# THE OFFICIAL PUBLICATION OF THE ACADEMY OF DOCTORS OF AUDIOLOGY®

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**08** Treating Tinnitus

ACADEMY of DOCTORS of AUDIOLOGY\*

The Power to Practice

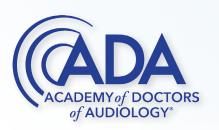
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## PRESIDENT'S MESSAGE

Dawn Heiman, Au.D.



## Make a Difference: Help Make MAAIA a Reality

I trust this message finds you well and that you are enjoying *Audiology Practices*, your source for the latest developments, insights, and best practices in the field of audiology. As your President, I am honored to share some exciting news and a call to action that directly impacts our profession.

This year marks a significant milestone as we find ourselves closer than ever to achieving three pivotal objectives:

- 1. Securing direct access for our patients with Medicare Part B,
- 2. Reimbursement for our full scope of practice within Medicare Part B, and
- 3. Practitioner classification for audiologists under Medicare Part B.

On July 17, 2023, the bipartisan Medicare Audiology Access Improvement Act (MAAIA) was introduced in the U.S. Senate. This legislative initiative could redefine the future of audiology healthcare. However, *achieving our goals requires a collective effort*, and this is where your support and involvement become paramount.

#### How You Can Make a Difference:

1. **Financial Contributions:** Your financial support will play a pivotal role in advancing our advocacy efforts, outreach campaigns, and educational initiatives aimed at informing lawmakers about the importance of the Medicare Audiology Access Improvement Act. Every contribution, big or small, will contribute to our shared success. Donate today at <a href="https://www.audiologist.org/resources/advocacy/pac-advocacy-donations">https://www.audiologist.org/resources/advocacy/pac-advocacy-donations</a>.

2. **Volunteer Your Time:** Beyond financial contributions, we are seeking dedicated volunteers who are willing to actively engage with lawmakers, attend meetings, and advocate for our profession. Your expertise as audiologists positions you as vital advocates in explaining the significance of this legislation to our elected officials.

3. Ask Your Patients to Help the Cause: Your patients can help tell their stories to your local Members of Congress and have a powerful impact when it comes time for officials to vote.

By uniting our efforts, we can amplify our voice and underscore the critical need for these audiology advancements. Together, we can ensure that patients with Medicare Part B gain direct access to our services and that audiologists are rightfully recognized as practitioners.

I urge you to consider how you can personally contribute to this vital cause. Whether through financial support or volunteering your time, your involvement will shape the future of audiology and expand access to audiological care.

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## EDITOR'S MESSAGE

Brian Taylor, Au.D.



## Reversing the Downhill Effects of Apathy and Indifference

Although the results of the ACHIEVE randomized controlled trial, which demonstrated hearing aid use slows down cognitive decline in an at-risk population, generated many headlines in the professional publications over the summer, we cannot forget untreated hearing loss is also associated with an increased risk of fallng, depression, social isolation, poorer mobility, underemployement, and reduced quality of life. Not to mention the impact of untreated hearing loss on daily communication and the negative effects it has on relationships with family, friends and colleagues. These are all great reasons for audiologists to be actively involved in hearing screening programs that are conducted on healthy middle-aged and older adults.

The downward sloping pattern in Figure 1 reflects a pattern found in several recent studies that have investigated the effectiveness of hearing screening programs: Even when primary care physicians take an active role in the hearing screening process, most individuals who fail the screen are not fitted with hearing aids. As Figure 1 shows, at each stage of the journey, a substantial number of individuals with hearing loss fail to take the necessary actions toward treatment. As illustrated in Figure 1, starting with a large pool of middle-aged and older adults who failed the hearing screening (just under 50% of the total group screened), a mere 10 to 15% of them acquired hearing aids and used them.

It's important to note the trend shown in Figure 1 represents a sort of best-case scenario in which physicians were actively involved in the screening program. In many of the studies there was also a control group who did not receive a hearing screening or an educational intervention that might have motivated someone into action. A considerably smaller percentage of that control group than what is depicted in Figure 1 consulted with an audiologist and eventually acquired hearing aids.

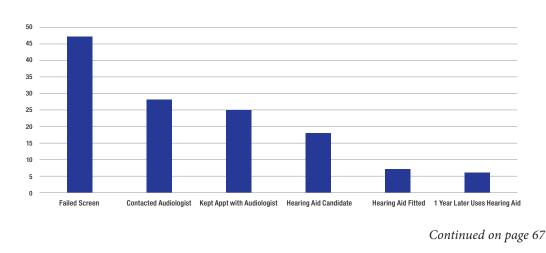


Figure 1. A summary of key findings in recent studies on the effectiveness of hearing screening programs on middle-aged and older adults. See references for list of studies summarized here.



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## HEADQUARTER'S REPORT



## Unleash Audiology's Potential through ADA Committee Service

ADA is more than just a collective of audiologists--it is a thriving community of passionate individuals, with unique perspectives, skills, and experiences. Whenever and wherever ADA members collaborate and apply their insight and input towards achieving common goals, audiology's potential is unleashed!

ADA committee service is a fantastic way to advance ADA's mission while also building relationships and resources to enhance your professional journey. Committees are the backbone of ADA, and oftentimes the catalysts of change and innovation that shape the profession of audiology.

ADA committees are platforms for voice, action, and impact—and each committee is empowered to make decisions that make a difference! Please consider serving on one of the following ADA committees:

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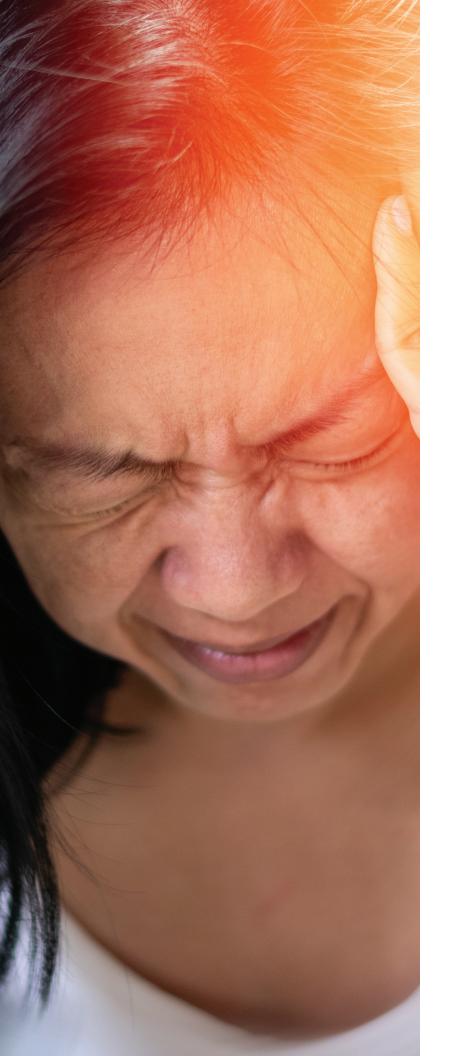
Together, ADA members can design the future of audiology and unleash its full potential! Join an ADA committee today to help advance the autonomous practice of audiology in every clinical setting and promote evidence-based clinical and business practices in the delivery of audio-vestibular services.

Please contact me at <u>sczuhajewski@audiologist.org</u> if you have any questions. Thank you for your consideration of this important request!

## Treating

C





## Sook Ling Leong PhD., Kimberly Rawn

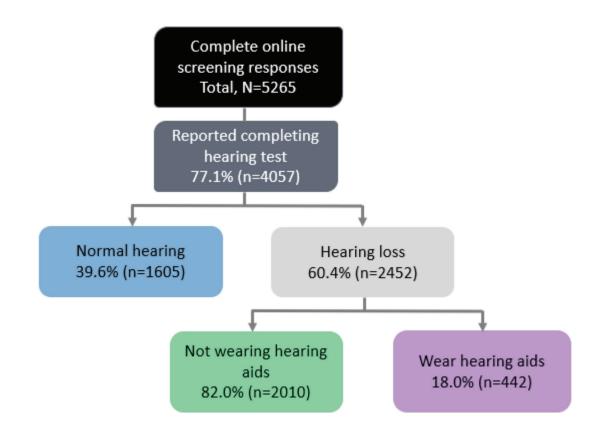
Tinnitus, the phantom perception of sound can be a debilitating condition.<sup>1,2</sup> While tinnitus is generally related to hearing loss, tinnitus in normal hearing accounts for a significant group of patients.<sup>3,4</sup> In normal hearing tinnitus patients, research has provided physiological evidence for deficits in cochlear processing (i.e., hidden hearing loss).<sup>5</sup> Although there are several tinnitus treatment approaches put into use, ranging from hearing aids with masking programs to cognitive behavioral therapy (CBT), tinnitus continues to be a major health issue globally with limited treatment options that are consistently effective or accessible across sufferers.<sup>6,7</sup>

The Treatment Evaluation of Neuromodulation for Tinnitus Stage 1 (TENT-A1) was a parallel-arm, double-blind, randomized study investigating the safety and efficacy of three different stimulation settings of bimodal neuromodulation for the treatment of tinnitus (clinicaltrials.gov: NCT02669069) with the Lenire<sup>®</sup> device.<sup>8</sup> *Lenire* is a non-invasive bimodal (sound and tongue) stimulation portable device that is FDA-approved in the United States and CE-marked in Europe for use in the treatment of chronic, subjective tinnitus. Detailed methods and results of the TENT-A1 clinical trial has been published in Science Translational Medicine.<sup>8</sup>

The TENT-A1 study recruitment prompted potential candidates to log on to the recruitment website to register their interest and complete an online screening which included a selection of assessments of their audiological profile, tinnitus, medical history, and demographics.

During the recruitment period, there were 5826 responses with 5265 participants providing complete analyzable data. Survey participants answered 'yes', 'no', or 'don't know' to the questions 'Have you had your hearing tested?', 'Do you have hearing loss in one or both ears?' and 'Is tinnitus more of a problem compared to hearing loss?' Participants also responded, 'yes' or 'no' to the question 'Does your tinnitus appear quieter (less intrusive) when wearing hearing aids?' Of the 5265 potential candidates for the TENT-A1 clinical trial with analyzable data, 77.1% reported completing a hearing test, of which 39.6% had normal hearing and 60.4% had hearing loss (**Figure 1**). Further categorization of data demonstrated that, among tinnitus sufferers who were diagnosed with hearing loss, only 18% were using hearing aids (**Figure 1**). In the United States, the overall rate of hearing aid adoption has been reported to be 34.1%.<sup>9</sup> In our survey, participants were not asked about the severity of their hearing loss or if they were recommended a hearing aid for their hearing loss, and as such the adoption rate reported in this study may be lower. The low uptake of hearing aids, in this cohort of tinnitus participants with hearing loss, could also be associated with a number of different factors. Although approximately 90% of tinnitus sufferers experience some degree of hearing loss,<sup>10</sup> patients may not consider their hearing loss a barrier or a cause of concern to justify amplification. Studies have also shown that tinnitus patients lack the motivation to use hearing aids that were originally designed to address hearing loss or are influenced by stigma associated with the use of hearing aids.<sup>11,12</sup> As detailed later in our survey, more than 55% of survey respondants reported that their tinnitus was more bothersome than their hearing loss.

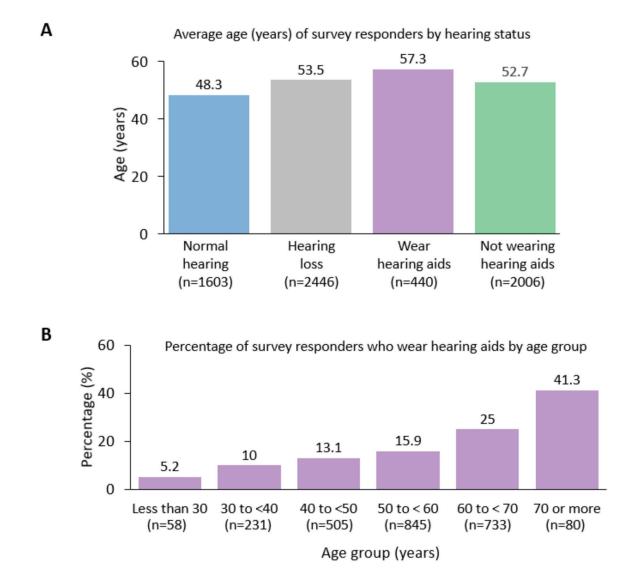
#### Figure 1. Participant flow diagram of self-reported hearing status during online screening of the TENT-A1 clinical trial.



Regardless of hearing status, the mean age of tinnitus participants in this survey was 51.5 years. Survey findings were consistent with published data from the United States National Health Interview Survey where the mean age of adults who reported experiencing tinnitus in the prior 12 months to the interview was 53.1 years.<sup>13</sup> In our survey, participants with hearing loss were on average slightly older than those with normal hearing (mean age; 53.5 years vs. 48.3 years; **Figure 2A**). Research has shown that sensorineural hearing loss in older adults is often accompanied by tinnitus with the highest occurrence around the age of 60 years.<sup>14</sup>

When categorized by age, 25% of participants in the 60 to 70-year-old group and 41.3% of participants in the 70 or older age group were using hearing aids (**Figure 2B**). At present, there is a lack of studies reporting the prevalence of hearing aid use among tinnitus sufferers. However, our results reflect a report that the average age of hearing aid owners in the United States overall population to be around 66 years old.<sup>9</sup>

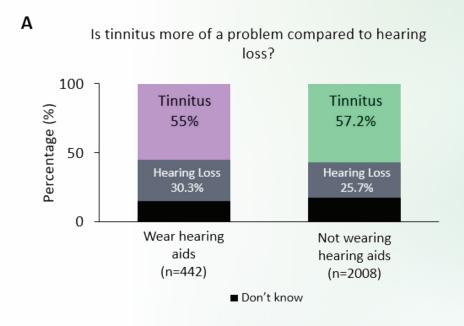
Figure 2. A. Average age of survey responders by hearing status. B. Percentage of survey responders who wear hearing aids by age group.



Among participants with hearing loss, 55% of those who were using hearing aids and 57.2% of those who were not using hearing aids reported that tinnitus is more of a problem compared to hearing loss (**Figure 3A**). Of note, only 43.5%, of 441 participants who used hearing aids, reported that their tinnitus appeared to be quieter when wearing hearing aids (**Figure 3B**). In our survey, participants were not asked if their hearing aid included a tinnitus masking component. In a scoping review of hearing aids for tinnitus relief, positive results of hearing aids for tinnitus relief were shown in 19 out of 28 research studies, whereas 9 studies demonstrated no change in tinnitus perception.<sup>15</sup> However, as stated by the authors of the scoping review, the quality of the evi-

dence across studies was variable, and no consensus can be reached regarding the use of hearing aids as a treatment for tinnitus. In addition, a Cochrane meta-analysis of six clinical investigations (553 participants) of sound therapy found (including hearing aids with/out maskers) that the reduction in tinnitus severity or tinnitus loudness was equal to reductions seen in interventions using patient education or relaxation techniques.<sup>16</sup>

Among participants with hearing loss, 55% of those who were using hearing aids and 57.2% of those who were not using hearing aids reported that tinnitus is more of a problem compared to hearing loss. Figure 3. Categorical responses to A. "Is tinnitus more of a problem compared to hearing loss?" and B. "Does your tinnitus appear quieter (less intrusive) when wearing hearing aids?"



В

Does your tinnitus appear quieter (less intrusive) when wearing hearing aids?

