

# **ADA Update: State Public Policy Initiatives Related to Prescription Hearing Aids**

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# Disclosure

- Stephanie Czuhajewski, MPH, CAE
  - Financial: Stephanie is employed by ADA
  - Non-Financial: none

# Overview of FDA's Regulatory Changes Governing Hearing Aids

FDA NEWS RELEASE

## FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

*More Affordable Hearing Aids Could Be in Stores as Soon as Mid-October*

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For Immediate Release: August 16, 2022

## Final Regulatory Changes

### OTC Hearing Aids

Hearing aids meeting certain regulatory controls may be sold to adults with “**perceived mild to moderate**” hearing loss without involvement of hearing care professional.



### Prescription Hearing Aids

Non-OTC hearing aid available with a “prescription or other order from a state-licensed practitioner.”

**Changes Became Effective October 17, 2022**

# Overview of Prescription Hearing Aid Regulation

## Prescription Hearing Aids

**Intended For**

**Both Adults and Children**

**Amplification**

**No Limits**

**Sold Online**

**Depends on State Law. If Allowed, Prescription Required**

**Labels**

**Specific Labels Required**

**Consumer Protections**

**Existing Federal and State Protections Apply**

**Prescription Required**

**Yes, pursuant to 21 CFR §801.109.**

# Ambiguity Leads to Stakeholder Request for Guidance from FDA

## Stakeholders Request FDA Guidance from FDA on Prescription Devices



October 13, 2022

Dear State Official:

It has come to our attention that there may be some confusion with FDA's final rule establishing a regulatory category for over-the-counter (OTC) hearing aids and amending certain FDA regulations. We published the final rule on August 17, 2022, and it goes into effect on October 17, 2022 (see [87 FR 50698](#)). The final rule primarily establishes a category of OTC hearing aids that consumers aged 18 years and older with perceived mild to moderate hearing impairment can purchase without the involvement of a hearing healthcare professional. The final rule also makes several changes to Federal regulations that apply to hearing aids, including: repealing the conditions for sale for hearing aids under 21 CFR [§ 801.421](#); defining non-OTC hearing aids as prescription devices, subject to 21 CFR [§ 801.109](#), rather than restricted devices (see [87 FR at 50755](#), removing [§ 801.421](#)); and providing updated labeling requirements for such prescription hearing aids (see *id.*, adding new 21 CFR [§ 801.422](#)).

We have received questions about some implications of these actions, including who may prescribe hearing aids and whether medical evaluations are necessary to obtain non-OTC hearing aids, which will be defined as prescription hearing aids under the rule. We clarify below 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.

A State can authorize many kinds of practitioners to order the use of (or prescribe) a prescription device. Federal regulations in [§ 801.109](#) do not require that a prescriber be a physician (a person licensed to practice allopathic or osteopathic medicine), physician assistant, or nurse practitioner. Instead, the relevant requirements for prescription devices apply in the case of practitioners licensed by the law of the State to use or order the use of the device (see [§ 801.109](#)). FDA's intent is that the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date would continue to do so for prescription hearing aids after the effective date. Further, the final rule does not require the involvement of an additional licensed practitioner such as a physician. A licensed audiologist, for example, would not need to consult a physician under FDA's final rule.

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
[www.fda.gov](http://www.fda.gov)

“We clarify 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.”

“FDA's intent is that the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date would continue to do so for prescription hearing aids after the effective date.”

**But...**

**FDA does not have jurisdiction over state licensure. As such, each state will need to adopt necessary policy changes to align with the federal changes to avoid any unintended consequences.**

# Practical Implication of Shift to “Prescription Device” Regulation

## FDA’s Prescription Device Regulation

### § 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)

(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

## What Does this Mean?

1. Prescription hearing aids may only be dispensed to patients with a “prescription or other order” from a state-licensed practitioner.
2. While FDA’s “Dear State Official Letter” was helpful in clarifying federal intent, FDA ultimately lacks jurisdiction to regulate the scope of state practitioner licensure.
3. Ultimately, states must define which specific practitioners have the authority to “prescribe” or “order” non-OTC hearing aids to protect patient access to prescription hearing aids.
4. Problematically, few states included the terms “prescribe” or “order” in the scope of practice for audiologists and hearing aid specialists.



**To ensure patient access to prescription hearing aids, the audiology and dispensing professions should proactively pursue appropriate policy changes under state laws and regulations.**

# State Policy Solutions: Two Options

States must clarify that both audiologists and hearing aid specialists have the authority to “prescribe or order the use of” prescription hearing aids.

