AAPAN | AMERICAN ASSOCIATION OF PAYERS, ADMINISTRATORS AND NETWORKS

HNA Hearing Network Alliance

ALIGNING STATE LAWS AND REGULATIONS TO FDA'S CLASSIFICATION OF NON-OTC HEARING AIDS AS PRESCRIPTION DEVICES

The American Association of Payers, Administrators and Networks' (AAPAN) Hearing Network Alliance (HNA) believe in the value of hearing benefits and their demonstrated efficacy in delivering quality outcomes. AAPAN provides a unified, integrated voice for payers, third-party administrators, networks and care management in the group/government health and workers' compensation market. HNA is a council within AAPAN that consists of members representing hearing network management organizations. HNA focuses on promoting the merits of hearing health care not only to better serve the tens of millions of Americans currently living with some form of hearing loss, but also on encouraging regular professional screening and preventative care to the millions more certain to develop hearing degeneration as they age.

HNA calls upon state legislatures and regulatory bodies to adjust their laws and regulations to make it clear that licensed audiologists and hearing aid specialists have the authority to "prescribe and order the use of" prescription hearing aids. Importantly, making these changes will ensure that patient access to hearing care and hearing aids is not hindered.

In August 2022, FDA promulgated regulatory changes establishing OTC hearing aids as a new category of medical devices while classifying all non-OTC hearing aids as prescription medical devices. These changes took effect on October 17, 2022.

Effectively, for the first time in the United States, consumers and patients may 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. Since 1977, these devices have been regulated by FDA as "restricted medical devices" governed by specific conditions of sale, labeling requirements, and device controls, but without the need for a prescription.

Unfortunately, FDA's policy shift to regulating non-OTC hearing as a "prescription devices" has generated confusion among practitioners and policymakers at the state level. Under 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.[1] Because FDA does not have jurisdiction over practitioner licensure, the agency ultimately left it up to states to define which providers are qualified to prescribe or order non-OTC hearing aids.

After becoming aware of the confusion generated by the policy shift, FDA issued supplemental guidance to states in a "Dear State Official" letter, making it clear that the agency's intent was not to disrupt access to prescription hearing aids dispensed by state-licensed audiologists and hearing instrument specialists (often referred to as hearing aid dispensers or specialists). Specifically, in its guidance, FDA clarified that the regulatory changes related to the classification of non-OTC hearing aids as prescription medical devices do "not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting, and dispensing of these devices." Additionally, the guidance clarified that "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."

Because FDA does not have jurisdiction over practitioner licensure, it is ultimately up to the states to define which providers are qualified to prescribe or order non-OTC hearing aids. Many states are now beginning to update their licensure and dispensing laws and regulations to align with FDA's Dear State Official guidance. HNA does not anticipate any state to enact changes different from this guidance because doing so would severely hamper access to prescription hearing aids, upend longstanding insurance coverage and reimbursement policies and would be contrary to the way in which hearing aids have been dispensed over the last 50 years.

[1] See 21 C.F.R. §801.109.