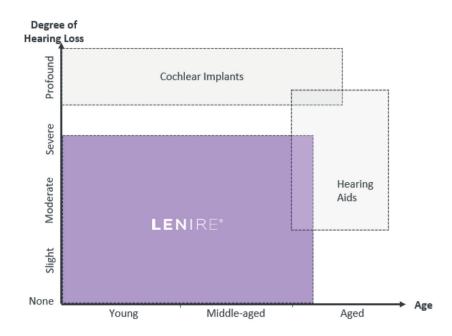


In summary, findings from our survey suggest that the majority (77.1%) of active tinnitus treatment seekers had their hearing tested. Moreover, a high percentage (60.4%) of patients who were diagnosed with hearing loss were seeking a solution for their tinnitus. The low adoption of hearing aids in this cohort (18%) is consistent with a report in a clinic providing a range of tinnitus management options where only 3% of all 297 patients who attended the clinic purchased hearing aids to treat their tinnitus.<sup>17</sup> Also, in our survey, less than 45% of hearing aid users reported that their tinnitus appeared quieter when their hearing aids were in use, suggesting that the benefits of hearing aids in tinnitus sufferers could be limited. 45%

In our survey, less than 45% of hearing aid users reported that their tinnitus appeared quieter when their hearing aids were in use, suggesting that the benefits of hearing aids in tinnitus sufferers could be limited. It is important for audiologists to be able to offer a range of treatment options for a wide and diverse patient population, given the heterogeneity of tinnitus. For example, individuals with tinnitus and hearing loss may benefit from a wide range of treatments such as bimodal neuromodulation (*Lenire*), CBT or sound therapy. Depending on a patient's profile and needs, *Lenire* may be used in conjunction with other therapies such as CBT. For those patients with tinnitus and aidable hearing loss, it is an appropriate opportunity for audiologists to provide solutions to their patients for all their audiological needs. In such cases, they can offer hearing aids to address their patient's hearing loss while addressing their tinnitus with other treatment options such as *Lenire*, particularly for those that are still bothered by their tinnitus despite using a hearing aid. For those not ready to address their hearing loss yet, particularly the younger cohort that mostly report less or even no hearing loss, tinnitus treatment may be the first step in their life-long hearing care journey until they are either ready to treat their existing hearing loss or the hearing loss that generally follows early-onset tinni-

tus in this population. Tinnitus is a specialized area that should be seen as an adjacent segment that can be complementary and beneficial to the hearing loss segment as many patients can be helped earlier on in their hearing care journey, even if they are not yet ready for hearing loss treatments, as is depicted in **Figure 4** below.

Figure 4. Lenire aims to address the tinnitus segment and should be seen as complementary to hearing aids for the treatment of tinnitus at an earlier stage of a patient's lifelong hearing care journey.



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*Kimberly Rawn* is a healthcare writer and marketer with 15 years of experience in the hearing health industry.

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recently published extensive analysis, conducted by Larry Humes, using the National Health and Nutrition Examination Survey (NHANES) data on hearing loss, self-reported hearing problems and hearing aid use reported that 85% of those who reported "trouble hearing" were not currently wearing hearing aids.<sup>1</sup> Providing further confirmation that an enormous swath of the adult U.S. population has an unmet hearing healthcare need.

Of course, it is too early to know how much of an impact over-the-counter hearing aids will have on this huge unmet need. Although OTC hearing aids have been available for about nine months, it has been reported in the press that they comprise a little over 1% of the total hearing aids sold in the U.S.

In addition to the usual suspects (cost, access, and stigma) it is becoming apparent that apathy and indifference drive a lot of this unmet need. Articles, both in the peer reviewed literature and trade publications, indicate that most adults – from unspeckled 30-somethings to weathered codgers – simply don't prioritize their hearing health.<sup>2,3</sup> This growing body of survey data shows that, compared to other common health conditions, Americans neglect their hearing. Perhaps even more unsettling, many primary care physicians and nurse practitioners, also failed to prioritize hearing health, according to a 2022 survey.<sup>4</sup>

Recently, a group of researchers, led by Sherri Smith at Duke University School of Medicine, showed that offering provider encouragement and screening facilities *in the primary care clinic* led to a significantly higher rate of adherence with hearing screening for middle-aged and older adults. In contrast, provider encouragement did not improve the significantly lower rate of adherence with home-based hearing screening.<sup>5</sup> This is a great example of how direct interaction between an audiologist and primary care clinic can improve hearing screening available in the clinic, combined with a caring primary care practitioner, gently pushing the patient to take a few minutes and have their hearing checked during a routine wellness visit makes a tremendous difference.

These findings also plainly demonstrate that we need more than just another low-cost, easy-to-buy hearing aid to move the meter on apathy and indifference surrounding hearing healthcare. It is an all-hands-on-deck problem that requires a variety of approaches.

Here to help us better understand the complexity of the challenge is Terry Mactaggart. He is the president and CEO of Summus Hearing. I've known Terry for about ten years. Maybe it's because he is Canadian, but his forward-looking viewpoints are always worth a listen. Read further to see what he has to say about the persistent problem of unmet need plaguing our industry and our profession. All of us play a key role in improving hearing screening participation and hearing aid uptake rates.

> —Brian Taylor, Au.D. Editor, Audiology Practices

# HEARING HEALTH IS FINALLY BEING DISRUPTED So What Now?

Terry Mactaggart, President and CEO, Summus Hearing

It has been over two years since my last commentary about hearing health and the road ahead, as foreseen at that time. Since then, implementation of over-the-counter devices, the introduction of new players and channels, rapid evolution of technologies, and a growing body of relevant research all suggest that steady progress is being made.<sup>6</sup>

## We still have a problem...

It was a recent editorial in The Lancet that provided the catalyst for another critical look.<sup>7</sup> Well worth a read (or reread), it argues that "hearing is a growing public health issue affecting people of all ages," a reality I've believed for some time. While ranked #3 after heart disease and cancer, evidence suggests that hearing loss is our **#1 untreated chronic health problem!** Another take on it is that apparently almost twice as many people report hearing loss than either diabetes or cancer.

The facts are known if not widely appreciated. Highlights, again from that The Lancet editorial, include the World Health Organization's (WHO) estimate that more than 1 billion people now experience some form of hearing loss, a number that could as much as quadruple by 2050. The article goes on to list some of the profound effects associated with hearing loss – employment and quality of life deficiencies, compromised learning (particularly among young people), and isolation and cognitive decline among older adults, all adding up to greater personal challenges and an enormous annual multi-billion-dollar cost.

10 years

Five years minimum, 10 years maximum defines the range between awareness of hearing loss and action to address it.

## = too long

## Recognizing the breadth and sum of this problem is vital. The overarching question remains 'What are we doing about it?' And 'Will such efforts be sufficient to stabilize, then demonstrate real improvements?'

One way of starting to address these questions is to break out the "hearing problem" into various components, examining the state of play with each. We did this exercise at Summus Hearing a couple of years ago and came up with this infographic highlighting seven common issues.

While simplified, the following comments still appear valid.

## 1. Only 2% are tested

This estimate for the United States is dated and may be different today. In any event, it's a very low percentage of the relevant population and stands out when compared, say, to testing for eyesight or blood pressure.

Conclusion - Not anywhere good enough!

## 2. Testing, when done, is often inadequate

Screening tests abound, particularly online. But unless undertaken by an unbiased provider, these tend to be skewed towards acquiring hearing aids. Adequate interpretation of results is a problem as almost all lack that capability.

**Conclusion** – This bias needs to be rectified if an entry into one's hearing journey or a check along the way is to be trusted.

## 3. Wait time between awareness and action is too long

Five years minimum, 10 years maximum defines the range between awareness of hearing loss and action to address it, with the median appearing to be 6-7 years; And that applies only to those who have been tested and ultimately decide to act!

**Conclusion** – Obviously a "Capital P" problem.

## 4. Relationships with other disease states require greater emphasis

Co-morbidities have multiplied and become more obvious.

**Conclusion** – In addition to further research, these relationships provide promising leverage. Much more could be done to insert a hearing test as part of the follow-up protocol when a disease state is detected or being managed.

## 5. Learning and behavioral issues need to be confronted

We know that undetected and untreated hearing loss compromises the learning and lifestyle trajectory of many children.

**Conclusion** – Testing of public-school age children should be mandated at regular intervals, and in many cases re-established.

## 6. Key healthcare providers are left out

This problem is enormous as family physicians and pharmacies (to name two prominent exclusions) are not connected sufficiently, if at all, with hearing health.

**Conclusion** – The imperative of mandating physicians to counsel and test appears to be gaining ground. And more pharmacy chains are adding hearing as a new revenue source. Engaging both fully would make a significant difference.

## 7. Productivity loss and social costs are too high

Billions of dollars are spent annually, often combined with other costs and therefore hidden.

**Conclusion** – Freeing up even a third of these costs represents a large amount that could be allocated to other pressing, underfunded public health problems.

## Looking Ahead: What's now needed...?

Adding up and combining this analysis suggests that, while progress is indeed underway, there is much more to do if "the growing aspect" of the public health issue is to be reduced and a broader and accelerating impact is to result. Typical of other "meta problems", short of extremes like the pandemic, present approaches appear to be fragmented and underfunded with insufficient public-facing messaging being consistently sent from credible public and private sources.

Our basic assessment is that hearing health needs not "just more of the same" but an actual REBOOT if the substantial gains warranted are to be made during the next decade.

Our perspectives are drawn from actively participating in several of the above areas, reviewing our large data sets while working with channel partners towards extending a reliable and trusted hearing guidance process.

**"Moving the meter" towards more impactful changes** in hearing health requires a commitment to common cause and a coalition approach adopted by public, private and non-profit parties. There are several moving parts that deserve greater commentary and cross-sectoral engagement.

In thinking about this, I'm reminded that significant change usually occurs when stimulated by crisis and/or opportunity. A persuasive argument can be made that both are now to some degree evident in hearing health.

A promising methodology could be to examine how other disease states have been confronted and managed. I looked, for example, at several contexts including colorectal cancer, multiple sclerosis (MS) and diabetes, each of which has a comprehensive ecosystem.

A multifaceted advance was critical with each involving various strategies and stakeholders. With the assistance of a chatbot, I came up with the following measures applicable to hearing.

## 1. Awareness and Education:

• Develop public health campaigns to raise awareness about hearing loss, its causes, prevention, and available treatments.

• Conduct educational programs in schools, workplaces, and communities to promote hearing health and safe listening practices.

## 2. Early Detection and Screening:

- Implement routine hearing screenings in healthcare settings, schools, and workplaces to identify hearing loss at an early stage.
- Provide accessible and affordable hearing tests and screenings in underserved areas or marginalized communities.
- Make sure these hearing screening are available in the clinic. An audiometer, a handheld screening device, even an app connected to a smartphone and high-quality earbuds are all options for in-clinic screenings.

## 3. Accessible and Affordable Hearing Care:

- Improve access to affordable hearing aids, assistive listening devices, and other hearing assistive technologies.
- Collaborate with manufacturers and policymakers to reduce the cost of hearing devices and promote insurance coverage for hearing-related services.

## 4. Professional Training and Capacity Building:

- Enhance training programs for healthcare professionals, audiologists, and hearing care specialists to ensure accurate diagnosis, appropriate treatment, and ongoing care for individuals with hearing loss.
- Encourage research and innovation in audiology to develop new treatments, technologies, and interventions.

## 5. Supportive Policies and Regulations:

- Advocate for the development and implementation of policies that prioritize hearing health, including noise regulations, occupational safety standards, and schoolbased hearing health programs.
- Support legislative efforts to include hearing healthcare in public health initiatives and insurance coverage.

## 6. Collaborative Partnerships:

• Foster collaboration between government agencies, healthcare providers, educational institutions, non-profit

organizations, and industry stakeholders to establish a comprehensive ecosystem for addressing hearing loss.

• Encourage partnerships to conduct research, share resources, and develop effective strategies for prevention, early intervention, and treatment.

## 7. Community Engagement and Empowerment:

- Engage local communities by organizing support groups, educational workshops, and awareness events.
- Involve individuals with hearing loss and their families in decision-making processes and empower them to advocate for their rights and access to quality care.

## 8. Data Collection and Surveillance:

- Establish a robust data collection system to monitor the prevalence, causes, and impact of hearing loss.
- Use data to identify at-risk populations, measure the effectiveness of interventions, and inform evidence-based policies and programs.

#### 9. Peer-to-Peer Networks:

• Match most other chronic conditions by developing and promoting an easily accessible platform for individuals to use to ask questions, share experiences and provide advice. Lack of such a peer-to-peer networks represent a current deficit in hearing health.

By combining these strategies, it should be possible to establish a comprehensive ecosystem that addresses the public health problem and promotes better hearing health for all individuals. A deeper dive, no doubt, would reorganize the list somewhat, ranking certain elements quite highly and well-advanced while others as barely evident.

## Building out the Ecosystem: An imperative for hearing health

A systems approach will recognize that managing the process leading to better performance is tricky. It would involve a much greater degree of coordination and collaboration among stakeholders than at least I observe presently, to ensure the delivery of effective care, support, and research. Significant change usually occurs when stimulated by crisis and/or opportunity.

We must also be mindful that there is no centralized authority to take on and oversee such an enterprise.

Speculating further, one could foresee a need to rely on several mechanisms to facilitate its management including key aspects like...

- Intensifying research collaboration between researchers, academic institutions, and hearing-related companies collaborating on studies and clinical trials to advance knowledge and treatment options for hearing.
- Enhancing the roles of professional associations bringing together healthcare professionals and researchers with a sharp focus to establish guidelines, protocols, and standards of care, thus promoting consistent and evidence-based practices.
- Encouraging nonprofit organizations through greater funding to provide resources, and coordinate efforts to improve awareness, patient education, and access to care as well as advocate for policy changes.
- Engineering greater and targeted government involvement to oversee policies and regulations as well as allocate research funding, enforce quality standards, and collaborate with stakeholders to improve patient outcomes.
- Expanding the reach of healthcare providers and institutions to play a more crucial part in managing the hearing health ecosystem by diagnosing, treating, and monitoring individuals as well as collaborating with other stakeholders, such as rehabilitation services and nonprofit organizations, to provide comprehensive care. Family doctors and pharmacies are obvious candidates, along with other health related networks.
- Fostering and supporting technological innovations by adding incentives that encourage collaboration between technology companies and hearing care providers to

# The time is now.

Improving the content and management of the hearing ecosystem will involve multiple stakeholders, collaboration, communication, and a person-centered approach to function effectively.



develop and improve solutions including digital platforms, telemedicine, and remote monitoring tools tailored to the needs of hearing health patients.

- **Increasing patient advocacy** through facilitating patient advocacy groups working closely with healthcare providers, researchers, and policymakers to influence policies, raise awareness, and improve the quality of care.
- **Improving education and training** for healthcare professionals to stay updated with the latest advancements in hearing health management.
- Encouraging prominent social influencers to add their voices by stressing the importance of paying attention to one's hearing health and taking action to protect and, when necessary, rehabilitate it.
- Empowering all members of the hearing health community to communicate with one another about personal experiences and needs as well as what resources are available and how the ecosystem is developing.

Improving the content and management of the hearing ecosystem will involve multiple stakeholders, collaboration, communication, and a person-centered approach to function effectively. Regular interactions, sharing of information, and alignment of efforts among stakeholders will contribute to improved care, support, and research outcomes for individuals living with hearing loss or prone to develop it.

One key metric should be increasing the proportion of the public who are aware of hearing health and acting proactively for their personal care.

That's a tall order to accelerate and sustain and will require consistent application of joint leadership. But such a process is possible if well conceived, financed, and managed. It's happened elsewhere. Those most involved will need to demonstrate a commitment not just to achieving the common milestones established but also to serving as leaders in some areas and followers in others.

Has not the time now come for such an initiative to take root?

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# Interventional Audiology:

An Example of How to Identify, Interpret and Incorporate Medical Research into Your Marketing Strategy

## Bob Tysoe

The law turns on the facts, as does the professions of medicine and audiology. Authoritative, peer-reviewed, trusted published sources of medical research may be found in several places, including the New England Journal of Medicine, the Annals of Internal Medicine, the Journal of American Medical Association, and The Lancet. Mayo Clinic and Johns Hopkins Medical Center are among the most esteemed medical institutions in the world and are also reliable sources for new diagnostic procedures and treatments for hearing loss, tinnitus, and balance disorders. Many of the target populations for this research, published in the aforementioned sources, might also benefit from audiological intervention. For this reason, audiologists must stay abreast of the medical literature, which can be a daunting task.

