

DG_Final Written Testimony_SB449.pdf

Uploaded by: Senator Gile

Position: FAV



THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

**Testimony in Support of SB449
Health Occupations - Practice Audiology – Definition**

Madame Chair, Vice Chair Klausmeier, and Fellow Members of the Senate Finance Committee:

Through the Food and Drug Administration Reauthorization Act of 2017 (FDARA), Congress directed the Food and Drug Administration (FDA) to establish a category of over-the-counter (OTC) hearing aids through regulatory rulemaking. FDA's final rule establishing this new category of hearing aids became effective on October 22, 2022.¹ In conjunction with the new OTC hearing aids, the FDA created a new category of "prescription" hearing aids that did not exist previously.

Prior to October 2022, hearing aids were "restricted" devices, meaning they could only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation. The final rule does not change the hearing aids being used; it only changes the conditions for sale.

The intent of the law and the corresponding rule is to provide more accessibility and affordability to hearing aids. Under the new FDA regulation, a consumer may obtain a hearing aid through a "prescription" or "order" from an audiologist or hearing instrument specialist. However, the FDA left it up to the states to update their laws to ensure that these practitioners have the authority to do so.

SB 449 updates the practice of audiology definition to mirror the FDA's final rule language, including ordering and prescribing prescription hearing aids. While the FDA uses the term "prescription" hearing aids, the agency is referring to the exact same hearing aids that audiologists and dispensers have been selling to consumers for decades.

¹ <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>

Since the finalized rule was published, third party commercial insurance payers (e.g., BlueCross/BlueShield, United Healthcare) have started referencing prescription hearing aids in their 2023 benefits. SB 449 will now ensure patients can use their insurance hearing aid benefits when purchasing prescription hearing aids.

To respond to stakeholder feedback and concerns raised in the Health and Government Operations Committee hearing on the House cross-file of this bill (HB401), I have submitted an amendment that would:

- Add language to include hearing aid dispensers' ability to continue working with (now) prescription hearing aids.
 - This alleviates the concerns from the International Hearing Society (IHS), Hearing Industry Association (HIA), and Amplifon/Miracle Ear.
- Remove all references of osseointegrated hearing aid, bone anchored hearing device, and cochlear implants.
 - This alleviates the concerns from the American Speech-Language-Hearing Association (ASHA) and ensures there is no scope of practice misunderstandings.
- Remove the clarifying language "ORDER, EVALUATE, DIAGNOSE, MANAGE, OR TREAT ANY AUDITORY OR VESTIBULAR CONDITION IN THE HUMAN EAR" from page 2, lines 15-16 that would have mirrored the practice of audiology definition with other clinical doctoring professions in Maryland and other audiology practice definitions in other states.
 - This alleviates the concerns from the ear, nose, and throat (ENT) surgeons and MedChi.

The FDA terminology must be codified to remove any ambiguity or misinformation to allow constituents to obtain prescription hearing aids from their provider, which this bill does.

For these reasons, I respectfully request a favorable report on Senate Bill 449.

SB449_FinalReprint

Uploaded by: Senator Gile

Position: FAV

UNOFFICIAL COPY OF SENATE BILL 449

SENATE BILL 449

J2

3lr2407
CF HB 401

By: **Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, and Ready**

Introduced and read first time: February 2, 2023

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 ~~Health Occupations - Practice Audiology - Definition~~ **Maryland Audiology, Hearing Aid**
3 **Dispensing, Speech-Language Pathology, and Music Therapy Act - Definitions and Application**

4 FOR the purpose of altering the definition of "hearing aid dispensing" to include certain actions taken for
5 the purpose of ordering certain hearing instruments and specifying that certain hearing instruments include
6 prescription hearing aids; altering the definition of "practice audiology" for the purposes of certain
7 provisions of law governing the licensure of audiologists; providing that certain provisions of law do
8 not apply to certain actions taken with respect to certain over-the-counter hearing aids; and
9 generally relating to
10 the ~~practice of audiology~~ Maryland Audiology, Hearing Aid Dispensing, Speech-Language Pathology,
11 and Music Therapy Act.

12 ~~BY renumbering~~

13 ~~Article - Health Occupations~~
14 ~~Section 2-101(r) through (u)~~
15 ~~to be Section 2-101(s) through (v), respectively~~
16 ~~Annotated Code of Maryland~~
17 ~~(2021 Replacement Volume and 2022 Supplement)~~

18 ~~BY adding to~~

19 ~~Article - Health Occupations~~
20 ~~Section 2-101(q)~~
21 ~~Annotated Code of Maryland~~
22 ~~(2021 Replacement Volume and 2022 Supplement)~~

23 BY repealing and reenacting, with amendments,

24 Article - Health Occupations
25 Section ~~2-101(e)~~ 2-101(h) and (q) and 2-102
26 Annotated Code of Maryland
27 (2021 Replacement Volume and 2022 Supplement)

28 BY repealing and reenacting, without amendments,

29 Article - Health Occupations
30 Section 2-301(a)(1)
31 Annotated Code of Maryland
32 (2021 Replacement Volume and 2022 Supplement)

2

UNOFFICIAL COPY OF SENATE BILL 449

1 ~~SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,~~
 2 ~~That Section(s) 2-101(r) through (u) of Article Health Occupations of the Annotated Code~~
 3 ~~of Maryland be renumbered to be Section(s) 2-101(e) through (v), respectively.~~

4 SECTION ~~2-1,~~ AND BE IT FURTHER ENACTED BE IT ENACTED BY THE GENERAL ASSEMBLY OF
 MARYLAND, That the Laws of Maryland read
 5 as follows:

6 Article - Health Occupations

7 2-101.

