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FDA Eliminates Hearing Aid Medical Clearance Regulation – Effective Immediately

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WASHINGTON, D.C. — Today during the National Academies of Science, Engineering and Medicine Dissemination Meeting, Hearing Health Care for Adults: Priorities for Improving Access and Affordability, Eric Mann, Chief, Ear, Nose and Throat Devices Branch of the U.S. Food & Drug Administration (FDA) announced that it does not intend to enforce the requirement for adults to obtain a medical evaluation before obtaining most hearing aids. This guidance is effective immediately. As many know, the majority of individuals waive this requirement prior to purchasing hearing aids.

In addition, the FDA announced its continued commitment to the possible creation of a category of over-the-counter (OTC) hearing aids. The rapidly aging population, and both the low uptake & high retail price of hearing aids were cited by the FDA as reasons new, lower cost products are needed. These types are new products are thought by the FDA and others to create more consumer choice and foster greater competition and innovative among manufacturers. The FDA per today's press release reaffirmed it is committed to seeking additional public input before proposing a new category of OTC devices.

Robert Califf, MD

"Today's actions are an example of the FDA considering flexible approaches to regulation that encourages innovation in areas of rapid scientific progress," said FDA Commissioner Robert Califf in the FDA press release.

"The guidance will support consumer access to most hearing aids while the FDA takes the steps necessary to propose to modify our regulations to create a category of OTC hearing aids that could help many Americans improve their quality of life through better hearing." ***–Robert Califf, FDA***

Commissioner

In October 2015, the President's Council of Advisors on Science and Technology (PCAST) issued recommendations intended to facilitate hearing aid device innovation, and improve affordability and patient access. And, this past June the National Academies of Sciences, Engineering and Medicine (NAS) published a comprehensive study examining the affordability and accessibility of hearing care for adults.

Over the past 15 months two organizations, PCAST and NAS, have cited FDA regulations regarding conditions for sale as a potential barrier to availability and accessibility of hearing aids. Both groups concluded that the regulation was providing little to no meaningful benefit to patients. As hearing care professionals know, since the early 1970s – and until today – the FDA regulation required all prospective hearing aid users obtained a medical evaluation by a licensed physician (or sign a waiver if 18 or older) prior to purchasing hearing aids.

According to today's FDA press release, under the new guidance, the FDA will continue to enforce the medical evaluation requirement for prospective hearing aid users under 18. Under the FDA's hearing aid regulations, hearing aid labeling must include information about medical conditions that should be evaluated by a licensed physician. In addition, the FDA requires that information and instructions about hearing aids be provided to consumers before any purchase from a licensed audiologist or hearing aid dispenser.

Guidance Effective Immediately

Since today's guidance is "Immediately in Effect," it is implemented without prior public comment "because it presents a less burdensome policy that is consistent with public health." In their press release the FDA did say the public can still comment on the guidance, and it will consider all comments received and revise the guidance document as appropriate.

Hearing News will continue to report on the reactions of all key stakeholders to this regulation change.