Audiologists must stay abreast of the medical literature, which can be a daunting task. Because these respected medical journals and institutions are continually generating relevant and germane research, it is critical for audiologists to be monitoring them by using resources such as PubMed to identify research that might affect prospective patients who might benefit from audiologic intervention. By taking the time to monitor the latest peer reviewed research, not only will you find new prospects who benefit from audiologic care, you will — because you are clearly communicating the relationship between untreated hearing and balance problems, with other conditions to medical professionals in your community — enhance your reputation as a leader in your field.

In this article a step-by-step process for uncovering new patients in the medical literature is discussed. Specifically, an example of acquiring new female patients who might benefit from audiologic intervention is reviewed. The process discussed below can be applied to any condition or

patient population that might have a comorbidity linked to hearing or balance disorders. The approach, outlined below, serves as an example of how scientific research can be used as part of a comprehensive marketing strategy that generates office traffic.



#### Step 1. Identify relevant articles in the medical literature.

Use vetted search engines like PubMed and conduct key word searches. In your key word search, enter the current year (2023) and "hearing loss" and "adult population" in the key word search box.



#### Step 2. Time is precious, so focus your initial review on the article abstracts.

Look carefully at where the article was published, the authors who published it, if the findings attained statistical or clinical significance, and the validity of the authors' conclusions.



#### Step 3. Develop a fact-based "call to action" that uses key findings from the relevant studies.

Usually, these key points can be culled from the abstract. Next, when you download the entire article, pay close attention to the first, second, and final paragraph where the authors place their "call to action" for the specialists with whom you seek to share the content. This "call to action" can be used to identify patient populations that might benefit from audiologic intervention.

Using these three steps, let's work through an example by using a recently published article that addresses gestational diabetes, a population with an unmet need for audiologic intervention.<sup>1</sup>

## **Key Demographic Facts**

The U.S. Census Bureau states that the population America is 340,205,185 as of August 12th, 2023, and the number of women aged 15 to 44 is 64,543,832. This means that 19% of Americans are of gestational age. Another important demographic fact is that the U.S. annual birthrate in 2021 was 3,664,292 or 11 births per 1000 people.

Why are these facts important? They demonstrate that a large segment of the population – in this example, 1 in 5 individuals are potentially impacted by the findings in this study.

## Key Facts About the Condition as Stated in the Article

Gestational Diabetes Mellitus occurred in nearly 1 in 8 pregnancies in the U.S., with even higher rates among individuals who identified as non-Hispanic, Asian/Pacific Islander, those with obesity, and those who are aged 35 years or older at time of delivery. This equates to approximately 7,809,703 pregnant women who give birth each year who might be affected by the condition.<sup>1</sup> Gestational Diabetes Mellitus or GDM (i.e., hyperglycemia first diagnosed during pregnancy) is associated with cardiometabolic disease including Type 2 diabetes (T2D) and cardiovascular disease (CVD) in the affected pregnant individual and the exposed fetus. In 2020, GDM occurred in nearly 1 in 8 pregnancies in the U.S., with even higher rates among individuals who identified as American Indian or non-Hispanic Asian/Pacific Islander, those with obesity, and those aged 35 years or older at delivery. The age-standardized rate of GDM at the first live birth has increased from 47.6 to 63.5 years of age per 1000 live births from 2011 to 2019 in the U.S., with further increases documented during the COVID-19 Pandemic.<sup>1</sup>

Up to half of pregnant individuals with GDM will develop prediabetes or TD2 postpartum. GDM is associated with an approximate 10-fold higher lifetime risk of TD2.

GDM identifies individuals who are at increased risk of subclinical CVD (eg, coronary artery calcium) and clinical CVD (eg ischemic heart disease, cerebrovascular events, and heart failure). A meta-analysis (involving 5 million female individuals and greater than 100,000 events) demonstrated that individuals with GDM have a 2-fold higher risk of CVD events within the first decade postpartum.

Why are these key facts important? They highlight that Gestational Diabetes Mellitus (GDM) has several serious health consequences if not identified and treated. Why is corroborating evidence important? It shows that the current study fits into a larger body of work with similar findings – a cornerstone of the scientific method.

## **Corroborating Evidence**

This finding is of significant concern because research conducted by the National Institutes of Health (NIH) on diabetes and hearing loss in the United States and published by Bainbridge, et al. (2008) surmises that diabetes affects the vasculature and neural system of the inner ear, leading to hearing loss.<sup>2</sup>

Bainbridge et al. (2008) go on to assert that hearing loss was more prevalent among adults with diabetes. Prevalence of low- or mid-frequency hearing loss of mild or greater severity in the worse ear was 21.3% vs 9.4% among adults without TD2 diabetes.<sup>2</sup>

## Key Findings to Communicate with Medical Gatekeepers

Hearing loss is common in adults with diabetes, and diabetes seems to be an independent risk factor for the condition. Adult patients with pre-diabetes, whose blood glucose was higher than normal, but not high enough for a TD2 diagnosis, had a 30% higher rate of hearing loss compared to those with normal blood sugar tested after an overnight fast.

Numerous studies have verified that there is cause and effect between pre-diabetes, diabetes, obesity, hyperlipidemia, hypercholesterolemia, high blood pressure, micro-vascular disease, cardiovascular disease, and hearing impairment and communication disorders.

It is worth noting that currently there are few, if any, recommendations for postpartum hearing healthcare testing. Effective lifestyle interventions to prevent TD2 delivered over a period of 1-to-3 years postpartum include dietary counseling and monitored exercise. These interventions likely reduce insulin resistance through weight loss and physical activity, which lowers the secretory demands of B-Cells.

Further, the rate of postpartum oral glucose screening has remained suboptimal (less than 50%). Reasons for suboptimal screening include clinician non-adherence (test was not ordered), lack of patient follow-up for postpartum care, patient burden associated with a fasting 2-hour laboratory procedure, and patient difficulty with accessing care while caring for an infant.

There are barriers to diabetes prevention, which include adverse social determinants of health and practical obstacles to patient engagement in intensive lifestyle modification (e.g., limited childcare and social support, emotional stress, and financial barriers), inadequate knowledge about the lifetime risk of Type 2 Diabetes, and access to postpartum care, including a timely transition to primary care.

Individuals who experience a pregnancy complicated by gestational diabetes mellitus, and their offspring in utero, are at higher risk for poor cardiometabolic health. Recognizing the lifetime and intergenerational risks associated with GDM requires greater awareness by clinicians, patients, and researchers. It is critical to highlight that GDM is a window into future cardiometabolic health, not merely an isolated complication of pregnancy that ends with delivery.

Pregnant individuals are at risk for developing hyperglycemia, which progresses to gestational diabetes, pre-diabetes, Type 2 diabetes, and quite possibly to impaired cardiometabolic health. Each of these conditions carries an increased risk of hearing loss and associated disabilities, which can be effectively managed by audiologists.

Why is communicating key findings with medical gatekeepers important? It is an opportunity to use evidence from peer-reviewed research to raise their awareness about an under-treated condition and also that audiology plays an instrumental role in the early identification and effective long-term management of this condition in a population that may have flown under the radar.

### Who is a target audience for the message?

A target market is a group of people that have been identified as the most likely potential customers for a product/service/ specialist because of their shared characteristics, (i.e., patient types) such as age, income, lifestyle, and comorbidities.

Identifying the target market is a key part of the decisionmaking process when audiologists advertise their audiology practices.

Marketing professionals divide consumers into four major segments:

**Demographic**: Main characteristics can be age, gender, income, occupation etc.

**Geographic**: Identify the country, state, city, and market area in which potential customers are located.

**Psychographic**: Consider lifestyle, attitudes, interests, and values.

**Behavioral**: Understand the research decisions of current customers, and the proven appeal of past products and services.

Carefully consider each of these marketing characteristics so that you are efficient with your new customer/patient "reach and frequency" planning objectives. The Obstetrics and Gynecology specialists have many patient-types in common with Audiology. Audiologists should identify the OB/GYN specialists who practice within a reasonable radius, (i.e., the zip codes that are within 15 miles of their practice). Then, create a digital list of names, phone numbers, addresses, fax numbers, and location maps. Mail out a letter of introduction with the goal of providing interventional audiology strategies and examples of scientific research, and clinical services that mesh with each physician's preventive care responsibilities and patient and outcome objectives.



Why is target audience a valuable consideration? Rather than broadly communicating the message, it is more effective to only target medical professionals who work with this population. This collaboration may lead to the audiologists sharing the now recognized proven risk that pregnant patients face in developing hyperglycemia which progresses to gestational diabetes, pre-diabetes, Type 2 diabetes, and eventually to impaired cardiometabolic health, and quite possibly hearing loss.

## The Benefit of Collaboration Between Specialties

Through shared exposure of respected scientific research OB/GYN specialists, primary care physicians, nurse practitioners, physician assistants, endocrinologists, and other gatekeepers will understand the reasons why pregnant women may end up suffering from hearing loss that potentially compounds postpartum disabilities, and associated co-morbidities.

Upon receipt of a new patient referral, audiologists should take an extensive personal and family medical history of female patients that reveals/uncovers hyperglycemia, hyperlipidemia, abnormal cholesterol labs, hypertension, atherosclerosis, ischemic heart disease, stroke, and obesity among other prominent maladies, that are proven precursors of hearing impairment. This may lead to an increase in physicians and staff referring more at-risk OB/GYN patients to an audiologist who will provide a baseline hearing evaluation and a routine annual follow up, plus a digital or hard copy patient report to the referring medical specialist, which subsequently may enable patients to achieve improved outcomes. Implementation bias on the part of physicians and audiologists is a reality that delays and impedes the provision of sorely needed health care, and worsens the quality of public health in the United States and around the world. The decision to act with urgency because of new scientific research can make a difference in millions of lives when we combine the results of new medical and audiological science with a well-defined target audience.

## **Final Thoughts**

Identifying, interpreting, and incorporating medical research into your marketing strategy requires intimate knowledge of evidence-based practice, strong communication skills, and an abundance of time. Turnkey methods of the approach outlined here can be tailored to your practice by contacting the author.

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## The Tools You Need to Run Your Practice.

ADA's Practice Resource Library offers a comprehensive collection of offthe-shelf forms, documents, and guidance materials. These resources will assist audiologists and their staff with practice operations, compliance, and patient management.

- Adult Case History
- Business Associate Agreement
- Employee Manual
- Hearing Aid Bill of Sale/Purchase Agreement
- Hearing Aid Insurance Waiver
- Hearing Aid Loaner Agreement
- Hearing Aid Orientation Checklist
- Hearing Aid Upgrade Notice

- HIPAA Security Policy Template
- Insurance Verification Form
- Notice of Non-Coverage
- Office and Financial Policies
- Patient Registration Form
- Policies and Procedures Manual
- Price Quote Form

ADA members receive a discounted rate when purchasing any of the above forms. Visit audiologist.org/forms for details!



# OCCUPATIONAL HEARING CONSERVATION:

## A MOBILE AUDIOLOGY BUSINESS PLAN

### By Lexi Rozycki & Kiersten Steinke

Aspiring private practice owners don't consistently receive formal business education from university audiology training programs. For those who do, it is often limited to a single course. Therefore, opportunities to receive practical advice from seasoned practice owners offer invaluable training for students considering private practice.

This article illustrates the painstaking details of creating a business plan for an industrial audiology practice. It serves as a good example of the attention to minutiae needed to get a loan approved by a lending agency. It also demonstrates how the owner must carefully plan for future growth and make decisions that are financially viable.

We thank Nancy Green, Au.D. and Larry Schmidbauer, Au.D. for allowing us to publish a portion of their thoughtful feedback on this proposed business plan. Their input can be used by the authors to strengthen the plan and create a solid framework for success.



## **Elevator Pitch**

Grand Rapids, Michigan is home to various manufacturing industries including metals, plastics, automotive, and food processing. Sound level measurements in manufacturing measure in the range from 81-115 dB(A) which can put employees at risk of noise-induced hearing loss and other auditory injuries, but there is a shortage of industrial audiologists nationwide.<sup>1,2</sup> A mobile audiology clinic focusing on tailoring hearing conservation programs (HCP) to businesses' specific needs and preventing noise-related work injuries has the potential to make a profit within the first three years of business. This business plan will outline the structure of this mobile audiology clinic.

## The Team

The team consists of an audiologist who is a member of the National Hearing Conservation Association (NHCA) as well as two industrial hygienists. The audiologist and industrial hygienists are certified by the Council for Accreditation in Occupational Hearing Conservation (CAOHC). The audiologist is dedicated, personable, and highly knowledgeable about hearing loss prevention and preservation practices and has years of experience conducting industrial hearing screenings and fitting custom hearing protection. In general, the audiologist oversees the noise surveys, marketing, creating, and developing the HCP, education, and training of employees, and assisting with the hearing testing when needed. One industrial hygienist oversees industrial testing and earmold impressions. The second holds these roles but also helps with tracking audiograms. Lastly, we have an office staff member who oversees the scheduling and bookkeeping and who will work remotely. The hearing conservation program services include noise monitoring, a written report of the noise survey, noise mapping, occupational hearing evaluations, tailored hearing conservation programs to the company's needs, and custom hearing protection.

## **Market Summary**

We have decided to base our mobile audiology business out of Grand Rapids, MI for a variety of reasons. Twenty-one percent of jobs in Grand Rapids, Michigan are manufacturing jobs which is twice the national average for large metro areas.<sup>3</sup> In 2020, there were 119,000 manufacturing jobs in the city which means a large portion of the population is at risk of damaging their hearing. Additionally, Grand Rapids is home to industry leaders in a variety of manufacturing sectors, including some of the nation's largest industry concentrations in metals, plastics, biopharmaceutical, medical devices, production technology, automotive, office furniture, and food processing.<sup>4</sup> Additionally, there are also eleven music venues in Grand Rapids we could work with to fit custom hearing protection.<sup>5</sup>

While there has been a decrease in manufacturing throughout the United States in the last few years, Table 1 from the U.S. Bureau of Labor Statistics.<sup>6</sup> shows the opposite trend in the Midwest. This increase is seen in the following Midwest states: North Dakota, Indiana, Minnesota, Iowa, South Dakota, Kansas, Nebraska, and Wisconsin.<sup>7</sup> FEEDBACK: This might be ambitious to start. Control of overhead is critical to survival of a small business. If the Audiologist is younger and this is full time effort they can do everything being asked for. If the business is brisk then an Audiologist and one other would be fine.

- Larry Schmidbauer, Au.D.

FEEDBACK: Great location and nice identification of diverse industries (i.e. not all automotive related).

- Larry Schmidbauer, Au.D.

FEEDBACK: This is an assumption that 1) they all work in production and 2) that they all are noiseexposed. Without proof, you discount the fact that in many facilities, there are more employees who are NOT noise-exposed than there are exposed ones.

What about the needs of facilities subject to MSHA, FRA, and DoD regulations, all of whom are plentiful in the area and could be potential customers?

- Nancy Green, Au.D.

Year	Illinois	Indiana	Iowa	Kansas	Michigan	Minnesota	Missouri	Nebraska	North Dakota	Ohio	South Dakota	Wisconsin
1990	17.6	11.6	4.2	3.4	15.9	6.6	7.5	1.9	0.3	20.3	0.6	10.1
2019	14.3	13.2	5.5	4.2	15.2	7.9	6.7	2.4	0.6	17.1	1.1	11.8

Table 1. State Share of Manufacturing Employment in the Midwest region, 1990 and 2019 (in percent)

Additionally, as shown in Table 2, the Midwest and particularly Michigan has a large number of manufacturing companies employing a substantial number of workers.