## Legislation (Preferred Option)

Enact legislation amending existing laws to insert specific authorizing language in relevant statutes for both professions

Appropriate Language is Key. It is important to ensure that specific language is used when amending existing laws to ensure satisfactory clarification is achieved. Relevant definitions, and in some cases, scope of practice provisions should be amended to include professional authority to “prescribe” or “order the use of” non-OTC devices.

## Guidance (Alternative Option)

Publication of administrative guidance by state regulatory bodies overseeing dispensing professionals

Note. Depending on status of a particular state’s legislative session, this may be the only option to secure an immediate clarification. If guidance is obtained, it should be viewed only as a temporary clarification until a permanent resolution is obtained through legislation.

**Importantly,** the audiology and dispensing professions should **proactively** pursue these changes **collaboratively** to ensure unintended consequences of impacting patient access.

# Challenges Facing State Advocacy Efforts

## Challenges

**Lack of Awareness Surrounding Implications of FDA's Changes**

**Mistaken Belief that Policy Changes are Not Needed**

**Policy Changes Not Being Pursued Proactively**

**Lack of Coordination and Collaboration Among Interested Stakeholders**

## Examples

Stakeholders, public officials, and policymakers understand the establishment of OTC but often fail to recognize the regulatory changes related to prescription devices and what this means practically.

**"Selling" ≠ "Prescribing"**

**Attorney General Opinions Helpful But Can Change**

**FDA Lacks Jurisdiction Over State Licensure**

Legislation is being introduced to align state and federal laws related to OTC hearing aids but typically fails to include necessary changes for prescription devices, forcing stakeholders to pursue changes quickly and with limited time to properly educate policymakers.

The audiology and dispensing professions are often engaging in these issues separately and without coordinating, putting each other at an increased risk of losing the authority to "prescribe or order the use of" prescription devices if one profession fails to obtain proper clarification.



# Good Examples

## Maryland

- Legislation signed into law amending audiology and dispensing laws to align with FDA regulations (HB 401/SB 449).
- Legislation includes language clarifying prescriptive authority of audiologists and dispensers.

**SENATE BILL 449**

J2 3/2/2023  
CP HB 401

By **Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, and Ready**, Ready, and Kelly  
Introduced and read first time: February 2, 2023  
Assigned to Finance  
Committee Report: Favorable with amendments  
Senate action: Adopted  
Read second time: March 8, 2023

CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Health Occupations—Practice Audiology—Definition**

3 **Maryland Audiology, Hearing Aid Dispensing, Speech-Language Pathology, and**

4 **Music Therapy Act—Definitions and Application**

5 FOR the purpose of altering the definition of "hearing aid dispenser" to include certain

6 actions taken for the purpose of ordering certain hearing instruments and specifying

7 that certain hearing instruments include prescription hearing aids, altering the

8 definition of "practice audiology" for the purpose of certain provisions of law

9 governing the licensure of audiologists, providing that certain provisions of law do

10 not apply to certain actions taken with respect to certain over-the-counter hearing

11 aids, and generally relating to the **practice of audiology**, Maryland Audiology,

12 **Hearing Aid Dispensing, Speech-Language Pathology, and Music Therapy Act.**

13 **BY-numbering**

14 **Article—Health Occupations**

15 **Section 2—101(a) through (c)**

16 **to be Section 2—101(a) through (c), respectively**

17 **Annotated Code of Maryland**

18 **(2022 Replacement Volume and 2023 Supplement)**


19 **BY-numbering**

20 **Article—Health Occupations**

21 **Section 2—101(a)**

22 **Annotated Code of Maryland**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.  
Blockbold indicates matter deleted from existing law.  
Underlining indicates amendments to bill.  
Shaded area indicates matter stricken from the bill by amendment or deleted from the law by amendment.



## Kentucky

- Legislation signed into law amending audiology and dispensing laws to align with FDA regulations (SB 58).
- Legislation includes language clarifying prescriptive authority of audiologists and dispensers.

