DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services Center for Medicare 7500 Security Boulevard, Mail Stop C4-21-26 Baltimore, Maryland 21244-1850



MEDICARE DRUG & HEALTH PLAN CONTRACT ADMINISTRATION GROUP

May 22, 2012

Shelly S. Chabon, PhD, CCC-SLP American Speech-Language-Hearing Association 2200 Research Boulevard Rockville, Maryland 20850-3289

Dear Dr. Chabon:

Thank you for your letter regarding the automated hearing tests that UnitedHealthcare (UHC) has been marketing through its subsidiary organization hi HealthInnovations (HHI). In your letter you expressed concern that the HHI hearing test kit does not require a trained health care professional to administer the test. Additionally, you were concerned that a pamphlet accompanying the hearing test provided misleading information to providers by suggesting that the hearing test kit could be billed to original Medicare under CPT code 92552.

As you may be aware, in its letter of March 28, 2012, the Food and Drug Administration (FDA) required that HHI cease marketing of its hearing test and stated that HHI had not obtained FDA approval for the marketing of the test in violation of the Federal Food, Drug and Cosmetic Act. My staff contacted UHC regarding this matter and UHC informed us that it has removed any references to the online hearing test from its Medicare Advantage marketing materials and the test is no longer an option for its Medicare members who are seeking a hearing test. Medicare Advantage members in UHC MA plans will have access to traditional options to receive a hearing test including through a PCP, audiologist, and an ear nose and throat specialist, or other qualified health professionals. We also expressed our concerns about possible future use of the online hearing test and indicated that we wanted to be informed in advance if UHC subsequently receives FDA approval to reintroduce this test.

I appreciate your bringing this matter to my attention. As discussed above, if UHC intends to reintroduce HHI online hearing test, we will ensure that it is in compliance with applicable Federal, Medicare and State laws. If I can provide further assistance, please do not hesitate to contact me.

Sincerely,

Danielle R. Moon, J.D., M.P.A

Daniem V. Noon

Director