#### Table 2. Number of Manufacturing Companies and Workers by State

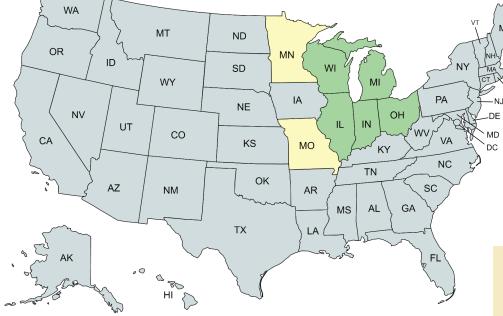
State	# of Manufacturing Companies	# of Workers in Manufacturing
Michigan	12, 238	711,807
Indiana	8,472	589,816
Illinois	14,660	735,084
Iowa	4,414	266,237
Kansas	4,423	205,534
Minnesota	7,992	453,918
Missouri	>8,000	>350,000
Nebraska	2,394	126, 358
North Dakota	1,479	Unknown
South Dakota	1,188	52,858
Ohio	15,326	890,926
Wisconsin	9,731	590,934

Due to the numbers and statistics listed above, we will aim to primarily service Michigan, Indiana, Illinois, Ohio, and Wisconsin by year three. These states are geographically close and have the highest number of manufacturing companies and workers. Additionally, we may travel to Minnesota or Missouri if we are contacted by a manufacturing company in one of those states.

FEEDBACK: Planned growth is good. Applause for that. How might the areas of growth differ? State regulations, perhaps? Licensure and major competitors?

- Larry Schmidbauer, Au.D.

#### **Image: Geographical Area for Services**



#### Geographical Area for Services

States we are actively providing services in
 States we may

provide services in if contacted

are not a very high bar; they are the bare minimum acceptable standards. If you want to make the kind of money you describe, and provide an elite, bestpractice-type service, you need to aim higher than OSHA. OSHA standards, even followed exactly, will still allow disabling loss of hearing to occur in 25% of workers exposed at 90 dBA TWA over a working lifetime.

FEEDBACK: OSHA standards

- Nancy Green, Au.D.

Despite the national trends showing there is an overall decrease in manufacturing; it is required for all individuals in manufacturing to follow OSHA requirements for a safe workplace. This means that our services are required by all manufacturing companies in the Midwest that meet OSHA requirements. Additionally, there has been an increase in protective health measures within society, so we are adopting this idea and promoting healthy hearing practices backed by OSHA standards to create tailored hearing conservation programs for manufacturers.

## Competitive Landscape & Advantage

According to Green,<sup>2</sup> while there are around 30 million workers who are exposed to damaging levels of sound, there are just ~200 audiologists who provide industrial audiology services nationwide. Consequently, there is a tremendous need for industrial audiologists nationwide — and only one other audiologist in Grand Rapids performs industrial tests. This audiologist does not serve as a direct competitor to us because workers must travel to them for the hearing test, while our mobile audiology clinic is more convenient and efficient for the workers. VanWyk Risk Solutions in Grand Rapids provides custom risk solutions to businesses and has a whole resource page about how to protect workers from workplace hearing injuries.9 Instead of viewing VanWyk Risk Solutions as a competitor, we could contact them to act as a referral system to encourage businesses to use us as their hearing conservation specialists. Our business utilizes Sensaphonics, a company based in Chicago, IL that specializes in in-ear-monitor systems and custom ear plugs, and was founded by audiologists.

Sensaphonics custom hearing protection uses medical grade silicone and is exacting about the ear impressions they take to make the best-fit custom plugs. Audiologists hold extensive knowledge about sound levels, noise-induced hearing loss, and ways to protect against noise-induced hearing loss, which will be to our advantage over competitors. Covered OSHA businesses must adhere to OSHA standards. Therefore there will continue to be a need for hearing conservation programs for many years to come. This means that employers must keep abreast of hearing evaluations and reduce workplace injuries related to noise.



## **Goals and Objectives**

What follows are key milestones that we expect to reach at the end of each of our first three years in business.

#### End of Year One

• Test one to two companies per month by establishing ourselves in Grand Rapids, Michigan

#### End of Year Two

- Add a second mobile practice (another "location")
- Double the number of company employees
- Test three to four companies per month
- Expand to Indiana and Ohio

#### End of Year Three

- Add a third mobile practice (another "location")
- Add another audiologist, two industrial hygienists, and one office staff
- Expand the company to Illinois and Wisconsin
- Plan to have the largest noise survey and hearing conservation program backed by OSHA protocols in the Midwest
- Be profitable and pay off our small business loan

## **Marketing Strategy**

#### How will our business be marketed?

Our marketing strategy will begin with our vehicle, which will be vinyl wrapped with our logo, mission statement, and contact information. According to the Out of Home Advertising Association of America, vinyl wrapping can be the most effective and efficient form of out-of-home advertising, reaching consumers at a lower cost per thousand impressions than any other form of advertising. Vinyl vehicle advertising costs approximately four cents per thousand impressions, which is significantly lower than other forms of advertising (outdoor signs cost ~\$3.65 per thousand impressions, and newspaper ads cost \$19.70 per thousand impressions).<sup>10</sup> We will be creating a website that advertises our mission statement, the importance of noise conservation, the services we provide, and contact information for a phone consultation. This will have the same logo and aesthetic as our mobile practice vinyl wrapping. Along with the website, we will be utilizing Facebook, Twitter, and Instagram social media platforms to create weekly marketing posts.

Additionally, we will be advertising in IndustryWeek Magazine, an online magazine, that markets to 760,722 subscribers whose companies range from 100 to 100,000 employees.<sup>11</sup> IndustryWeek is a business publication that focuses on manufacturing, with its readers consisting of corporate and executive management (43% of readers), operations, production, and plant managers (31% of readers), and engineering, R&D, and design and technical management (18% of readers). Advertising in IndustryWeek will help launch our services to a broad audience and position ourselves within the manufacturing industry.

FEEDBACK: None of these people will likely be involved in decision making, except the Plant Manager may have to give final approval. You may be marketing to the wrong crowd.

Nancy Green, Au.D.

#### How will the patient caseload be developed?

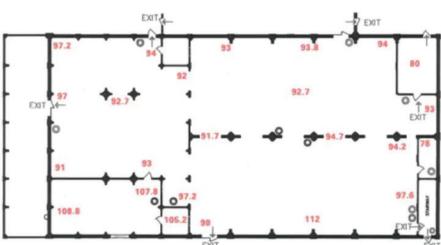
In the beginning stages, we will develop a caseload by reaching out to industries in the Midwest, such as factories, power plants, oil rigs, and other industries with a large amount of noise exposure. We will be conducting our own searches of these companies and contacting them via email or phone to introduce ourselves, the business, and provide a cost estimate. We also hope to gain business from the ad placed in IndustryWeek and referrals received from Van Wyk Risk Solutions.

## Services and Pricing Structure

#### Noise Survey and Mapping: \$1,000<sup>12</sup>

The first and most important step of a hearing conservation program is to measure the noise levels and workers' noise exposure during the workday. This will help identify hazardous work locations and specific employees who are exposed to hazardous sound levels by acquiring personal time-weighted average (TWA) samples throughout the facility, even in areas that may not appear to be particularly noisy. Noise sampling needs to be conducted every three years, or any time there is a change in facility processes or equipment.<sup>13</sup>

A noise map allows the HCP team to identify noise levels that contribute to a worker's cumulative exposure and indicate where noise reduction efforts are needed to reduce the possibility of noise-induced hearing loss. To create a noise map, a floor plan of the workplace is used, and specific noise readings are logged on the floor plan. Few workplaces have steady noise so the sound level measurements will be obtained at three different times per location and averaged and a range of noise will be recorded.<sup>13</sup>



A noise map allows the HCP team to identify noise levels that contribute to a worker's cumulative exposure and indicate where noise reduction efforts are needed.

#### Image 2. Example of Noise Mapping<sup>14</sup>

## Occupational Hearing Evaluations and Customized Hearing Conservation Program: *\$200/employee/year.*<sup>15</sup>

The Occupational Safety and Health Administration (OSHA) requires employers to establish a hearing conservation program to educate employees on noise-induced hearing loss when employees are exposed to 85 dB(A) or greater for an 8-hour time-weighted average (TWA).<sup>16</sup> The education under a hearing conservation program includes information about the effects of noise on hearing, the different types of hearing protection and their purpose, and the importance of audiometric monitoring. Audiometric monitoring includes baseline and annual audiograms as well as notifying the required OSHA personnel of the results. If a Standard Threshold Shift (STS) is identified, then a retest will need to be scheduled within 30 days of the annual audiogram to determine if there is a shift in hearing. Records will need to be kept regarding noise exposure measurements, audiograms, and data on hearing loss due to occupational noise exposure.

#### *Custom Hearing Protection: \$225/worker*

Research shows proper fit hearing protection can protect against noise-induced hearing loss which can occur at 85 dB(A) over an 8-hour time-weighted average. In comparison, the normal level for a typical conversation is 60 dB. When noise levels exceed 100 dB, a person can experience hearing damage in as little as 15 minutes.<sup>17</sup>

There are many consequences of occupational noise exposure including noiseinduced hearing loss and other auditory injuries such as tinnitus, hyperacusis, and misophonia which can affect productivity and increase the company's liability. According to current OSHA regulations employers have a legal duty to "prevent or reduce the risks to health and safety from exposure to noise at work."<sup>18</sup> While the best way to protect against noise-induced hearing loss is to eliminate noise hazards, this change is not possible in many occupational settings. With this in mind, wellfitted hearing protection is crucial.<sup>17</sup> Under OSHA regulation, hearing protection should be readily available to employees that are exposed to levels of sound at 90 dB(A) or more over an 8-hour TWA.<sup>16</sup> FEEDBACK: What am I, as a company, getting for \$200 per employee? My experience is that onsite services include a mobile unit location fee and a per test fee typically in the range of \$15-\$25. I have never seen Industrial testing priced on a Per Employee Per Year basis and I don't know what you are providing my employee for the other eleven months once the test is done.

- Larry Schmidbauer, Au.D.

FEEDBACK: Retests are not required by OSHA; they are a company option, and therefore cannot be counted on as revenueproducing services.

- Nancy Green, Au.D.

FEEDBACK: Nice offer. I have done a few Custom Plugs In my career – not every plant. Most companies will ask what the OSHA Reg requires and provide that, and only that. Is there direct proof that a custom plug is better? How many dB attenuation is in 'tighter'?

- Larry Schmidbauer, Au.D.

While non-custom hearing protection is the standard among industrial and manufacturing workers, there are many benefits to providing all employees with custom hearing protection. Custom hearing protection is more effective than other forms of hearing protection because of the tight fit. The strength of the filter can also be adjusted due to the worker's needs and sound exposure which benefits the employee and their hearing.<sup>19</sup> Taking an earmold impression of the employee's ears allows the hearing protection to be more comfortable than universal fit earplugs. One of the biggest complaints from employees is that hearing protection devices are not comfortable, and providing customs to employees would eliminate this barrier.<sup>19</sup> Finally, custom hearing protection is a better value than universal earplugs. Universal earplugs are one to two-time use, while custom devices can be used repeatedly which prevents employers from repeatedly purchasing earplugs.<sup>19</sup> The patient, or in this case, the worker will benefit from the custom hearing protection by reducing their risk of noise-induced hearing loss which in return prevents the business from having to report a workplace injury.

Part of our plan is to provide custom-fit hearing protection to employers at slightly above the cost from the manufacturer. In the long term, this will provide a higher investment in the health and wellness of their employees. To ensure the value of our services, the earmold impressions will cost \$100 dollars per employee, and the hearing protection will cost \$125 per employee, which are combined creating an overall cost of \$225 per employee.

FEEDBACK: I don't think a "slight increase" is going to begin to cover the costs of the extra time involved. Will you drive to Ohio to remake custom plugs for one employee who lost his?

- Nancy Green, Au.D.

#### **Overall Summary of Services and Costs**

- Noise survey and mapping: \$1,000
- Occupational Hearing Evaluations and Customized Hearing Conservation Program: \$200/worker/year
- Custom hearing protection: \$225/worker

#### Start-Up Financing and Start-up Costs

To start our business, we will be taking out a small business loan of \$100,000 with a four-year loan term and a 6% interest rate. This will equal a total principal of \$100,000 and a total interest of approximately \$24,000 over that term. Additionally, this will result in forty-eight monthly payments of \$2,584, which will be calculated into the ongoing costs per month.

#### The Mobile Practice Vehicle and Upgrades

For our mobile practice, we wanted an affordable and reliable vehicle that could be renovated into a small audiology practice that contains an OSHA-approved sound booth and storage for ear impression material and sound level measurement equipment. We considered three different types of vehicles for our practice: a tiny home, a box truck, and a school bus. Based upon our research, we determined a used 2010 Chevrolet Thomas 8+2 Thomas ADA Type A School Bus would best suit our needs, which cost \$21,850. The school bus, which is ADA accessible, is large enough for external marketing, a sound booth, and equipment storage.

For exterior upgrades to the bus, we will be using a vehicle wrap for exterior marketing. There is often a misconception about car wrapping that it is used for large companies for vehicle fleets, however, there are many benefits to choosing vinyl wrapping over a traditional paint job. Vinyl wraps are a cost-effective solution in comparison to the price of painting a vehicle and provide the vehicle with a new appearance. The vinyl wrap will include our business's name, email, and company phone number. The average cost of a vinyl wrap is \$1500-\$5000, and we will be using the high average of \$5000 for our start-up costs. We plan to remove unneeded seats ourselves on the interior of the bus (while keeping seats for our two employees) and using the bus to transport all the equipment which reduces interior renovations.

#### Equipment

We plan to use two audiometers and two collapsible/mobile sound booths to start our mobile hearing conservation practice. We will be purchasing KUDUwave audiometer which connects to a PC and uses an ambi-dome to attenuate ambient noise and has the ability to perform air and bone conduction, speech reception thresholds, word recognition testing, speech-in-noise testing, central auditory processing testing, masking for both air and bone conduction, and extended highfrequency audiometry. The KUDUwave system can be automated or manual, with in-person or remote testing in synchronous or asynchronous modes. The KUDUwave features the Ambi-dome headset, which consists of circum-aural earphones connected with insert earphones to increase sound attenuation and measure the ambient noise levels. Testing is only performed during periods where ambient noise falls below the noise floor limit. Per system specifications, the combined earcup and ear-insert technology provides 31-52.3 dB of attenuation while operational background noise levels range from 50 to 70 dB SPL which allows testing down to 0 dB HL from 125-8000 HZ. Additionally, reports on the validity of the KUDUwave system have found that average air conduction thresholds measured in adults were

FEEDBACK: There is no mention of how you are going to power this equipment, nor a contingency plan for when the A/C or heat goes out, or when it's raining or snowing. The show must go on, and these issues need to be planned for. Just think, "What's the worst that can happen," and then fix that before it does.

- Nancy Green, Au.D.

FEEDBACK: These are referral services and have no place in an OHCP. A case could be made for masking, but it is a clinical service and if you provided such services onsite, it would be another time suck and slow down the progress of your industrial testing operations. By trying to provide a clinical diagnostic service in the middle of industrial OSHA/ MSHA-type testing, you also rob either yourself or the local clinical audiologist of the clinical revenue involved in follow-up referral activity. Plus, Industrial Hygienists can't provide clinical audiology services, even with a KUDUWave.

- Nancy Green, Au.D.

within 5dB and well within test/retest reliability.<sup>20</sup> The KUDUwave costs approximately \$4000.00.<sup>21</sup> We will be purchasing two KUDUwave audiometers and using the automated air conduction threshold testing feature to test one employee while the industrial hygienist sets up and instructs the next person.