UNOFFICIAL COPY 23 05 58 583N

1 AN ACT relating to professions assessing hearing and speech.

2 **Be it enacted by the General Assembly of the Commonwealth of Kentucky:**

3 **SECTION 1. KRS 334.010 IS REPEALED AND REENACTED TO READ**

4 **AS FOLLOWS:**

5 **As used in this chapter, unless the context otherwise requires:**

6 (1) **"Apprentice" means any applicant in training to become a licensed specialist in**

7 **hearing instruments;**

8 (2) **"Apprentice permit" means a permit issued while the applicant is in training to**

9 **become a licensed specialist in hearing instruments;**

10 (3) **"Board" means the Kentucky Licensing Board for Specialists in Hearing**

11 **Instruments;**

12 (4) **"Client" means the user or purchaser of the hearing instrument;**

13 (5) **"License" means a license issued by the board under this chapter to specialists in**

14 **hearing instruments;**

15 (6) **"Over-the-counter hearing aid" means air conduction hearing aids that satisfy**

16 **the requirements in the Over-the-Counter Hearing Aid Controls, 21 C.F.R. sec.**

17 **800.2051 to (f), and are considered available over the counter pursuant to 21**

18 **L.S.C. sec. 3602(a)(2)(A)(i), but do not satisfy the regulatory requirements for**

19 **prescription hearing aids;**

20 (7) **"Practice of fitting hearing instruments" means the measurement of human**

21 **hearing by means of an audiometer for the purpose of making selections,**

22 **adjustments, and adjustments of hearing instruments, including both over-the-**

23 **counter hearing aids and prescription hearing aids. The practice of fitting**

24 **hearing instruments also includes the making of ear mold impressions and**

25 **custom earmolds and ordering the use of hearing instruments;**

26 (8) **"Practice of selling and fitting hearing instruments" means selling, ordering the**

27 **use of, and fitting prescription hearing aids and over-the-counter hearing aids.**

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## Next Steps and How You Can Help

**Proactively Seek Opportunities to do the Following:**

**Educate Licensed Audiologists and Dispensers and Encourage Collaboration**

**Ensure State Board and State Agencies have Access to Appropriate Technical Guidance**

**Pursue Appropriate Regulatory Guidance**

**Pursue Appropriate Legislation**

# American Academy of Audiology

# Disclosure

- Susan Pilch, JD
  - Financial: Susan is employed by AAA
  - Non-Financial: none

# ***American Board of Audiology Certified***

## **Eligibility for Certification**

- Doctoral degree from an accredited audiology program
- Current, valid license to practice audiology ***or license eligible*** with proof of licensure within one year
- 2000 hours of professional, mentored experience after completion of degree coursework (externship hours are eligible)
- Adherence to the ABA Code of Ethics

## **Renewal Retention**

- 89.5% in 2022; 87% so far in 2023



# ***American Board of Audiology Certified***

## **Maintenance of Credential**

20 hours of continuing education every year, including:

- 1 hour in Ethics
- 5 hours with Tier 1 designation
  - A minimum duration of 1 hour
  - Focused on one subject-area or various aspects of one subject
  - Instructional level of content presented must be intermediate or advanced
  - Includes interactivity



# ***American Board of Audiology Certified***

## **ABAC and State Licensure**

- 10 states require either ABAC or CCC-A for licensure: AK, DE, HI, MA, MS\*, NV, NM, SC, VA, WY
- 18 states allow either ABAC or CCC-A in lieu of some licensure requirements: AL, AR, CA, CT, DC, FL, GA, ID, KS, MD, MI, MN, OK, OR, PA, RI\*, TX, WA
- 17 states allow only CCC-A in lieu of some licensure requirements: AZ, CO, IL, IN, IA, KY, LA, ME, NE, NJ, NY, NC, OH, TN, UT, WV, WI
- 6 states make no mention of certification relative to licensure: MO, MT, NH, ND, SD, VT

\*With Master's degree only



# ***Pediatric Audiology Specialty Certification (PASC)***

**Established in 2011; pediatrics considered a vulnerable population**

**Recognizes highly experienced professionals in the practice of pediatric audiology, who have knowledge in areas including child development, rehabilitation, and screening and assessments.**

***Online examination with live remote proctoring since 2022***

***Online application and exam registration since 2021***

***Not tied to any other credential or membership***

**Next exam administration: May 6-20, 2024**





# ACAЕ

## AuD Program Accreditation

**ACAЕ** is the only accreditation body for audiology education that is sponsored entirely by, for, and of audiology.

ACAЕ is recognized by the Council for Higher Education Accreditation (CHEA) through 2029

Seeking recognition by all state boards



a c a e

Accreditation Commission for Audiology Education

C A P Computerized Accreditation Program®



# What's Next

- **Review and Update of Standards**
- **Mentoring Priorities for Developing and New Programs**
- **Partner to advocate at the state level**

# Academy Focus: Federal

- The Medicare Audiologist Access Improvement Act of 2023
- Audiologists as “practitioners” (implications for telepractice); allow treatment services
- Remove physician referral requirement

# Academy Focus: State

- Update state audiology practice acts
- ASLP-IC
- Adjustments to state laws/regs re: OTC
- Support state Medicaid coverage of HA/CI

