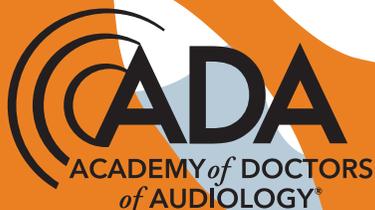


THE OFFICIAL PUBLICATION OF THE ACADEMY OF DOCTORS OF AUDIOLOGY®

# Audiology PRACTICES



*The Power to Practice*

VOLUME 13, NUMBER 2 ■ JUNE 2021 | [WWW.AUDIOLOGIST.ORG](http://WWW.AUDIOLOGIST.ORG)

# How to Take Advantage of Current and Future Opportunities in Hearing Health

With 10,000 people turning 65 every day, the senior population continues to grow.<sup>1</sup> With this growth, we can expect to see an increased demand for sales and services, including a greater need for hearing health.



**Patty Greene, M.A., F-AAA, Director of Provider Engagement at TruHearing,** shares insights into how hearing professionals can best position themselves to make the most of this growing opportunity.

**While demographic trends point to an increase in the need for hearing health solutions, the obstacle of the desire or willingness of people to seek out care still exists. What can providers do to address this?**

**GREENE** As we know, hearing health is essential to a person's ability to live a well-connected life. So what we do as hearing care professionals is essential, and we need to make sure that patients and their families are informed and educated about this. Information and education are big contributors to motivating people to seek out hearing health solutions. That's one contributing factor. Another factor that motivates people to seek hearing health solutions is that many older people are remaining in the work force longer.<sup>2</sup> They're more active physically and socially, so the demands on their hearing are still great. Lastly, we know cost is a barrier which prevents many people from seeking hearing care solutions. MarkeTrak VIII data has shown that consumers are 20-50% more likely to address their hearing loss if they have a hearing aid benefit.<sup>3</sup> Therefore, providers can

increase a patient's willingness to purchase hearing aids by helping them utilize any insurance benefit or discount available to lower their out-of-pocket costs.

**Given current trends and their related factors, how can providers set their practices up for success?**

**GREENE** There are a variety of ways that providers can set themselves up for success, but first I think it's important to have a deep understanding of who they're trying to attract — their target audience. As an industry, we're very accustomed to working with and communicating with traditionalists, those consumers born prior to 1946. That's because they've been the foundation of the hearing industry. However, today's consumers, primarily the baby boomers, are different.

Providers who wish to attract more of the baby boomer demographic can't continue with business as usual. What I mean by that is we need to adapt to these consumers and not expect them to fit into our traditional ways of conducting business. We need to communicate in ways that work with their lifestyle, and leverage technology to educate and treat those

<sup>1,2,3</sup> See next page for details.

with hearing loss. For just a quick example, if they prefer to be communicated with via text, chat or email, we need to be able to offer those options.

Now, that's not something we may typically be accustomed to offering patients, but if that's what they want, we need to adapt to them. If they want to book their appointments online or if they want telehealth, as providers we need to make sure that we're offering changes to meet the demands of the consumer.

### **You're basically talking about understanding who the patient of the future is and adapting to them?**

**GREENE** Absolutely. Because it's a competitive world, hearing care providers need to have a unique selling position that's not only relevant to their future patient, but also sustainable. That requires a clear vision of the consumers they're trying to attract and the type of practice they want to be as well as, adapting practice methods, communication methods, whatever it is, that will appeal to the patient they want to serve. Because you can't be all things to all people, you need to figure out what's your niche.

### **Given the changes in demographics and insurance coverage, do you think the baby boomer patient will be more or less cost-sensitive?**

**GREENE** I'd say both. There are going to be patients that are very cost-sensitive and some less so. That's why it's important to provide a variety of ways to make hearing devices more affordable. If we're looking at affordability, one avenue that helps lower the out-of-pocket costs for patients is through managed care. We're seeing year-over-year growth in the number of Medicare Advantage Plans offering some degree of hearing care coverage, which helps

lower the members' out-of-pocket costs. So it's important for providers to contract with a health plan directly or through third-party managed care companies, because that's where their target consumers are.<sup>4</sup>

I've also had the opportunity to speak to many consumers at member events for health plans. I can tell you the first thing that 9 out of 10 people say is, "Is there any financing available? And, do I have to come up with this all out-of-pocket?" So I think having a financial solution like the CareCredit credit card is certainly a wonderful and needed addition to help make it more affordable for patients. Remember, most of the people that we're working with are on a fixed budget, so accepting the CareCredit credit card is a great opportunity for both patients and providers.

### **Do you have any final thoughts about the future of hearing healthcare?**

**GREENE** I really think the future of our industry for providers, and the future of hearing health and wellness for consumers, is extremely positive. The key is to make sure we're doing our part to be ready to adapt in ways to best serve our patients how they want and when they want, now and in the future. Adaptability is key. ■

1 "10,000 baby boomers turn 65 every day." Transamerica Center. <https://www.transamericacenter.org/retirement-research/retirement-survey/infographics/10000-baby-boomers>, accessed February 20, 2021.

2 Yoe, Jonathan (July 2019). "Why are older people working longer?" U.S. Bureau of Labor Statistics. <https://www.bls.gov/opub/mlr/2019/beyond-bls/why-are-older-people-working-longer.htm>.

3 Kochkin S. (October 2019). "MarkeTrakVIII: 25-year trends in hearing health market." Hearing Review. <https://www.hearingreview.com/practice-building/marketing/marketrak-viii-25-year-trends-in-the-hearing-health-market>.

4 Jacobson, Gretchen (October 24, 2019). "Medicare Advantage 2020 Spotlight: First Look." Kaiser Family Foundation. <https://www.kff.org/medicare/issue-brief/medicare-advantage-2020-spotlight-first-look/>.

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ADAAP2021AA

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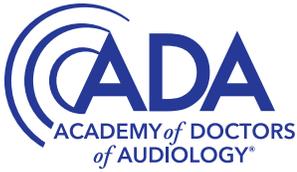
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*Audiology Practices* (USPS 025-476) ISSN (21645248) is published quarterly by the Academy of Doctors of Audiology, 446 East High St., Suite 10, Lexington, KY 40507. Periodicals Postage Paid at Lexington KY and at additional mailing offices. Subscriptions are \$25 as part of membership dues. POSTMASTER: Send address changes to *Audiology Practices*, 446 East High St., Suite 10, Lexington, KY 40507.

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# AuDACITY 2021

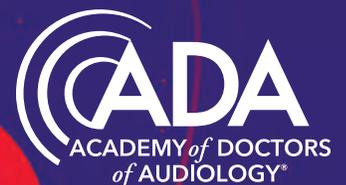
## AUDIOLOGY UNLEASHED

Join us at the **Marriott Downtown Waterfront Hotel in Portland, Oregon, October 25 - 27 for AuDacity 2021!**

AuDacity is designed to bring together bold and innovative audiologists to share bold and innovative ideas. Registration is now open—visit [audiologist.org/2021](http://audiologist.org/2021).



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## The Importance of Your State Audiology Organization

It was a little over a century ago, in 1915, that Patrick Geddes coined the term to Think Globally, Act Locally. While that idea was initially applied to community planning and conservation of resources, it directly applies to us today. The “Global” objective is that the Medicare Audiologist Access and Services Act (MAASA) legislation that needs to be passed for the nation by way of a unified House bill (H.B. 1587) and Senate bill (S. 1731) that is signed by President Biden in this 2021-2022 cycle.

As for “Local”, Tip O’Neill said so many times: ‘All politics is local’. Passage of MAASA does not just happen in Washington, DC. It happens, or does not happen, in each of the 435 House district seats and each of the 100 Senate seats across the United States. Everyone reading this presidential message has the ability to influence at least three of the 535 Congressional votes: your representative and your two senators.