Despite the KUDUwave advertising they are a booth-less audiometer system, we want to ensure all tests meet all ANSI and OSHA standards for hearing conservation programs. Due to this, we will be purchasing two portable sound booths via Whisper-Room via the Audiology Basic Package. As advertised, the WhisperRoom Audiology package sound booths meet ANSI/OSHA standards, as well as being portable and easy to relocate. The Audiology Basic Package includes the MDL 4872 S, a single-wall booth with dimensions of 4' 2" x 6' 11". The booth comes with ventilation, a door window, and cable passages. Based on the WhisperRoom product catalog, the cost of the Audiology Basic Package is \$9,598.80. Additionally, we will need two booths, as we will be conducting two occupational hearing tests at the same time.<sup>22</sup>

#### Inventory

Since we will be providing hearing screenings, occupational hearing tests, and custom earmolds, we will need some supplies. Below is a table of basic inventory items we will need when visiting sites, and how much we will purchase at the start of our company.

> FEEDBACK: You are not providing clinical services. Cerumen Removal is a clinical service. If the ears need cleaning you would be better to refer it out.

- Larry Schmidbauer, Au.D.

We will be creating our website using Squarespace, using the business model plan for \$23/month which allows us to save money by not hiring an individual to create the website for us and allows us to make edits or changes at any time.

#### Marketing

We will be advertising in IndustryWeek's ENewsletter under the sponsor exclusivity section (only one paid ad is allowed per each ENewsletter) and using an above-the-fold placement (ad placed at the top of the newsletter). The ad includes a 40-character headline, 75-word URL, and a 180x150 pixel logo. We will be placing an ad every Tuesday for 6 weeks, which will total \$19,500.<sup>23</sup>

#### Table 3. Mobile Practice Initial Inventory with Projected Costs

	Table 3. Mobile Practice Initial Inventory	
Area of Supplies	Name Of Supply Item	Cost of Item (USD)
Cerumen Removal	Audiologist Choice Aud-Gel Lubricant (2 pack)	\$15.95
	Graham Plasbak Tissue/Polyback towel (500/box)	\$49.99
	Audiologist's Choice Earwax Removal Drops x 3	\$26.85
	Lightbeam Rechargeable Lighted Curette Starter Kit	\$124.99
	Economy Chrome Alligator Forceps, Pointed	\$24.99
	Tidal Wave Irrigation Basin with Irrigation tip	\$41.98
	Waterproof Irrigation Patient Cape	\$39.99
Otoscope	Diagnostic Otoscope, 2.5 Volt	\$55.89
	Disposable Otoscope Specula, 2.5 mm (1000/bag)	\$21.21
Hearing Tests	KUDUwave Reusable Eartips (Pack of 200) x 2	\$140.80
	KUDUwave Hygiene Kist x 2	\$55.00
Ear Impressions	Audiologist Choice DM-50 Impression Material w/ tips (100/bag) x20	\$1,200.00
	Manual Impression Gun for DM-50 Cartridges	\$57.00
	Foam Ear Drums - Large (50/pack) x 5 - Medium (50/pack) x5 - Small (50/pack) x5	\$69.00
	Audiologist Choice LED Light with Straight Probe Tip x 2	\$40.00
General PPE/Hygiene	Paper Towel	\$7.28
	Sani-Cloth PLUS Disinfectant Wipes (160/canister) x2	\$29.98
	Purell Advanced Instant Hand Sanitizer (2 liter pump bottle)	\$19.99
	Disposable 3-ply protective face mask (50/container)	\$7.99
	Nitrile Exam Gloves (100/box) x 3	\$29.97
	Total Cost:	\$2,003.88

#### **Record Keeping and Documentation**

For record keeping and documentation, we will be using CounselEar. CounselEar is designed for Audiology clinics and clinicians to customize professional reports, chart notes, fax cover sheet, cover letters, and medical clearance forms, as well as the ability to fax and email reports directly from CounselEar. CounselEar is HIPPA Compliant and can be used to meet our need of storing occupational health audiograms, as well as manage the hearing conservation program. CounselEar is approximately \$50 per clinic, with no upfront cost and no contract to sign.<sup>24</sup>

Summary of Start-Up Costs	
Bus	\$21,850.00
Vinyl	\$5,000.00
Website	\$23.00
+ IndustryWeek Marketing	\$19,500.00
CounselEar	\$39.95
Inventory	\$2,003.88
KUDUwave (\$4,000 x 2)	\$8,000.00
Soundbooth (\$9,598.80 x 2)	\$19,197.60
Total Start-Up Costs	\$75,614.43

#### **Projected Labor Costs**

There are three types of employees associated with this practice, each of which has their own individual cost structure. Table 4-6 provide an analysis of the labor costs associated with each employee type.

#### Salary of Employees (Plus Cost of Benefits)

As of Apr 30, 2023, the average annual pay for an Entry Level Industrial Hygienist in the United States is \$50,392 a year. This is equivalent to \$969/week or \$4,199/month.<sup>25</sup> Table 4 is a thorough breakdown of all compensation related to employment of the industrial hygienists in this practice.

#### Table 4. Total Compensation Analysis for Industrial Hygienists

Table 4. Total Compensation Analysis for Industrial Hygienists		
Time Off Benefits	Value	% of Salary
Vacation Days (10)	\$1,938	3.85%
Paid holidays (7)	\$1,357	2.69%
Personal days (10)	\$1,938	3.85%
Break minutes per day (20)	\$2,100	4.17%
Total time off (added in wages)	\$7,333	14.55%
Government Benefits	Value	% of Salary
Social Security and Medicare	\$3,855	7.65%
Worker's Compensation	\$504	1.00%
Unemployment Benefit	\$250	0.50%
Insurance Benefits	Value	% of Salary
Medical	\$24,000	47.63%
Life	\$1,800	3.57%
Disability	\$3,000	5.95%
Dental \$2,880 5.72%		5.72%
Total Paid by Employer in Addition	on to Salary: \$36,289.00	
Total for Salary and Compensation	on/Year: \$86,681.00	
Total Salary/Compensation/Mon	th: \$7,223.42	

FEEDBACK: How do you pay this with only a \$100,000 loan? Same question about the audiologist's compensation package.

- Nancy Green, Au.D.

For the office staff, the average national salary is \$30,537 per year. This is equivalent to \$587/week or \$2,544/month.<sup>26</sup> Table 5 is an estimate of the costs associated with employing office workers in this practice.

Table 5. To	Table 5. Total Compensation Analysis for Office Workers		
Time Off Benefits Value % of Salary			
Vacation Days (10)	\$1,174	3.85%	
Paid holidays (7)	\$822	2.96%	
Personal days (10)	\$1,174	3.85%	
Break minutes per day (20)	\$1,272	4.17%	
Total time off (added in wages)	\$4,444	14.55%	
Government Benefits	Value	% of Salary	
Social Security and Medicare	\$2,336	7.65%	
Worker's Compensation	\$305	1.00%	
Unemployment Benefit	\$250	0.50%	
Insurance Benefits	Value	% of Salary	
Nedical	\$24,000	47.63%	
ife	\$1,800	3.57%	
Disability	\$3,000	5.95%	
Dental	\$2,880	5.72%	
Fotal Paid by Employer in Additic	on to Salary: \$34,571.00		
otal for Salary and Compensatio	on/Year: \$65,108.00		
Fotal Salary/Compensation/Mon	th: \$5,425.00		

#### **Table 5. Total Compensation Analysis for Office Workers**

~200

According to Green,<sup>2</sup> while there are around 30 million workers who are exposed to damaging levels of sound, there are just ~200 audiologists who provide industrial audiology services nationwide.



The practice will start out with a \$100,000 annual salary for the audiologists, which is equivalent to \$1,923/week or \$7,692/ month. Table 6 is a detailed projection of the compensation for the audiologists in this practice.

Table 6. Total Compensation Analysis for Audiologists			
Time Off Benefits	Value	% of Salary	
Vacation Days (10)	\$3,846	3.85%	
Paid holidays (7)	\$2,692	2.96%	
Personal days (10)	\$3,846	3.85%	
Break minutes per day (20)	\$4,167	4.17%	
Total time off (added in wages)	\$14,551	14.55%	
Government Benefits Value % of Salary		% of Salary	
Social Security and Medicare	\$7,650	7.65%	
Worker's Compensation	\$1,000	1.00%	
Unemployment Benefit \$250 0.50%		0.50%	
Insurance Benefits Value % of Salary		% of Salary	
Medical	\$24,000	47.63%	
Life \$1,800 3.57%		3.57%	
Disability \$3,000 5.95%		5.95%	
Dental	Dental \$2,880 5.72%		
Total Paid by Employer in Additio	n to Salary: \$40,580.00	•	
Total for Salary and Compensation/Year: \$140,580.00			
Total Salary/Compensation/Mont	Total Salary/Compensation/Month: \$11,715.00		

#### Table 6. Total Compensation Analysis for Audiologists

Table 7 is a summary of projection of costs associated with compensation of staff (costs of labor).

#### Table 7. Summary of Total Compensation for all Employee Types

Salary and Compensation / Month for Two Industrial Hygienists \$7,2	
Salary and Compensation / Month for One Office Staff \$5,42	
Salary and Compensation / Month for One Audiologist \$11,71	
Total Salary and Compensation // Month for All Employees \$24,	

#### Insurance

We will be purchasing general liability insurance for our business, professional liability insurance, worker's compensation insurance, and car insurance for our mobile practice. This will all be necessary to protect the business, the workers, our products, and equipment. Table 8 is an estimate of all insurance costs related to the operation of the practice.

#### Table 8. Insurance Costs

General Liability Insurance	\$42 / month
Professional Liability Insurance	\$61 / month
Car Insurance \$147 /	
Total for all Insurance	\$250 / month

#### Vehicle Gas and Maintenance

In our first year of business, we plan on serving customers primarily in Michigan, as we are located in Grand Rapids which will allow us to have less travel time and commit to servicing businesses. Based on the travel, we estimate an average of \$100 in gas per site visit. Once we expand to the other states (as outlined in Year 2 and 3 goals), we estimate an average of \$200-300 in gas per business. For the purpose of the financial roadmap, we will be using \$250 as our cost of gas per business served.

Additionally, we will be performing yearly maintenance on our minibus, which will equate to \$1,700 per year. This includes four oil changes, air filters, fuel filters, two tire rotations, A/C service, brake, and other miscellaneous services that may be required.<sup>27</sup>

#### **Cost and Revenue Projections**

Here we estimate the ongoing costs and projected revenue associated with servicing one company in Year 1 of business operations.

Overall Summary of Ongoing Costs Per Month with One Company Serviced for Year 1

- Total salary and compensation/month for all employees: \$24,363
- Total for all insurance: \$250
- Total bus cost: \$241
- + Restock supplies: \$1,500
- Room and board: \$3,080
- Business loan payment: \$2,584
- Food stipend: \$2,100
- Website and CounselEar subscriptions \$80

Total: \$34,198 per month

Annual estimated costs: \$410,376

#### Average Revenue Per Business Serviced

Based on statistics from the U.S. Bureau of Labor Statistics, we will be using an average of 250 employees per manufacturing company. Although this number will fluctuate per company, we believe that 250 employees is representative of most of the companies we will be servicing and will provide a valid baseline for our revenue projections.<sup>28</sup>

With this number established, we will first be reviewing the services (and the cost of these services) that our mobile practice is providing:

- Noise survey and mapping: \$1,000/company
- Occupational hearing evaluations and customized hearing conservation program: \$200/worker/year
- Custom hearing protection: \$225/worker

With these prices in mind, we can calculate the average revenue per company serviced:

- Noise survey and mapping: \$1,000
- + Occ. hearing evals./customized HCP: 250 workers x \$1200 = \$50,000,500

Custom hearing protection: 250 workers x \$225 = \$56,250

Total revenue: \$107,250 per business

To cover our annual costs of \$410,300 and make a marginal 10% profit, at the beginning of Year 2 we plan service 5 businesses, each with a minimum of 250 employees. Given the number of personnel, we can achieve 5 large clients by the beginning of Year 2.

By the beginning of Year 3, we plan to service 12 large clients. The table shows the projected costs, revenue and profits for the first three years of business. Note that we plan to scale from 2 businesses in Year 1, to five businesses in Year 2, to 12 businesses in Year 3.

#### Table 9. Summary of Projected Profits for First Three Years.

	Year 1	Year 2	Year 3
Projected Costs	\$410,376	\$420,696	\$501,984
Projected Revenue	\$214,500	\$536,250	\$1,287,000
Projected Profits	(\$195,876)	\$115,554	\$785,016

#### **Risk Analysis**

As mentioned above, the number of manufacturing jobs is decreasing nationwide, but there will always be businesses that must adhere to OSHA workplace standards. As more people are exposed to damaging levels of sound, the need for education about safe listening habits and the importance of hearing protection, universal or custom, increases.<sup>29</sup> Risks include the number of companies that will need or utilize our services being underestimated which results in less income. To limit this risk, we will market the services audiologists can provide to tailor a hearing conservation program that will reduce the number of workplace injuries. Another risk is that we underestimate the amount of growth we plan on. To reduce this risk, we will monitor our profits and workload at the end of both years one and two. Also, we could consider utilizing the Midwest Manufacturers Directory, which is a database for industrial service providers. The cost of this service is \$1,241 annually and may be able to help us recruit more clients.<sup>30</sup>

#### Summary

Our hearing conservation business is a mobile audiology clinic that focuses on creating tailored hearing conservation programs for manufacturing businesses in Grand Rapids, Michigan. We focus on hearing loss prevention which in return helps businesses decrease the number of workplace hearing injuries they experience. This is important because businesses must comply with OSHA standards and audiologists are knowledgeable about hearing loss prevention, necessary communication on the job, and custom hearing protection.

FEEDBACK: How are you going to attract business away from a competitor when your fees are dramatically higher. The Safety and Health Director cannot walk into his meeting with Management team and tell them he wants a \$50,000 increase in the Hearing Conservation budget. The overall revenue projections are too high.

- Larry Schmidbauer, Au.D.

FEEDBACK: There are many good ideas here and you have done well to include things that many would have overlooked or missed completely. Practicality is important, too. Understanding what services are currently offered by other competitors and what (barebones) a company needs to "check the box" for compliance are realities you do not seem to be dealing with, from my review. From my experience, your business 'tailored' is wanting me, as a company, to do much more than I can or would afford.

My job, when I was providing onsite mobile testing, was to get someone off the line and back to the line ASAP meaning they were in my unit for 7–12 minutes. You cannot provide the services you're considering in that kind of time

- Larry Schmidbauer, Au.D.

## \$410,300

To cover our annual costs of \$410,300 and make a marginal 10% profit, at the beginning of Year 2 we plan service 5 businesses, each with a minimum of 250 employees.

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Lexi Rozycki & Kiersten Steinke are AuD students at the University of Wisconsin.

## UP TO II



# HAVE YOU HEARD?

#### **ADA Board of Directors Election Results:**

#### Drs. Amlani, Davis, and O'Brien Elected to Serve

The Academy of Doctors of Audiology (ADA) is pleased to announce that Amyn Amlani, Ph.D. has been elected to serve as ADA President-Elect for the 2024 program year. Dr. Amlani is President of Otolithic, LLC—a for-profit firm with its global headquarters in Frisco, TX—that provides healthcare companies with competitive market analysis and support strategy, economic and financial assessments, and consumer insights, to ensure long-term profitability and economic viability.



**Dr. Amlani** holds a Doctor of Philosophy Degree (Ph.D.) in Audiology/Psychoacoustics from Michigan State University, a Master of Science in Audiology from Purdue University, and a Bachelor of Arts in Communication Disorders from University of the Pacific. He also holds a Certificate in Health Economics and Outcomes Research (C-HECOR) from the University of Washington. Dr. Amlani is a regular contributor to national and international publications on topics related to audiology and hearing industry economics.



**Jill Davis, Au.D.**, has been elected to serve as a director-at-large on the ADA Board of Directors. She is the owner and audiologist at Victory Hearing and Balance in Austin, Texas. Driven by her desire to help patients hear their best, she created a music-based auditory training program called Victory Brain Training, which is designed to improve memory and speech in noise processing. Because of this program, she developed a specialty in cognitive hearing science and enjoys working with audiologists across the country on implementing cognitive screening into practice.

