Food and Drug Administration is responsible for protecting safety, efficacy, and security of... medical devices. FDA is responsible for health by helping to speed innovations that make medical products affordable and by helping the public get the accurate, science-based medical products and foods to maintain and improve their health."

**IHS Advocacy**

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On Behalf Of: [\(select\)](#)

**Advocacy**

- [International Affairs](#)
- [US Federal Affairs](#)
- [State and Provincial Affairs](#)
- [IHS Policy Statements](#)
- [Payer Advocacy](#)
- [IHS Advocacy Alliance](#)
- [IHS Advocacy Center](#)

**Direct to Consumer & Over the Counter Hearing Aids**

- [IHS Policy](#)
- [National Policy Updates](#)
- [FDA Proposed Rulemaking](#)

**Related Resources**

**State Action**

- [5/12/21 KVOA article "AZ AG company sign settlement agreement on hearing aid claims"](#)
- [AZ Attorney General Consumer Alert](#)
- [AR Attorney General Consumer Alert](#)
- [CT Attorney General and Commissioner Consumer Alert](#)
- [GA Attorney General Consumer Alert](#)
- [KY Attorney General Consumer Alert](#)
- [LA Attorney General Consumer Alert](#)
- [MI Attorney General Consumer Alert](#)
- [NC Attorney General Consumer Alert](#)
- [OH Attorney General Consumer Alert](#)

*The purchase of hearing aids direct by consumer using*

**WE are all about YOU**

**IHS**

# IHS Advocacy: Fit to Serve

- IHS remains committed to its campaign to enable Veterans to attain hearing care through hearing aid specialists.
- In 2016 and 2020, IHS attained passage of federal bills that authorize and direct the Department of Veterans Affairs (VA) to hire hearing aid specialists at each of the VA's 170 Medical Centers.
- VA released national hiring qualifications in March 2022. They fall short of meeting the needs for veterans by limiting providers who would be eligible for VA employment; and undermine the valuable services hearing aid specialists can contribute to the VA team.
- IHS is continuing engagement with Congressional Veterans Affairs leaders, who have championed our cause, to seek explanation and resolution. These champions, the chair and ranking members of both the House and Senate Committee on Veterans Affairs, recently sent a letter to the VA requesting feedback on these hiring qualifications and seeking clarity on the process. IHS will be sure to continue to monitor this issue as the deadline for hiring is quickly approaching.
- IHS is pleased to report that there have been job postings for hearing aid specialists in several states including Arizona, Colorado, Connecticut, Delaware, Florida, Oklahoma, Indiana, Iowa, Texas, Utah, and West Virginia

# IHS Advocacy: Fit to Serve

With national qualifications for hearing aid specialist in place, IHS can use them to bolster our efforts to:

- Attain an update to VA Audiology policies to enable hearing aid specialists to contract with the VA
- Pursue ways to use the Community Care Program to deliver hearing aids through VA contracting



Stay in touch and learn more  
at: [www.Fittoserve.us](http://www.Fittoserve.us)

# IHS Advocacy

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- IHS tracks and works directly with its state and provincial chapters on bills and regulations that would affect the profession and patients you serve.
- We engage with coalitions to raise awareness of hearing care, hearing aid professionals, and join efforts when needed.
- We advocate for hearing aid specialist recognition in federal and state programs, and with health plans and credentialing bodies.
- For example, through IHS advocacy, CAQH now allows hearing aid specialists to use its ProView product for credentialing, which is required by many health plans for participation!



# IHS Advocacy: International

- International Organization for Standardization released its Hearing Aid Fitting Management (HAFM) standard in 2020.
- IHS representation on the work group ensured the standard reflects the role of hearing aid specialists and U.S. practice.
- ISO is now developing a Telehealth HAFM standard, with IHS again represented.



International  
Organization for  
Standardization

ISO 21388:2020, Acoustics —  
Hearing Aid Fitting Management  
is available for purchase through  
ISO or ANSI

# Please Donate

All our advocacy work relies on voluntary donations. To make a secure donation using your credit card, please visit:

[bit.ly/2022IHSDonation](https://bit.ly/2022IHSDonation)

or use the QR Code Below!



Thank you for your support!