All legislators respond to the constituents and the needs of their constituents. In advocacy for MAASA, the constituents are you, your colleagues, your patients, and their communication partners. All elected Congressional representatives work hard to understand the points of view of their constituents and to pass legislation that meets the needs of their constituents. This is no secret or surprise as this strategy is the path to their reelection. You must educate your legislators that this is an important constituency issue and become involved to advance the legislation.

In communicating with the three legislators who represent you, you need to (a) be able to describe the three legs of MAASA (Medicare beneficiary direct access to audiologists, reimbursement for Medicare-covered treatment services performed by audiologists under their state-defined scope of practice, and Medicare reclassification of audiology to practitioner status). But more importantly is for you to be able to personalize the problems with the current rules and regulations. You will be most effective when you describe how the proposed legislation will resolve the problems you are having. For example, in the recent ADA/AAA/ASHA Town Hall, 83% of the participants reported that Medicare coverage policies prevented them from providing medically necessary rehabilitative services to Medicare beneficiaries, 93% reported that their Medicare patients have difficulties obtaining the physician orders mandated for coverage, and 67% reported being in contact with physicians who did not understand the need for, or even the reason for, a physician order for a hearing evaluation to be performed on a Medicare beneficiary.

As part of your in-state advocacy, join your state audiology academy or audiology association and motivate them to formally endorse MAASA. Then have the academy/association leadership team send advocacy letters to their U.S. senators describing the importance of the legislation combined with the endorsement demonstrating wide-spread support for the legislation. Next, organize your local audiology

*Continued on page 51*

# HEAR AND NOW Early Career AuD Resources



**The Academy of Doctors of Audiology offers a variety of resources for early career professionals.**

**Early Career Resources:** A collection of resources that will help you in your transition from student to professional.

**Mentorship Program:** What did you do right? What was harder than you expected? What do you wish you could change? As a recent graduate, you are a perfect candidate to help shape the future of audiology by becoming a mentor! Mentee opportunities are also available.

**Monthly Virtual Networking/Learning:** Join fellow early career professionals in an informal virtual environment for networking and learning and participate in an early career messaging group.

Visit [audiologist.org](https://audiologist.org) for access to these resources and more!





## Overcoming Hearing Aid Objectives: It is More than Cost

That two-thirds of adults do not wear hearing aids, primarily due to high retail costs, is a well-worn industry trope. A recent paper in *JAMA Otolaryngology* by Katherine Sternasty and Sumit Dhar at Northwestern University, entitled *Barriers to Hearing Aid Adoption Run Deeper Than the Price Tag*, sheds valuable light on other reasons for non-use. According to the authors, “focusing on cost as the sole barrier to hearing aid uptake is overly simplistic and perhaps a hindrance to a more effective solution.”

If retail costs were the main barrier to hearing aid use, countries with programs that keep out-of-pocket costs extremely low would see a much higher rate of hearing aid use. The data from several studies, as cited in this paper, does not support the assertion that cost is the primary barrier to non-use of hearing aids.

The authors focus their attention on the concept of perceived benefit, which is a combination of monetary value and the social value of hearing aids. They suggest the subsidies provided by some countries that cover much of the out-of-pocket costs of hearing aids do not outweigh the lack of perceived social value for many individuals who might otherwise benefit from hearing devices. Social value as defined by the authors, “is the sum of self-perceived benefit and benefit perceived by others related to the purchase of a product.”

To support their point, Sternasty and Dhar cite a German survey in which the top five reasons for not seeking hearing aids were: (1) physical comfort, (2) the inability of hearing aids to restore natural hearing, (3) hearing well enough in most situations, (4) hearing loss not severe enough, and (5) having more serious priorities. Of course, social value is likely linked to all five of these self-reported barriers.

Perhaps the most valuable part of this paper is the authors’ reflections on the concept of locus of control (LOC) and how LOC influences personality traits. Locus of control refers to the extent by which individuals believe they have control of their own life outcomes. People with an externally focused LOC believe their outcomes are out of their control and are a result of factors such as luck or fate. As the authors point out, an individual with an external LOC who has hearing loss would not be motivated to seek hearing aids unless they were recommended by a trusted expert such as a physician.

In contrast, individuals with an internal LOC believe that life outcomes are consequences of their own actions – that a person determines their own fate. An individual with an internal LOC who experiences hearing loss would be self-driven to seek hearing aids without the need to be validated by others. Locus of control, as the authors suggest, shapes how a person plans to acquire hearing aids but also underlying personality factors and stigma.

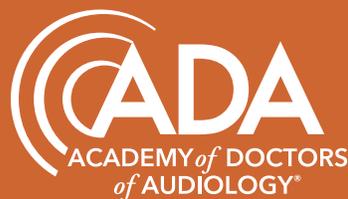
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*The Power to Practice*



## ADA Strategy in Action

The ADA Board of Directors recently met to put together and operationalize a plan to address the most pressing issues facing ADA members, our organization, and the profession. Board members gathered data and information and assessed the political, economic, social, and technological landscape—both in the wake of the unparalleled trials and events of the past year, but also in the context of the aspirations, opportunities, and challenges on the horizon. Input from ADA members and volunteers was also evaluated to determine where to apply resources for the greatest benefit to members and impact to the profession over the next 12-18 months.

Reimbursement policies (including government, employer, and commercial managed care and fee-for-service insurance models), therapeutic and technological advances related to the diagnosis, treatment, and delivery of audiovestibular services and devices, audiology workforce development, and state laws related to licensure and practice emerged as the most pressing issues to address immediately.

The Board translated these focus areas into 5 objectives:

- Pass the Medicare Audiologist Access and Services Act (H.R. 1587 and S. 1731)
- Advocate for DTC/OTC hearing aid and telehealth policies that align with evidence-based practices in the delivery of hearing and balance care *and* support the autonomous practice of audiology.
- Ensure that state laws impacting the practice of audiology and the utilization of audiology assistants align with evidence-based practices in the delivery of hearing and balance care *and* support the autonomous practice of audiology.
- Develop and disseminate information and resources that provide ADA members, policy makers, consumers, and other stakeholders with timely, accurate, and useful information that will improve reimbursement policies for hearing and balance services.
- Launch the ADA Audiology Practice Accreditation Program to recognize clinics that meet or exceed national standards, which exemplify best clinical and business practices in the delivery of audiologic care.

### ADA TOP STRATEGIC PRIORITIES 2021-2022



ADA volunteers and staff are already working on your behalf to achieve these objectives. Please stay tuned for updates. Please contact me at [sczuhajewski@audiologist.org](mailto:sczuhajewski@audiologist.org) anytime if you have any questions or if you would like to volunteer! ■

# An Analysis of US Hearing Aid Pricing

INSIGHTS AND COMMENTARY FOR THE PRACTICE MANAGER



By Aryn M. Amlani, Ph.D.

