Speech-Language Pathology and Audiology

July 19, 2024

Public Comment Summary

Title:

Proposed Rules for West Virginia Board of Speech-Language Pathology and Audiology.

Date:

The call for Public Comments ran from May 31, 2024 to June 30, 2024.

Mission Statement:

The mission of the West Virginia Board of Examiners for Speech-Language Pathology and Audiology is to protect consumers by ensuring that all licensed practitioners meet or exceed educational standards and adhere to the of Code of Ethics as presented in the WV or Code.

Public Comment Summary:

The various comments came from Hearing Aid Dealers, ASHA, and International Hearing Society. The commenters concern was not being able to perform cerumen (ear wax) management and tinnitus (ringing or other noise). They feel it would prohibit West Virginia hearing impaired from receiving log lasting hearing healthcare.

American Speech Language-Hearing Society recommended SLPA supervisors should be able to communicate with patient and SLPA in real time via telecommunication software.

International Hearing Society agreed with Legislature Rule §29-19-9 but recommended hearing aid dispenser supervisors have more flexibility in supervision to accommodate life events, such as illness preventing the direct supervision from being in the building. They feel the supervisor should be able to designate another licensed hearing aid dispenser to supervise a trainee when life occurs.

99 Edmiston Way, Box 11 – Suite 214, Buckhannon, WV 26201
Email: [redacted]
Web Site: [redacted]
Phone: 304-473-4289 Fax: 304-473-4291 In-state toll free number: 877-462-5460
~Pamela Coughlin~ Executive Director~

International Hearing Society recommended we amend WV Code §30-26-1 definitions. See public comment attached.

We appreciate all the comments provided. As such, the proposed rules are strong reflections of our Mission Statement and the WV Code.

Thank you,

Pamela Coughlin

Pamela Coughlin
Executive Director

99 Edmiston Way, Box 11 -- Suite 214, Buckhannon, WV 26201
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~Pamela Coughlin~ Executive Director~

BESLPA, WV <wvbeslpa@wv.gov>

Please rescind proposed rules 29-01 section 8.2.3 and section 8.2.6

1 message

Robert Knapp <robert.knapp@hearbetterwv.com> Fri, Jun 28, 2024 at 4:30 PM

To: wvbeslpa@wv.gov

Dear Chairperson Pullins, and Members of the Board,

I am opposed to the proposed rules 29-01 section 8.2.3 (cerumen management) and section 8.2.6 (tinnitus) that prohibit hearing aid dispensers to remove cerumen and provide tinnitus care. The following negative consequences will ensue if these proposed changes are enacted:

- Limit access to care: These changes will restrict access to hearing healthcare services from licensed hearing aid dispensers for over 343,000 West Virginians seeking hearing healthcare, including those in rural and underserved areas that rely on hearing aid dispensers for care.
- Increase consumer costs: Requiring patients to schedule additional medical appointments will result in incurring unexpected expenses and adding weeks or months to the process of attaining hearing healthcare services.
- Reduce competition: The proposal will stifle competition by imposing unsubstantiated prohibitions or limitations not based on data or previous disciplinary actions.
- Create an uneven playing field: The proposed modifications significantly change the hearing aid dispenser rules misaligning them with the current statute. This introduces new restrictions and referral requirements for dispensers, potentially creating an uneven playing field between hearing aid dispensers and audiologists.

I recognize that hearing aid dispensers do not provide comprehensive treatment for tinnitus or cerumen. They can however perform initial evaluations and basic management to determine the severity of such and recommend appropriate follow-up care. In cases where complications arise or there are signs of underlying medical issues, they refer patients to a physician for further evaluation.

Licensed hearing aid dispensers have an essential role in bridging the communication gap between their patients and other individuals around them. Dispensers have long been recognized by patients and the healthcare community as vital providers and we are dedicated to exceptional patient care and safety, achieved through comprehensive training, a strict code of conduct, and ongoing education.

I therefore respectfully ask the Board to rescind the proposed scope of practice restrictions in proposed changes 29-01 section 8.2.3 and section 8.2.6 on hearing aid dispensers.

