Michael J. Astrue Commissioner Social Security Administration P.O. Box 17703 Baltimore, MD 21235-7703

Re: Revised Medical Criteria for Evaluating Hearing Loss (Docket No. SSA-2008-0016) (73 Fed. Reg. 47103, August 13, 2008)

Dear Commissioner Astrue:

The Social Security Administration (SSA) published this proposed rule to revise the criteria in the Listing of Impairments that are used to evaluate claims of hearing loss. The SSA will apply the criteria when evaluating claim benefits based on disability under title II and title XVI of the Social Security Act.

The Regulatory Flexibility Act (RFA) requires federal agencies to take small businesses into consideration when promulgating rules. Section 603 of the RFA requires those agencies to either certify that the proposed rule will not have a significant impact on a substantial number of small entities, or perform an Initial Regulatory Flexibility Analysis that describes the impact of the proposed rule on small entities. In the RFA section of this rulemaking, the SSA certified that the proposed rule will not have a significant economic impact on a substantial number of small entities because the rule only affects individuals. I am writing because my office has heard from some small health care businesses that are concerned that this rulemaking will have a significant economic impact on their industry.

While I do not argue with SSA's position that the effects of this rule are likely to be indirect on these small health care providers, I believe it is foreseeable that any rule that provides patients with instructions on the criteria that SSA will use to determine their disability will impact the health care providers that will perform the testing. Therefore, these small health care providers' concerns should be taken into consideration as this rule moves towards finalization.

¹ 73 Fed. Reg. 47109 (August 13, 2008).

Advocacy Background

Congress established Advocacy under Pub. L. 94-305 to represent the views of small business before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the RFA also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.²

On August 13, 2002, President George W. Bush signed Executive Order 13272, requiring Federal agencies to implement policies protecting small businesses when writing new rules and regulations.³ Executive Order 13272 instructs Advocacy to provide comment on draft rules to the agency that has proposed a rule, as well as to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.⁴ Executive Order 13272 also requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁵

Audiologist and Hearing Instrument Specialists Concerns

In Section 2.00B(2), the proposed rule requires that testing be performed in a "soundproof booth." The rule infers that patients that do not have the hearing test performed in the booths will not meet the criteria for hearing disability. Therefore, it will be incumbent upon health care providers that wish to perform the auditory testing to use soundproof booths. Industry representatives agree that some hearing health care providers use such booths. However, other hearing health care providers use sound-proofed "operatories" to test hearing. Advocacy understands that the operatories are essentially similar to recording studios. Some small businesses suggest that they should not be required to invest in soundproof booths - a cost that will have a significant impact on their revenues. Industry representatives told Advocacy that requiring a specific booth would cost up to \$6,000 per operatory. One business that contacted us has five operatories, so the rule would result in a \$30,000 operating expense.

Stakeholders are also concerned with Section 2.00B(1)(d) requiring that audiometric testing be performed by, or under the supervision of, an otolaryngologist or by an

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² Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996). 5 U.S.C. § 612(a).

³ Exec. Order No. 13,272 § 1, 67 Fed. Reg. 53,461 (Aug. 13, 2002).

⁴ E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.

⁵ Id. at § 3(c), 67 Fed. Reg. at 53,461.

audiologist qualified to perform such tests. SSA considers an audiologist to be qualified if the audiologist is currently and fully licensed or registered as a clinical audiologist by the state or U.S. territory in which he or she practices. If no licensure or registration is available, the audiologist must be currently certified by the American Board of Audiology or have a Certificate of Clinical Competence (CCC–A) from the American Speech-Language-Hearing Association (ASHA). Stakeholders told Advocacy that few audiologists own their own businesses (15% per one Association estimate). A much larger percentage of Hearing Instrument Specialists (HIS) own their practices and most of the remaining HIS are employed by small health care businesses. Stakeholders believe that excluding HIS from the rule's testing requirements does have an effect on small businesses.

Conclusion

It is my hope that the SSA will take these comments into consideration while drafting the final rule establishing revised criteria for evaluating hearing loss. Advocacy appreciates being given a chance to provide the SSA with these comments. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel Linwood Rayford at (202) 401-6880, or via e-mail at linwood.rayford@sba.gov.

Sincerely,

Thomas M. Sullivan Chief Counsel Advocacy

Linwood L. Rayford, III Assistant Chief Counsel