8 ~~(q) "OSSEO-INTEGRATED DEVICE" MEANS A BONE-ANCHORED HEARING~~
 9 ~~DEVICE OR COCHLEAR IMPLANTS.~~

(h) (1) "Hearing aid dispensing" means performing, conducting, and
interpreting hearing assessment procedures to determine the type and extent of
hearing loss for the purpose of:

(i) Fitting AND ORDERING suitable hearing
instruments, INCLUDING PRESCRIPTION HEARING AIDS;

(ii) Selecting suitable hearing instruments;

(iii) Programming a hearing aid by selecting and determining the
frequency response, compression, output, gain, or other parameters of the hearing aid
for initial wear by an individual or any required alterations throughout the use of the
hearing aid;

(iv) Making ear molds or ear impressions; and

(v) Providing appropriate counseling.

(2) "Hearing aid dispensing" includes:

(i) An act pertaining to the ORDERING, selling, renting,
leasing, or delivering of a hearing instrument, INCLUDING A PRESCRIPTION
HEARING AID; and

(ii) Providing maintenance or repair services for a hearing aid.

10 ~~{(q)} (r)~~ [(1)] "Practice audiology" means to [apply]:

11 (1) APPLY the principles, methods, and procedures of measurement,
 12 prediction, evaluation, testing, counseling, consultation, and instruction that relate to the
 13 development and disorders of hearing, vestibular functions, and related language and
 14 speech disorders, to ~~prevent or modify the disorders or assist individuals in hearing and~~
 15 ~~auditory and related skills for communication.~~ ~~ORDER, EVALUATE, DIAGNOSE,~~
 16 ~~MANAGE, OR TREAT ANY AUDITORY OR VESTIBULAR CONDITION IN THE HUMAN EAR;~~
 17 AND

18 (2) ["Practice audiology" includes the fitting or selling of] PRESCRIBE,
 19 ORDER, SELL, DISPENSE, OR FIT hearing aids ~~OR OSSEO-INTEGRATED DEVICES TO~~
 20 AN INDIVIDUAL FOR THE CORRECTION OR RELIEF OF A CONDITION FOR WHICH
 21 HEARING AIDS ~~OR OSSEO-INTEGRATED DEVICES~~ ARE WORN.

2-102.

(a) This title applies to an individual who practices audiology, hearing aid
dispensing, speech-language pathology, or music therapy, or assists in the practice of
speech-language pathology or audiology in the State.

(b) This title does not:

(1) Limit the right of an individual to practice a health occupation that the individual is authorized to practice under this article;

(2) Prohibit an individual from practicing any other profession that the individual is authorized to practice under the laws of this State;
[or]

(3) Limit the right of a physician who is authorized to practice medicine under the laws of the State to treat the human ear or fit hearing aids; OR

(4) APPLY TO THE SERVICING, MARKETING, SALE, DISPENSING, USE, CUSTOMER SUPPORT, OR DISTRIBUTION OF OVER-THE-COUNTER HEARING AIDS THROUGH IN-PERSON TRANSACTIONS, BY MAIL, OR ONLINE AS AUTHORIZED BY FEDERAL LAW AND REGULATIONS.

22 2-301.

23 (a) (1) Except as otherwise provided in this title, an individual shall be
24 licensed by the Board before the individual may practice audiology, hearing aid dispensing,
25 speech-language pathology, or music therapy, or assist in the practice of speech-language
26 pathology or audiology in this State.

27 SECTION ~~2~~ 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
28 ~~October~~ July 1, 2023.

SB449_SponsorAmendment

Uploaded by: Senator Gile

Position: FAV



SB0449/253425/1

AMENDMENTS
PREPARED
BY THE
DEPT. OF LEGISLATIVE
SERVICES

24 FEB 23
15:19:27

BY: Senator Gile
(To be offered in the Finance Committee)

AMENDMENTS TO SENATE BILL 449
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 2, strike “**Health Occupations – Practice Audiology – Definition**” and substitute “**Maryland Audiology, Hearing Aid Dispensing, Speech–Language Pathology, and Music Therapy Act – Definitions and Application**”; in line 3, after the first “of” insert “altering the definition of “hearing aid dispensing” to include certain actions taken for the purpose of ordering certain hearing instruments and specifying that certain hearing instruments include prescription hearing aids;”; in line 4, after “audiologists;” insert “providing that certain provisions of law do not apply to certain actions taken with respect to certain over–the–counter hearing aids;”; in line 5, strike “practice of audiology” and substitute “Maryland Audiology, Hearing Aid Dispensing, Speech–Language Pathology, and Music Therapy Act”; strike in their entirety lines 6 through 16, inclusive; and in line 19, strike “2–101(q)” and substitute “2–101(h) and (q) and 2–102”.