I welcome you to contact me if you would like to discuss this issue further.

Sincerely,

Robert L Knight

LHIS, BC-HIS

Technical & Support Services Manager

McCandless Enterprises, LLC

Dear Chairperson, Pullins, and Members of the Board,

As the President of the W.V. Hearing Society, a certified Audioprosthologist, and Nationally Board Certified Hearing Instrument Specialist that provides many and varied services for my clients and as a representative of hearing specialist throughout West Virginia I find I must express opposition to proposed rules 29-01 section 8.2.3 (cerumen management) and section 8:2.6 (tinnitus) that seeks to prevent cerumen removal and tinnitus care.

I and many of the hearing specialists in this state provide services for over 300,000 West Virginians seeking hearing healthcare services that they find difficult to access due to the often rural and undeserved nature of the state.

While our services are often offered in homes and at local senior and various service centers throughout this state, the scheduling of cerumen and tinnitus care with physicians can cause serious unexpected expenses to many. A number of hearing specialist take great care in helping those undeserved clients with cerumen management in an initial and minimal capacity while understanding that serious blockages or any other medical needs must be referred to medical clinics for appropriate follow-up care. Taking away such care will harm these undeserved populations.

Furthermore, tinnitus care can be a much more difficult and expensive service to access from medical facilities. Keeping in mind that many Hearing Aids today have built in tinnitus maskers that can help relieve the symptoms of mild to moderate tinnitus issues at no additional expense or scheduling difficulties, taking such care from these clients would be detrimental to their healthcare and give them an unfair disadvantage to getting proper treatment.

Unnecessarily limiting such care will limit competition and can cause rising pricing for hearing healthcare to a majority of the hearing impaired in West Virginia. Adding new restrictions on hearing specialist, who in some cases have gone to expense for the added training, only limit our effectiveness and ability to care for our clients who depend on our care and can create an uneven and unfair playing field. Surely using all of the specialists, Audiologists and ENT doctors will give the population of West Virginia the best possible care at all levels of expertise.

As recognized vital providers by clients and other professional in this state, much the same as many other states across the country, we are dedicated to exceptional patient care and safety that comes from training and years of experience, and a strict code of conduct in the hearing healthcare field.

Therefore, I respectfully request the Board to rescind the proposed scope of practice restrictions in 29.01 section 8.23. and section 8.26 on hearing aid dispensers.

Please feel free to contact me if you would like to discuss this further.

Regards,
Martin J. Elbin, President, W.V. Hearing Society, ACA, BC-His, lic. State of OH/WV
Elbin Hearing Centers, inc.
520 Grand Central Avenue, ste 201
Vienna, WV 26105 304-893-9484

ASHA
American
Speech-Language-Hearing
Association

June 27, 2024

Ms. Vickie Pullins, CCC-SLP
President
West Virginia Board of Examiners for Speech-Language Pathology and Audiology
99 Edmiston Way, Ste. 214, Box 11
Buckhannon, WV 26201

RE: Assistant Regulations

Dear Ms. Pullins:

On behalf of the American Speech-Language-Hearing Association (ASHA), I write to express support, with recommended amendments, for the rules governing audiology assistants and speech-language pathology assistants (SLPAs) and their supervisors.

ASHA is the national professional, scientific, and credentialing association for 234,000 members, certificate holders, and affiliates who are audiologists; SLPs; speech, language, and hearing scientists; audiology assistants and SLPAs; and students. Over 1,100 ASHA members reside in West Virginia.[1] The following are ASHA's recommended amendments.

Recommended Changes to Allow for the Remote Supervision of Assistants

Under Sections 29-2-2 (Definitions), 4.1.0, and 7.1.9, a supervisor must be physically present for both direct and indirect supervision. We recommend adjusting both. As these definitions are currently worded, they don't allow the supervisor to adjust based on the skills and experience of the assistant. The level of supervision should be determined during the initial onboarding period. ASHA's guidance relating to assistants supports supervision, including remote supervision, based on the needs, competencies, skills, expectations, philosophies, and experience of the assistant and the supervisor; the needs of clients, patients, and students served; the service setting; and the tasks assigned.[2]

For audiology assistants under Sec. 7.1.9, we recommend this section include remote supervision by incorporating the following policy:

> A licensed audiologist may remotely supervise an audiology assistant using real-time audio-visual telecommunication software that enables the patient and the audiology assistant to see and hear the audiologist and vice versa. Further, remote supervision should only be allowed if the supervising audiologist deems the assistant is capable of performing the duties without a licensed audiologist physically present.