# AAA 2024 + HearTECH Expo

- April 17-20, 2024
- Atlanta, Georgia



# Increase Engagement and Connection: Benefits and Resources

- AAA 2024+HearTECH Expo, April 17-20, Atlanta, Georgia
- Audiology Community Collaboration and Discussion Forum
- Career Resources: HearCareers.org, Salary Survey, Resume Review Service, Professional Development Series at AAA 2024
- eAudiology.org Web Seminars

# OTC Task Force

## Over-the-Counter Hearing Aid Resources

On October 17, the over-the-counter (OTC) hearing aid regulations from the U.S. Food and Drug Administration (FDA) went into effect. Media outlets across the country have reported widely on OTC devices for sale, and Academy representatives have been busy participating in interviews to reinforce the essential role that audiologists play in hearing health care. Continue to check back on the Academy's OTC resources as further information is released and resources are created.

[ACCESS RESOURCES](#)

[OTC WEBINAR: ON DEMAND](#)



# A Resource for You

American Academy of Audiology

Reston, VA

703-790-8466

Susan Pilch, [spilch@audiology.org](mailto:spilch@audiology.org)

Kitty Werner, [kwerner@audiology.org](mailto:kwerner@audiology.org)

Andrew Stafford, Director of Professional Standards and Credentialing

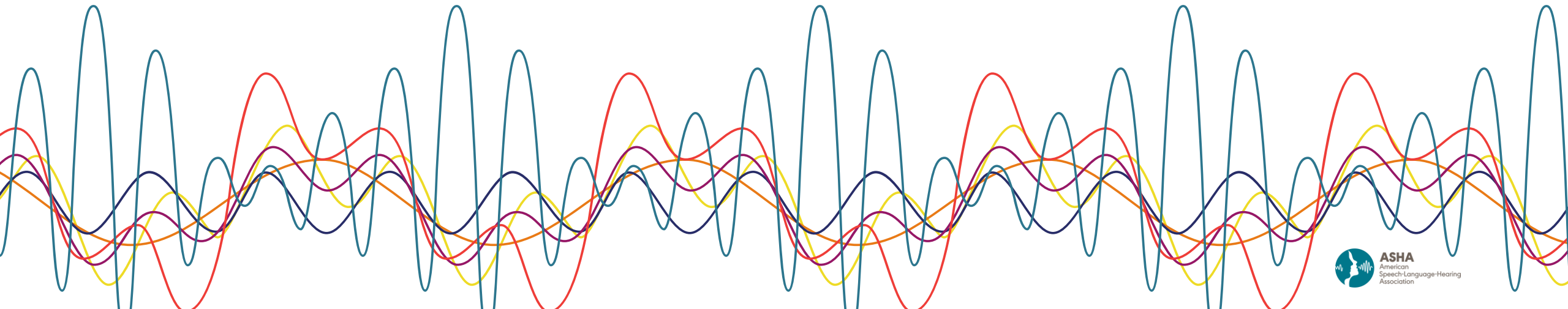
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# ASHA

American  
Speech-Language-Hearing  
Association



# Disclosure

- Susan Adams, Esq., CAE
  - Financial: Susan is employed by ASHA.
  - Non-Financial: Susan is the national speech-language pathology organization ex-officio to the ASLP-ICC Executive Committee

# State Priorities: Audiology



- Maintaining the vital role of audiologists in hearing aid dispensing and hearing health
- Working with state licensing boards on regs to implement OTC rules
- Creating 50-state resource on state hearing aid licensing rules, OTC rules
- Ensuring teleaudiology regs address future technology updates
- Promoting and protecting the scope of practice of audiologists
- Supporting insurance coverage of hearing aids and cochlear implants
- Adopting the C-AA

# 2023 Accomplishments: Audiology

- **Member Value:** Safety Challenges in Audiology: Starting the Conversation and Making Changes (On Demand Webinar); Practice Management Member Advisory Group comprised of ASHA members who are concerned with audiologist safety.
- **Member Value/Value to the public:** Early identification of adult hearing loss and the importance of seeing an audiologist early for hearing loss identification and management; hearing loss intervention and the importance of audiologists as well as to public health practitioners, physicians, and other healthcare professionals.
- **Technical Support and Assistance:** Thus far in 2023, the Audiology Practices team has responded to over 500 phone calls/emails from both members and the public regarding audiology related issues.
- **Enhanced Connections with other associations:** MOUs between ASHA and other related audiology and healthcare associations are in place to cross promote resources and events for members.
- **Member Value:** 2023 Portal Pages: Tinnitus and Hyperacusis, Cleft Lip and Palate, Head and Neck Cancer, Executive Function, Dementia (in progress), CAPD (in progress), Bilingual Service Deliver (in progress), Documentation in Audiology (in progress)
- **Students:** 2nd cycle of the Audiology Mentorship Program for Students (AMP-S): Audiology Mentor Program for Students (AMP-S)