AMENDMENT NO. 2

On page 2, strike in their entirety lines 1 through 3, inclusive; in lines 4 and 27, strike “2.” and “3.”, respectively, and substitute “1.” and “2.”, respectively; in line 4, strike “AND BE IT FURTHER ENACTED” and substitute “BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND”; strike in their entirety lines 8 and 9; in line 10, strike the first set of brackets; in the same line, strike “(R)”; in line 14, strike the bracket; strike beginning with the period in line 15 down through “EAR” in line 16; and in lines 19 and 21, in each instance, strike “OR OSSEO–INTEGRATED DEVICES”.

AMENDMENT NO. 3

On page 2, after line 9, insert:

“(h) (1) “Hearing aid dispensing” means performing, conducting, and interpreting hearing assessment procedures to determine the type and extent of hearing loss for the purpose of:

(i) Fitting AND ORDERING suitable hearing instruments, INCLUDING PRESCRIPTION HEARING AIDS;

(ii) Selecting suitable hearing instruments;

(iii) Programming a hearing aid by selecting and determining the frequency response, compression, output, gain, or other parameters of the hearing aid for initial wear by an individual or any required alterations throughout the use of the hearing aid;

(iv) Making ear molds or ear impressions; and

(v) Providing appropriate counseling.

(2) “Hearing aid dispensing” includes:

(i) An act pertaining to the ORDERING, selling, renting, leasing, or delivering of a hearing instrument, INCLUDING A PRESCRIPTION HEARING AID; and

(ii) Providing maintenance or repair services for a hearing aid.”.

AMENDMENT NO. 4

On page 2, after line 21, insert:

“2-102.

(a) This title applies to an individual who practices audiology, hearing aid dispensing, speech–language pathology, or music therapy, or assists in the practice of speech–language pathology or audiology in the State.

(b) This title does not:

(1) Limit the right of an individual to practice a health occupation that the individual is authorized to practice under this article;

(2) Prohibit an individual from practicing any other profession that the individual is authorized to practice under the laws of this State; [or]

(3) Limit the right of a physician who is authorized to practice medicine under the laws of the State to treat the human ear or fit hearing aids; OR

(4) APPLY TO THE SERVICING, MARKETING, SALE, DISPENSING, USE, CUSTOMER SUPPORT, OR DISTRIBUTION OF OVER–THE–COUNTER HEARING AIDS THROUGH IN-PERSON TRANSACTIONS, BY MAIL, OR ONLINE AS AUTHORIZED BY FEDERAL LAW AND REGULATIONS.”;

and in line 28, strike “October” and substitute “July”.

MD Senate Finance Committee_HIA Letter of Support

Uploaded by: Bridget Dobyhan

Position: FWA



February 27, 2023

The Honorable Melony Griffith, Chair
The Honorable Katherine Klausmeier, Vice Chair
Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

RE: SB 0449 (support for amendment)

Dear Members of the Senate Finance Committee:

We write today to express appreciation for your support for licensed hearing professionals, both audiologists and hearing aid dispensers, and urge you to adopt the revisions provided in HB 0401, as amended, to SB 0449.

HB 0401, as amended, will make clear the continuing authority of both licensed audiologists and hearing aid dispensers to dispense prescription hearing aids. This change is necessary following the October 2022 effective date of the final rule establishing over-the-counter hearing aids ("OTC hearing aids"), published by the U.S. Food and Drug Administration ("FDA").¹ This rule provided that all hearing aids that are not OTC hearing aids are reclassified as "prescription hearing aids" that may "be sold only to or on the prescription or other order of a practitioner licensed by law to use or order the use of (prescribe) the devices." As part of the rule, FDA defers to States to determine appropriate licensing requirements for dispensing prescription hearing aids.

Before the effective date of the OTC hearing aid rule, FDA issued guidance to States clarifying that a prescriber need not be a physician, physician assistant, or nurse practitioner, but that the intent of FDA 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."²

HB 0401, as amended, is consistent with FDA guidance, a memo issued by the Maryland Department of health, and the actions of other States to ensure the continued authority of

¹ Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing aids, 87 Fed. Reg. 50698 (August 17, 2022)

² U.S. Food and Drug Administration, Dear State Official Letter (October 13, 2022), <https://www.fda.gov/media/163084/download>

licensed audiologists and hearing aid dispensers to provide what are now deemed “prescription hearing aids” as they have prior to the effective date of the OTC rule issued by FDA.³

We appreciate your support for licensed hearing professionals and, more importantly, support for those with hearing loss. As amended, the House bill makes clear the authority of licensed hearing professionals to provide prescription hearing aids and supports continued access for those who need them. We urge the Senate to adopt these changes to SB 0449.

