RIDOH Guidance Regarding FDA Final Rule on OTC Hearing Aids

On August 17, 2022, the US Food and Drug Administration ("FDA") published its Final Rule establishing a regulatory category for over the counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids. This rule, which preempts any inconsistent State law, becomes effective on October 17, 2022. The FDA rule may be accessed here: https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

The Rhode Island Board of Hearing Aid Dealers and Fitters addressed two issues of particular concern to members of the profession licensed under R.I. Gen. Laws § 5-49-1, et seq, and audiologists licensed under R.I. Gen. Laws § 5-48-1, et seq. Staff from RIDOH also participated in a meeting with representatives of the FDA on October 7, 2022 regarding these matters.

1. ***Certificate of Need and Waivers under RI State Law***

Rhode Island state law, in an effort to be consistent with old Federal law, requires a Certificate of Need signed by a physician for a consumer to engage in the purchase of a hearing aid. Also consistent with old Federal law, the State statute allows an adult consumer to sign a medical waiver for this requirement, which allows engagement with the hearing aid dealer without presentation of a Certificate of Need. The FDA's new rule eliminates the medical evaluation waiver, as well, under Federal law. As a result, The Board expressed concern that the State Certificate of Need required under RI Gen Laws §5-49-2.1 might be enforced by the state and could not be cured by the presentation of the medical waiver. In the future, RIDOH believes that the state statute and regulations on this topic will have to be amended or repealed to bring Rhode Island into conformance with Federal law. Until that time, RIDOH will recognize the

State medical waiver, as it has in the past. We adopt this position to assure that our State law follows the spirit of the new FDA rule, which is intended to lower barriers and costs for hearing aids.

2. Prescription Devices

The FDA final rule creates the detailed, technical category of OTC hearing aid. Any hearing aid that does not meet FDA's definition of an OTC hearing aid is considered by default to be a "prescription device," a term that is not defined in the relevant Rhode Island state laws. RIDOH understands that the lack of definition in state law may create confusion as to whether licensed audiologists and hearing aid dealers and fitters may continue to dispense hearing aids under their current licensure.

RIDOH will be considering amendments to the statute and/or regulations to incorporate FDA's new terminology. In the interim, we consider the "practice of fitting and dealing in hearing aids" under R.I. Gen. Laws § 5-49-1(6) as inclusive of the ability of licensed audiologists and hearing aid dealers and fitters licensed to order the use of "prescription devices" under their existing licensure, consistent with guidance issued by FDA on October 13, 2022. In summary, licensed audiologists and hearing aid dealers and fitters may continue to order and dispense traditional (Class I and Class II air conduction) hearing aids after the Final Rule implementation date (October 17, 2022) in accordance with their current licensure to maintain the status quo until such time as Rhode Island laws and regulations can be revised in accordance with Federal law and intent.

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Dated: October 14, 2022