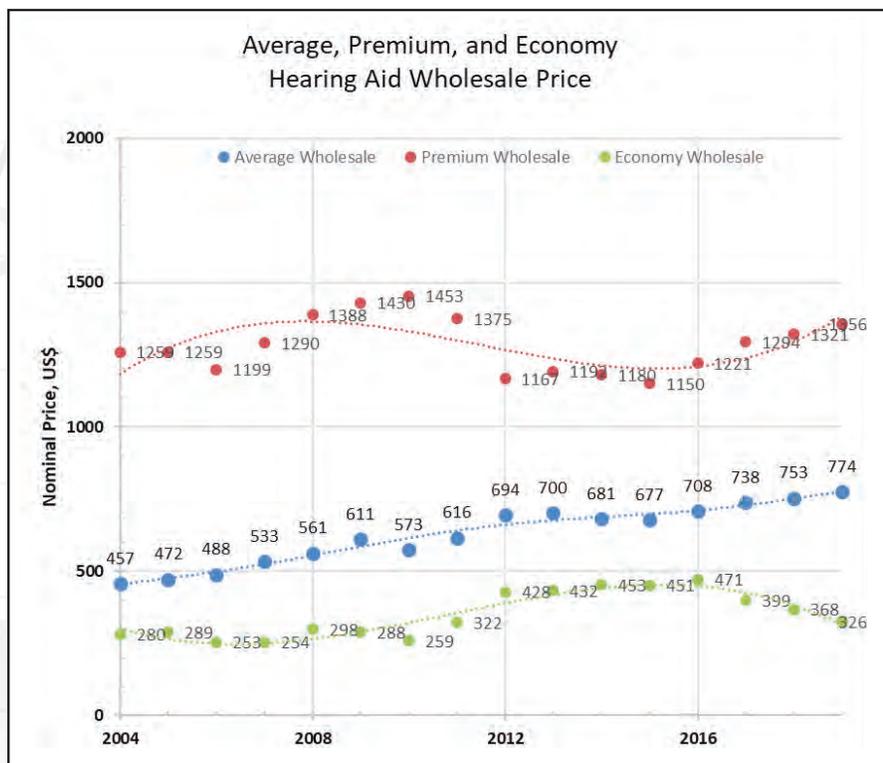
*This article is a reprinted 5-part blog post from Hearing Health and Technology Matters (HHTM). It is reprinted with permission of HHTM and the author. Unlike the original HHTM blog posts, this version includes some Q&A between the author of the article, Aryn Amlani, and Brian Taylor, editor of Audiology Practices. If you're a practice manager, owner or a clinician who wants to learn more about the intricacies of hearing aid pricing, find a quiet space and dig in.*



## NOMINAL WHOLESALE-SIDE TRENDS

Before diving into a chasm of figures and numbers, I take this opportunity to calibrate the reader to several aspects related to the wholesale data. The caveats written in 2013 and 2016, paraphrased below, remain true today:

- The categorical lines that separate hearing aid tiers—Economy to Mid-Level to Premium—are somewhat blurred given variations across product lines, manufacturer interpretation of technology tiers, and price points adopted by the market.
- The dataset is truly a sample, provided by a small faction to whom I am beholden.
  - Prices reported are for a single-unit purchase with no additional discounts.
- There is no data available prior to 2004.
- Transparency is king.



**Figure 1.** Nominal wholesale hearing aid prices, in US dollars, for average (blue filled circles), premium-tiered (red filled circles), and economy-tiered (green filled circles) product lines.

## Premium-Tier Wholesale Pricing

- Premium products are depicted as red filled circles in **Figure 1**.
- Comparisons are derived using nominal comparisons (i.e., not adjusted for inflation).
- In 2004, providers paid an average of \$1259 for a premium-tiered product. In 2019, a markedly more advanced, premium-tiered product was available for the average wholesale price of \$1356.
  - The nominal difference in wholesale price between 2019 and 2004 is \$97. Over a 16-year span, this difference equates to just over a \$6 per year increase.
- Over time, the wholesale pricing for premium-tiered hearing aids is nonlinear, reaching a peak of \$1453 in 2010, and a low of \$1150 in 2015.
- Wholesale prices began rising in 2016 when a single unit could be acquired for \$1221. In 2019, a single unit averages \$1356.
  - In 2019, the nominal wholesale price has increased by \$206 per unit compared to the average price in 2015.
  - This increase in pricing is not surprising, given technological advances in Bluetooth connectivity, rechargeability, artificial intelligence, and the transformation of hearing aids to track the user’s health and wellness.
    - In Part 2 of this series, we will assess whether providers are accounting for this increase in cost of goods (COGS) in their retail pricing.

## Economy-Tier Wholesale Pricing

- Economy products are depicted as green filled circles in **Figure 1**.
- Comparisons are derived using nominal comparisons (i.e., not adjusted for inflation).
- The wholesale pricing for economy hearing aids is also nonlinear, reaching a peak of \$471 in 2016, and a low of \$253 in 2006.
  - The astute reader will note that economy-tiered pricing patterns are inverse to premium-tiered pricing patterns. That is:
    - As economy-tiered pricing increases, premium-tiered pricing decreases, and as economy-tiered pricing decreases, premium-tiered pricing increases.
    - These pricing patterns are essentially synchronized in time.
- Economy-tiered products in 2019 cost a nominal average of \$46 more per unit than in 2004.
- Since 2016, when a single-unit product cost \$471, single-unit prices have dropped nominally by \$145 in 2019.
  - In Part 2 of this series, this decrease in COGS is expected to yield increased revenue for the practice.
  - It is assumed that wholesale costs for this tier were reduced—and are expected to be reduced in the future—for the provider to compete with direct-to-consumer products.

## Average Hearing Aid Wholesale Pricing

- The average wholesale price for a hearing aid is depicted by blue filled circles in **Figure 1**.
- Comparisons are derived using nominal comparisons (i.e., not adjusted for inflation).
- The average wholesale price includes all product tiers (e.g., Economy, Economy-Premium, Mid-Level, Advanced, Premium).
- Since 2004, the average wholesale price of hearing aids increases in a rather linear manner.

- Premium-tiered vs. Average Wholesale Cost
  - In 2004, the nominal difference in wholesale cost between a premium-tiered product and the average hearing aid yielded \$802.
  - In 2019, the nominal difference in wholesale cost between a premium-tiered product and the average hearing aid is narrowed to \$582.
  - The narrowing of price differences between premium-tiered and the average hearing aid over time suggests that the wholesale cost of mid-tiered devices has increased markedly.
    - This was an unexpected finding and data to substantiate this outcome has been requested.
- Average Wholesale Cost vs. Economy-Tiered
  - In 2004, the nominal difference in wholesale cost between the average hearing aid and an economy-tiered product was \$177.
  - In 2019, the nominal difference in wholesale cost between the average hearing aid and an economy-tiered product ballooned to \$448.
  - This nominal difference of \$271 supports the earlier claim that COGS for mid-level products are driving up the average wholesale price of hearing aids.
    - Again, an unexpected finding that I hope to assess in an upcoming blog.

### What we we've covered so far...

Thus far, the reader was provided a glimpse of nominal hearing aid wholesale pricing trends for premium- and economy-tiered products, as well as for the average hearing aid. Findings indicate an inverse pricing relationship between premium- and economy-tiered products, as well as a linear increase in the average wholesale cost of hearing aids. The latter finding is conjectured to be driven by wholesale pricing increases in the mid-tiered products.

**Q** *I noticed that back in 2012 the average wholesale premium price dropped a rather astonishing \$200 per unit before slowly, over the course of several years, moving back in alignment with pre-2012 wholesale premium prices. What might be the cause of this premium price drop and why didn't we see it for the other two wholesale tiers?*

**A** You have an observant eye! The most likely answer to the \$208 drop in average premium wholesale pricing is the manufacturer's intent to increase the provider's demand to dispense this technology. For the practice, an additional five units sold would equate to an additional \$1040 (i.e., \$208 x 5 units) in revenue.

Additionally, it may seem that the manufacturer is losing revenue given the reduction in average wholesale price of their premium product. This is *not* the case. In 2011, the average wholesale economy-tier product was \$322, which increased to \$428 in 2012, or an *additional* expense of \$106 to the provider. Further, note that the overall average wholesale price of a single unit device—independent of technology tier—*increased* from \$616 in 2011 to \$694 in 2012. For providers and their staff, there is a constant need to adjust hearing aid retail pricing—in both directions—based on demand. Failure to assess these changes will influence the practice's revenue.