Hearing health is essential, and the use of hearing aids can help avoid the negative social, emotional, and health consequences of hearing loss. Beyond the associated comorbidities of hearing loss, there are significant positive impacts on overall health and wellbeing, with 8 in 10 individuals who treat their hearing loss reporting life-changing results. Access to licensed hearing professionals is an important part of treating hearing loss, as those with hearing loss report even higher rates of satisfaction with their hearing professional.

We are pleased to support your efforts to clarify the authority of licensed audiologists and hearing aid dispensers to order the use of prescription hearing aids. We look forward to continuing to work together to support licensed hearing professionals and individuals with hearing loss.

Sincerely,

A handwritten signature in black ink that reads "Kate Carr". The signature is written in a cursive, flowing style.

Kate Carr
President
Hearing Industries Association

³ Over-the-Counter Hearing Aids FAQs, Maryland Department of Health (October 17, 2022), <https://health.maryland.gov/boardsahs/Documents/OTC%20Memo.pdf>

IHS and Chapter Testimony Re SB 449.pdf

Uploaded by: Christine Seitz

Position: FWA

February 27, 2023

On behalf of the Hearing Society of Maryland, Washington, D.C. & Delaware (Chapter) and the International Hearing Society (IHS), I would like to thank the Chair, Vice Chair, and the Committee members for the opportunity to testify and submit comments on Senate Bill 449, "Altering the definition of "practice audiology."

Passage of this bill in its current form would be extremely problematic for licensed hearing aid dispensers in Maryland and the hearing-impaired public they serve. While we understand one intention is to add services related to osseointegrated devices to licensed audiologists' scope of practice, the bill also authorizes audiologists to be able to "prescribe" and "order" hearing aids while failing to also include the same authorization to licensed hearing aid dispensers. IHS and the Maryland Society respectfully request an amendment to SB 449 to add to hearing aid specialists' scope of practice the acts of prescribing and ordering hearing aids.

Despite their historical role as hearing aid providers, without amendment, passage of SB 449 could have the unintended consequence of restricting licensed hearing aid dispensers from being able to prescribe and/or order the use of non-over the counter hearing aids that were newly classified by the Food and Drug Administration as prescription medical devices in October 2022. If hearing aid dispensers, who presently dispense about half of all hearing aids to the public, are not granted the authorization to also prescribe and order hearing aids, and this bill goes into effect, they could be accused of practicing audiology without a license. Further, excluding licensed hearing aid dispensers would drive up consumer costs due to the need for multiple healthcare appointments, potentially put many of these providers out of business, and it **would create a barrier to hearing healthcare services by limiting your hearing-impaired constituents to 50% of the points of access.**

According to the Centers for Disease Control ([CDC](#)) 4 percent of Maryland residents have a hearing disability. Hearing loss can affect a person in three main ways:

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

The FDA notified states in October, related to its updating federal rules governing hearing aids, that its intention is for licensed hearing professionals to continue to dispense hearing aids as they have historically done, and that despite their reclassifying (non-over the counter) hearing aids as prescription devices, a licensed provider who is authorized by the state to prescribe or order hearing aids shall continue to be able to do so. The FDA concluded the October letter by stating that "the final rule defining non-OTC hearing aids as prescription devices does not, and 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." While we take no issue with the practice of audiology newly incorporating the services of prescribing and ordering hearing aids this cannot be done without its reciprocal inclusion in the definition of hearing aid dispensing, the practice of which hearing aid dispenser have been authorized to perform for decades prior to these devices being reclassified.

We respectfully request SB 449 be amended to authorize hearing aid dispensers to order and sell prescription hearing aids.

The Chapter and IHS thank Senator Gile for championing this important piece of legislation.

Thank you Chair, Vice Chair and the Committee members for hearing us out and considering an amendment to SB 449 that adds the acts of prescribing and ordering hearing aids to a licensed hearing aid dispenser's scope of practice. I welcome any questions.

MSO Testimony 2023 - Support with Amendment- Senat

Uploaded by: Daniel Shattuck

Position: FWA

MARYLAND SOCIETY OF OTOLARYNGOLOGISTS

SUBJECT: Senate Bill 449 – Health Occupations – Practice Audiology – Definition
COMMITTEE: Senate Finance Committee
The Honorable Melony Griffith, Chair
DATE: Tuesday, February 28, 2023
POSITION: Support with Amendment

The Maryland Society of Otolaryngologists (MSO) represents more than 300 physicians who live and practice in Maryland. Otolaryngologists are physicians who diagnose and treat the ear, nose, throat, and related structures of the head and neck; most commonly referred to as ear, nose, and throat specialists (ENTs).