For SLPAs under Sec. 4.1.0, we recommend incorporating the following policy:

> To supervise the SLPA, the SLP should be able to communicate with the patient and SLPA in real time via telecommunication software (e.g., virtual platforms), webcam, telephone, or similar devices and services. Further, remote supervision should only be allowed if the supervising SLP deems the SLPA is capable of performing the duties without a licensed SLP physically present.

Additional Proposed Changes to the Regulations

Under Sec. 3.1.2, we recommend adding language specifying how the practicum hours are achieved. ASHA recommends providing the option of obtaining these hours via the academic practicum or on the job with a current/former licensed audiologist or SLP.

Under Sec. 4.1.2 and 7.1.2, the language should identify the specific supervision training. We recommend adding language requiring at least two hours of professional development in clinical instruction/supervision and the completion of a minimum of nine months of professional experience. This language would be consistent with the requirements of ASHA's assistants certification program.

Under Sec. 4.1 and 7.1, we recommend adding a requirement for supervisors to obtain continuing education to stay current with clinical standards for supervision. ASHA's guidance states that the supervisor is responsible for ensuring that they have the skills and competencies needed to provide appropriate supervision. This includes completing required continuing education in supervision and seeking additional continuing education to remain current in this area.

Under Sec. 4.1.3 and 7.1.3, ASHA asks the board to clarify what is meant by "participate significantly in the hiring of the assistant."

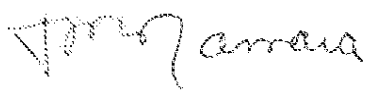
Under Sec. 4.1.10 and 7.1.9, we suggest deleting the language listing the specific types of facilities that an assistant may practice, as the list may not be all-inclusive and may cause confusion.

Under Sec. 4.1.8 and 7.1.7, ASHA asks the board to clarify what is meant by "weeks of treatment." As written, this term may cause confusion about how often supervisors are to have direct contact with each patient/client.

Under 7.1.19, the regulation incorrectly references an SLPA and needs to be changed to audiology assistant.

Thank you for considering ASHA's support, with recommendations, for the rules governing audiology assistants and SLPAs and their supervisors. If you or your staff have any questions, please contact Eileen Crowe, ASHA's director of state association relations, at ecrowe@asha.org.

Sincerely,



Tena L. McNamara, AuD, CCC-A/SLP
2024 ASHA President

[1] American Speech-Language-Hearing Association. (2023). *West Virginia* [Quick Facts]. https://www.asha.org/siteassets/advocacy/state-fliers/west-virginia-state-flyer.pdf.
[2] American Speech-Language-Hearing Association. (n.d.). *Scope of Practice for the Speech-Language Pathology Assistant (SLPA)*. https://www.asha.org/policy/slpa-scope-of-practice/

International Hearing Society

www.ihsinfo.org

June 28, 2024

West Virginia Board of Examiners for Speech-Language Pathology and Audiology
99 Edmiston Way
Box 11, Suite 214
Buckhannon, WV 26201

Subject: Public comments to proposed rule changes to Title 29 Legislative Rule West Virginia Board of Examiners for Speech-Language Pathology and Audiology for consideration by the West Virginia Board of Examiners for Speech-Language Pathology and Audiology

Dear Chairperson, Pullins, and Members of the Board,

The West Virginia Hearing Aid Society and International Hearing Society (IHS) appreciates this opportunity to share with the West Virginia Board of Examiners for Speech-Language Pathology and Audiology (herein referred to as "the Board") our concerns to proposed rule changes to Title 29 Legislative Rule West Virginia Board of Examiners for Speech-Language Pathology and Audiology (herein referred to as "29-01"). We respectfully urge the Board to rescind and revise the proposed rules 29-01 section 8.2.3 (cerumen management) and section 8.2.6 (tinnitus). Our comments will address the contradictions of the proposed changes and the appropriate and necessary role of hearing aid dispensers in providing cerumen and tinnitus care. We understand the Board's intent is to provide vague language; nevertheless, clarity is needed for compliance, thus helping individuals and organizations understand their legal obligations.