**Q** *How much of a factor does Costco and other large retail chains have on these wholesale pricing trends?*

**A** Good question. The pricing data that we receive at HHTM from manufacturers is for self-pay patients in the independent channel only, based on a bundled-pricing approach. Manufacturers offer differing price options as a function of payor (e.g., patient self-pay, insurance, third-party administrators, Medicaid) and channel (e.g., independent channel, hospital, VA, big box). Whole prices are negotiable, and the provider—regardless of their business channel—has the greatest leverage in those discussions *prior* to signing the contract. The same negotiation leverage does not always exist as a function of payor. Thus, providers should have a clear understanding of the varying wholesale price options in the market, and how the market and payor interactions dictate the conditions of their contract.

**PART  
2**

## INFLATION-ADJUSTED WHOLESALE-SIDE TRENDS

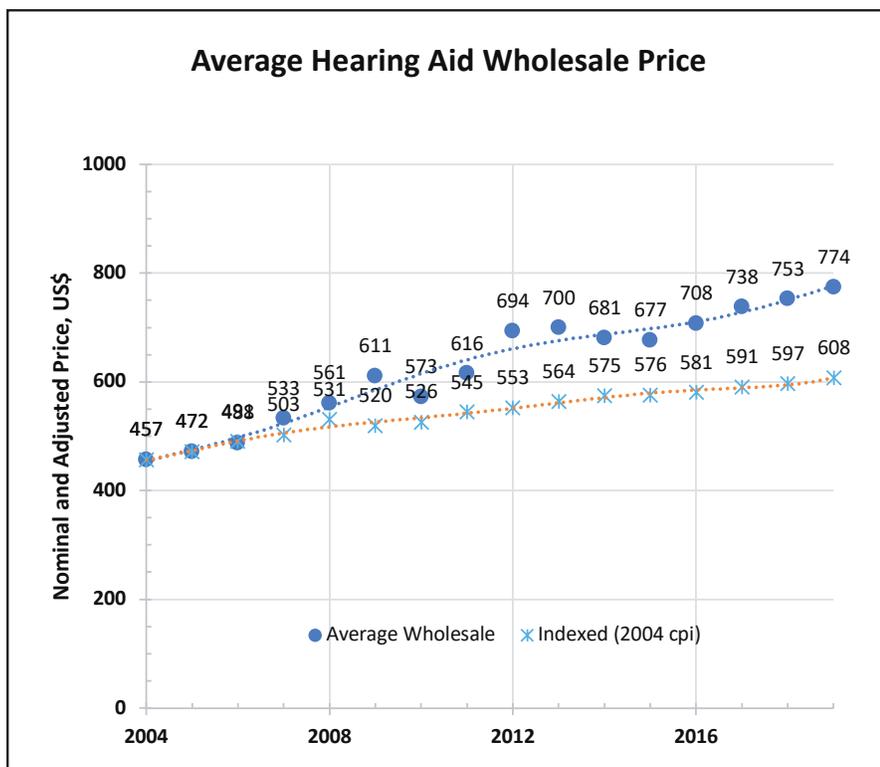
Let's continue a review of pricing in the US hearing aid market, comparing unadjusted and inflation-adjusted, wholesale cost of a single unit device over time.

### Consumer Price Index (CPI)

The Consumer Price Index (CPI) was used to assess historical changes in US inflation. CPI data, available through the US Bureau of Labor Statistics, allows for the assessment of whether a good or service has increased or decreased in price compared to the same good service at another point in time.

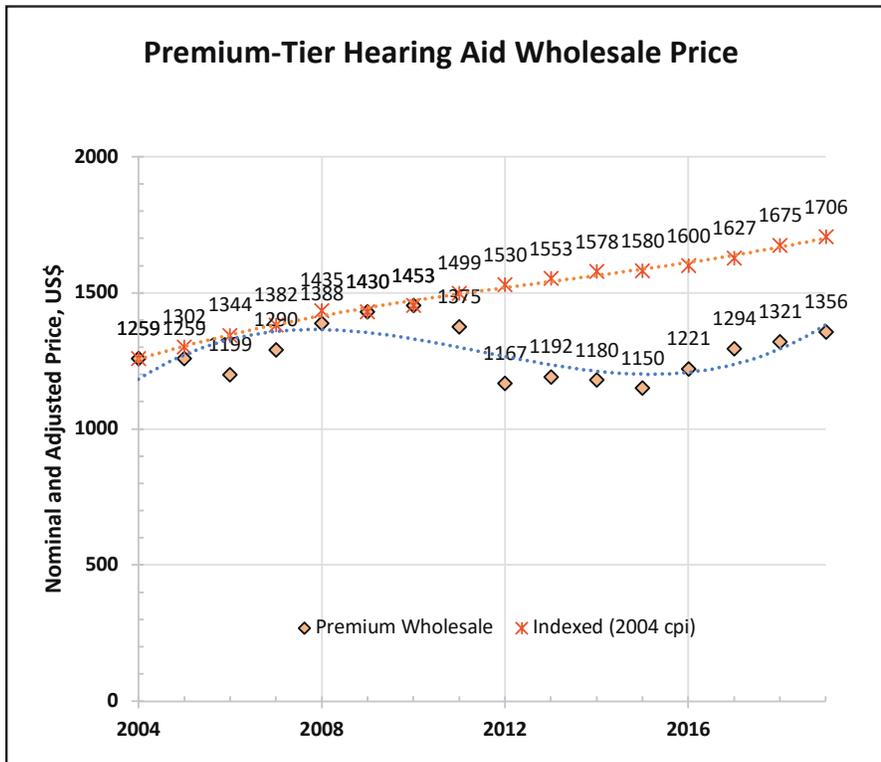
### Average Hearing Aid Wholesale Price

Figure 2 compares the unadjusted, average, single-unit wholesale hearing aid prices (blue filled circles), in US dollars, and a 2004 average-priced, single unit wholesale hearing aid adjusted for inflation (blue asterisks) across all technology tiers.



**Figure 2. Comparison between unadjusted, average, single-unit wholesale hearing aid prices (blue filled circles), in US dollars, and a 2004 average-priced, single unit wholesale hearing aid adjusted for inflation (blue asterisks) across all technology tiers.**

- In 2004, the average wholesale cost for a single unit hearing aid was \$457. In 2019, the average wholesale cost for a single unit hearing aid was \$774, unadjusted for inflation. Over time, the average wholesale cost per unit has increased by \$317, or an annual average increase of \$19.81.
- When CPI data are applied to the 2004 wholesale single unit cost (i.e., \$457), the average cost of a single unit hearing aid in 2019 is calculated to be \$608. This finding indicates that the 2004 unit increased in inflationary cost by \$151 in 2019, or at an annual rate of \$9.42.
- In comparison, the unadjusted average wholesale price of a single unit hearing aid, in 2019, exceeds the rate of inflation by 47.5%.
- This trend of the unadjusted wholesale cost exceeding inflation-adjusted wholesale cost rooted itself in 2007.