Senate Bill 449 as introduced would expand the scope of services and procedures an audiologist can provide in Maryland. This would include allowing Audiologists to:

- (1)...ORDER, EVALUATE, DIAGNOSE, MANAGE, OR TREAT ANY AUDITORY OR VESTIBULAR CONDITION IN THE HUMAN EAR; AND
- (2) PRESCRIBE, ORDER, SELL, DISPENSE, OR FIT hearing aids OR OSSEO-INTEGRATED DEVICES TO AN INDIVIDUAL FOR THE CORRECTION OR RELIEF OF A CONDITION FOR WHICH HEARING AIDS OR OSSEO-INTEGRATED DEVICES ARE WORN.

The bill as drafted is broad and greatly expands an audiologist's scope of practice. The terms "...diagnose, manage [and] treat" are among the roles being added to the "practice of audiology. This terminology traditionally falls under the practice of medicine. When these terms are used in other health occupations they are limited or qualified by a requirement for a higher level of education and training within that specialty.

The medical disorders treated by our physicians are among the most common that afflict everyone, young and old. They include chronic ear infection, sinusitis, hearing loss (from gradual to sudden onset), swallowing disorders, hoarseness, dizziness, balance issues and head and neck cancer. These disorders and conditions while seemingly simple can often be complex and multi-factorial. Our member Otolologists diagnose and treat the conditions impacting the structure and function of the ear and auditory system. Our member Otorhinolaryngologists diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck.

In response to these concerns, the bill has been amended by the House Health and Government Operations Committee (attached). We understand that those same amendments will be introduced at this hearing. These amendments address our concerns with regard to the expansion of scope and aligns with the Audiologists' current scope under law and regulation.

Our foremost commitment is to deliver the best patient care and use best practices. We often work side by side with our Audiologists colleagues and together face the challenging conditions and disorders our patients present. **With these agreed to amendments we ask for a favorable report on Senate Bill 449.**

For further information please contact: Mark Dettelbach M.D. – President, madmd1964@yahoo.com

AMENDMENTS from the HOUSE HGO Reprint of House Bill 401:

The amendments below remove proposed language that would expand the scope of Audiologists practice:

1. Lines 15-16 STRIKE "~~ORDER, EVALUATE, DIAGNOSE, MANAGE, OR TREAT ANY AUDITORY OR VESTIBULAR CONDITION IN THE HUMAN EAR;~~"
2. Lines 19 and 21 STRIKE: "~~OR OSSEO-INTEGRATED DEVICES~~"

With these essential amendments MSO supports passage of this bill.

AMENDED BILL TEXT:

10 ~~(q)~~ ~~(r)~~ (q) [(1)] "Practice audiology" means to
[apply]:

11 (1) APPLY the principles, methods, and procedures of measurement,
12 prediction, evaluation, testing, counseling, consultation, and instruction that relate to the
13 development and disorders of hearing, vestibular functions, and related language and
14 speech disorders, to prevent or modify the disorders or assist individuals in hearing and
15 auditory and related skills for communication. ~~ORDER, EVALUATE, DIAGNOSE,~~
16 ~~MANAGE, OR TREAT ANY AUDITORY OR VESTIBULAR CONDITION IN THE HUMAN EAR;~~
17 AND

18 (2) ["Practice audiology" includes the fitting or selling of] PRESCRIBE,
19 ORDER, SELL, DISPENSE, OR FIT hearing aids ~~OR OSSEO-INTEGRATED DEVICES TO~~
20 AN INDIVIDUAL FOR THE CORRECTION OR RELIEF OF A CONDITION FOR WHICH
21 HEARING AIDS ~~OR OSSEO-INTEGRATED DEVICES~~ ARE WORN.

A Spoor SB 449 Testimony- final 20230228.pdf

Uploaded by: Dr. Alicia Spoor

Position: FWA



Maryland Academy of Audiology

P.O. Box 710

Parkville, MD 21234

<https://maaudiology.org/>

February 28, 2023

The Honorable Melony G. Griffith, Chair
Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: SB 449 Practice Audiology – Definition

Position: **SUPPORT WITH AMENDMENTS**

Alicia D.D. Spoor, Au.D. Testimony

Madam Chair Griffith, Vice Chair Klausmeier, and Committee Members,

My name is Alicia Spoor, and I am a licensed Maryland audiologist, small business owner in Howard County, and the current Legislative Chair for the Maryland Academy of Audiology (MAA). The MAA represents the more than 520 licensed audiologists in the State of Maryland.

I am here in **strong** support of Senate Bill 449 and am pleased to be working with Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, and Ready to codify the recent Food and Drug Administration Final Rule language on Over The Counter (OTC) hearing aids by updating the Maryland Practice of Audiology Definition.