# Professional Tools and Resources



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# Licensure Preparation

Resources for apprentices and trainers:

- Trainer Toolbox featuring best practices for recruiting and hiring, leadership and management, and skills for mentoring
- IHS Clinical Practice Guidelines and policy statements
- Webinars for clinical and business skills
- Interactive exercises for apprentices – trainers get the answer key and explanation
- Test questions designed to build knowledge and confidence before licensing exams

## KEY FEATURES



**Interactive  
Exercises**



**New Test  
Questions**



**Optional  
E-Books**



**Trainer Tasks &  
Skills Practice**



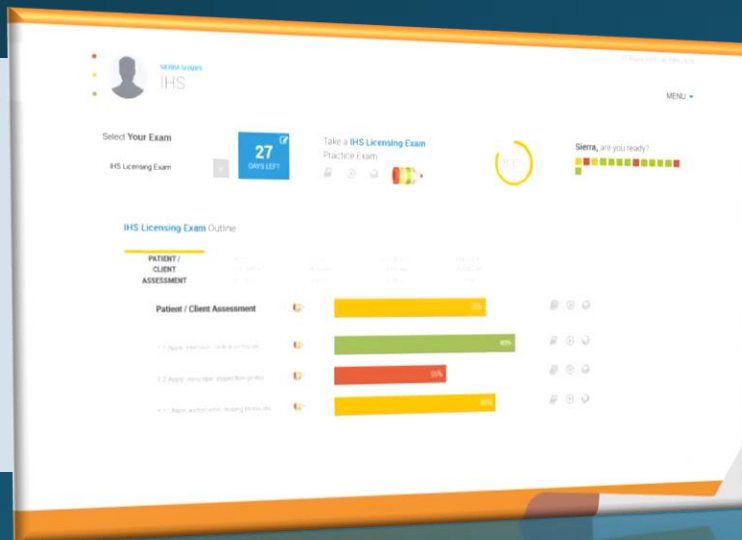
**Easy-to-use  
Assessments**



# Licensure Preparation

The first and only official PREP tool available for the International Licensing Examination (ILE). Subscribers get instant access to:

- 200+ previously-used exam questions
- Topic-level feedback
- Flashcards relevant to ILE questions
- Two practice exams with instant results



**Prepare. Perfect. Pass.**

Learn more at  
[ihsinfo.org/testprep](https://ihsinfo.org/testprep)

# Gain a Competitive Edge

The Tinnitus Care Provider  
Certificate Program  
empowers participants to:

**Virtual, January 27-29, 2023**

**Register at [ihinfo.org/tinnitus](https://ihinfo.org/tinnitus)**

- Provide relief to their patients with tinnitus
- Attract new patients to grow their practice
- Quantify and qualify tinnitus for their patients
- Immediately integrate tinnitus care into their clinic



“Becoming proficient in tinnitus management skills means that you can help more people live fuller lives. This service has been well received as we welcome both new and familiar faces.”

**Ted Blanford, ACA**

*Tinnitus Care Provider Since 2017*

Save The Date



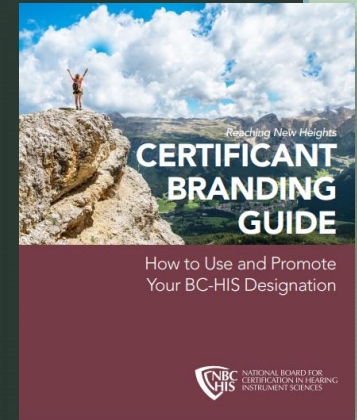
71<sup>ST</sup> ANNUAL  
CONVENTION  
& EXPO  
PALM SPRINGS, CA





# What is new with NBC-HIS?

- ✓ Branding Guide
- ✓ Digital Badge
- ✓ E-Newsletter
- ✓ Logoed Business Tools and Products
- ✓ Updated Testing Forms in 2021 and New Study Guide Development in 2022!





# Steps toward Board Certification

## 1. Review the requirements

Current State/Provincial dispensing license (or registration) **and** meet a minimum of 2 years of full-time dispensing experience within the last 5 years (or a diploma from an approved accredited program).

## 2. Complete and submit the application

Include copy of license (registration). Include letter from employer attesting to two years of experience. Pay \$225 application fee.