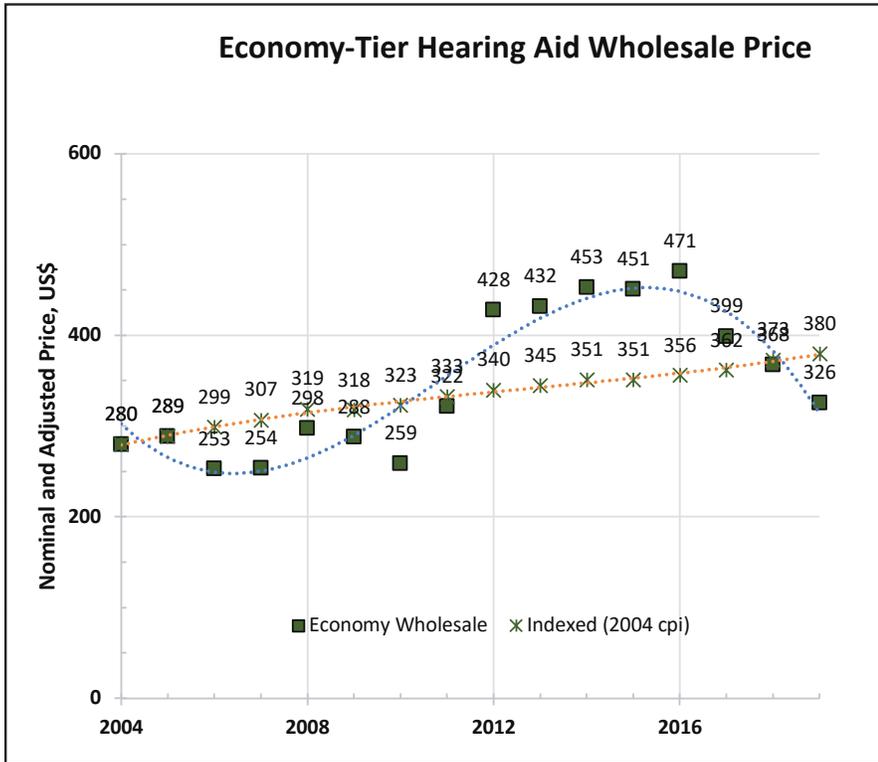


**Figure 3. Comparison between unadjusted, average, single-unit wholesale hearing aid prices (red filled diamonds), in US dollars, and a 2004 average-priced, single unit wholesale hearing aid adjusted for inflation (red asterisks) for the premium-technology tier.**

### Premium-Tiered Wholesale Pricing

Figure 3 compares the unadjusted, average, single-unit wholesale hearing aid prices (red filled diamonds), in US dollars, and a 2004 average-priced, single unit wholesale hearing aid adjusted for inflation (red asterisks) for the premium-technology tier.

- In 2004, the average wholesale cost for a single unit, premium-tiered hearing aid was \$1259. In 2019, the average wholesale cost for a similar technology-tier hearing aid was \$1356, unadjusted for inflation. Over this span, the average wholesale cost per unit increased by \$97, or by an annual average of \$6.06.
- When CPI is applied for inflation, the average cost of a single unit hearing aid in 2019 was \$1706. This finding indicates that the 2004 unit was \$447 more expensive in 2019, yielding an annual average increase in wholesale price of \$27.94.
- For this technology tier, manufacturers are providing premium-tier hearing aids below the rate at which inflation has increased over time. In fact, manufacturer pricing is 4.61 times *less than* the rate at which inflation has grown.
- The data in Figure 2 show that wholesale hearing aid pricing was rather consistent with inflation from 2004 to 2011. Starting in 2012, the wholesale price of this technology was reduced markedly and has stayed well below inflationary levels since.



**Figure 4. Comparison between unadjusted, average, single-unit wholesale hearing aid prices (orange filled squares), in US dollars, and a 2004 average-priced, single unit wholesale hearing aid adjusted for inflation (orange asterisks) for the economy-technology tier.**

### Economy-Tiered Wholesale Pricing

Figure 4 compares the unadjusted, average, single-unit wholesale hearing aid prices (orange filled squares), in US dollars, and a 2004 average-priced, single unit wholesale hearing aid adjusted for inflation (orange asterisks) for the economy-technology tier.

- In 2004, the average wholesale cost for a single unit, economy-tiered hearing aid was \$280. In 2019, the average wholesale cost for a similar technology-tier hearing aid was \$326, unadjusted for inflation. Over this span, the average wholesale cost per unit has increased by \$46, or by an annual average of \$2.88.
- When CPI is applied for inflation, the average cost of a single unit hearing aid in 2019 was \$380. This finding indicates that the 2004 unit is \$100 more expensive in 2019, yielding an annual average increase in wholesale price of \$6.25.
- Over the years, the unadjusted wholesale pricing for economy-tier technology has vacillated, with pricing well-below inflation between 2006 and 2010, and well-above inflation between 2012-2016. The current trend indicates that wholesale pricing is, again, below the rate of inflation. It will be interesting to see whether wholesale pricing continues to stay low as direct-to-consumer products begin to penetrate the market in the future.

**Q** I guess it's no surprise we are seeing the same interesting trend in the premium pricing data that begins in 2012. Why do you think the premium wholesale price took a dip relative to the indexed values, while economy wholesale prices saw an increase at that time? Does this dip say more about the volatility of premium wholesale prices or the stability of the US inflation index over the past few decades?

**A** The annual inflation rate in the US between 2010 and 2019 has remained essentially stable at roughly 2-3% over this span. The fluctuations in wholesale hearing aid pricing have to do more with consumer purchasing behavior, for example, as a function of the rising cost of healthcare premiums and co-pays. As patients pay more each year for their healthcare needs, it appears that manufacturers intentions are to reduce the costs of higher priced products in hopes that the providers follow suit with retail pricing. At the same time, and to sustain their corporate revenue goals, manufacturers increase the wholesale prices of the economy-line products for those that purchase products at this technology tier.

**PART  
3**

**NOMINAL RETAIL-SIDE TRENDS**

So far readers have seen data on nominal and inflation-adjusted wholesale hearing aid prices. In this third section, the reader is presented with nominal retail hearing aid pricing. Let's examine a pivotal question, what is the retail cost of a hearing aid?

**What is the Retail Cost of a Hearing Aid?**

The response to this question varies, with retail prices ranging between \$1000 to >\$6000 per device ([www.healthyhearing.com/help/hearing-aids/prices](http://www.healthyhearing.com/help/hearing-aids/prices)). Internet information—for what it's worth—also suggests that hearing aid prices are always on the rise, potentially increasing by 15% over a five-year span starting in 2015 (<https://myhearingcenters.com/blog/what-will-hearing-aid-prices-be-in-5-years-do-you-really-want-to-wait/>).

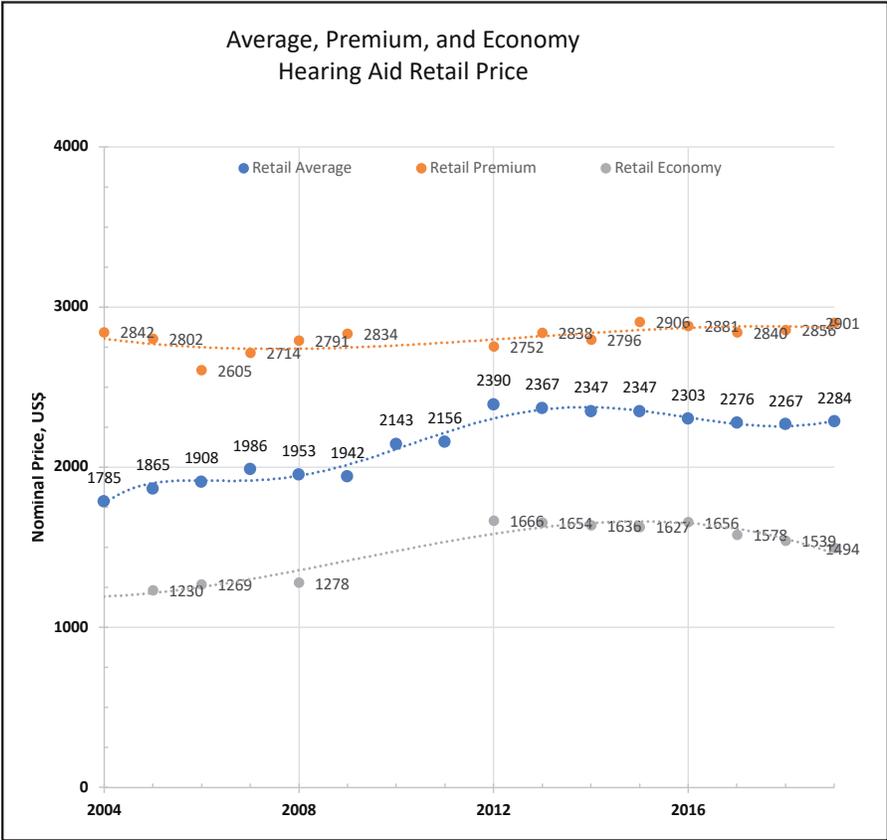


Figure 5. Nominal retail hearing aid prices, in US dollars, for average (blue filled circles), premium-tiered (orange filled circles), and economy-tiered (gray filled circles) product lines.