Since 2014, numerous government agencies have discussed the accessibility and affordability of hearing healthcare in the United States, including the National Academies of Science, Engineering, and Medicine¹ (NASEM), the Food and Drug Administration² (FDA) and the Federal Trade Commission³ (FTC). One of the NASEM recommendations (Recommendation 7) was to 'Implement a New Food and Drug Administration Category for Over-The-Counter Wearable Hearing Devices'. The United States Congress addressed this recommended and passed the "Over The Counter Hearing Aid Act in 2017" as part of the FDA Reauthorization Act of 2017⁴ (FDARA). In October, 2022 the FDA released the Final

¹ <https://www.nationalacademies.org/our-work/accessible-and-affordable-hearing-health-care-for-adults>

² <https://www.federalregister.gov/documents/2016/01/07/2016-00065/streamlining-regulations-for-good-manufacturing-practices-for-hearing-aids-public-workshop-request>

³ <https://www.ftc.gov/news-events/events/2017/04/now-hear-competition-innovation-consumer-protection-issues-hearing-health-care>

⁴ <https://www.congress.gov/bill/115th-congress/house-bill/2430>

Rule for OTC Hearing Aids to allow consumers aged 18 years or older to purchase non-surgical, air-conduction hearing aids for perceived mild to moderate hearing loss without the involvement of a licensed professional (e.g., audiologist, hearing aid dispenser, physician).

The FDA took additional action and created a new category of “prescription” hearing aids. A prescription hearing aid is defined as “...a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.”⁵ The FDA Final Rule requires prescription hearing aids to be dispensed by licensed providers as governed by state law.

Very simply, before the FDA Final Rule became effective in October 2022, audiologists recommended, fit, sold, and dispensed what was termed “restricted” hearing aid devices. Those same identical ‘restricted’ devices are now in a new category of ‘prescription’ devices.

To make sure there is absolute, unambiguous clarifying language in the audiology practice definition, audiologists must be able to continue to prescribe and order prescription hearing aids to comport with the new Federal Rule.

Updating the audiology practice definition to mirror other Maryland clinical doctors (e.g., optometrists, chiropractors, podiatrists, dentists) and other states’ audiology practices with well-defined language to evaluate, diagnose, manage, and treat auditory and vestibular conditions in the human ear distinctly separates audiologists from physicians, who practice medicine: diagnose, heal, treat, and provide surgery.⁶

Maryland’s licensed audiologists have been prescribing hearing aids to minors for many years, in accordance with established statute (§15-838).⁷ Children are often considered one of the most vulnerable populations and significant safeguards are placed to guarantee their welfare. Audiologists are the primary providers in their hearing healthcare by virtual of audiologist’s education and training. Therefore, prescribing and ordering hearing aids to individuals over the age of 18 years do not introduce any new concerns that are not already addressed with minors.

When passed, SB 449 will update and codify the Maryland Statute with the FDA Final Rule language to ensure it does not become more difficult for your constituents to obtain hearing aids now (prescription hearing aids) than it was before October, 2022, when the hearing aids were categorized as “restricted” devices.

⁵ <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>

⁶ <https://dhs.maryland.gov/documents/Licensing-and-Monitoring/Maryland%20Law%20Articles/RCC/HEALTH%20OCCUPATIONS%20Title%2014%20Physicians.pdf>

⁷ <https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=gin§ion=15-838&enactments=false>

Thank you for your time and consideration Madam Chair Griffith, Vice Chair Klausmeier, and Sponsor Senator Gile and all co-sponsors. I ask for a favorable committee report on SB 449 to help your constituents.

Alicia D.D. Spoor, Au.D.
Legislative Chair, Maryland Academy of Audiology

BB Holtan SB 499 Testimony- final 20230228.pdf

Uploaded by: Dr. Briana Holtan

Position: FWA



Maryland Academy of Audiology

P.O. Box 710

Parkville, MD 21234

<https://maaudiology.org/>

February 28, 2023

The Honorable Melony G. Griffith, Chair
Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: SB 449 Practice Audiology – Definition

Position: **SUPPORT WITH AMENDMENTS**

Briana Bruno Holtan, Au.D. Testimony

Madam Chair Griffith, Vice Chair Klausmeier, and Committee Members,

My name is Briana Holtan, and I am a licensed practicing audiologist and business partner of one of the largest and oldest private practices in the State of Maryland. On behalf of the Maryland Academy of Audiology, we are pleased to be working with Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, and Ready to codify the recent Food and Drug Administration (FDA) Final Rule¹ language on Over The Counter (OTC) hearing aids by updating the Maryland Practice of Audiology Definition.

The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation.² They are often referred to as one of *the* most careful, deliberate, and conservative government agencies.

As a daily provider of audiologic care, one of my duties is to verify benefits from third-party insurance payers (e.g., BlueCross/BlueShield, United Healthcare, Aetna, Cigna). The 2023 hearing aid benefits from payers already incorporate the FDA's Final Rule and use the terminology of "prescription" hearing aids. SB 449 legislation would ensure the audiology practice language is consistent with governmental agencies and third-party insurance payers' systems and will therefore allow patients to use their benefits and have coverage for the newly

¹ <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>

² <https://www.usa.gov/federal-agencies/food-and-drug-administration>



MARYLAND ACADEMY OF
AUDIOLOGY

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<https://maaudiology.org/>

defined 'prescriptive' hearing aid devices when ordered and prescribed by a licensed audiologist in Maryland.