The proposed changes to Title 29 will have negative consequences:

- **Limit access to care**: These changes will restrict access to hearing healthcare services from licensed hearing aid dispensers for over 343,000 West Virginians seeking hearing healthcare, including those in rural and underserved areas that rely on hearing aid dispensers for care.
- **Increase consumer costs**: Requiring patients to schedule additional medical appointments will result in incurring unexpected expenses and adding weeks or months to the process of attaining hearing healthcare services.
- **Reduce competition**: The proposal will stifle competition by imposing unsubstantiated prohibitions or limitations not based on data or previous disciplinary actions.
- **Create an uneven playing field**: The proposed modifications significantly change the hearing aid dispenser rules misaligning them with the current statute. This introduces new restrictions

and referral requirements for dispensers, potentially creating an uneven playing field between hearing aid dispensers and audiologists.

While hearing aid dispensers do not provide comprehensive treatment (medical management) for tinnitus or cerumen, they can perform initial evaluations to determine the severity of the condition and basic management, as well as recommend appropriate follow-up care as warranted through the dispensing of hearing aids and related devices. If complications arise, their condition is severe, or there are signs of underlying medical issues, they refer patients to a physician for further evaluation, as they have historically done.

Rulemaking Authority:

Our comments are based on a review and evaluation of whether the proposed changes align with the current practices of hearing aid dispensers in West Virginia and nationwide. This analysis helps ensure that the proposed provisions in 29-01 do not impose unreasonable requirements or prohibitions on the regulated community and align with existing best practices while ensuring public safety.

Below are the specific concerns with the Board's proposed provisions:

Proposed Rule: 8.2.3: "The scope of practice for hearing aid dispensers DOES NOT include and prohibits…cerumen management."

IHS considers cerumen management, a practice encompassing cerumen removal as understood by the hearing healthcare community, to be within the scope of practice for a hearing aid dispenser. This includes administering cerumen removal when examining ears, taking ear impressions, and/or fitting hearing aids. If, during routine cerumen removal, a hearing aid dispenser discovers any trauma (e.g., continuous bleeding, lacerations), they are trained to refer their patient to an otolaryngologist (ear, nose, and throat specialist) as soon as possible. Patients exhibiting contraindications to cerumen removal requiring medical consultation should be referred to a medical liaison (established beforehand) for further evaluation.

Individuals with hearing impairment often present with cerumen, which can cause hearing problems, limit a prescription hearing aid's effectiveness, prevent an accurate ear assessment, or all three. The amount of cerumen and its impact can vary, from little cerumen, to fully impacted.

It is unnecessary to require licensed hearing aid dispensers to refer all their patients with cerumen impeding a thorough hearing exam or proper ear impression mold (used to determine hearing aid specifications) to schedule an appointment with their primary care physician for removal, leading to potentially two extra appointments because they would then need to return to their licensed hearing aid dispensers for a hearing test and/or another attempt at the mold. Alternatively, patients may resort to purchasing a do-it-yourself ear cleaning kit to avoid the cost of the extra doctor's visit.

There are many available education courses on cerumen removal available courses; workshops include both theoretical and practical components for effective earwax removal. These courses and workshops are readily available to hearing aid dispensers, audiologists, and ENTs. Courses are offered by AAO-

HNS, IHS, AAA and Ear Care & Cerumen Management (Institute of Otorhinolaryngology). These courses teach students:

- Cerumen classification,
- Use of appropriate instruments,
- Safe and effective removal techniques,
- Identifying complications and contraindications,
- Asking for relevant medical history and current medications, and
- Knowing when to refer a patient to their medical liaison.