## Premium-Tier Retail Pricing

- Premium products are depicted as orange filled circles in **Figure 5**.
- Data are nominal (i.e., not adjusted for inflation).
- In 2004, hearing aid users paid an average of \$2842 for a premium-tiered product. In 2019, a markedly more advanced, premium-tiered product was available for the average retail price of \$2901.
  - The nominal difference in retail price between 2019 and 2004 is \$59. Over a 16-year span, this difference equates to < \$4 per year increase.
  - Between 2015 and 2019, hearing aid retail prices are essentially the same. So much for the predicted 15% increase over this time period!
- Over time, the retail pricing for premium-tiered hearing aids increased modestly, with a low of \$2605 in 2006 and reaching a peak of \$2906 in 2015.

## Economy-Tier Retail Pricing

- Economy products are depicted as gray filled circles in **Figure 5**.
- Data are nominal (i.e., not adjusted for inflation).
- The retail pricing for economy hearing aids demonstrates a low of \$1230 in 2005, a peak of \$1666 in 2012, with prices slightly recovering to <\$1500 in 2019.
- Economy-tiered products in 2019 cost a nominal average of \$264 more per unit than in 2004. Over a 16-year span, this difference equates to a \$16.50 per year increase.

## Average Hearing Aid Retail Pricing

- The average retail price for a hearing aid is depicted by blue filled circles in **Figure 5**.
- Data are nominal (i.e., not adjusted for inflation).
- The average retail price includes all product tiers (e.g., Economy, Economy-Premium, Mid-Level, Advanced, Premium).
- Between 2004 and 2012, the average retail price of a hearing aid increased by \$605.
- Between 2012 and 2019, the average retail price of a hearing aid has remained within roughly \$100.

## Premium-tiered vs. Average Retail Cost

- In 2004, the nominal difference in retail cost between a premium-tiered product and the average hearing aid yielded \$1057.

- In 2019, the nominal difference in retail cost between a premium-tiered product and the average hearing aid is narrowed to \$617.

## Average Retail Cost vs. Economy-Tiered

- In 2005, the nominal difference in retail cost between the average hearing aid and an economy-tiered product was \$635.
- In 2019, the nominal difference in retail cost between the average hearing aid and an economy-tiered product increased to \$790.

Q

*If I understand these last four bullet points, it tells us that average premium-tiered retail price has dropped and average economy-tiered has increased. What's driving this divergence in pricing for these two tiers?*

A

You are correct. This theme pervades through this analysis for both the wholesale and retail pricing segments and is supported by the *price elasticity of demand*. The price elasticity of demand is an economic concept that measures consumer purchasing between price and quantity demanded. When the demand is determined to be elastic (i.e., demand is  $> |1|$ ), consumers are responsive to changes in price. When the demand is determined to be inelastic (i.e., demand is  $< |1|$ ), consumers are not responsive to changes in price. Overall, the hearing aid market has an inelastic demand.

We can further analyze the demand function by comparing price and quantity demanded between price points. This is called *arc elasticity*. Here, the hearing aid market is *elastic* for products at the premium-technology tier (i.e., consumers are responsive to price changes) and *inelastic* for products at the economy-line tier (i.e., consumers are *not* responsive to price changes).

To maximize total revenue—defined as Price x Quantity Demanded—an elastic demand (i.e., premium-tier) requires reducing price (and increasing quantity demanded), while increasing total revenue in an inelastic demand (i.e., economy-tier) dictates increasing price (resulting in a decrease in quantity demanded). The details and calculations of this concept will be covered in a future article in *Audiology Practices*.

**PART**  
**4**

**INFLATION-ADJUSTED RETAIL-SIDE TRENDS**

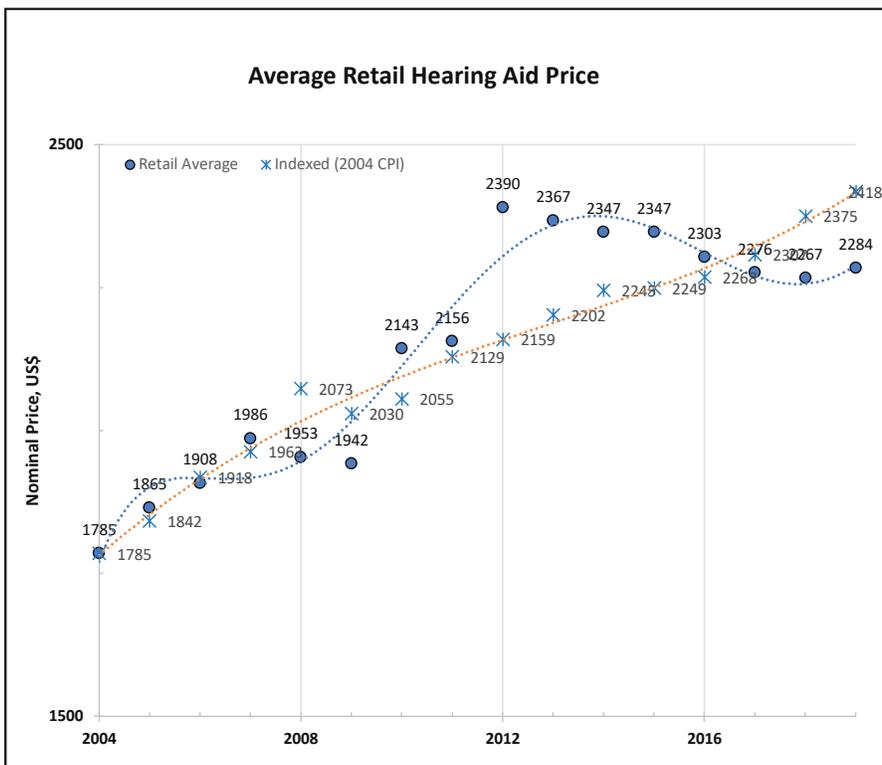
Part 4 compares unadjusted and inflation-adjusted average retail cost of a single unit device over time.

**CPI...A Reminder**

Historical changes in US inflation are captured by the US Bureau of Labor Statistics and reported as the Consumer Price Index (CPI). CPI data allows for the assessment of whether a good or service has increased or decreased in price compared to the same good service at another point in time.

**Average Hearing Aid Retail Pricing**

Figure 6 compares the unadjusted, average, single-unit retail hearing aid prices (blue filled circles), in US dollars, and a 2004 average-priced, single unit retail hearing aid adjusted for inflation (blue asterisks) across all technology tiers.



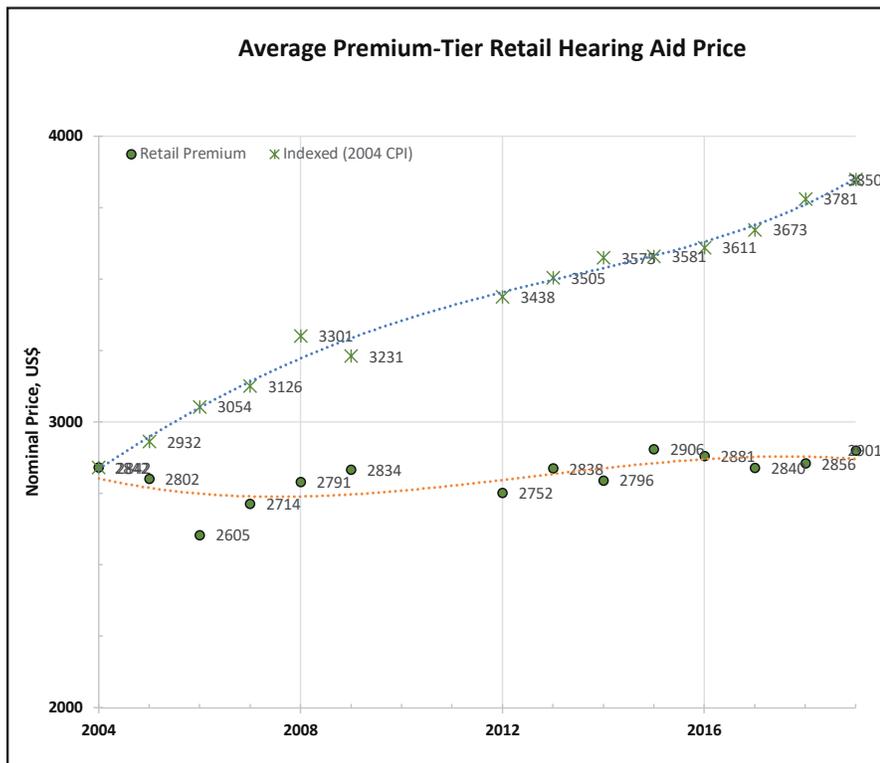
**Figure 6. Comparison between unadjusted, average, single-unit retail hearing aid prices (blue filled circles), in US dollars, and a 2004 average-priced, single unit retail hearing aid adjusted for inflation (blue asterisks) across all technology tiers.**

- As shown in **Figure 6**, the average retail cost for a single unit hearing aid was \$1785 in 2004. In 2019, the average retail cost for a single unit hearing aid was \$2284, unadjusted for inflation. Over time, the average retail cost per unit increased by \$499, or an annual average increase of \$32.27.
- When CPI data are applied to the 2004 retail single unit cost (i.e., \$1785), the average cost of a single unit hearing aid in 2019 yields a value of \$2418. This finding indicates that the 2004 unit increased in inflationary cost by \$633 in 2019, or at an annual rate of \$42.20.
- It should be noted that between 2009 and 2016, the unadjusted average retail price was notably higher than the inflation-adjusted average retail price. The difference was greatest in 2012, when unadjusted retail pricing exceeded inflation-adjusted pricing by \$231.

- It will be interesting, in time, to track whether the unadjusted average retail price remains below inflation. This trend began in 2017 and continues through 2019, as seen in **Figure 6**.

### Premium-Tier Retail Pricing

Figure 7 compares the unadjusted, average, single-unit retail hearing aid prices (orange filled diamonds), in US dollars, and a 2004 average-priced, single unit retail hearing aid adjusted for inflation (orange asterisks) for the premium-technology tier.



**Figure 7. Comparison between unadjusted, average, single-unit retail hearing aid prices (orange filled diamonds), in US dollars, and a 2004 average-priced, single unit retail hearing aid adjusted for inflation (orange asterisks) for the premium-technology tier.**

- In 2004, the average retail cost for a single unit, premium-tiered hearing aid was \$2842 (**Figure 7**). In 2019, the average retail cost for a similar technology-tier hearing aid was \$2901, unadjusted for inflation. Over this span, the average retail cost per unit increased by \$59, or by an annual average of < \$4.00.
- When CPI is applied for inflation, the 2004 price tag of \$2842 had ballooned to an average cost per single unit to \$3850 in 2019. This translates to a difference of \$949, yielding an annual average increase in inflation to the retail price of \$63.27.
- Clearly, premium-tier hearing aids are being dispensed at a rate well below that of inflation over time.

## Economy-Tier Retail Pricing

Figure 8 compares the unadjusted, average, single-unit retail hearing aid prices (red filled squares), in US dollars, and a 2004 average-priced, single unit retail hearing aid adjusted for inflation (red asterisks) for the economy-technology tier.

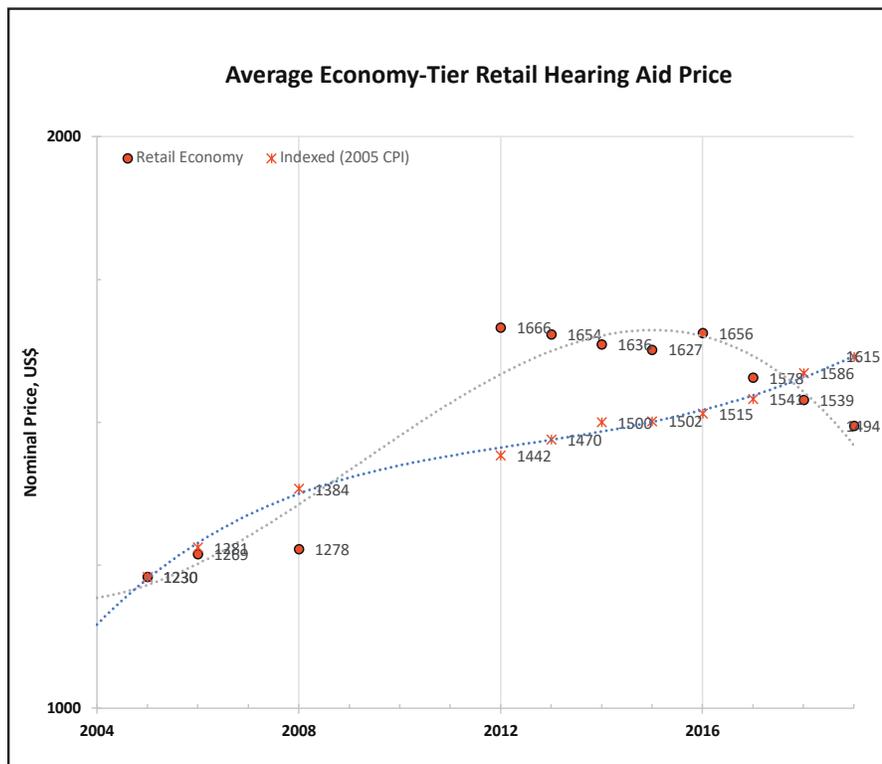


Figure 8. Comparison between unadjusted, average, single-unit retail hearing aid prices (red filled squares), in US dollars, and a 2004 average-priced, single unit retail hearing aid adjusted for inflation (red asterisks) for the economy-technology tier.

- As seen in **Figure 8**, the average retail cost for a single unit, economy-tiered hearing aid was \$1230 in 2005. (Note: we do not have data before 2005 for this technology tier.) In 2019, the average retail cost for a similar technology-tier device was \$1494, unadjusted for inflation. Over this span, the average retail cost per unit has increased by \$264, or by an annual average of \$18.86.
- When CPI is applied for inflation, the average cost of a single unit hearing aid in 2019 was \$1615. This inflation-adjusted value is \$385 above the unit price of \$1230 (in 2005), of which \$121 can be attributed to inflation.

**Q** Let's take a closer look at the recent dip in retail prices relative to inflation. What are some of the reasons for this drop? What consequences might practice managers face because of this dip?

**A** In my opinion, the drop in retail prices for economy-line technology—for 2018 and 2019—are being challenged by the segment of direct-to-consumer (DTC) products. Today, consumers can purchase most personal sound amplification products (PSAPs)—with decent to excellent audibility and sound quality—between \$100 and \$800. Traditional hearing aid manufacturers are reducing wholesale prices so that providers can compete by dispensing traditional hearing aid technology at lower retail prices. This pricing strategy is known as “the race to the bottom.” For providers to breakeven by offering lower retail prices, they would have to increase patient flow *and* prospect conversion rates markedly. For most practices, this business model is neither profitable nor sustainable given the inefficiencies of our current service delivery model.