Thank you for your time and consideration Madame Chair Griffith, Vice Chair Klausmeier, and Sponsor Senator Gile and all co-sponsors. I ask for a favorable committee report on SB 449 to help your constituents.

Briana Bruno Holtan, Au.D.

Doctor of Audiology

Audiology Associates, Inc.

M Segev SB 449 Testimony- final 20230228.pdf

Uploaded by: Melissa Segev

Position: FWA



Maryland Academy of Audiology

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February 28, 2023

The Honorable Melony G. Griffith, Chair
Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: SB 449 Practice Audiology – Definition

Position: SUPPORT WITH AMENDMENTS

Melissa Segev, Au.D. Testimony

Madam Chair Griffith, Vice Chair Klausmeier, and Committee Members,

My name is Melissa Segev, and I am a second generation licensed audiologist and small business owner of one of the largest and oldest private practices in the State of Maryland. On behalf of the Maryland Academy of Audiology, we are pleased to be working with Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, and Ready to codify the recent Food and Drug Administration (FDA) Final Rule language on Over The Counter (OTC) Hearing Aids by updating the Maryland Practice of Audiology Definition.

Prior to the Food and Drug Administration Final Rule¹, hearing aids were categorized as “restricted” devices. When the FDA released the OTC Hearing Aid Final Rule in October, 2022, they created a new category of “prescription” hearing aids, although it was not required under the Congressional mandate. FDA defined “prescription” hearing aids as hearing aids that do not meet the definition of OTC hearing aids. Further, a prescription hearing aid is defined by technical specifications and intended use, must be dispensed by a licensed person as governed by state law, and federal preemptions are limited.

In practice, “prescription” and “restricted” hearing aids are not different. The labeling has changed to comply with the new category, but the requirement for a professional to dispense the device, the technical specifications, main components of the device (microphone, receiver/speaker, amplifier, and battery) and intended use are mainly unchanged. What was a

¹ <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>



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“restricted” hearing aid in September, 2022 was essentially renamed a “prescription” hearing aid in October, 2022.

As an audiologist, I followed in my father’s footsteps to provide quality of life to patients in the area of hearing and balance healthcare. The FDA Final Rule caused a pause with the new prescription hearing aid category as it affected my patients’ ability to obtain devices from my colleagues and me. SB 449 would update the semantics of the Audiology code to eliminate any ambiguity around the FDA’s new hearing aid categories and ensure that my patients and your constituents can choose their path for improved hearing healthcare.

Thank you for your time and consideration Madame Chair Griffith, Vice Chair Klausmeier, and Sponsor Senator Gile and all co-sponsors. I ask for a favorable committee report on SB 449 to help your constituents.

Melissa Segev, Au.D.
Doctor of Audiology
Audiology Associates, Inc.

Letter of Support_Miracle Ear (Maryland SB 449) (1

Uploaded by: Shruti Kulkarni

Position: FWA



February 27, 2023

Honorable Melony Griffith, Chair
Honorable Katherine Klausmeier, Vice Chair
Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, Maryland 21401

RE: Support of SB449 (as amended in the House reprint for HB401)

Dear Members of the Senate Finance Committee:

I am Chief Audiology Officer for Miracle-Ear, Inc. – a leading hearing aid provider with 18 offices in Maryland. Miracle-Ear believes that patient safety, satisfaction, and access are of paramount importance in helping individuals address their hearing needs.

I write in support of SB449, as amended and issued as a reprint on February 22, 2023, for HB 401, which authorizes licensed audiologists and hearing aid dispensers to order the use of prescription hearing aids, consistent with intent of the U.S. Food and Drug Administration (FDA) and the Maryland Department of Health.¹ We ask that you adopt the language approved by the house for HB 401 for SB 449.

As you know, in August 2022, FDA promulgated regulatory changes to increase access to hearing aids, including establishing OTC hearing aids as a new category of medical devices.²

In the same regulation, FDA reclassified all Class I and II non-OTC hearing aids (i.e., traditional hearing aids that have been dispensed by state-licensed audiologists and hearing aid dispensers for the last 50 years) from “restricted medical devices” to “prescription medical devices” governed by 21 C.F.R. 801.109. Pursuant to 21 C.F.R. §801.109, non-OTC hearing aids may only be dispensed upon “the prescription or other order” of a practitioner licensed by law to direct the use of such device. In other words, for the first time in the United States, consumers and patients may only obtain non-OTC hearing aids upon a prescription or other order from a practitioner licensed under state law to direct the use of a “prescription hearing aid.”

FDA leaves it to states the authority to define which providers are qualified to prescribe or order non-OTC hearing aids (i.e., now effectively “prescription hearing aids”). FDA delegated this authority to states because the Agency does not have jurisdiction over practitioner licensure—this is left to states. However, shortly before the regulatory changes became effective, FDA issued supplemental guidance to states in a “Dear State Official” letter, making it clear that the agency’s intent was not to disrupt access to

¹ U.S Food and Drug Administration, Dear State Official Letter (October 13, 2022), *available at* <https://www.fda.gov/media/163084/download>; Maryland Department of Health, Over-the-Counter Hearing Aid, [OTC Memo.pdf \(maryland.gov\)](#)

² U.S Food and Drug Administration, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, (August 17, 2022), *available at* <https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids>

prescription hearings dispensed by state-licensed audiologists and hearing instrument specialists (referred to as hearing aid dispensers in Maryland). Specifically, in its guidance, FDA clarified that the regulatory changes related to the classification of non-OTC hearing aids as prescription medical devices:

“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.”³

Additionally, the guidance clarified that “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.”