Dr. Davis works with students from the University of Texas and surrounding Au.D. programs to encourage full scope audiologic care in the private practice setting and educates on small business ownership. She is a member of the Texas Academy of Audiology (TAA), Texas Speech-Language Hearing Association (TSHA), Academy of Doctors of Audiology (ADA), and American Academy of Audiology (AAA). Dr. Davis is a graduate of the University of Cincinnati, where she received both her Doctorate of Audiology and Bachelor of Science degrees.



**Stacy O'Brien, Au.D.**, has been elected to serve as a director-at-large on the ADA Board of Directors. Dr. O'Brien is the founder of Atlantic Hearing, Balance and Tinnitus Center with locations along the east coast of Florida and leads a team who offer hearing, tinnitus, vestibular and cochlear implant services. She is also a partner with Acuity Healthcare Partners, providing strategic business consultation and resources for marketing, strategic planning, all things HR (payroll, recruiting, onboarding, training and retaining for success), patient-centered pathways, creating passionate team culture, special team event planning, strategic planning, and increased profitability.

Dr. O'Brien received her undergraduate education from the University of Nevada, Las Vegas, and her Doctor of Audiology degree from the University of South Florida, Tampa. As an audiology student she was a participant and award winner in the inaugural ADA student business plan competition.

Dr. Amlani, Dr. Davis, and Dr. O'Brien will begin their terms of service on January 1, 2024. Continuing in service on the ADA Board of Directors will be Dr. Dawn Heiman (2024 Immediate Past President), Dr. Jason Leyendecker (2024 President), Dr. Liz Rogers, and Dr. Judy Huch. Ending their terms on the ADA Board of Directors are Dr. Kristin Davis, Dr. Audra Branham, and Dr. Stephanie Sjoblad. ADA is grateful for their service.

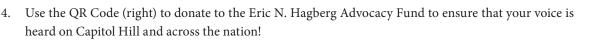
#### Make the Medicare Audiologist Access Improvement Act a Reality

The Medicare Audiology Access Improvement Act (S. 2377) will align Medicare policies with evidence-based practices in the delivery of hearing and balance care through the following provisions:

- Amends the definition of "audiology services" in the Medicare statute, which specifies the services that audiologists may provide, to include all services already covered by Medicare that are also within an audiologist's scope of practice;
- Amends the Medicare definition of practitioner to include audiologists, which improves beneficiary access to audiologic and vestibular care, a change that is consistent with Medicare's classification of similar health care providers such as clinical social workers and clinical psychologists;
- Makes technical changes to remove the pre-treatment order requirement, which does not exist with any other federal or commercial payer, allowing beneficiaries to have direct access to audiologists;
- Ensures seniors and people with disabilities can receive the full scope of audiology services covered by Medicare at Rural Health Centers and Federally Qualified Health Centers; and
- Makes no changes to the scope of hearing health benefits covered by Medicare or the scope of practice of audiologists.

#### ADA members—we need you! Please take action to build momentum for S. 2377 today!

- 1. Contact your legislators today through Congressional Connect (<u>www.congressionalconnect.net</u>) and let them know how important this legislation is to you and your patients.
- 2. Set up a meeting to meet with your legislator(s) and/or their staff virtually. Contact Stephanie Czuhajewski at <u>sczuhajew-ski@audiologist.org</u> to arrange for a virtual meeting with your Senate and Congressional officials.
- 3. Reach out to your patients, colleagues, and other stakeholders to encourage them to make some noise about the Medicare Audiology Access Improvement Act.

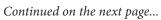




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<b>November 2-5, 2023</b> BONITA SPRINGS, FLORIDA	Ш
ACADEMY of DOCTORS of AUDIOLOGY	m
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THURSDAY, NOVEMBER 2, 2023 — PRE-CONFERENCE WORKSHOPS	
	Legal Issues in Audiology
	Speaker: Brandon Pauley, Esq.
	Utilizing HIS Extenders: Optimizing Efficiencies and Outcomes in the Audiology Practice
8:00 AM - 2:45 PM	Speakers: Kristin Davis, Au.D., Rachel Garcia, Marilyn Hinrichs, Au.D., Marsha Henry, Tonya Muncy, NBC-HIS, Liz Rogers, Au.D., Kristen Weinbaum, Au.D.
	Clinical Workshop on Auditory Processing Disorders
	Speakers: John Coverstone, Au.D., Gail Whitelaw, Ph.D.
8:00 AM - 12:00 PM	AuDacity Student Track: Sponsored by Starkey
THURSDAY, NOVEMBER 2	2, 2023
	What's WHO Got to Say About it?
9:00 AM - 10:00 AM	Speaker: Nimet Adam, Au.D.
	Student Humanitarian Initiative Panel
12:45 PM - 1:15 PM	Speakers: Jane Baxter, Au.D., Rachel Appleton, Au.D., Chloe Lammers
1:15 PM - 2:45 PM	Opening the Doors for Audiology Opportunities Worldwide
	Speakers: Nimet Adam, Au.D., Princess Kasume of Zambia, Deputy Speaker Madalitso Kazombo of Malawi
1:15 PM - 2:45 PM	Things to Know before You Buy or Sell an Audiology Practice

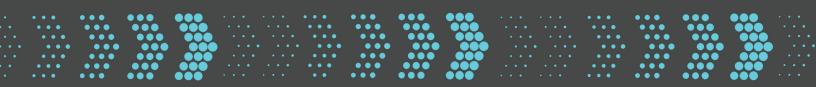
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	Clinical Workshop on Auditory Processing Disorders
	Speakers: John Coverstone, Au.D., Gail Whitelaw, Ph.D.
3:00 PM - 4:30 PM	Featured Keynote Session — Industry CEO Panel: Audiology Unstoppable
	Moderator: Stephanie Czuhajewski, CAE, MPH
	Speakers: Randy Baldwin, MBA, Bill Brownie, Carsten Buhl, Sara Burdak, Au.D., Brian Maguire, Tom Tedeschi, Au.D.
4:35 PM - 6:00 PM	Featured Keynote Session — Industry CEO Panel: It>s Your Tomorrow, Right Now
	Moderator: D'Anne Rudden, Au.D.
	Speakers: Danny Aronson, Adam Karp, Jason Mayer, Gary Rosenblum, Eric Timm
6:00 PM - 7:30 PM	AuDacity Opening Reception in the Exhibit Hall
FRIDAY, NOVEMBER 3, 20	123
7:00 AM - 8:00 AM	Breakfast in the Exhibit Hall
8:00 AM - 8:30 AM	President's Address: Go Beyond
8.00 AW - 8.30 AW	Speaker: Dawn Heiman, Au.D.
8:00 AM - 9:30 AM	Featured Keynote Session — ACHIEVE Study: An Overview of Outcomes
8.00 AWI - 9.30 AWI	Speaker: Frank Lin, M.D.
9:30 AM - 10:00 AM	Break in the Exhibit Hall
10:00 AM - 11:30 AM	Featured Keynote Session — ACHIEVE Study: Practical Implications for Audiologists
10.00 AW - 11.30 AW	Speakers: Nicholas Reed, Au.D., Victoria Sanchez, Au.D., Ph.D.
11:30 AM - 12:30 PM	Lunch in the Exhibit Hall
	Speech in Noise Inventories: In One Ear and
	Speakers: Victoria Sanchez, Au.D., Ph.D., Elizabeth Thompson, Au.D., Christine Ulinski, Au.D.
	Cognitive Screening: Somebody Check My Brain
12:30 PM - 2:00 PM	Speakers: Jill Davis, Au.D., Lisa Gumina, Au.D., Laura Sherry, Au.D.
12.30 FWI - 2.00 FWI	Communication and Functional Needs Assessment Panel
	Speakers: Natalie McKee, Au.D., Erica Person, Au.D., Alicia Spoor, Au.D.
	Falls Risk: Bedside Vestibular Assessments: Getting the Right Balance and Getting the Balance Right
	Speakers: Jana Brown, Au.D., Danielle Dorner, Au.D., Sara Jagger, Au.D.





#### **FRIDAY, NOVEMBER 3, 2023** (continued from the previous page)

	Outcome Measures in Audiology: Keep'n It 'Real'
	Speakers: Laura Pratesi, Au.D., John Pumford, Au.D., Laura Sherry, Au.D.
	Auditory Rehabilitation: Hello, Hello Again
	Speakers: Ariel B. Fruendt, Au.D., Dusty Jessen, Au.D., Joe Montano, Ed.D.
2:30 PM - 4:00 PM	Tinnitus Evaluation and Care Planning: For Whom the Bell Tolls
2.50 PIVI - 4.00 PIVI	Moderator: Jason Leyendecker, Au.D.; Speaker: Sara Downs, Au.D., Tricia Scaglione, Au.D.
	Cochlear Implant Evaluation: I've Got the Power
	Speakers: Arun Joshi, Au.D., D'Anne Rudden, Au.D., Kayla Wilkins, Au.D.
	Auracast: Can I Get a Connection?
	Speaker: Andrew Bellavia
4:15 PM - 5:45 PM	ADA Member Business Meeting
6:30 PM - 9:00 PM	AuDacity Reception and Dinner
SATURDAY, NOVEMBER 4	, 2023
7:00 AM - 8:00 AM	Breakfast in the Exhibit Hall
8:00 AM - 9:30 AM	Using KPIs to Find Your Rhythm: We Got the Beat
8.00 AIVI - 5.50 AIVI	Moderator: Amyn Amlani, Ph.D.; Speakers: Natalie McKee, Au.D., Eric Stevens, MBA, Kristen Weinbaum, Au.D.
9:30 AM - 10:00 AM	Break in the Exhibit Hall
	Business Financing Workshop Part I: I Need a Dollar
	Speaker: Tom Ethen, Joshua Gutstein, JD, MBA, Stacy O'Brien, Au.D., Brandon Pauley, Esq., Alicia Spoor, Au.D.
	Audiology Managed Care Part 1: Why'd You Have to Go and Make Things So Complicated?
	Moderator: Kim Cavitt, Au.D.; Speakers: Patty Greene, MA, Carrie Meyer, Au.D., Laura Richardson, Au.D.
10:00 AM - 11:30 AM	Public Speaking Training: Here I Go It's My Shot, Feet Fail Me Not
10.00 AM - 11.50 AM	Speaker: Annetta Wilson
	Attracting and Hiring the Right Clinical and AdministrativeTalent: Here's My Number, So Call Me Maybe
	Speakers: Carly Girard, Au.D., Karri Kiefat, MBA, Tress Montecalvo
	ENT/PT/SLP Audiology Practice Models: Ex's and Oh's!
	Speakers: Sal Gruttadoria, Au.D., Liz Rogers, Au.D., Meghanne Wetta, Au.D.
11:30 AM - 12:30 PM	Lunch in the Exhibit Hall



#### **SATURDAY, NOVEMBER 4, 2023** (continued from the previous page)

	Business Financing Workshop Part II: Money, Money, Money
	Speakers: Tom Ethen, Joshua Gutstein, JD, MBA, Stacy O'Brien, Au.D., Brandon Pauley, Esq., Alicia Spoor, Au.D.
	Audiology Managed Care Part II: Know When to Hold 'Em, Know When to Fold 'Em
	Moderator: Kim Cavitt, Au.D.; Speakers: Peter Kleckner, Au.D., Nikki Kopetzky, Au.D., Natalie McKee, Au.D.
12:30 PM - 2:00 PM	Media Training for Audiologists: Say What You Wanna Say
12.30 1 101 - 2.00 1 101	Speaker: Annetta Wilson
	Training and Retaining Clinical and Administrative Talent: We've Got to Hold on to What We've Got
	Speaker: Megan Lynch, SHRM-CP, Ram Nileshwar, Au.D., Jordan Strong, Au.D.
	Serving the Underserved: We Could Be Heroes
	Speakers: Sarah Curtis, Au.D., Judy Huch, Au.D.
2:00 PM - 2:30 PM	Break in the Exhibit Hall
2:30 PM - 3:55 PM	Challengers and Champions: Trials, Triumphs, and Lessons Learned Panel
2.30 PIVI - 3.35 PIVI	Speakers: Jane Baxter, Au.D., Audra Branham, Au.D, Victor Bray, Ph.D., Bryan Greenaway, Au.D., Alexandra Tarvin, Au.D.
4:00 PM - 5:00 PM	Believe and Beyond: Building Your Personal Practice Roadmap
5:00 PM - 6:00 PM	AuDacity Closing Reception

	SUNDAY, NOVEMBER 5, 2023		
	8:00 AM - 11:30 AM	Operationalizing and Monetizing AuDACITY and Research Evidence Based Care	
		Speakers: Kim Cavitt, Au.D.	



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### THE SOURCE: ADA'S SUBMISSION TO CMS



September 11, 2023

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1784-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

## Re: CMS-1784-P; Medicare Program; CY 2024 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment and Coverage Policies

The Academy of Doctors of Audiology (ADA) appreciates the opportunity to comment on the CY2024 Medicare Physician Fee Schedule (MPFS) Proposed Rule (2024 MPFS Proposed Rule) put forward by the Centers for Medicare and Medicaid Services (CMS).

#### The Continued Annual Decrease in Reimbursement for Audiology Services is Unsustainable

The 2023 Medicare Physician Fee Schedule (MPFS) Proposed Rule includes yet another decrease in the conversion factor (from \$33.89 in 2023 to a proposed \$32.75 in 2024). This reduction in the conversion factor would translate to an estimated 3.36% reduction in reimbursement for audiology and vestibular services. This continued, yearly assault on Medicare reimbursement is unsustainable and devastating to practices as they grapple with inflation and increasing labor costs.<sup>1</sup> We respectfully request that CMS re-evaluate this reduction and begin to explore alternative means of retaining budget neutrality other than solely through reductions in healthcare provider reimbursement.

#### ADA Supports the Creation and Implementation of New Auditory Osseointegrated Device Codes, and Opposes their Valuation

ADA supports the creation and implementation of 926X1 (Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any

<sup>&</sup>lt;sup>1</sup> https://www.pwc.com/us/en/industries/health-industries/library/behind-the-numbers.html

type; first 60 minutes) and 926X2 (Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes [list separately in addition to code for primary procedure]) for CY 2024.

However, ADA strongly disagrees with the valuation of 926X1 and 926X2. The RVU work value of 1.25 for 926X1 is lower than other, less technical timed audiology codes (for example, 92620 has a work value of 1.50 and 92626 has a work value of 1.40) and inconsistently valued to other similar durable medical equipment programming codes (92601 has a work RVU of 2.30 and 92603 has a work RVU of 2.25).

The paltry reimbursement of these new codes, will make it financially challenging for audiologists to continue to provide these procedures given the time and equipment required. Access to care will most certainly suffer as a result. ADA, therefore, respectfully requests that CMS reconsider their valuation of these new codes and ensure that it is commensurate with other similarly timed or programming codes.

#### ADA Commends CMS for Identifying Statutory Challenges Impacting the Provision of Audiology Services Under Medicare in the CY2023 MPFS Final Rule and Recommends Expansion of Beneficiary Direct Access to Include all Audiology Services in 2024

The CY2023 MPFS Final Rule contained provisions to allow audiologists to furnish certain diagnostic audiology services without a physician order, through use of an AB modifier. ADA applauds CMS for confirming its administrative authority to remove the physician order requirement as a condition of coverage for audiology services via notice and rulemaking, for attempting to align Medicare reimbursement policies with best practices in the delivery of hearing and balance services, and for taking ADA recommendations to create and implement the AB modifier, instead of the originally proposed GAUDX code.

ADA recommends that CMS take further steps to streamline access to audiology services for Medicare Part B beneficiaries by eliminating the physician order requirement for coverage in its entirety.

