AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

May 23, 2016

Institute of Medicine
Committee on Accessible and Affordable Hearing Health Care for Adults
Keck Center
500 Fifth St. NW
Washington, DC 20001

Attn: Cathy Liverman, Study Director
Sarah Domnitz, Study Director

Dear Members of the Committee on Accessible and Affordable Hearing Health Care for Adults:

Hearing loss is one of the most common issues faced by individuals as they age. Despite this, far too few adults seek appropriate intervention when symptoms of hearing loss first appear. In an effort to mitigate this issue, stakeholders from across the hearing healthcare community have engaged with applicable governing/regulatory bodies (PCAST, FDA, IOM) over the last year to put forth recommendations to potentially ease barriers associated with the availability and accessibility of hearing healthcare for adults. The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) has participated in the aforementioned process, and in anticipation of the forthcoming Institute of Medicine report on the same issue, respectfully offers the following comments as a means to reiterate our position pertaining to the delivery of hearing healthcare services in the United States.

As background, the AAO-HNS is the world's largest medical organization representing specialists who treat the ear, nose, and throat, and related structures of the head and neck. The Academy represents approximately 12,000 otolaryngologist—head and neck surgeons who diagnose and treat disorders of those areas. The medical disorders treated by our physicians are among the most common that afflict all Americans, young and old. They include chronic ear infection, sinusitis, snoring and sleep apnea, hearing loss, allergies and hay fever, swallowing disorders, nosebleeds, hoarseness, dizziness, and head and neck cancer.

The AAO-HNS recognizes there is significant momentum both in the United States and worldwide to increase the utilization of hearing healthcare services, particularly the adoption of technology designed to improve the hearing of those with significant loss. We also acknowledge that to achieve this goal, structural changes regarding access to, and the delivery of, hearing healthcare services will be necessary.

There are many reasons why those with significant hearing loss are not participants in the current system, including, but not limited to: failure to realize the problem, denial of the problem, perceptions regarding a potentially complex system, and cost. While the AAO-HNS agrees that efforts must be made to overcome these barriers, we must move forward with careful consideration and analysis relating to what can be done to significantly increase utilization (by easing entry and reducing costs) while retaining necessary protection for patients.

To this end, the AAO-HNS is generally supportive of the concept of denoting a "basic" category of hearing aids, which would be more easily available for purchase by seniors. **Although the AAO-HNS believes providing access to a lower-cost or "basic" hearing aid could/would likely benefit a large portion of the senior population, we caution that specific action should first be taken to ensure that a particular individual/patient's condition actually falls into designated categories of hearing loss (e.g. bilateral, gradual onset, mild-to-moderate age-related hearing loss).** Although we find ourselves in a period of disruptive technology that has made it possible for many patients to participate in self-screening and monitoring of many diseases, we assert it is an overstatement to conclude that all patients/consumers could or would be able to self-diagnose, self-treat, and self-monitor their hearing loss. For example, an individual living alone may personally evaluate his/her hearing loss as only mild or moderate, not realizing that another individual with normal hearing would not be able to tolerate the excessive television, etc. volume used to compensate for the person's hearing loss.

Therefore, the AAO-HNS strongly recommends the retention of a medical evaluation by a physician, followed by a standardized hearing test (via a hearing health professional or appropriate online/technological source), BEFORE an individual could seek purchase of any type of basic hearing aid or other FDA-regulated assistive hearing device. Even if the resulting end-product is purchased OTC, a patient will still benefit, and will certainly not be harmed, by receiving an appropriate evaluation of their actual hearing loss. The potential *medical* issues associated with hearing loss should not be made light of, especially given that a large percentage of Medicare beneficiaries suffer from multiple and complex medical conditions. For example, according to a 2014 U.S. Department of Health and Human Services report, in 2011-2013, the most frequent occurring conditions among the senior population included: hypertension (71%), diagnosed arthritis (49%), heart disease (31%), cancer (25%), and diabetes (21%). Of the five aforementioned medical conditions, three have correlations to hearing loss. In addition, ototoxic and vestibulotoxic drugs can have a direct correlation with hearing loss; a factor exacerbated by advanced age (over 65).

Retention of a medical evaluation requirement should not be seen as a limiting aspect of the hearing healthcare delivery system. **The AAO-HNS emphasizes that primary care and/or most specialty physicians (MD/DOs) are able to provide an *initial* examination of the ear, and if necessary, a subsequent referral for audiological/hearing aid services.** According to the Agency for Healthcare Research and Quality (AHRQ), there were approximately 209,000 practicing primary care physicians in the United States[i], in addition to the approximately 10,000 otolaryngologists.

Finally, the AAO-HNS recognizes for a variety of reasons, hearing aids (and their associated costs) have not necessarily benefited from the vast technological advances that have occurred since hearing aids (in various forms) entered the market. **It is in this context that the AAO-HNS urges interested parties to differentiate between the "access" issues associated with the cost of hearing aids, versus alleged "access" issues to qualified hearing-healthcare professionals** (e.g. otolaryngologist—head and neck surgeon, primary care physicians, audiologists, etc.) which tend to offer hearing aid services in the same urban and rural areas. While

patients/consumers will undoubtedly benefit from the creation of additional pathways for hearing loss treatment or mitigation (e.g. PSAP, "basic" hearing aid, or other "hearable" device), it remains critically important that the same patients/consumers are, from the first step (evaluation), pointed in the right direction. If not, the effort is done in vain. **It is for those reasons that the AAO-HNS supports efforts to *pragmatically* deregulate the availability of various assistive hearing devices, while still retaining requirements for a patient to receive the appropriate medical evaluation and hearing testing.**

Ideally, commonsense efforts to deregulate and thereby increase access to "basic" hearing devices and "hearables" will spur additional technological innovations – naturally driving costs down, much like what has been seen in regards to smart phones.

As these and other recommendations are evaluated, the AAO-HNS looks forward to working with the Committee, and other stakeholders, to ensure timely and affordable access to hearing healthcare services. If you have any questions or would like additional information, please contact legfederal@entnet.org.

Sincerely,

James C. Denneny III, MD
Executive Vice President/CEO

[i] http://www.ahrq.gov/research/findings/factsheets/primary/pcwork1/index.html