AMERICAN ACADEMY OF AUDIOLOGY

11480 Commerce Park Drive
Suite 220
Reston, VA 20191

tel 800-AAA-2336
fax 703-790-8631
www.audiology.org

August 24, 2022

Jeffrey Shuren, MD, JD
Director, Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: ***RIN 0910-AI21: Items of Clarification in Final Rule Establishing Over-the-Counter Hearing Aids and Related Amendments***

Dear Dr. Shuren:

I am writing on behalf of the American Academy of Audiology ("The Academy") with respect to two issues stemming from the recent final rule establishing a regulatory category for over-the-counter hearing aids and making related amendments to update the regulatory framework for hearing aids. It is our contention that clarification is needed for both of the items we raise in this communication to ensure that this final rule can be implemented in an expeditious manner. The Academy is the largest organization of, by, and for audiologists. We are dedicated to the provision of quality hearing and balance care services through professional development, education, research, and increased public awareness of hearing and balance disorders.

Existing State Requirements for Medical Clearance/Waiver and "Types" of Hearing Aids

We understand through our review of the final rule, and specifically Comment 125 with the Agency's response, that state or local requirements that were previously preempted because they differed from or were in addition to federal requirements (and for which FDA previously granted exemptions from Federal preemption) may continue in effect with respect to prescription hearing aids.

Many state audiology licensing laws currently include a requirement that an individual receive medical clearance or sign a document waiving that requirement prior to receiving a hearing aid. The final rule appears clear that these state provisions may continue to exist with regard to "prescription hearing aids." However, it is critical to note that current state laws or regulations do not differentiate between the two "types" of hearing aids as now defined in the final rule and instead reference only "hearing aids." We understand that the intent of this final rule is to eliminate barriers that would "restrict or interfere with" commercial activity involving OTC hearing aids, so to that end we would expect that states could not apply their medical clearance or waiver provisions to over-the-counter hearing aids.

Many state licensing boards may feel it necessary to change the applicable statute or regulation to clearly delineate the application of any medical clearance/waiver to the appropriate "type" of hearing aid before allowing or advising *licensees* (audiologists) as to the appropriate application of the requirement. Until a time when state licensing rules might be updated to differentiate requirements for OTC HAs versus prescription hearing aids, it will be important for the FDA to provide guidance to states in terms of how these provisions should be applied when the requirement applies to "hearing aids" but not specifically over-the-counter hearing aids or prescription hearing aids. It does not seem feasible for a rule to be

applied differently depending on the hearing aid being offered when the language is not specific in current state rules. This uncertainty on the part of state licensing boards may delay the timely implementation and uptake of these new devices. State-licensed audiologists are bound by the rules and regulations governing the practice of audiology and sale of hearing aids in the states, and they may be wary of deviating from existing rules and regulations and potentially imperiling their state license without some express declaration from either the FDA or their state licensing board. This differs from "dispensers," as defined in the final rule of OTC devices, who are not similarly bound by a state practice act. This dichotomy may impede the provision of these new devices through certain channels and have a deleterious impact on the intended goal of expanding access to consumers.

We request that the FDA issue a clarifying statement to ensure the timely implementation and usage of these new devices by consumers.

"Prescription Hearing Aids" Vs. Prescriptive Authority

We certainly understand the reasoning behind the delineation between "prescription" hearing aids and "hearing aids" or OTC hearing aids. However, we are concerned that some interests may equate "prescription" hearing aids as requiring a "prescription" from an individual with prescriptive authority as that term is currently used. Prescriptive authority is currently defined at the state level for mid-level practitioners such as nurse practitioners and physician assistants—and may differ depending on the type of practitioner. Audiologists are not included in this classification. In many cases, the state definition refers only to the prescribing of prescription drugs and controlled substances; however, there are some states (including but not limited to PA, VA, TX, WA) in which prescriptive authority is defined in some instances to also include devices and durable medical equipment.[1]

The entry-level degree for audiologists entering the field today is a clinical doctorate or AuD that requires four years of coursework/ practicum after the completion of a bachelor's degree. Graduate-level academic curriculum and training for audiologists require extensive coursework and practicum in all aspects of hearing aid fitting and aural rehabilitation and this is also reflected in the state practice acts for audiology in virtually all fifty states. Audiologists currently do not hold prescriptive authority in any state—and did not need or seek this designation because traditionally hearing aids have not been designated as specifically "prescription" devices.

This is another area that we request that the FDA provide additional clarification specifically regarding the distinction between "prescription hearing aids" and actual "prescriptive authority" as currently designated and used by mid-level practitioners in the states.

The Academy appreciates this opportunity to bring these questions or items for additional clarification to your attention. These issues potentially create unintended consequences that could limit access to hearing health care provided by audiologists. Clearly, it is not the intention of the final FDA rule to limit access, but rather the intent was to increase access. We would be happy to meet to provide further elaboration on our questions, as needed. We look forward to your anticipated prompt response so that we may provide additional guidance to our members.

---

[1] https://www.pacode.com/secure/data/049/chapter21/s21.285.html
https://law.lis.virginia.gov/vacode/title54.1/chapter29/section54.1-2957.01/
https://www.law.cornell.edu/regulations/texas/22-Tex-Admin-Code-SS-222-1
https://apps.leg.wa.gov/wac/default.aspx?cite=246-840-300

If you have any questions about this letter, please contact Susan Pilch, J.D., Senior Director of Government Relations as spilch@audiology.org.

Sincerely,

Sarah Sydlowski, AuD, PhD, MBA
2022 AAA President