Many states have begun to update their licensure and dispensing laws and regulations to align with this guidance. None of these states have sought to enact changes different from this guidance because doing so would severely hamper access to prescription hearing aids and would be contrary to the way in which hearing aids have been dispensed over the last 50 years.

Hearing loss is a serious health condition that can be associated with comorbidities of dementia, social isolation, and balance problems. Hearing aid dispensers and audiologists play a critical role in helping those suffering hearing loss obtain the help they need, including identifying whether hearing aids are needed, ruling out other underlying conditions that would impact a patient’s hearing, and ensuring that hearing aids are customized to the needs of the patient.

Without this legislation to provide necessary clarification that both licensed audiologists and hearing aid dispensers are authorized to prescribe or order the use of non-OTC hearing aids (again, now regulated by the FDA as prescription medical devices), Maryland remain vulnerable to losing crucial access to hearing care.

Please know I am available at (763) 710-1830 to answer any questions you or your policy staff may have regarding the concerns expressed herein.

Respectively,

Thomas J. Tedeschi

Dr. Thomas J. Tedeschi, AuD., FNAP
Chief Audiology Officer
Miracle-Ear, Inc.

³ U.S Food and Drug Administration, Dear State Official Letter (October 13, 2022), *available at* <https://www.fda.gov/media/163084/download>.

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Uploaded by: State of Maryland (MD)

Position: FWA



Board of Examiners for Audiologists, Hearing Aid Dispensers, Speech-Language Pathologists & Music Therapists

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

*Arifa Qureshi, Chair – Ohuremi Dean, Executive Director
4201 Patterson Avenue, Baltimore MD 21215 Phone: 410-764-4725*

2023 SESSION POSITION PAPER

BILL NO: SB 449
COMMITTEE: Finance
POSITION: SWA

TITLE: Health Occupations – Practice Audiology - Definition

BILL ANALYSIS: SB 449 will expand the definition of “practice audiology” and clarify the law generally related to the practice of audiology and governing the licensure of Audiologist.

POSITION AND RATIONALE: The Board of Examiners for Audiologists, Hearing Aid Dispensers, Speech-Language Pathologists, and Music Therapists (the Board) support with amendments SB 449 – Health Occupations – Practice Audiology – Definition.

The Board is in support of expanding the definition of “practice audiology” to remain consistent with Federal law. On October 17, 2022, the Over the Counter (OTC) Hearing Aids Final Rule went into effect. According to 21 CFR §801.109(a)(2), prescription hearing aids are any device that is not an OTC Hearing Aid. The Food and Drug Administration (FDA) also issued a response stating the final rule “Does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids”. Upon receiving clarification from the FDA, the Board believed amendments to our statute were not necessary. However, after a review of written testimony submitted for HB 401 and the reprint of the bill, the Board is in support of adding language to specify use of prescription hearing aids for both Audiologists and Hearing Aid Dispensers. The Board also wants to ensure that Audiologists working within various fields such as in research are not restricted within their scope of practice. Based upon the HB 401 reprint the Board recommends the following amendments:

Amendment 1

On page 2, strike lines 8-9.

Amendment 2

On page 2, lines 15-17 strike **ORDER, EVALUATE**; strike **ANY** and **IN THE HUMAN EAR** and substitute **CONDITIONS** for **CONDITION**.

This should read:

(1) "...and related language and speech disorders, to **DIAGNOSE, MANAGE, OR TREAT AUDITORY OR VESTIBULAR CONDITIONS; AND** "

Amendment 3

One page 2, lines 18-21, strike **PRESCRIBE, ORDER, SELL, DISPENSE, OR**; after **FIT**, strike **HEARING AIDS** through **WORN** and insert **DISPENSE, OR REPAIR PRESCRIPTION HEARING DEVICES SUCH AS HEARING AIDS**.

This should read:

(2) “**FIT, DISPENSE, OR REPAIR PRESCRIPTION HEARING DEVICES SUCH AS HEARING AIDS.**”

Thank you for your consideration of this testimony. The Board of Examiners for Audiologists, Hearing Aid Dispensers, Speech-Language Pathologists, and Music Therapists respectfully request a favorable report on SB 449 with proposed amendments.

For more information, please contact me at 410-764-4723 or at Oluremi.Dean@maryland.gov.

Sincerely,



Oluremi Dean, MHA
Executive Director
Board of Examiners for Audiologists,
Hearing Aid Dispensers, Speech-Language
Pathologists, & Music Therapists

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.