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October 17, 2022

The Honorable Karen Lewis Young
Maryland General Assembly
416 House Office Bldg.
Annapolis, Maryland 21401
Via email

Dear Delegate Young:

You asked for advice after the Maryland Academy of Audiology raised concerns about the effect of the Food and Drug Administration's ("FDA") new regulations relating to hearing aids on the practice of audiology in the State of Maryland. I reached out to colleagues at the Maryland Department of Health and, as explained below, the new regulations should have no effect on that practice.

As you are aware, the FDA will soon classify hearing aids as either Over the Counter ("OTC") Hearing Aids that are intended to treat perceived mild to moderate hearing impairment or Prescription Hearing Aids, which include any device that are *not* OTC Hearing Aids. The FDA indicates that prescription hearing aids are "prescription devices" as defined by 21 C.F.R. § 801.109(a)(2), meaning that they may "be sold only to or on the prescription or other order of a licensed practitioner."

Section 2-101(q) of the Health Occupations Article defines the practice of audiology under Maryland law as the application of "the principles, methods, and procedures of measurement, prediction, evaluation, testing, counseling, consultation, and instruction that relate to the development and disorders of hearing, vestibular functions, and related language and speech disorders, to prevent or modify the disorders or assist individuals in hearing and auditory and related skills for communication," including "the fitting or selling of hearing aids." This definition of the practice of audiology includes what is commonly understood as "prescribing"—that is, advising and authorizing a patient to use a specific medication or medical device.

The FDA's response to several comments on its proposed rule supports that conclusion. It states that the FDA will treat prescription hearing aids as prescription devices that can "be sold only to or on the prescription *or other order* of a practitioner licensed by law to use or order the use of the devices in the course of professional practice. *See* 87 Fed. Reg. 50741 (Aug. 17, 2022) (emphasis added). The response further notes that "States, not FDA, generally determine the licensing requirements for practitioners to use or order the use of a prescription device." *See id*. The FDA expanded on that response in a letter to State officials dated October 13, 2022, in which it clarified that its intent was 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."

In conclusion, the FDA's new rule is primarily focused on expanding access to hearing aids that will make up the new "OTC Hearing Aid" category and does not, in our view, conflict with existing Maryland statute or regulation governing the practice of audiology.

Sincerely,

Sandra Benson Brantley
Counsel to the General Assembly