ADA agrees with CMS' assessment that the classification of audiologists within the Medicare statute is incongruent with statutory classifications for similarly trained non-physician providers (NPP), who are categorized as practitioners under section 1842(b)(18)(C) of the Act. ADA also concurs with CMS' assessment that the statutory classification of audiology services as "other diagnostic tests" under section 1861(s)(3) of the Act prohibits coverage of audiology treatment services when delivered by audiologists. CMS documented the misalignment between CMS policies and audiology's scope of practice, in the Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services, as follows:

"F. Audiological Treatment. There is no provision in the law for Medicare to pay audiologists for therapeutic services. For example, vestibular treatment, auditory rehabilitation treatment, auditory processing treatment, and canalith repositioning, while they are generally within the scope of practice of audiologists, are not those hearing and balance assessment services that are defined as audiology services in 1861(II)(3) of the Social Security Act and, therefore, shall not be billed by audiologists to Medicare."<sup>2</sup>

Members of Congress, with support from ADA and a broad coalition of audiologists, physicians, consumers, and industry representatives are seeking a legislative remedy to address Medicare's statutory deficiencies in the classification of audiologists and audiology services. This legislation, the Medicare Audiology Access Improvement Act (S.2377), seeks to amend the definition of audiology services to include Medicare-covered treatment services that audiologists are licensed to provide under their state scope of practice, to reclassify audiologists as practitioners under 1842(b)(18)(C) of the Act, and to remove the physician order requirement as a condition of coverage for all Medicare-covered audiology services.

Despite existing statutory deficiencies that must be addressed to optimize delivery of audiology treatment services, CMS should use its administrative authority to completely eliminate the physician order requirement for coverage for Medicare Part B beneficiaries to obtain medically necessary diagnostic services from an audiologist. Doing so will markedly improve service delivery and decrease time to obtain treatment for older adults experiencing hearing and balance problems.

#### • CMS Should Remove the Physician Order Requirement as a Condition of Coverage for All Medicare-Covered Audiology Services

Despite the implementation of the AB modifier, ADA continues to request the complete removal of the physician order requirement for services performed by qualified licensed audiologists. Medicare beneficiaries, taxpayers, and providers will be best served by the complete removal of the physician order requirement for medically necessary audiologic and vestibular services (listed on the CMS Audiology Code list at <u>https://www.cms.gov/audiology-services</u>) when provided by a licensed audiologist.

Audiologists should be authorized to provide these medically necessary, audiologic and vestibular services, as they do to every other payer, including Medicaid, Tricare, and commercial health plans, without a physician order or modifier. If over utilization is concern, CMS could create a National Coverage Determination (NCD) consistent with the current Novitas Local Coverage Determination (less the physician order requirement) at <a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35007">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35007</a>.

• CMS has a longstanding history of deferring to state scope of practice as a means of qualifying providers to deliver services for coverage.

<sup>&</sup>lt;sup>2</sup> Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services (Rev. 11426, 05-20-22) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

CMS manuals and Medicare benefit policy transmittals align eligibility for reimbursement with state scope of practice.<sup>3,4,5</sup> Audiologists' scopes of practice are far more consistent across the United States than are many other providers for whom Medicare defers to state scope of practice in coverage determinations.

Licensed audiologists are legally authorized in every U.S. state and territory to provide Medicarecovered audiologic and vestibular services without physician oversight or supervision. Audiologists are licensed in every state to provide comprehensive, diagnostic audiologic assessments, tinnitus evaluations, auditory processing evaluations, auditory prosthetic device evaluations, activation, and programming, evoked potential testing, and vestibular evaluations, without documented incident. Because of the availability of remote assessment tools, resources, and portable equipment, these services can be provided in most places of services, including, but not limited to, the patient's home, via telehealth, an office, in- or outpatient hospital, assisted living or nursing facilities, and/or specialty clinics/centers. The complete removal of the Medicare physician order requirement would greatly improve beneficiary access to audiologic and balance care, especially in assisted living and nursing facilities and in rural areas.

## • Audiologists are already responsible for determining medical necessity regardless of whether a physician order is obtained.

As CMS noted in its comments, audiologists have been allowed to enroll in the Medicare program and bill independently for their audiology services since 2008. A 2020 study demonstrated that primary care physicians billed far more rotary chair vestibular tests than either audiologists or otolaryngologists, so much so, that the authors recommended a need for training to stem overutilization.<sup>6</sup> Maintaining a physician order requirement for any of the Medicare-covered services that audiologists provide forces beneficiaries to spend time and money for an unnecessary office visit that has not been shown to have any meaningful clinical impact on outcomes.

#### • Other Programs and Payers Allow and Encourage Uncompromised Direct Access for Beneficiaries

#### CMS stated the following in the 2023 MPFS Proposed Rule:

"In addition, we have heard from interested parties that an order is not required for audiology services by certain other public or private health insurers including Medicare Advantage plans, Medicaid, plans under the Federal Health Benefit Program, and the Veterans Administration. We do not know the scope of services that are covered by these plans or insurers when furnished by audiologists, including whether these health insurers cover only hearing and balance assessment services (as the Medicare program does in accordance with the statute) or also hearing aid examinations for the prescription, fitting, and programming of hearing aids or other services

<sup>&</sup>lt;sup>3</sup> https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c07.pdf

<sup>&</sup>lt;sup>4</sup> https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\_a\_hospitals.pdf

<sup>&</sup>lt;sup>5</sup> https://www.cms.gov/files/document/r10639bp.pdf

<sup>&</sup>lt;sup>6</sup> Adams ME, Yueh B, Marmor S. Clinician Use and Payments by Medical Specialty for Audiometric and Vestibular Testing Among US Medicare Beneficiaries. *JAMA Otolaryngol Head Neck Surg.* 2020;146(2):143–149. doi:10.1001/jamaoto.2019.3924

excluded from payment under Medicare Part B and/or whether only some or all of the plans allow payment directly to audiologists for some or all of the covered services without a physician/NPP order. Additionally, we note that some of these health insurance programs involve closed systems with greater levels of interprofessional communication and control (for example, within certain accountable care organizations (ACOs), managed care plan networks, or through various Veterans Affairs medical centers). In contrast, the physicians and practitioners furnishing care under the fee-for-service Medicare Part B program often practice independently from each other, which can pose barriers to communication and coordination of care between health care professionals such as audiologists and the treating physicians or other practitioners."

ADA is pleased to provide supporting documentation as evidence that a physician order is not mandated for coverage for beneficiaries seeking audiology services under Medicare Part C (Advantage), Medicaid, the Veteran's Health Administration, Tricare, Federal Employee Health Benefit Plans, and commercial health plans<sup>7</sup>. None of these non-HMO health plans require a physician order for coverage of medically necessary, comprehensive, audiologic or vestibular items or services, irrespective of the relationship between the audiologist and the beneficiary's treating/attending physician or non-physician practitioner.

- o No Physician Order Required for Medicare Part C Beneficiaries
  - Publicly available Medicare Advantage plan data for plan benefit packages (PBP) related to hearing benefits denotes information about diagnostic hearing evaluations (typically covered under medical portion of the plan and not the supplemental portion). With the exception of HMO plans, the vast majority do not have a referral/order requirement. CMS, having oversight of the Medicare Advantage program should be able to provide documentation if such a requirement exists. If such a requirement does exist, commercial insurers participating in Medicare Advantage are not complying with it.
- <u>No Physician Order Required for Medicaid Beneficiaries</u>
   While Medicaid provisions for audiology services vary greatly state by state, ADA has found no evidence of a statutory or regulatory requirement for a physician order for patients seeking audiology services. CMS, having oversight of the Medicaid program should be able to provide documentation if such a requirement exists. If such a requirement exists, the vast majority of Medicaid plans are not complying with it.
- <u>No Physician Order Required for The U.S. Veteran's Health Administration (VHA)</u> <u>Beneficiaries</u>

As reported in her 2019 commentary<sup>8</sup>, Carolyn Clancy, M.D., the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks at the VHA, the practice of direct scheduling for audiology and optometry services, which is allowed throughout the VA system, reduced patient wait times and resulted in more productive use of primary care clinician time. Further, patients have praised the program.

 <sup>&</sup>lt;sup>7</sup> https://www.amplifonusa.com/content/dam/ahhc/documents/downloadable-files/provider/2022%20Provider%20Resource%20Manual.pdf
 <sup>8</sup> Clancy, Carolyn, MD, Creating World-class Care and Service for Our Nation's Finest: How Veterans Health Administration Diffusion of Excellence Initiative is Innovating and Transforming Veterans Affairs Health Care. The Permanente Journal, Volume 23, No. 4. December 1, 2019. https://doi.org/10.7812/TPP/18.301

- <u>No Order Required for Tricare Beneficiaries</u>
   Tricare, the uniformed services health care program for active duty service members (ADSMs), active duty family members (ADFMs), National Guard and Reserve members and their family members, retirees and retiree family members, does not mandate a physician order for audiology services.
- <u>No Order Required for Federal Employee Health Benefit Plan Beneficiaries</u>
   In 1998 Congress amended Title 5, Chapter 89 Section 8902 (k)(1) of the U.S. Code, clarifying that the U.S. Office of Personnel Management (OPM) and Federal Employee
   Health Benefits Plans were authorized to allow direct access to any licensed or certified provider (by Federal or State law), as follows:

"(2) Nothing in this subsection shall be considered to preclude a health benefits plan from providing direct access or direct payment or reimbursement to a provider in a health care practice or profession other than a practice or profession listed in paragraph (1), if such provider is licensed or certified as such under Federal or State law."<sup>9</sup>

Federal Blue Cross and Blue Shield began allowing beneficiaries to have coverage for audiology services without a physician order on January 1, 2001.

#### • Direct Access is Safe and Effective

There is no evidence to support deficiencies in care coordination or communication from audiologists to treating/attending physicians or non-physician practitioners in these direct access care delivery models.

Audiology malpractice insurance rates at \$500 a year on average, are among the lowest of any clinical doctoring profession in the nation. Data obtained from the National Provider Data Bank (NPDB) indicates that audiologists are among the providers with the fewest malpractice claims.<sup>10</sup> According to CMS' own <u>fee schedule</u>, the majority of Malpractice Relative Value Units (RVU) for audiology and vestibular services range from 0.01 to 0.05. By comparison, physician and non-physician practitioners have malpractice RVUs that range from 0.01 to .32 for Evaluation and Management (E/M) codes 99202 through 99215.

There is also no significant evidence of cases or complaints filed with state licensure boards or state attorneys general against audiologists. ADA could find no documented evidence of mismanagement, misdiagnosis, and/or malpractice associated with audiologists evaluating audiologic and/or vestibular conditions, nor any evidence illustrating that an audiologist does not refer to medical personnel, specifically otolaryngologists/otologists, dermatologists, neurologists, when medically necessary and warranted.

A 2008 study demonstrated the effectiveness of audiologists triaging vestibular disorders, when compared to other providers<sup>11</sup>, and a 2010 study conducted at the Mayo Clinic Jacksonville

<sup>&</sup>lt;sup>9</sup> Title 5, Section 8902 (k)(1) of the U.S. Code, amended in 1998, <u>https://www.congress.gov/105/plaws/publ266/PLAW-105publ266.pdf</u> <sup>10</sup> : <u>https://www.npdb.hrsa.gov/resources/publicData.jsp</u>

<sup>&</sup>lt;sup>11</sup>Polensek SH, Sterk CE, Tusa RJ. Screening for vestibular disorders: a study of clinicians' compliance with recommended practices. Med Sci Monit. 2008 May;14(5):CR238-242. PMID: 18443546.

demonstrated the safety of Medicare beneficiary direct access to audiologists.<sup>12</sup> On the contrary, there is significant evidence of mismanagement and misdiagnosis of auditory and vestibular conditions by physicians and other medical personnel.<sup>13,14,15</sup>

As reported previously in this comment, Medicare Part B is the only payer that requires a physician order for coverage of audiologic and vestibular evaluation and treatment services. A 2017 AAO-HNS guideline on BPPV

(https://journals.sagepub.com/doi/full/10.1177/0194599816689667) acknowledges audiologists among the providers that diagnose and treat, acknowledges the prevalence among older adults, and acknowledges significant burdens associated with delayed care. Please find enclosed correspondence from Senator Elizabeth Warren and Senator Rand Paul requesting removal of the physician order requirement for audiology services.

There is no data to support that direct access to audiologists for evaluation of audiologic and vestibular disorders poses more risks than the same patients being first evaluated by a physician or non-physician practitioner, who have documented evidence of misdiagnosis of these conditions. CMS must use the data available to improve beneficiary access to care.

Audiologic and vestibular evaluation and treatment occurs safely and effectively every day in audiology practices across the United States. The only time that ADA has been able to document "patient safety" concerns related to Medicare direct access to audiology services, they have been raised by very providers who stand to lose the office visit fee for services to write the order.

Medicare beneficiaries should not require a physician order prior to the provision of any medically necessary, Medicare covered audiologic and/or vestibular service. As we have previously reiterated, the physician order requirement does not exist in state licensure, nor in any other corner or facet of healthcare delivery or health plan coverage and no legitimate safety issues have been documented.

#### Other ADA Recommendations for Improvements to the CMS Regulations for Providing Medicare Beneficiary Direct Access to Audiology Services

• Implementation of the AB Modifier

While ADA recommends the complete removal of the physician order requirement as a condition for coverage for Medicare Part B beneficiaries seeking care from an audiologist, ADA provides additional recommendations to address the significant challenges and limitations

<sup>&</sup>lt;sup>12</sup> Safety of Audiology Direct Access for Medicare Patients complaining of Impaired Hearing, Journal of the American Academy of Audiology, Volume 21, Number 6, 2010, David Zapala et al.

<sup>&</sup>lt;sup>13</sup>Kerber KA, Newman-Toker DE. Misdiagnosing Dizzy Patients: Common Pitfalls in Clinical Practice. Neurol Clin. 2015 Aug;33(3):565-75, viii. doi: 10.1016/j.ncl.2015.04.009. PMID: 26231272; PMCID: PMC9023124.

<sup>&</sup>lt;sup>14</sup> Mirly, Alan & Brockett, Jeff. (2018). Sudden Sensorineural Loss in Primary Care : An Often-Missed Diagnosis. Physician Assistant Clinics. 3. 10.1016/j.cpha.2017.12.001.

<sup>&</sup>lt;sup>15</sup> Royl, Georg & Ploner, Christoph & Leithner, Christoph. (2011). Dizziness in the Emergency Room: Diagnoses and Misdiagnoses. European neurology. 66. 256-63. 10.1159/000331046.

experienced by providers and beneficiaries related to implementation of the CY2023 regulations, authorizing limited audiologic services to be provided once per 12 months without a physician order.

First, there are still Medicare Administrative Contractors (MAC) that are denying accurately submitted claims where the physician order was not required, and the AB modifier was appropriately utilized. We respectfully request that CMS immediately engage with contractors to remedy this situation.

Secondly, limited guidance has been made available at <u>https://www.cms.gov/audiology-services</u> to guide stakeholders in the operationalization of these changes. Some of the most prominent challenges are:

- Lack of beneficiary education and understanding of the policy change, especially as to whether or not they have received additional audiologic testing, without a physician order, in the past 12-months.
- Lack of provider access to information as to whether or not the beneficiary has received additional audiologic testing, without a physician order, in the past 12months.
- Lack of ordering physician/provider education and understanding of the policy change, especially as to whether or not they have received additional audiologic testing, without a physician order, in the past 12-months. As a result, there are physicians and ordering providers who are refusing to provide orders, when required (i.e. acute, vestibular, and additional medically necessary testing beyond one visit per 12 months).
- Lack of definition as to what constitutes "non-acute" versus "acute" hearing problems. ADA's expectation was that CMS would develop a national coverage policy better defining these terms and what diagnoses constitute an "acute" condition or illness.

If CMS decides to retain the AB modifier and the limited direct access, we respectfully request that CMS work with stakeholders to create additional guidance and coverage policies to reflect their intended operationalization and implementation of the AB modifier and limited direct access to audiologic evaluation.

ADA reiterates that the most effective approach for improving access to audiology services via removal of the physician order requirement for coverage is to make the policy universal for all the audiology services that are currently covered when delivered by audiologists and to use the mechanisms and protocols that CMS has already implemented to track outcomes.

