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## **Center for Hearing & Speech urges caution as FDA changes hearing aid rules.**

**ST. LOUIS**— The Food and Drug Administration announced last week it is easing rules governing hearing aids, eliminating the need for a medical exam or waiver before buying hearing devices.

The St. Louis-based Center for Hearing & Speech works to increase access to hearing aids for low-income individuals but urges the importance of proper care for hearing loss.

“Everyone deserves the fundamental ability to hear; however, people need specialized care to properly treat hearing disorders,” Rita Tintera the Center’s executive director said.

The Center is a nonprofit that provides hearing aids and audiology services, as well as speech-language therapy, for individuals in the St. Louis region, regardless of their ability to pay.

The FDA’s decision eliminated the requirement that adults must get a medical ear exam from a physician before they can purchase hearing aids. This medical clearance is meant to ensure there is no available medical treatment for a client’s hearing loss.

Under the previous rules, adults were able to waive the medical exam. In last week’s announcement, the FDA stated it would no longer enforce the need for a medical exam or the waiver. When announcing these changes, the FDA also signaled its intention to create a new category of over-the-counter hearing aids.

While these moves could improve overall access to hearing aids, the Center and its doctors urge caution.

“There’s a big difference between buying a pair of reading glasses from a corner store and a pair of prescription glasses. Just like a glasses prescription, hearing loss is different for everyone,” Dr. Koach Baruch Frazier, the Center’s chief audiologist said.

“If someone gets a hearing aid that’s not suited to their specific needs, it can be frustrating and ineffective. We focus on our clients’ long-term quality of life and their ultimate goal of connecting with their loved ones and the world around them,” Frazier said.

Typically, when diagnosing hearing loss, the audiologist spends time with the client to determine their exact listening needs and uses this information to determine what level of care or hearing device is necessary.

The audiologist then creates the appropriate fitting or ear-mold, programs the hearing aid based on the clients exact needs and provides ongoing adjustments and care for the client.

As these changes take effect, the Center wants to ensure people living with hearing loss aren’t left to guess work and self diagnose what could be a very complicated disorder.

“Everyone deserves the ability to hear, and there is an enormous amount of unmet need, but we want people to be cautious and get help from qualified sources,” Tintera said.

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FDA release announcing the changes:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm>