January 20, 2015

Dan Blazer, M.D., Ph.D.
Committee on Accessible and Affordable Hearing Health Care in Adults
National Academy of Medicine
Keck Center
500 Fifth St. NW
Washington, DC 20001

Dear Dr. Blazer:

The attached recommendations are respectfully submitted to the Committee on Accessible and Affordable Hearing Care in Adults of the National Academy of Medicine on behalf of the members of the Academy of Doctors of Audiology and the American Academy of Audiology. Combined, these professional associations represent more than 13,000 licensed and certified audiologists across the country that are committed to improving access to hearing health care and to making that hearing care affordable.

Representatives from our professional organizations attended the public Committee hearings both in-person and via the webcast. We applaud the Committee's breadth of investigation and the diversity of invited speakers. In particular, we applaud the Committee's inclusion of the perspectives of the hearing care consumer during the study. One of the consistent messages heard was with respect to the obstacles that exist that reduce access and increase costs. As a profession that is intimately engaged in the delivery of hearing care, we appreciated hearing the concerns and ideas presented over the past year.

In the broad sense, we appreciate the dual goals of increasing access and decreasing costs in hearing health care. We also understand, however, that these goals have to be balanced with the additional goals of securing successful functional outcomes and assuring patient safety. With these concepts in mind, our organizations offer the following recommendations to the Committee. We believe these recommendations will result in increased access and reduced costs, without sacrificing successful outcomes or patient safety.

Recommendation1: ***Hearing loss should be considered a chronic medical condition, rather than simply an age-related phenomenon.***

The literature does not support a single uniform definition of a chronic medical condition, although most definitions include the recurrent themes of a condition that has a non–self-limiting nature, an association with persistent health problems, and a duration measured in months and years, not days and weeks[1]. For example, the US Department of Health and Human Services defines chronic illness[2] as conditions "that last a year or more and require ongoing medical attention and/or limit the activities of daily living." The Center for Disease Control's National Center for Health Statistics[3] defines a chronic illness as conditions that last more than 3 months and The World Health Organization defines chronic diseases[4] as conditions that are of long duration and generally slowly progressive. As the most common forms of hearing loss in adulthood are persistent, permanent, progressive, and impose functional limitations, hearing loss meets all the definitions of a chronic health condition.

In 2001, the Institute of Medicine, in the report titled *"Crossing the Quality Chasm: A New Health System for the 21st Century*" noted that chronic conditions lasted at least 3 months, were not self-limiting, and were one of the leading causes of disability in the United States[5]. The report noted advances in medical science and technology had resulted in an increased life expectancy with the consequence that 1 in 5 people will be over the age of 65 by 2030. The report further noted the increased life expectancy would result in an increase in the number of persons with chronic conditions. One can conclude that the incidence of hearing loss will only increase in the coming years, and the increase in life expectancy will result in people living with hearing loss for longer periods of time.

While most lay persons consider hearing loss in the geriatric population to be a condition of aging and confined to the ears, evidence suggests that considering hearing loss as "age-related" is an incorrect conclusion. Roth[6] notes that age-related hearing loss is a multifactorial, genetically driven process that is influenced by oxidative stress that gradually leads to a cell loss and changes in physiologic responses within the ear. This stress is caused by damaging factors such as noise, infectious processes, and other systemic factors. Thus, hearing loss in the geriatric population is more likely due to the cumulative effect of stress-related factors over a lifetime than of simply aging.

Additionally, changes in brain function, and specifically the central auditory system also contribute to the perceptual difficulties experienced by adults during listening activities. Any changes in brain function, specifically the auditory pathways and the auditory cortices, will thus affect an individual's perception of sound and his/her communicative function. Moreover, recent evidence suggests a correlation between hearing loss and depression, dementia, and even mortality[7, 8]. Thus, classifying hearing loss as an age-related phenomenon is simplistic and ignores the extensive nature of the problem, as well as the physiologic and functional implications.

The Centers for Medicare and Medicaid Services (CMS) currently classifies hearing loss as an age-related condition, and therefore not subject to coverage by traditional Medicare Part B. This lack of coverage results in a paucity of data on the true consequences, in terms of quality of life, cost, and outcomes, for this condition, as beneficiary, claims and assessment data are not available from the CMS databases. Reclassifying hearing loss as a chronic condition would allow research to address factors such as quality of life and long term outcomes, including costs. As an example, the CMS Chronic Conditions Data Warehouse (CCW) provides researchers with Medicare and Medicaid beneficiary, claims, and assessment data across the continuum of care. This information is made available to support research designed to improve the quality of care and reduce costs and utilization.

The Audiology organizations recommend that hearing loss be classified as a chronic medical condition and not an age-related phenomenon. This classification provides a foundation on which both public and private agencies can build clinical and research programs designed to reduce costs and increase access to hearing care for the public.

Recommendation 2: ***Eliminate the medical evaluation requirements, including the use of a waiver, for adults as currently required by the Food and Drug Administration.***

The Food and Drug Administration regulations for the requirement for a medical evaluation prior to the purchase of a hearing aid, or the use of a waiver for adults to opt-out of the evaluation[9], was first promulgated in 1977 and can be found in Section 801.420a in the Code of Federal Regulations (Title 21, Volume 8.) The regulations state:

> *Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.*
>
> *(2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement*

The regulations require that the labeling for hearing aids include the following statements:

> *Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all*

medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

The Audiology community is unaware of any credible research designed to measure the compliance with the medical evaluation requirement, and, more importantly, that the medical evaluation requirement actually leads to the identification and treatment of medical conditions that would otherwise not be identified *a priori* by the patient. Anecdotally, most patients either waive the medical evaluation or self-select into the appropriate path to medical care based on their signs and symptoms.

As noted in testimony before the committee, there is no evidence that the required medical evaluation, as a condition of purchasing a hearing aid, reduces costs, increases access, or improves the outcome for patients seeking hearing care. Furthermore, the evidence suggests that more than 90 percent of older individuals with hearing loss have sensorineural hearing loss not due to a medically treatable condition. Hearing loss is identified through diagnostic testing, commonly known as a hearing test, not through a medical evaluation. In our 1996 submission to the FDA, Dr. Kessler, then Director of the Food and Drug Administration, stated: " Studies…have provided evidence that the waiver provision may not have fulfilled the original function as envisioned by the FDA. [The] waiver is used far more extensively than was expected."

The elimination of the current requirement of a medical evaluation by a physician should serve to improve access and reduce costs. Models of hearing care suggest that both the time and cost involved of accessing physicians for the purpose of obtaining the medical evaluation can be obstacles to patients. Bratt, et al.[10] diagramed the additional burdens, in terms of time and costs, by requiring a patient to seek a medical evaluation as part of the hearing care process. The direct costs to the patient, and the indirect costs to a third party payer, increase with any additional steps in the process. Porter[11] noted that the value of medical care is based on the outcomes relative to the costs, with costs referring to the total costs over the full cycle of care for a patient's condition, not the cost of individual services. Thus, the value of hearing care, including amplification, is related to the total of all costs to the patients, including the cost associated with the medical evaluation. These additional costs serve to reduce the perceived value of hearing care to the patient.

When the FDA first developed regulations for hearing aids in 1977, the necessity of a medical evaluation was included as there was the assumption that no one dispensing hearing aids was capable of reliably identifying underlying disease or the necessity to see a physician. Audiology, as a profession, has continued to evolve and grow; now

requiring doctoral level education. Thus the need for medical clearance is no longer necessary as audiologists are trained in identifying underlying causes of hearing loss that require medical attention.

Our organizations recommend the elimination of the medical evaluation requirement as a condition for purchasing a hearing aid. There is no evidence that the waiver is necessary, or that it meets the stated goals of assuring that treatable medical conditions are identified.

Recommendation 3*: An audiologic evaluation should be obtained prior to obtaining any amplification device.*

Patients should be strongly advised to seek a comprehensive audiologic evaluation from an audiologist, or physician, prior to utilizing any type of amplification device or other treatment for hearing loss, especially if the patient exhibits any of the warning signs of ear disease (tinnitus, dizziness, drainage, sudden hearing loss, asymmetry, foreign body in the ear, cerumen impaction, and/or congenital or traumatic deformity of the ear). The purpose of an audiologic evaluation is not to determine the necessity of a hearing aid, but rather to determine:

- The onset and time course of the hearing loss,
- The degree, type and configuration of hearing loss,
- The possible etiology of the hearing loss,
- The functional limitations imposed by the loss, particularly with regards to communication, and
- The need for additional medical or audiological services, including the development of a treatment plan

While one of the outcomes of an audiologic evaluation might be the recommendation of an amplification device, the primary purpose is to discern the status of the auditory system. This evaluation helps to differentiate hearing loss attributable to the ear and peripheral auditory system from that of the brain and central auditory nervous system. It provides a basis for the treatment plan and supplies the patient with information that allows them to make informed decisions about their hearing healthcare.

Online, do-it-yourself "hearing tests" can be helpful **screening** tools, but should not be equated with professional diagnostic testing, and thus should only be considered as a "screening" measure. Today's internet-based hearing tools are simply not capable of providing an accurate diagnosis due to coupling/receiver issues (on the consumer side), the inability to standardize ambient noise at the test site, the lack of bone conduction testing, and the inability to self-perform an otoscopic exam. As a result, an online hearing assessment cannot establish the true type, configuration or etiology of hearing loss, but can merely estimate degree of loss. Nor can online hearing tests establish the degree of functional limitations, often the basis for determining the need for amplification.