 ADA strongly recommends removal of the term "non-acute" as the term does not exist in the International Classification of Diseases, 10<sup>th</sup> Revision (ICD-10) diagnoses that correspond to the vast majority of audiologic or vestibular conditions experienced commonly by Medicare beneficiaries. The physician order requirement should be driven by the procedures being performed and not predicated on factors that are not commonly used to represent audiologic disorders and conditions.  ADA strongly recommends allowing the following procedures to have no limitations on the number of visits per 12 months without a physician order. These procedures are indicated in Table A.

These procedures, by their very nature, 1) require physician involvement during candidacy and as the implanting surgeon, 2) require an on-going, collegial relationship between the audiologist and implanting surgeon throughout the process, 3) require limited physician involvement post-activation, and 3) require a re-evaluation time frame that typically exceeds once per 12 months. The required physician order has always been an administrative nuisance and barrier to care for the beneficiary. Also, given the numbers of auditory prosthetic device recipients, over-utilization should not be a concern as data can be tracked via the surgical procedure codes. In an effort to contain misuse and over-utilization, this AB modifier use could also be tied to specific ICD-10 diagnosis codes, such as H90 (conductive and sensorineural hearing loss), Z44 (encounter for fitting and adjustment of external prosthetic device), Z45 (encounter for adjustment and management of implanted device) and Z96.2 (presence of otological and audiological implants). These codes accompanying this modifier and, possibly, the associated ICD-10 codes, would be paid individually at their calendar year (CY) allowable rates and would not be subject to the one visit per 12 months limitations.

Table A: Audiologic Services Furnished Personally by an Audiologist Without a Physician/NPP Order for Evaluation to Determine Candidacy for a Surgically Implanted Hearing Device (for Example, a Cochlear Implant or an Osseointegrated Implant), for Post-Surgical Evaluation of Performance or for the Diagnostic Analysis and Subsequent Reprogramming of a Cochlear Implant Or Auditory Brainstem Implant

CPT Code		Short Descriptor
	92601	Cochlear implt f/up exam <7
	92602	Reprogram cochlear implt <7
	92603	Cochlear implt f/up exam 7/>
	92604	Reprogram cochlear implt 7/>
	92626	Eval aud funct 1 <sup>st</sup> hour
	92627	Eval aud funct ea addl 15
	92640	Aud brainstem implt program
	926X1	Diagnostic analysis, programming,
	and verific	cation of an auditory osseointegrated
	sound pro	cessor, any type; first 60 minutes
	926X2	Diagnostic analysis, programming,
	and verification of an auditory osseointegrated	
	sound processor, any type; each addnl 15	
	minutes	

#### ADA Recommendations for Code Additions to Telehealth Category 3

ADA wholeheartedly supports transitioning all of the currently assigned Category 2 Telehealth procedures to Category 3 procedures through CY2024 and beyond.

ADA recommends, for consideration, the following codes be added to the Telehealth Category 3 list:

- 92620: Evaluation of central auditory function, with report; initial 60 minutes.
- 92621: Evaluation of central auditory function, with report; each additional 15 minutes.
- 92540: Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal or peripheral stimulation, with recording, and oscillating tracking test, with recording.
- 92541: Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording.
- 92542: Positional nystagmus test, minimum of 4 positions, with recording.
- 92544: Optokinetic nystagmus test, bidirectional, foveal, or peripheral stimulation, with recording.
- 92545: Oscillating tracking test, with recording.
- 92546: Sinusodial vertical axis rotational testing.
- 92547: Use of vertical electrodes.
- 92537: Caloric vestibular test with recording, bilateral; bithermal (i.e. one warm and one cool irrigation for each ear for a total of four irrigations).
- 92538: Caloric vestibular test with recording, bilateral; monothermal (i.e. one irrigation in each ear for a total of two irrigations).
- 92548: Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform, and visual sway), including interpretation and report.
- 92549: Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform, and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT).
  - All of these services can be provided with technical support and allow for technical/professional component split in CPT coding.
- 92517: Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report, cervical (cVEMP).
- 92518: Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report, ocular (oVEMP).
- 92519: Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report, cervical (cVEMP) and ocular (oVEMP).
- 92650: Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis.
- 92651: Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report.

- 92652: Auditory evoked potentials; for threshold determination at multiple frequencies, with interpretation and report.
- 92653: Auditory evoked potentials; neurodiagnostic, with interpretation and report
- 926X1: Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes
- 926X2: Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes

As it pertains to patient safety, the Veteran's Administration has shown, for many years, that audiology services can be safely provided, via telehealth, without sacrificing patient outcomes or quality of care.<sup>16</sup> The technology required to perform these procedures via telehealth, in many cases with the assistance of an audiology assistant or technician at a remote location, is readily available. Audiologists outside the VHA system may be reluctant to invest in these technologies, personnel, and necessary infrastructure if Medicare coverage is not permanently established.

#### ADA Recommendations for Proposed MIPS Provisions

As it pertains to the Merit Based Incentive Payment System (MIPS) and as outlined in the Proposed Rule, ADA is supportive of the addition of Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented and Connection to Community Service Provider.

ADA thanks CMS for their continued support of the inclusion and expansion of audiology within the MIPS system.

ADA also respectfully requests that the following measures be added to the Audiology Specialty Set. These include:

- Closing the Referral Loop: (Quality ID#374)
  - Assigned to procedures: 69200, 69209, 69210, 92517, 92518, 92519, 92537, 92538, 92540, 92541, 92542, 92544, 92545, 92546, 92547, 92548, 92549, 92550, 92552, 92553, 92555, 92556, 92557, 92550, 92567, 92570, 92584, 92650, 92651, 92652, 92653, 92620, 92621, 92625, 92626, 92627, and 95992.

#### **Conclusion**

ADA appreciates the opportunity to provide CMS with its detailed analysis of the 2024 MPFS Proposed Rule and constructive recommendations for improvement. ADA is grateful for CMS' interest in expanding access for Medicare beneficiaries to audiology services by taking steps to remove the physician order requirement for coverage of certain audiology services.

The physician order mandate, which is unique to the Medicare Part B program, creates barriers, however implemented, to access to audiology services for Medicare beneficiaries that other

<sup>&</sup>lt;sup>16</sup> (Chad Gladden, AuD presentation), NASEM:

https://www.nationalacademies.org/documents/embed/link/LF2255DA3DD1C41C0A42D3BEF0989ACAECE3053A6A9B/file/DC856F457C400E2D 48316693C42F75CEABA3F3EBCBB0?noSaveAs=1

Americans do not face. Evidence supports the universal removal of the physician order requirements and the use of current mechanisms and protocols for tracking beneficiary access and service utilization. Even with the statutory challenges related to the classification of audiologists and audiology services, astutely described by CMS in its proposal, implementation of universal direct access will be the most effective, least burdensome approach that will allow CMS to achieve state goals.

ADA believes that Medicare policies should be constructed to align with evidence-based practices and modernizing policies related to the provision of audiology services is long overdue. Streamlining access to safe, effective audiologic care can help save the system and the beneficiary resources, which can be used to stabilize reimbursement and ensure continued patient access to the care that they need when they need it.

ADA will be pleased to offer further information or expertise in policy design or implementation in the provision of audiology services and we look forward to working with CMS on developing educational resources that will be most useful for beneficiaries and audiologists in the coming months.

Please contact Stephanie Czuhajewski at <u>sczuhajewski@audiologist.org</u> if we can assist you in any way.

Respectfully,

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Dawn Heiman, AuD President

Kim Cavitt, Au.D. Reimbursement Chair

Ducia DS. pour. Ais

Alicia D.D. Spoor, Au.D Advocacy Chair

Enclosure:

October 12, 2022 Letter from Senator Elizabeth Warren and Senator Rand Paul to Administrator Chiquita Brooks LaSure regarding removal of the physician order requirement for audiology services.

## United States Senate

WASHINGTON, DC 20510

October 12, 2022

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244–8016

Dear Administrator Brooks-LaSure:

We write regarding the Calendar Year 2023 Medicare Physician Fee Schedule proposed rule that would use the Centers for Medicare & Medicaid Services' (CMS) existing administrative authority to allow patients limited access to audiology services without a physician order. We support removal of the physician order requirement and appreciate CMS's recognition of its authority to make that change without further statutory authority. However, the remaining conditions of the proposal still pose burdens on patients seeking audiology services. We urge CMS to streamline access to audiology services by removing the physician order requirement entirely for Medicare Part B beneficiaries, as reflected in the bipartisan Medicare Audiologist Access and Services Act (MAASA).

Access to hearing health services is a critical part of overall health care. While hearing loss is common, access to hearing health services is not. Nearly 38 million Americans experience some degree of hearing loss.<sup>1</sup> Older Americans are particularly affected, with nearly one in three people between the ages of 65 and 75<sup>2</sup> and around half of adults 75 or older reporting difficulty hearing.<sup>3</sup> Americans with hearing loss are at a greater risk of developing Alzheimer's disease and Alzheimer's disease related dementias,<sup>4</sup> and they are also more likely to experience feelings of loneliness and isolation, which the COVID-19 pandemic has only exacerbated.<sup>5</sup> Although Medicare covers a range of hearing health services, outdated regulations prevent many beneficiaries from actually accessing these services. Medicare is an outlier among most federal and private insurance providers in requiring a physician order for

<sup>3</sup> Id.

<sup>&</sup>lt;sup>1</sup> The New York Times, "Hearing Aids for the Masses," Shira Ovide, April 12, 2021,

https://www.nytimes.com/2021/04/12/technology/hearing-aids.html.

<sup>&</sup>lt;sup>2</sup> National Institute on Aging, "Hearing Loss: A Common Problem for Older Adults," November 20, 2018, <u>https://www.nia.nih.gov/health/hearing-loss-common-problem-older-adults</u>.

<sup>&</sup>lt;sup>4</sup> U.S. Department of Health and Human Services, "National Plan to Address Alzheimer's Disease: 2021 Update," December 27, 2021, <u>https://aspe.hhs.gov/reports/national-plan-2021-update</u>.

<sup>&</sup>lt;sup>5</sup> NPR, "Untreated Hearing Loss Linked To Loneliness And Isolation For Seniors," Rochelle Sharpe, September 12, 2019, https://www.npr. org/sections/health-shots/2019/09/12/760231279/untreated-hearing-loss-linked-to-loneliness-and-isolation-for-seniors; The Seattle Times, "For older adults, isolation can lead to overwhelming loneliness," Paige Cornwell, September 19, 2021, https://www.seattletimes.com/seattlenews/mental-health/for-older-adults-isolation-can-lead-to-overwhelming-loneliness/#:~:text=The%20Mental%20Health%20Project%20 is,mobility%20for%20children%20and%20families.

coverage of audiology services. The Department of Defense, the Veterans Health Administration, and a majority of plans offered through the Federal Employees Health Benefit system allow direct access to covered audiology services without a physician referral.<sup>6</sup> Many private insurance plans and Medicare Advantage plans similarly allow direct access.

We were glad to see CMS recognize and use existing authority to expand access to audiology services by removing the burdensome requirement for a physician order. The requirement for a physician order for a diagnostic test was only put in place with the 1996 regulations and only refers to the statutory prohibition in the Social Security Act against Medicare paying for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."<sup>7</sup> Therefore, this language in no way requires a physician referral for audiology services, but rather prohibits paying for unnecessary services.<sup>8</sup>

While we support your acknowledgement that there is no statutory language to prohibit Medicare from allowing direct access to audiologists, the current proposal is complex and limited. The proposed rule creates an unnecessary barrier for patients by allowing direct access to an audiologist without a physician referral only for certain "non-acute" hearing assessments and only once every 12 months.<sup>9</sup> Allowing beneficiaries direct access to audiologists in all cases could reduce the number of appointments and referrals needed before a patient receives care, increase provider choice, and lower program costs and out-of-pocket expenses for patients.

Streamlining beneficiary access to services provided by audiologists – both through improved access to the full range of Medicare covered services audiologists are expertly qualified to provide, and through enactment of MAASA – will support the Food and Drug Administration's recent actions to make hearing aids available over-the-counter (OTC) for approximately 30 million Americans with mild to moderate hearing loss.<sup>10</sup> Now, providing more robust direct access to audiology services could make it even easier for older Americans considering OTC or prescription hearing aids to obtain expert audiological assessments to determine the best product for their specific type of hearing loss.

This proposal is a welcome first step. However, CMS has the authority to allow Medicare beneficiaries streamlined access to audiology services by removing the physician order

http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx. <sup>7</sup> 42 USC 1395y.

<sup>&</sup>lt;sup>6</sup> National Academies of Sciences, Engineering, and Medicine, "Hearing Health Care for Adults: Priorities for Improving Access and Affordability," 2016, p.128,

<sup>&</sup>lt;sup>8</sup> Memorandum from Sheree Kanner, Hogan Lovells, to Academy of Doctors of Audiology, "Medicare Coverage of Diagnostic Audiology Services," October 14, 2016,

https://www.audiologist.org/\_resources/documents/news/Scope-of-Practice-Patients-Over-Paperwork.pdf. <sup>°</sup> Center for Medicare and Medicaid Services, Calendar Year (CY) 2023 Medicare Physician Fee Schedule Proposed Rule, July 7, 2022, <u>https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-proposed-rule</u>.

<sup>&</sup>lt;sup>10</sup> Tweet by the White House, September 26, 2022,

https://twitter.com/WhiteHouse/status/1574530518233894912?s=20&t=XtMeiUN\_KUikmgbm94A7Gg.

requirements. Therefore, we urge CMS to use existing authority to fully eliminate the physician order requirement to help improve access to critical hearing health care services.

Sincerely,

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Elizabeth Warren United States Senator

Rand Paul

Rand Paul United States Senator

### PRESIDENT'S MESSAGE

#### Continued from page 3

To learn more about how you can get involved and contribute to our advocacy efforts, please visit <u>www.audiologist.org</u> or reach out to Stephanie Czuhajewski, Executive Director, who can help you schedule meetings with your lawmakers. Together, we can make a profound difference and steer our profession toward a brighter future.

Thank you for your unwavering dedication to audiology and for your commitment to enhancing access to quality audiological care for all.

### EDITOR'S MESSAGE

#### Continued from page 5

One recent study is especially relevant. Smith et al (2023) compared hearing screening conducted *in the clinic* with encouragement from a primary care physician to two additional groups: One group completed hearing screening at-home with encouragement from a primary care physician and the other group also completed screening at home but without encouragement from the doctor. Their results showed that offering encouragement and screening in the clinic led to significantly higher rates of patients following the provider's recommendations for further follow-up. However, encouragement from the primary care provider for the at-home screening did not improve adherence to follow-up recommendations. It seems the simple act of encouraging people to get screened must be combined with completing the screening *in the clinic* for the program to be most effective.

#### Shoring Up the Leaks

What do these results and the downward slope in Figure 1 mean for business-minded clinical audiologists?

- 1. Build strong relationships with medical gatekeepers and encourage them to provide in-person hearing screenings. Given the added costs associated with establishing an in-clinic hearing screening program, audiologists should be willing to advise primary care providers on cost-effective strategies for setting up these programs. Specifically, the results from Smith et al (2023) indicate that in-clinic hearing screening is more effective than screenings conducted at home.
- 2. Be a trusted referral source. Considering that about half of all individuals who fail an initial screening do not contact an audiologist, make sure that patients know you exist and that your primary role is to educate them and gather more detailed information about their hearing loss not sell them hearing aids.
- 3. Dispense and service over-the-counter (OTC) hearing aids. The results of the studies, summarized in Figure 1, show that when physicians and other medical gatekeepers are actively involved in the hearing screening program even when conducting the screening in-person in their clinic -- most individuals who fail the screening will eventually fall through the cracks. There are probably several reasons for this, but at the top of the list must be apathy and indifference on the part of both the person with hearing loss and the medical gatekeeper. By dispensing OTC hearing aids either in your clinic or on your website and servicing (for a fee) OTCs bought elsewhere, you are providing additional consumer choice that could break the cycle of apathy and indifference surrounding hearing loss. ■

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