



October 31, 2011

Lisa Tseng, MD
Chief Executive Officer
hi Health Innovations
P.O. Box 356
Minneapolis, MN 55440

Dear Dr. Tseng,

We are writing to you regarding the recent press releases stating that your group, hi Health Innovations, a subsidiary of United Health Group, will offer Medicare Advantage subscribers a new hearing benefit. Some of the marketing includes the phrases: 'high quality hearing devices at a fraction of the retail price', 'eliminates the middleman...eliminates the high markups', 'custom programmed hearing devices...free online hearing test.'

Although our respective groups admire the overarching goal to increase access to hearing healthcare for Medicare beneficiaries, we are compelled to contact you in the hopes that we might work with you on creating a more comprehensive and sustainable hearing health benefit. We believe that by working together, we can truly help the patients who subscribe to your plan to ensure that their individual hearing needs are assessed fully, safely, and competently and that the results are tailored in a scientific and proven manner.

The line of hearing devices available on the hi Health Innovations website, manufactured by IntriCon Corporation, appear to be marketed as hearing aids even though they are not labeled as such directly on the website. However, in the corresponding descriptions, each product discusses how the device can 'treat' hearing loss. We would note that after taking the hearing test and hearing the softest sounds presented, we were 'advised' that we needed hearing devices for each ear, when in fact, normal hearing was previously determined by conventional audiometry, performed in a sound treated room.

The Food and Drug Administration (FDA) has very clear and specific guidelines for the labeling of hearing aids versus personal sound amplification products (PSAPs): www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127086.htm Based on this information, we are requesting clarification as to whether the devices being promoted through your proposed plan are actually hearing aids or personal sound amplification products (PSAPs). And if these devices are indeed marketed as personal sound amplification products (PSAP) as opposed to hearing aids, then why would an online hearing test be warranted? The FDA description of hearing aids requires a hearing evaluation performed by an audiologist; PSAPs do not require a hearing test as they are not to be used to treat hearing loss. In addition, the Federal Trade Commission (FTC) provides guidance for consumers regarding the use of hearing aids and PSAPs: www.ftc.gov/bcp/edu/pubs/consumer/health/hea10.shtm

Additionally, we are sure you are aware of the statutory licensing requirements for dispensing hearing aids as well as the current regulatory requirements of a physical examination of the patient prior to a hearing aid purchase. These requirements are developed and reviewed as safety measures to protect consumers, and audiologists are well-versed in the state licensure and regulatory mandates and offer our expertise to you in this area as well.

The hearing benefit you are proposing contends that the hearing device is the sole method of treatment. This statement is inaccurate. The hearing aid is just one component in the overall treatment and management plan afforded to the patient by the audiologist, and the physician when there are conditions requiring medical intervention. There is much more to treating hearing loss than the device: 1) There is the assessment of the patient's listening needs to determine the need for directional microphones which, when, used effectively can help with hearing in a background of noise. 2) There is the assessment of how well the patient hears on the telephone and the discussion that will ensue to determine if the patient needs a wireless connection in their hearing aid to pair with their smart phone or if the patient could benefit from the use of a telephone coil built into the hearing aid that will allow for easier connectivity with non-digital phones. These telephone coils can

also be used for ease of hearing in a place where there is looping technology installed. (See recent New York Times article on looping technology: www.nytimes.com/2011/10/24/science/24loops.html?hpw). 3) Additionally, hearing aids, when properly prescribed by the audiologist as part of an overall treatment plan, can be programmed with multiple listening programs that will allow the patient maximum flexibility for their varied listening situations. 4) And beyond the hearing aid, the audiologist can work with the patient to customize online or at-home computerized training programs that will ensure maximum benefit from the use of the hearing aids. Additionally, as indicated above, audiologists work closely with our physician colleagues to ensure that medical problems are addressed in a timely manner. An online hearing assessment cannot provide these critical care components.

An online hearing screening and a pre-programmed hearing device, which by definition is limited in its capability, cannot be effective for the vast majority of patients. Our patients and your consumers need and deserve so much more to meet their medical needs than the hype that a \$700 or \$900 hearing device can address their complex hearing needs.

We are glad that hi Health Innovations recognizes the need to expand access for hearing healthcare – that is a positive approach for those who deserve and require access to their listening environments. However, what is vastly missing from this current plan is the human factor: the patient is more than an online hearing screening with beeping tones and a few situational questions. And, the audiologist is more than a hearing aid fitter – we improve the patient's quality of life because the care we provide is centered on the person sitting in front of us – not centered on a piece of technology. By excluding the health care services provided by the audiologist and the physician, you are doing a disservice to patients and this creates the potential for many dissatisfied subscribers to your services. Audiologists and physicians must be a part of a sustainable delivery model.

We offer you our expertise, including many, many years of direct patient care, research and education, to assist hi Health Innovations and United Healthcare to create a delivery model that includes the services provided by an audiologist and provides state of the art, cost-effective care for your subscribers – our patients.

We would appreciate a response to this letter in sufficient time to address the issues raised and again, we look forward to working with you to develop a sustainable hearing benefit for your subscribers and our patients. Please contact Melissa Sinden, Senior Director of Government Relations for the American Academy of Audiology (msinden@audiology.org or 703.226.1028). Thank you for your time.

Sincerely,



Therese Walden, AuD
President, American Academy of Audiology



Bruce Vircks, AuD
President, Academy of Doctors of Audiology

cc Rhonda Medows, MD, Chief Medical Officer/Executive Vice President, United Health Group

The American Academy of Audiology is the world's largest professional organization of, by, and for audiologists. With an active membership of more than 11,000 audiologists, the Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research. For more information about the American Academy of Audiology, visit www.audiology.org and www.HowsYourHearing.org.

The Academy of Doctors of Audiology is dedicated to the advancement of practitioner excellence, high ethical standards, professional autonomy and sound business practices in the provision of quality audiologic care. For more information about ADA, visit www.audiologist.org or contact Stephanie Czuhajewski at sczuhajewski@audiologist.org.