# State Priorities: SLP



**ASHA**  
Speech-Language Pathology  
Dedicated to Advancing the Profession  
of Speech-Language Pathology

- Maintaining the vital role of speech-language pathologists in schools and healthcare settings
- Ensuring SLPs can work in any setting with one license
- Promoting and protecting the scope of practice of SLPs
- Advocating for salary supplements to support a robust workforce
- Working with insurers to recognize CF licensees as qualified providers
- Adopting the C-SLPA

# 2023 Accomplishments: SLP – Clinical Team

- **Member value:** Private Practice Online Conference: Supported ASHA members in their SLP Private Practice pursuits and learned from innovative private practitioners working in specialized areas of clinical practice and networking with other SLPs across the country.
- **Technical Support and Assistance:** ASHA Clinical Issues Team provides professional consultation for members and consumers:(approx 1500-2000/year). Answering questions related to clinical practice including private practice, SLPAs, AAC, early intervention, voice disorders, fluency, autism and neurodiversity,
- **Innovation:** Tracking and documenting how AI and technology can be used in SLP practice supporting teams like Leader and APD on accuracy and relevance of content
- **Member Value:** Trauma-Informed Care resources and web event from February and March 2023. More than 900 participants in live chats and positive feedback from members and presenters
- **Member Value:** New practice portal page on executive function

# 2023 Accomplishments: SLP – Schools Team

- **Member Value:** Curated and facilitated 60 professional development opportunities for school-based members including in-person and virtual conferences; and webinars.
- **Member Value:** Practice Portal page update/revision: Caseload and Workload, Selective Mutism, Spoken Language Disorders, Multilingual Service Delivery, Executive Functioning, Childhood Hearing Screening, and Early Intervention
- **Innovation:** ASHA Workload Calculator pilot with graduate students
- **Innovation:** Workload Boot Camp preconference session
- **Technical Support and Assistance:** Engaged in professional consultation for members and consumers on clinical and professional school-based topics (1400-2300 contacts per year)
- **Member Value:** Development of 18 professional resources and tools SLPs to support their school-based practice

# State Priorities: Audiology & SLP

- Ensuring ease of licensure across state lines, including advocating for passage of the ASLP-IC
- Supporting the ability of audiologists and SLPs to practice to the fullest extent of their education and training.
- Advocating for anti-discriminatory policies and practices that support audiologists, SLPs, and people with communication.
- Advocating for initiatives that expand technology capacity to support the provision of services



# Federal Priorities: SHARE Act

- Interstate Compact Access to Background Check Determinations
  - The FBI is applying inconsistent interpretations of whether interstate compacts can receive information on background check determinations.
  - This delays interstate compact processes that are meant to simplify and speed up recognition of a privilege to practice.
- The SHARE Act Addresses this Issue
  - Authorizes the FBI to share background check determination information between states for licensure purposes.
  - Allows cooperation between states while protecting each states' authority to determine whether a provider is eligible to practice in the state.
- Bipartisan Legislation introduced by Rep. Tracey Mann (R-KS) and Rep. Joe Neguse (D-CO)
- Referred to Education & Workforce and Judiciary Committees
- 21 bipartisan cosponsors

ASHA [Issue Brief](#) for SHARE Act

# Federal Priorities: Medicare Audiology Access Improvement Act

- Would authorize Medicare reimbursement for both diagnostic and treatment services; remove the physician order requirement; and reclassify audiologists as practitioners under the Medicare statute
- The bill includes minor updates from versions introduced in prior Congresses to reflect technical assistance from CMS.
- Minimal fiscal impact (\$111 million over 10 years)
- Estimated savings of \$36 million in patient out-of-pocket costs over 10 years by eliminating the physician order requirement.
  
- Bipartisan Legislation introduced by by Senators Elizabeth Warren (D-MA), Chuck Grassley (R-IA), and Rand Paul (R-KY).
- Referred to the Senate Finance Committee.
- 8 total cosponsors
- House bill is expected to be introduced soon

[ASHA's joint statement with AAA and ADA](#)

# Code of Ethics

- ASHA's revised Code of Ethics went into effect on March 1, 2023.

# Contact

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