The Hearing Loss Association of America Policy Statement on Hearing Healthcare[12] notes, "Every potential hearing aid candidate should receive a comprehensive audiological evaluation, conducted by an audiologist with an appropriate state license to practice audiology…" We also believe patients are best and most affordably served, by undergoing a comprehensive audiologic evaluation prior to purchasing any amplification device (hearing aid, personal sound amplification product, assistive listening device, phone app, etc.), regardless of whether the device itself is obtained over the counter, via the internet, or through a licensed provider.

Recommendation 4: ***Devices should be coupled with audiologic rehabilitation to assure optimal outcomes for patients.***

For many individuals with hearing loss, communication challenges are not fully resolved with the addition of one or more hearing aids. Patients with hearing aids may continue to present with challenges understanding speech in environments with a degraded signal-to-noise ratio or even demonstrate poor speech understanding despite adequate speech audibility. Audiologic/aural rehabilitation (AR) is an ecological, interactive process that facilitates a patient's ability to minimize or prevent the limitations and restrictions that auditory dysfunctions can impose on well-being and communication, including interpersonal, psychosocial, educational, and vocational functioning.

Developing an appropriate and comprehensive audiologic rehabilitative management plan may involve

- Recognizing and responding to the influence of cultural background on the patient and family/caregivers,
- Providing recommendations for selection, fitting, and dispensing of amplification,
- Educating the consumer and family/caregivers in the use of and adjustment to hearing aids,
- Offering skills training and consultation related to effective communication strategies,
- Offering options for auditory training,
- Identifying other appropriate Hearing Assistive Technology Systems (HATS), and/or
- Conducting an evaluation and modification of the audiologic management plan.

Counseling patients is vital to positive outcomes. It begins during the initial patient contact and continues through the hearing aid fitting and the entire treatment process. Counseling is necessary to achieve communication success with hearing aids. Patients must learn to overcome their maladaptive listening behaviors and to employ new strategies to become successful users of amplification devices. Counseling a patient with hearing loss may require making information available and understandable as well as providing support for adjustment to hearing loss and/or amplification. A systematic evidenced based review by Hawkins[13] examining the effectiveness of

counseling and communication strategy-oriented group adult aural rehabilitation programs provided evidence that participation in an adult aural rehabilitation program provides short-term reduction in self-perception of hearing handicap and potentially better use of communication strategies and hearing aids.

An important component of an audiologic rehabilitation plan is the employment of validation measures to determine the outcome and impact of the amplification intervention. It is important to include validation that disability has been reduced and that appropriately established goals have been addressed in each comprehensive hearing aid selection and fitting process.

Hearing care can be a complex and manifold process, of which hearing aids may represent only one part of a comprehensive audiologic rehabilitation plan. A progression in the model of hearing health provision toward a patient-centered approach, along with appropriate use of hearing technology, has been described.[14] Laplante-Levesque, Hickson, and Worrall[15] stressed that, "increased client participation, for example via client-centeredness, joint goal setting, and shared decision making, constitutes a more holistic approach that respects the client as a person and that may hold promise to improve the quality of life." Through analysis of previous research, Erdman, Wark, and Montano[16] encouraged a service delivery model for audiologists that engages patients and encourages their participation in personal hearing-management decisions. Thus, to achieve the greatest probability of successful hearing aid fitting, a comprehensive rehabilitation plan will incorporate the combined efforts and input of the audiologist, patient, and family/caregivers.

Recommendation 5: ***Traditional Medicare Part B coverage for hearing aid services should be revised to remove barriers that impede accessibility or raise the costs of hearing care.***

The National Institute of Deafness and Other Communication Disorders (NIDCD) estimates that “Among adults aged 70 and older with hearing loss who could benefit from hearing aids, fewer than one in three (30 percent) have ever used them. Even fewer adults aged 20 to 69 years of age (approximately 16 percent) who could benefit from wearing hearing aids have ever used them.”[17] (Many of these same individuals rely on Medicare as not only their primary health insurer, but also as the source of information regarding medical questions, including hearing care.) As you know, traditional Medicare Part B does not provide coverage for hearing aids or for services associated with age-related hearing loss.

