



Maryland Academy of Audiology
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<https://MAAudiology.org/>

October 3, 2022

The Honorable Brian E. Frosh
Maryland Attorney General
200 St Paul Place, 17th Floor
Baltimore, MD 21202

Re: Inadvertent Restriction of Audiologists Scope in Maryland to Now Prescribe Hearing Aids as a Result of FDA's Federal Final Rule

Dear Attorney General Frosh:

The Maryland Academy of Audiology (MAA) is asking you for an informal opinion, but a firm and immediate directive, as to the continuing ability of licensed Maryland audiologists to fit, dispense, recommend, and sell ('prescribe') hearing aids for patients under their current scope of practice.

The current scope authorizing section is found in Maryland Health Occupations Article, 2-101(q).

Since the inception of the statute, licensed audiologists in Maryland have been able to measure, evaluate, counsel, and describe the 'development and disorders of hearing.' In effect, de facto, audiologists have been prescribing hearing aids all along to 'prevent or modify' auditory or related issues for patients.

However, because the term 'prescription' has never been used federally to label hearing aids, 2-101(q) did not include this terminology. Audiologists have been performing all the elements of a 'prescription' by evaluating, counseling, fitting, and selling hearing aids since the 1970s.

On August 16, 2022, a 200+ page Federal Rule from the Food and Drug Administration (FDA) Final Rule was published enacting the Over the Counter (OTC) Hearing Aids legislation, allowing devices to be purchased by consumers, with an effective date of October 17, 2022. Audiologists welcome the means for consumers to purchase OTC hearing aids as access and affordability are key to hearing healthcare management and treatment.

In addition to the OTC hearing aids, the FDA re-classified all hearing aids that are not OTC devices, as "Prescription Devices" (Page 11/220, Definitions references 'Conditions for sale' and prescription

hearing aids), this technically restricts what Maryland Licensed Audiologists can prescribe because our current statute does not include the word 'prescribe'.¹

We acknowledge that what is ultimately needed is an update to the Maryland Statute to reconcile the new operative language that created a new labeling category of hearing aids and implemented the sale of Over-the-Counter hearing aids as a result of the FDA Final Rule.

However, the current problem (i.e., the lack of the word prescription) impacts audiologists in all 50 states and the District of Columbia (DC). Because the effective date of the change will go into effect on October 17, 2022, it is unlikely that the FDA will even consider amending the language timely.

Parenthetically, we note that the federal rule took five years to issue as a result of the Over-the-Counter Hearing Aid Act of 2017, passed by the 115th U.S. Congress as a rider to the FDA Reauthorization Act of 2017, Public Law No. 115-52.

Furthermore, the Maryland legislature will not be in session until January 2023 to address this legislatively. We have spoken to Senator Guy Guzzone, Chair of Budget and Taxation, who recognizes the problem and would support emergency legislation to address this issue, but that remedy would not be available until January 2023, at the earliest.

Without an immediate recognition that audiologists can continue to treatment individuals with hearing loss using hearing aids (that will remain unchanged, other than labeling), as they have in the past, without regulatory, civil, or criminal liability, the fear that a consumer or even another health care profession might seek an injunction against an audiologist or audiologist's practice for the same thing they did before the federal rule, would be a disaster for all Marylanders that seek access to audiologists for their professional help.

The MAA firmly believes that the FDA did not intend to potentially shut down audiology practices in all the states that do not have the word 'prescribe' or a variation in their statutes, merely because they created new labeling categories for hearing aids.

The MAA has been a proponent for an individual's access and affordability to hearing and balance healthcare, including services and devices. The MAA can only presume that the FDA's intent was in the best interest of patients and to assist in procuring not only OTC devices, but new prescription category hearing aids, not make it **more** difficult for individuals to obtain devices and services from licensed audiologists.

¹ <https://www.fda.gov/news-events/press-announcements/fda-finalizes-historic-rule-enabling-access-over-counter-hearing-aids-millions-americans>. The new final rule established a new category of OTC hearing aids. The OTC category allows for the sale of air-conduction hearing aids to adults (individuals over the age of 18 years) who have perceived mild to moderate hearing loss. The new OTC category provides access and affordability to many individuals seeking help for their hearing acuity. In addition to the OTC hearing aid category, the FDA created a new "prescription" category for hearing aids that are different from the OTC requirements. Currently, hearing aids are FDA-registered class I and II devices. Although the devices **will not** change in October, the categories **will** change to comply with the FDA Final Rule.

Until a statutory change can be passed and signed by the Governor, we ask that the Attorney General Opine that audiologists are allowed to continue to practice as they have for the past 50 years and are not prohibited from 'prescribing' any of the hearing aids they tested, fitted, dispensed and/or sold previously to October 17, 2022.

In addition to your determination of no liability, as audiologists continue to perform their medical services in good faith after October 17, 2022 you may wish to consider requesting that the Maryland Governor in conjunction with the Maryland Secretary of Health, issue an Executive Order that would implement your directive up and until the Maryland legislature can pass legislation that will reconcile the new federal terminology of categories of hearing aids (OTC and 'Prescriptive Devices') into the Maryland Health Occupations Article, Title 2, et seq.

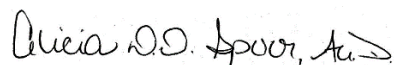
For your information, the MAA represents the more than 500 licensed audiologists who practice audiology in the state of Maryland, and the patients they serve. The MAA's goal is to enhance the ability of members to achieve career and practice objectives by fostering professional autonomy, providing quality continuing education, and increasing public and consumer awareness of hearing and balance disorders and the value of audiologic services. By virtue of education and licensure, Audiologists are the most qualified professionals to manage hearing and balance disorders.

An audiologist is a state-licensed professional who specializes in evaluating, diagnosing, treating, and managing patients with hearing loss, tinnitus, and balance (vestibular) disorders. Audiologists work in a variety of settings: private practice offices, hospitals, medical centers, out-patient clinics, public and private schools, universities (teaching and research), regulatory agencies, large-scale research centers, rehabilitation centers, skilled nursing facilities, assisted living facilities, the Veterans Administration, and the U.S. Military. Audiologists work closely with federal, state, and private third-party payers to optimize coverage of services provided for the evaluation and treatment of the patients in their care.

Please contact me at (443) 410-4410 or by email (Alicia.Spoor@gmail.com) for specific historic and current practice questions or Gil Genn of the Bellamy Genn Group at (301) 367-3191 or by email (Gil@BellamyGennGroup.com) for further information or if any clarification is necessary.

The MAA and the tens of thousands of Maryland patients whom audiologists serve look forward to your favorable opinion to clarify this unique situation.

Sincerely,



Alicia D.D. Spoor, Au.D.
Doctor of Audiology
Legislative Chair, MAA

Cc: Gil Genn, Esq.
Bellamy Genn Group, LLC