While regulations in most states do not explicitly mention cerumen management, licensing laws generally authorize the performance of services that involve at least a limited degree of cerumen management, such as otoscopic evaluation, taking ear impressions for ear molds, and cleaning hearing aids. Currently, North Carolina, Tennessee, South Dakota, and Wisconsin explicitly authorize hearing aid specialists to perform cerumen management – marking the growing recognition of this service and need for hearing instrument specialists to fill the need statutorily.

In April 2018, the U.S. Department of Labor (DOL) adopted national guidelines for a hearing aid specialist apprenticeship program. Within the DOL guidelines, the DOL recognized the profession as: "In a manner consistent with the individual licensee's state law" to include "Elicit patient case histories; perform otoscopy for the purpose of identifying contraindications to testing or ear impression; administer cerumen management if properly trained; perform audiometric testing to determine candidacy for hearing aids or assistive devices; take ear impressions; refer to other healthcare providers for appropriate clinical, rehabilitative, or medical interventions; select and fit appropriate hearing aids and assistive devices; assess hearing aid efficacy; design and modify ear molds and auditory equipment; provide counseling and aural rehabilitative services; provide tinnitus management to patients who exhibit symptoms of tinnitus during an evaluation of hearing loss conducted for the purpose of determining the appropriateness of hearing aids and/or tinnitus devices; provide supervision and in-service training of those entering the dispensing profession; and provide ongoing hearing aid care and repair services.

Suggested revisions for the Board's consideration:

§29-1-8. Scope of practice for Hearing Aid ~~Dealers~~ Dispensers

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8.1.4 A hearing aid dispenser may remove cerumen in the course of examining ears, taking ear impression molds, or fitting of hearing aids. If a hearing aid dispenser, while engaged in cerumen removal for those purposes, discovers any trauma, including, but not limited to, continuous uncontrolled bleeding, lacerations, or other traumatic injuries, the hearing aid dispenser shall, as soon as possible, refer the patient to an otolaryngologist or a licensed physician if no otolaryngologist is available. The hearing aid dispenser shall be responsible for obtaining the training, knowledge, and skills necessary to perform cerumen removal.

Proposed Rule: 8.2.:6 "The scope of practice for hearing aid dispensers DOES NOT include and prohibits… tinnitus evaluation and therapies."

It is the position of IHS that tinnitus management falls within the scope of practice for a hearing aid dispenser. This includes assessing tinnitus during a hearing evaluation, and recommending and selecting appropriate tinnitus management devices when a patient exhibits tinnitus symptoms while being evaluated for hearing aids or tinnitus devices.

The U.S. Food and Drug Administration (FDA) defines a tinnitus masker as "an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech." The FDA does not restrict licensed hearing aid dispensers from using tinnitus maskers. Use of the masking feature enables the patient to utilize all the features of their hearing aid, enabling licensed hearing aid dispensers to provide optimal and continuous hearing healthcare for their patients, provide symptom relief for patients, keep patients' healthcare costs down, and free up other hearing healthcare providers' time to work on more complex hearing healthcare issues. Licensed hearing aid dispensers have used a standard practice for evaluating tinnitus for many years across North America. This process includes using recognized standard tools including but not exclusive of the Tinnitus Handicap Inventory questionnaire to assess the severity of tinnitus and determine if tinnitus masking could be beneficial; audiologists commonly use this same tool. Nearly everyone experiencing chronic tinnitus also experiences hearing loss.

Available tinnitus care education programs for hearing healthcare professionals:

- IHS Tinnitus Care Provider Certificate Program: Offered by the International Hearing Society, this program taught by audiologists provides comprehensive training on tinnitus management and when to refer patients to other healthcare professionals.
- American Academy of Audiology (AAA) Tinnitus Management Program: AAA offers resources and continuing education opportunities focusing on tinnitus assessment and management.
- American Tinnitus Association (ATA): ATA provides various educational materials, webinars, and resources for both patients and healthcare professionals on tinnitus management.

Manufacturers and other education providers like Audiology Online also commonly offer tinnitus courses for hearing aid dispensers.

