2/6/2023

Chair Joseline A. Pena-Melnyk
House Health & Government Operations Committee
Taylor House Office Building, Room 241
6 Bladen Street
Annapolis, MD 21401

RE: HB401 Practice Audiology -- Definition
Position: **SUPPORT**

Madam Chair Peña-Melnyk, Vice Chair Ariana Kelly, and Committee Members,

Thank you for taking the time to consider this testimony. I am writing to you as a private citizen in support of HB 401.

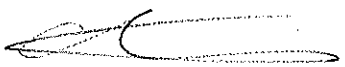
As you are undoubtedly aware, the FDA issued its ruling that allowed for the sale of OTC hearing aids. This was a good, pro-consumer change. Unfortunately, that was not all they did. As has been noted by Dr. Jeffrey Singer of the Cato Institute (included with testimony), the new rule redefined non-OTC hearings from being "restricted medical devices" to "prescription-only" devices and removed federal preemptions of state law that allowed audiologists to provide hearing aid services to their patients.

This unfortunate shift, which went beyond any congressional mandate for the creation of OTC-aids, means that without change in state law, patients with severe hearing loss or those under 18 will be blocked from getting the care they need without also getting a prescription from a physician.

The FDA has made clear they did not intend this outcome, expressly stating "*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.*" However, the agency is ignoring the fact that the new change removes federal protections and preemptions ensuring that is how things operate, leaving the onus on states to update their rules to preserve the old handling of non-OTC aids.

Given this reality, I strongly urge the committee to give a favorable report to this bill and move quickly to ensure Marylanders under 18 and those with severe hearing loss remain able to get the medical care they need from the professionals most qualified to provide it, without having to waste time, money, and quality of life jumping through hoops no one ever intended.

Sincerely,



Kevin Waterman

OCTOBER 18, 2022 3:09PM

OTC Hearing Aids—Did the FDA Give Patients Access with One Hand and Take Access Away with the Other?

By **Jeffrey A. Singer**

October 17, 2022 marked the day that hearing aids became available over the counter to people over age 18 with mild-to-moderate hearing loss. The Over-the-Counter Hearing Aid Act of 2017, a rider to the FDA Reauthorization Act of 2017, ordered the Food and Drug Administration to create a new category, OTC hearing aids, as devices that use air conduction to improve hearing for people in the above category.

This good news can make hearing aids more affordable and accessible for an estimated 30 million people who suffer from hearing loss. Opening this market will generate competition and innovation, drive down prices and increase consumer choice. A pair of hearing aids can cost as much as $6,000, and the FDA estimates the new rule will save consumers roughly $2,800 for a pair of hearing aids.

But there's one possible—though unintentional—wrinkle in the new FDA rule. The new OTC hearing aid rule creates a new "prescription-only" category for people with severe hearing loss or those under age 18. That might make it even more costly and difficult for those people to get hearing aids.

For the past several decades, the FDA has classified hearing aids as "restricted medical devices," not as "prescription-only" devices. Under this classification, patients could not obtain hearing aids without first seeing a professional who would test and fit them with the device. But those regulations expressly permitted audiologists to fill that role and did not require patients to see a physician or other prescribing health care practitioner. The federal regulations preempted state laws restricting access to hearing aids and limiting audiologists' roles.

The new OTC rule removes the "restricted device" designation from air-conduction hearing aids for people over 18 with mild to moderate hearing loss and preempts any state laws that might block such patients' access to OTC hearing aids. But the FDA also lifted all remaining state law preemptions. It also created a new, "prescription-only" category for the remaining types of hearing aids that were previously classified as "restricted." Congress did not mandate the new "prescription-only" category. Nor did Congress require the FDA to remove preemptions of state laws on hearing aid dispensing.

The FDA's removal of the old preemptions might mean that some states' old laws may now block patients under 18 or with severe hearing loss from getting hearing aids without a prescription from a physician. For example, Rhode Island law requires patients to obtain a certificate of need from a state-licensed physician before they can purchase hearing aids. This would mean the FDA's new rule might make it easier for some patients to get hearing aids while making it harder for others.

Responding to state officials' queries, the FDA claims the agency does not intend for its new rule to have that effect:

> **A State can authorize many kinds of practitioners to order the use of (or prescribe) a prescription device**. Federal regulations in § 801.109 do not require that a prescriber be a physician (a person licensed to practice allopathic or osteopathic medicine), physician assistant, or nurse practitioner. Instead, the relevant requirements for prescription devices apply in the case of practitioners licensed by the law of the State to use or order the use of the device (see § 801.109). **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**. Further, the final rule does not require the involvement of an additional licensed practitioner such as a physician. A licensed audiologist, for example, would not need to consult a physician under FDA's final rule. (Emphasis added in bold)

While the FDA's intent might be clear, states have the police power to license occupations and professions and define their scope of practice. The FDA's new "prescription-only" classification for some hearing devices makes the rules ambiguous. Do state regulators enforce heretofore preempted state laws, or do they reinterpret those laws to comport with the FDA's intent? States can also update their laws, but most state legislatures have adjourned and won't be convening until early next year. Hopefully, federal and state policymakers will clear the confusion quickly.

Of course, none of this regulatory perplexity would occur if Congress ended the FDA monopoly on requiring prescriptions, as Michael Cannon and I point out in this white paper. And if states replaced occupational and professional licensing laws with third-party certification, consumers wouldn't have to rely on regulators' interpretations of ambiguous edicts to exercise their right to self-medicate.

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