

May 4, 2012

Mr. Steven Silverman
Director of the Office of Compliance
FDA Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Silverman:

The American Academy of Audiology is the world's largest professional organization of, by, and for audiologists. The American Academy of Audiology (the "Academy") promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research. On behalf of over 11,000 members, the Academy writes to thank you for your recent correspondence to hi HealthInnovations regarding their online hearing test.

As you know, United Healthcare/hi HealthInnovations introduced the online hearing test as part of a new 'hearing aid benefit' during the nationwide open enrollment period for Medicare Advantage insurance plans in October 2011. In addition to the online test, another component of the benefit is the availability of a limited variety of hearing aids for purchase by the beneficiary directly from hi HealthInnovations. It has been the Academy's position from the inception that this benefit, in its current state, poses health and efficacy concerns to consumers.

The Academy appreciates the fact that FDA Office of Compliance staff responded to the concerns of Academy members regarding patient safety and the efficacy of the United Healthcare/hi HealthInnovations online hearing test. We are pleased that the concerns of the Academy, along with those of numerous other organizations and persons committed to quality hearing health care, resulted in the FDA's investigation and issuance of a letter requiring hi HealthInnovations to obtain marketing approval under current FDA regulations. The Academy urges the Agency to continue its efforts and conduct a full investigation into the hi HealthInnovations online hearing test given our continuing concerns with this benefit which purports to diagnose hearing loss without direct patient contact.

The Academy strongly believes that the best model for hearing health care consists of a comprehensive evaluation by a licensed hearing health professional, such as an audiologist, followed by, when applicable, the appropriate fitting of a hearing aid, performing verification measures, as well as rehabilitation and counseling. Intervention by a highly qualified health care

provider is not a part of the direct-to-consumer model being marketed to United Healthcare beneficiaries. This critical component is necessary to ensure the safety of the consumer.

Audiologists have Master's or Doctoral Degrees in audiology and hold state licenses that reflect their scope of practice, which includes diagnostic and treatment services for persons with hearing and balance disorders. Audiologists are uniquely educated and trained in the evaluation, assessment, diagnosis, management, treatment and prevention of hearing and balance problems. Part of an audiologic evaluation includes identifying "red flags" which may indicate the presence of a medical condition, for which an audiologist is required to refer the patient to a physician. Through the hi HealthInnovations benefit, there are no safeguards in place to identify medical conditions through the online hearing test.

Further, the line of hearing devices available on the hi HealthInnovations website, manufactured by IntriCon Corporation and obtainable through the online hearing screening, are pre-programmed, and by definition are limited in capability and may be ineffective for the vast majority of beneficiaries. Hearing aids, when properly prescribed by the audiologist as part of an overall treatment plan, can be configured, programmed and verified to effectively address the hearing needs of the individual and can allow the patient maximum flexibility for their varied listening situations. Limiting the technology available to patients, again, raises patient safety concerns and can also lead to lack of use or misuse of a device by a beneficiary with hearing loss.

For the reasons outlined above, the Academy maintains its position that the direct-to-consumer hearing benefit currently offered to Medicare Advantage subscribers by hi HealthInnovations poses significant safety concerns and limits access to high quality, professional care by well-trained, licensed providers. The Academy commends the Agency on your recognition of these concerns.

Should you have any questions regarding this information, or if the Academy may be of further assistance, please contact Melissa Sinden, Senior Director of Government Relations at (202)544-9335 or by email at msinden@audiology.org.

Sincerely,

A handwritten signature in black ink, appearing to read "T Walden". The signature is fluid and cursive, with a large initial "T" and a long, sweeping underline.

Therese Walden, AuD
President

Cc: Dr. Eric Mann