Lastly, erecting barriers to the ability of those experiencing tinnitus to obtain the relief provided by tinnitus masking features of hearing aids not only through the activation of the tinnitus masking feature(s), but the exact setting of said feature is unnecessary, unsupported by evidence, and will cause those who suffer from tinnitus in addition to hearing loss to go without the help they seek. Any professional who has assisted a hearing-impaired individual with a tinnitus masker knows that ultimately it is the user who, after listening to multiple settings, determines which setting works best for them. To fit a masker properly, a professional generally needs to spend at least 45-60 minutes, spread out over two visits, to activate and adjust the settings in consultation with the user to arrive at the preferred setting. Many individuals with hearing loss are reluctant to seek help, and enacting a medically unsupported hurdle to obtain relief is inconsistent with the public interest and should be remedied.

Suggested revisions for the Board's consideration:

§29-1-8. Scope of practice for Hearing Aid ~~Dealers~~ Dispensers

***

8.1.5 A hearing aid dispenser may provide tinnitus care, including the assessment of tinnitus symptoms, and advising patients on sound therapy techniques and other strategies to address tinnitus symptoms, to a patient who exhibits symptoms of tinnitus during an evaluation of hearing loss conducted for the purpose of determining the appropriateness of hearing aids .The licensed hearing aid dispenser shall be responsible for obtaining the training, knowledge, and skills necessary to perform tinnitus management.

Anti-competitiveness:
Additionally, we have concerns over what may be perceived as anticompetitive provisions in the proposed addition of 16.26.3 - an issue the U.S. Federal Trade Commission (FTC) has taken interest in recent years, especially when one profession is making rules that affect another profession in which they have a personal stake. June 3, 2013, the FTC charged that the North Carolina Board of Dental Examiners impermissibly ordered non-dentists to stop providing teeth-whitening services, which has made it harder to obtain these services and more expensive for North Carolina consumers. On February 25, 2015, the U.S. Supreme Court affirmed the 4th Circuit's decision and the position of the FTC by stating that "a state board on which a controlling number of decision makers are active market participants in the occupation the board regulates" is not exempt from scrutiny or immune from liability unless the board is actively supervised by the state. The Supreme Court said that more than "a mere façade of state involvement" is required; N.C. State Bd. of Dental Examiners v. Fed. Trade Comm'n.

The Board is tasked with protecting the public from unsafe practices and from occupational practices that tend to reduce competition in the profession under its purview. The proposed prohibitions reduce competition between the licensees the Board oversees.

Trainee supervision:
Proposed section 19.9 prohibits "a person holding a trainee permit to engage in the practice of dispensing hearing aids except while under the direct supervision of a specified licensed hearing aid dispenser or audiology dispenser." While we agree that a trainee should only be authorized to dispense hearing aids under supervision, we ask for more flexibility in supervision to accommodate life events, such as illness preventing the direct supervisor from being in the building. We respectfully ask the Board to allow a licensed supervisor (primary supervisor) to designate another licensed hearing aid dispenser to supervise a trainee when a life event occurs.

We recommend an option for the Board's consideration that is similar to Kentucky's training/apprenticeship stages:

1. Stage I (up to 30 days): The trainee works under direct supervision but cannot fit or test patients for hearing instruments.
2. Stage II (up to 150 days): The trainee, supervised by a licensed hearing aid dispenser, conducts testing, fitting of hearing instruments, and makes ear impressions. Direct supervision is required for final fittings by the primary supervisor or their designee.
3. Stage III (up to 180 days): The apprentice engages in all activities of a licensed specialist but remains under the supervision by the primary supervisor or their designee.

Training documentation clarification is needed by the Board. We recommend that the Board develop and distribute a training document form for each training stage for the supervisor to complete and submit to the Board to comply with training requirements, preferably in consultation with the West Virgina Hearing Aid Society. Additionally, the form should be posted on the Board's publicly available website.