Currently, traditional Medicare does not even cover hearing screenings or periodic, routine hearing evaluations. Also, in the Welcome to Medicare evaluation (Initial Preventative Physical Examination), the exam merely states that physicians should use “any appropriate screening questions or standardized questionnaires recognized by national professional medical organizations to review, at a minimum, the following areas: hearing impairment.”[18] Unlike vision, “hearing” is not commonly

screened and, as a result, individuals with a potential hearing impairment are not being referred for comprehensive audiologic assessment when needed.

It is recommended that a formal acoustic hearing screening (92551) or, at a minimum, a standardized hearing handicap inventory such as the Hearing Handicap Inventory for the Elderly be a required part of all IPPE visits.[19, 20] Hearing screening has been found to be a vital aspect of healthcare.[21] Additionally, if a patient fails an acoustic hearing screening, or yields a minimum of a mild hearing handicap on a hearing handicap inventory, that s/he be referred to an audiologist, or physician, for a comprehensive hearing evaluation and that the hearing evaluation be a covered service, even if the outcome is hearing within normal limits.

Currently, all traditional Medicare (Part B) beneficiaries are required to obtain an order from a physician for the audiologic evaluation to be covered. This typically involves a patient presenting to their primary care physician (PCP) to obtain an order for a hearing evaluation/be referred to an audiologist, be seen by an audiologist, and present back to the PCP for follow-up. In addition, some PCPs refer patients to an otolaryngologist first, who then refers to an audiologist for the assessment. This elaborate system of referrals costs Medicare an estimated $20.9M each year and places an undue time and financial burden on the patient.[22] Eliminating the Medicare requirement for a physician order for an evaluation could remove barriers that impede access and increase costs. Only 5-10% of adults have a medically treatable hearing loss,[23] suggesting that the majority of Medicare beneficiaries would benefit from changes to this process.

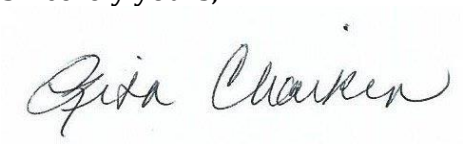
The recommendation to eliminate the physician referral for an audiologic evaluation is consistent with the prior recommendation to eliminate the medical evaluation prior to obtaining a hearing aid. Among the underlying reasons for these current requirements is concern about patient safety in identifying the presence of treatable otologic disease. However, the Mayo Clinic study results published in the Journal of the American Academy of Audiology demonstrated that patient safety would not be compromised.[24] According to the study outcomes, "…the majority (95%) ultimately required audiological services, and in most of these cases, audiological services were the only hearing health care services that were needed. Audiologist treatment plans did not differ substantially from otolaryngologist plans for the same condition; there was no convincing evidence that audiologists missed significant symptoms of otologic disease; and there was strong evidence that audiologists referred to otolaryngology when appropriate." These findings suggest that patient safety is not compromised, and that audiologists are capable of making determinations about referring to physicians. It should be noted that the patients studied were individuals covered by Medicare.

Eliminating the coverage-dependent physician referral for audiologic evaluations would bring Medicare (Part B) in line with best practices in patient care, which is consistent with other third party payers, including most Medicare Advantage plans and the Federal Employees Health Benefits Plan.

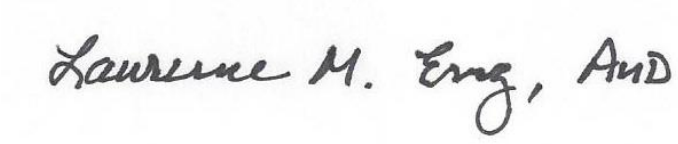
In addition, Medicare (Part B) should reimburse all recognized, qualified Medicare providers for the Medicare-covered audiology services that they are licensed to provide. Currently, Medicare only reimburses audiologists for diagnostic services, despite the fact that audiologists are specifically trained and licensed to provide a full range of treatments, which Medicare covers when provided by other providers such as speech pathologists. As noted earlier, successful outcomes may include both devices and audiologic rehabilitation services for some patients to overcome the functional limitations imposed by the loss. Under the current Medicare system, these services can be provided by other providers, which, again, increase costs and limits access due to having to engage multiple providers.

The audiology community recognizes the need to improve access and reduce the costs of hearing care across all populations. We believe the above recommendations will lower the costs and increase access, and therefore we appreciate the opportunity to submit these recommendations to the Committee. Again, we applaud the work of the Committee in examining the obstacles to accessing hearing care and to reducing the costs associated with hearing care. We recognize that only a small percentage of people with hearing loss actually pursue treatment options, in part due to the costs, and in part due to barriers in the delivery system. We stand ready to work with the Committee to identify and overcome the obstacles that reduce access and increase costs.

Sincerely yours,



Rita R. Chaiken, Au.D., President
Academy of Doctors of Audiology



Lawrence Eng, Au.D., President
American Academy of Audiology

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