## 3. Review the Study Guide

## 4. Schedule the exam



# What's YOUR why?



*"My colleagues have spoken highly of you and recommended I apply."*

*"Known about it for years, just need to get it done."*

*"I have known about the NBC-HIS since getting in the business in 1992 but have never taken the exam and feel the need to become certified now."*

*"I found out about NBC-HIS when I started down this career path. It was a goal for me to obtain BC-HIS."*

*"My company greatly encourages board certification."*

*"Ever since I became a trainee, my sponsor instilled in me that obtaining my NBC would be great in the future."*



# Learn more about Board Certification



A Mark of  
Excellence



An  
Achievement

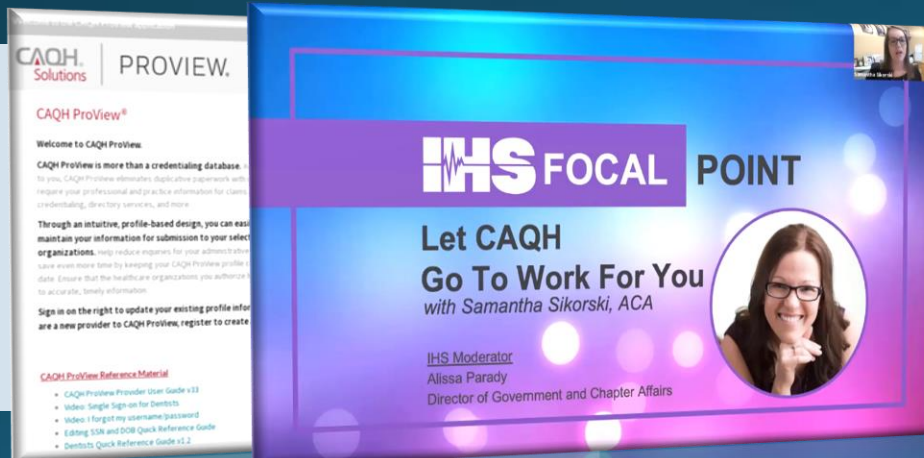


Assures the Public  
of Expertise

[info@nbc-his.com](mailto:info@nbc-his.com)  
[www.nbc-his.com](http://www.nbc-his.com)

# Health Plan Credentialing

- **Hearing Aid Specialists can now use CAQH ProView** for managing their credentialing data - which means less paperwork, less time, and an improved ability to apply for insurance networks that rely on CAQH for credentialing decisions.
- Until IHS intervened, hearing aid specialists had no identifier in the ProView program, affecting their ability to use this program, which is essential for participation in many health plans.



To learn more, go to  
[bit.ly/IHSCAQH](https://bit.ly/IHSCAQH) or  
 IHS' Practice  
 Management page.

# Strengthen Compliance Activities

- **Exclusively for IHS members**, the Compliance Plan Development Guide offers the small hearing aid business a step-by-step outline for developing a compliance plan, tips to increase its effectiveness, and a sample plan.
- If you don't yet have a compliance plan or want to refine your existing one, check it out!

## Effective use of a compliance plan contributes to:

- Minimizing organizational and individual risk
- 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.





**SOLUTIONS**

MEMBERS - COMMUNITY - MARKETS

# Health Insurance

- Protect yourself, your family, your employees with affordable Healthcare Insurance Options.
- IHS has partnered with **LIG Solutions** to offer IHS Members affordable health insurance coverage for individuals, families, and businesses/ employees with Major Medical, Medicare, Short Term Policies, Vision, Dental, Critical Care, and Supplemental Insurance Coverage as well as Health Reimbursement Arrangements (HRAs)!



Visit the **Resources** section of the  
IHS Member website:  
**[myhome.ihsinfo.org](http://myhome.ihsinfo.org)**

*WE are all about YOU* **IHS**

# At IHS, our mission is our members.

## Other benefits of being part of the IHS community:

- ✓ Concierge-level service
- ✓ Online community, *the hearing hub*
- ✓ Advocacy for your profession
- ✓ *The Hearing Professional Magazine* – digital & print versions
- ✓ Soundboard e-newsletters
- ✓ Exclusive website content
- ✓ Free and discounted products, including coding/billing resources and OfficeMax discounts
- ✓ Free CE transcripts
- ✓ Wallet card, membership sticker for wall certificate
- ✓ Earn All-Star rewards, recognition, and gifts
- ✓ Patient referrals through web and Hearing Aid Helpline



# Not an IHS member yet?

*Don't delay. JOIN NOW!*

PROUD MEMBER



International  
Hearing  
Society

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

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

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