U.S. FDA OTC Final Rule:
We would be remissive if we did not take this opportunity to discuss the August 2022 United States Food and Drug Administration's (FDA) regulatory changes that:

1. Created the new "Over-The-Counter (OTC) hearing aid" category and
2. Reclassified any non-OTC hearing aids as "prescription" hearing aids that now require a "prescription or other order from a state-licensed practitioner."[1]

These changes necessitate states to make corresponding statutory and regulatory technical amendments to ensure continued access to essential hearing health care services. IHS recommends the appropriate technical amendments be made to West Virgina's hearing aids laws and regulations.

The reason this is important is because the phrase "order the use of" is not synonymous with the words "sell" or "selection" (currently included in §30-26-1. Definitions). Example amendment:

> Unless the context clearly requires otherwise, as used in this article:
> ***
> (8) "Practice of dealing in or fitting of hearing aids" means and includes:
>
> (a) The measurement or other testing of human hearing by means of an audiometer, or by any other means;
>
> (b) The ordering the use of selection, adaptation, fitting or sale of hearing aids by a person for the use of another person; or
>
> (c) The making of impressions for earmolds.
>
> ***

Furthermore, due to the new federal OTC rule and the FDA's reclassification of "traditional hearing aids," which have been dispensed by licensed hearing aid dispensers and audiologists for decades, as "prescription medical devices," (now commonly referred to as non-over-the-counter hearing aids) must be "prescribed or ordered the use of" by a "state-licensed practitioner."[2] Since licensure is under the jurisdiction of the state, states must authorize licensed hearing aid dispensers and licensed audiologists to "prescribe or order the use of" these devices for their hearing-impaired patients. This is the phrase the FDA uses and that is why IHS is recommending adding "order the use of" as a technical amendment.

To alleviate confusion, the FDA affirmed its intention, in an October 2022 letter to the States, that the reclassification of non-OTC hearing aids should not change who is authorized to prescribe or order the

[1] 21 C.F.R. § 801.109(a)(1).
[2] 21 C.F.R. § 801.109(a)(1).

use of these hearing aids.[3] The FDA reiterated that "the final rule defining non-OTC hearing aids as prescription devices is not intended to create barriers to accessing hearing aids, including prescription devices. It does not require the involvement of different or additional health care providers or examinations upon the effective date."

As the Board knows, hearing loss can affect a person in several ways, including but not limited to:

- Fewer educational and job opportunities due to impaired communication.
- Social withdrawal due to reduced access to services, inadequate care, and difficulties communicating with others.
- Emotional problems caused by a drop in self-esteem and confidence.

A January 10, 2023, research paper titled "Hearing Loss and Dementia Prevalence in Older Adults in the US" from Johns Hopkins linked hearing loss to walking problems, falls, and even dementia, with a fivefold increased risk for severe hearing impairment. Additionally, the Johns Hopkins research found that mild hearing loss doubled dementia risk. Moderate loss tripled dementia risk, and people with a severe hearing impairment were five times more likely to develop dementia. Furthermore, the additional cost and inconvenience of seeing more than one healthcare provider is a potential one of many barriers for some individuals seeking hearing aids. In other words, attaining timely hearing healthcare and removing unnecessary barriers to care is critically important.

In addition, it takes about five years for someone to accept help from the time they suspect they need hearing healthcare services, and someone may opt to forgo care, seek other avenues of care that are not clinically proven, and revert to the beginning of the long acceptance cycle.

Finally, this letter represents our concerns at this time and should not limit us from providing future comments or concerns regarding proposed rules 29-01, 29-04, and 29-05.

Thank you for your attention to our concerns, as well as those of numerous stakeholders, with these proposed additions. We respectfully urge the Board to rescind and revise proposed rules 29-01 section 8.2.3 and 8.2.6.

Any questions on this issue, please contact IHS' Manager of Government Affairs, Christine Seitz, at cseitz@ihsinfo.org or (734) 522-7200.

Respectfully,

Marsha Mattingly, BC-HIS
Vice President, West Virginia Hearing Aid Society

[3] FDA Letter to State Officials, dated October 13, 2022, *available at* https://www.fda.gov/medical-devices/consumer-products/hearing-aids#:~:text=Letter%20to%20State%20Officials%20about%20access%20to%20prescription%20hearing%20aids.