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National Council of Insurance Legislators (NCOIL)

Resolution Regarding Audiology Services, Hearing Instrument Specialists Services, and Classification of Non-Over The Counter Hearing Aids as Prescription Devices

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Sponsored by Rep. Deanna Frazier Gordon (KY) and Rep. Michael Sarge Pollock (KY)

Draft as of March 26, 2025. To be introduced and discussed during the Health Insurance & Long-Term Care Issues Committee on April 25, 2025.

WHEREAS, in August 2022, the United States Food and Drug Administration (FDA) promulgated regulatory changes establishing over-the-counter (OTC) hearing aids as a new category of medical devices while classifying all non-OTC hearing aids as prescription medical devices; and

WHEREAS, as a result of the FDA's actions, for the first time in the United States, consumers and patients may now only obtain a Class I and II non-OTC hearing aid (i.e., traditional hearing aids) with a prescription or other order from a state-licensed practitioner; and

WHEREAS, since 1977, these devices were regulated by the FDA as "restricted medical devices" governed by specific conditions of sale, labeling requirements, and device controls, but without the need for a prescription; and

WHEREAS, the FDA's policy shift to regulating non-OTC hearing aids as "prescription devices" has generated confusion among practitioners and policymakers at the state level; and

WHEREAS, under the FDA's "prescription device" regulation, non-OTC hearing aids may only be dispensed upon "the prescription or other order" of a practitioner licensed by law to direct the use of such device; and

WHEREAS, because the FDA does not have jurisdiction over practitioner licensure, the agency ultimately left it up to the States to define which providers are qualified to prescribe or order non-OTC hearing aids; and

WHEREAS, NOW, THEREFORE BE IT RESOLVED, that the National Council of Insurance Legislators (NCOIL) recommends that States amend applicable statutes and

regulations to allow for the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date of the new FDA rules to continue to do so for prescription hearing aids after the effective date of FDA's regulatory changes; and

WHEREAS, NOW, THEREFORE BE IT FURTHER RESOLVED, as the FDA recommended to states, it is critically important to update State statutes to expressly authorize both hearing instrument specialists (also referred to as hearing aid specialists, hearing aid dispensers, among others) and audiologists to "order (or prescribe) the use of" hearing aids, consistent with the FDA's prescription device regulation (21 CFR 801.109); and

WHEREAS, NOW, THEREFORE BE IT FURTHER RESOLVED, that NCOIL finds that by adopting the statutory definitions contained in Appendix A to this Resolution, States will ensure that Audiology and Hearing Aid Specialist professions will continue to have the same authority as prior to the FDA's rule change and disruption in care for consumers will be avoided; and

WHEREAS, BE IT FINALLY RESOLVED, a copy of this Resolution shall be sent to the Chairs of the Committees with jurisdiction over healthcare, and occupational and professional licensure in each legislative chamber in each state.

APPENDIX A

Definitions

(1) "Over-the-counter hearing aid" means air conduction hearing aids that satisfy the requirements in the Over-the-Counter Hearing Aid Controls, 21 C.F.R. sec. 800.30(c) to (f), and are considered available over the counter pursuant to 21 U.S.C. sec. 360j(q)(1)(A)(v), but do not satisfy the regulatory requirements for prescription hearing aids.

(2) “Practice of audiology” means [prescribing or ordering], selling, dispensing, or fitting hearing aids to an individual for the correction or relief of a condition for which hearing aids are worn.

(3) “Practice of hearing instrument specialists” means [prescribing or ordering], selling, dispensing, or fitting suitable hearing instruments, including prescription hearing aids.

(4) “Prescription hearing aid” means a Class 1 or Class 2 device as defined in the federal Food, Drug and Cosmetic Act, 21 U.S.C. sec. 321(h), that is not an over-the-counter hearing aid as defined in Over-the-Counter Hearing Aid Controls, 21 C.F.R. sec. 800.30, or a hearing aid that does not satisfy the regulatory requirements for over-the-counter hearing aids.