# PART 5

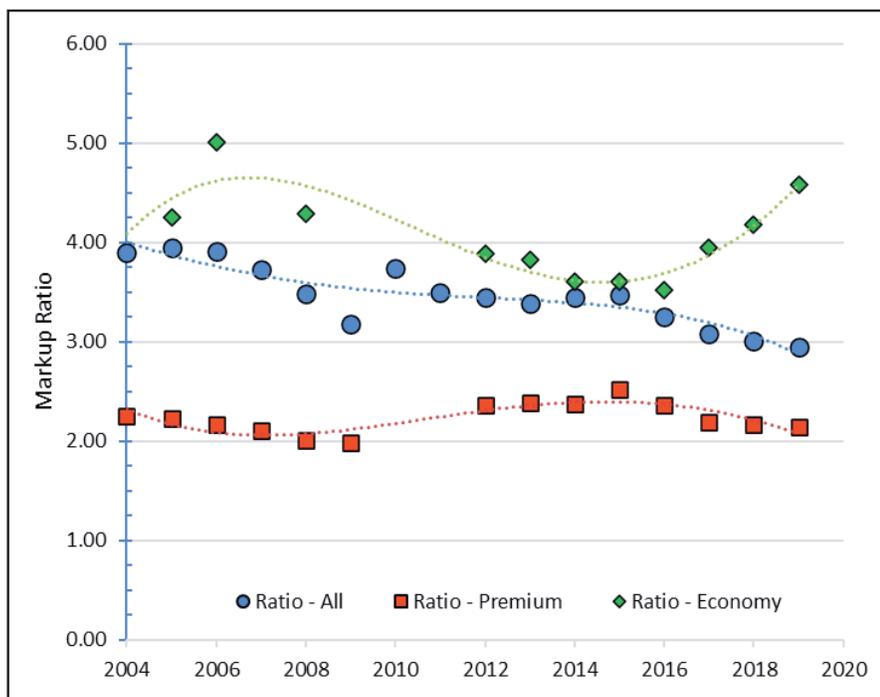
## THE MARKUP RATIO

Drum roll, please. In the fifth, and final, part of this article, we do the unthinkable and assess the markup ratio between nominal pricing retail and wholesale prices over time. For those readers involved in determining the retail prices of your products, hang onto your hat because you might find the final section the most illuminating.

### Cost-Plus Pricing and Markup Ratio

Of all the pricing strategies available, cost-plus pricing is the simplest strategy to employ because it (almost) guarantees that a business does not lose money on a sale. This pricing strategy is probably the most used one in the hearing care space. Cost-plus pricing is based on knowing (1) the wholesale cost of the product or service (i.e., invoice price) and (2) determining how much margin, or markup, is needed to generate operating profit (i.e., revenue minus expenses).

In this article, the reader is provided with the markup ratio for average, premium, and economy-line products, which is determined by dividing the nominal retail price by the nominal wholesale price at a given point in time. The data used to generate the markup ratios was adopted from pricing found in Parts 1 (i.e., wholesale) and 3 (i.e., retail) of this article.



### Summary of Findings

Figure 9. Markup ratio (i.e., retail price divided by wholesale price), over time, for all hearing aids (denoted by the blue circles), the average premium hearing aid (represented by the red squares), and the average economy-line hearing aid (designated by the green diamonds).

### Average Hearing Aid

- For the average hearing aid, the markup ratio has decreased from 4x to 3x between 2004 and 2019.
  - This decrease in markup ratio stems from a greater relative increase in wholesale prices compared to retail prices, although both wholesale and retail prices have increased.
  - In 2004, the average retail price for a hearing aid was \$1785 and the average wholesale invoice was \$457, yielding a markup ratio of 3.91 (i.e., \$1785/\$457).
  - In 2019, the average price for a hearing aid was \$2284 and the average wholesale invoice was \$774. The markup ratio for these data points is 2.95 (i.e., \$2284/\$774)
  - The average markup ratio for a hearing aid—independent of technology tier—has remained between essentially between 3x and 4x. This ratio has steadily decreased over the past decade and we will continue to monitor whether this trend holds in future blogs.

- Analysis: The finding from this exercise indicates that the average provider is receiving a smaller margin (i.e., 3x instead of 4x) from overall hearing aid sales when we compare data over time.

### Premium-Tier Hearing Aids

- For the average premium hearing aid, the markup ratio is relatively unchanged over time.
  - The lack of gross changes in markup ratio stem from the fact that average retail prices have increased by only \$59 between 2004 (i.e., \$2842) and 2019 (i.e., \$2901). Similarly, average wholesale prices have increased by a mere \$97 during this same period (i.e., \$1356-\$1259).
  - Analysis: The lack of substantial price increases at this technology tier are consistent with the inelastic demand in the hearing aid market (i.e., lower markup at higher price points), and a primary factor that supports the rationale for why this technology tier comprises the largest segment of units sold on an annual basis.

### Economy-Tier Hearing Aids

- The highest markup ratio belongs to the economy-tier devices, ranging between 3.5x (in 2016) to 4.6x (in 2019).
  - The variability in markup stems primarily from changes in retail pricing. Economy-tier devices have ranged from \$1230 (in 2005) to \$1666 (in 2012).
  - Between 2005 and 2019, retail prices have increased by \$264.
  - Wholesale prices, on the other hand, show a \$37 difference between 2005 (\$289) and 2019 (\$326).
  - In 2016, wholesale prices peaked at \$471 and retailed at a near-high price point of \$1656. This markup ratio of 3.5 was also the lowest recorded for this tier using this dataset.
  - Analysis: The larger markup noted for the economy-tier also supports the market's inelastic demand structure. A post-hoc review of the percentages by tiers indicated that in 2019, the quantity-demanded for economy-line devices was roughly 3% less than the quantity demanded for the same tiered product in the years 2012-2016. In other words, these outcomes indicate that market demand—and, ultimately, operating profit—is higher when the retail price of economy-line products are increased, not decreased.



*What are your thoughts on unbundling as it relates to the downward trend on the mark-up ratio? That is, as more practices unbundle or itemize, does it affect the reduced markup ratio?*

Love this question. The answer is that the markup ratio becomes less of a factor with itemization. I provided a table below to help readers follow my response.



|                               | Bundled | Itemized |
|-------------------------------|---------|----------|
| Wholesale Price (single unit) | \$10    | \$10     |
| Cost-plus Ratio               | 2.5     | 1.5      |
| Retail Price (single unit)    | \$25    | \$15     |

Assume that the wholesale price of a device is \$10 for a single unit. In the bundled approach, the provider elects to utilize a cost-plus ratio of 2.5 that covers their product and service expenses, resulting in a revenue. The retail price is then listed at \$25 (i.e., \$10 x 2.5) per unit and includes unlimited services and hearing evaluations.

On the other hand, the itemized approach also assumes the wholesale price of a device is \$10. The cost-plus ratio of the product only is 1.5, resulting in a retail price of \$15 per device (i.e., \$10 x 1.5). In the itemized approach, services are included for the first-year only. For subsequent years, patients are scheduled for routine (not unnecessary) services, such as maintenance checks, hearing evaluations, cerumen removal, and hearing aid repairs. The reader will note that the itemized approach offers \$10 less gross revenue than the bundled approach.

For our examples, assume a breakeven rate of \$1 for service delivery. The itemized approach will require that patients be scheduled only for routine, necessary services. This model of recurring revenue, along with an increase in long-term patient engagement, is the financial foundation in physician and dental offices. In our example, the itemization approach would require at least 10 patient visits over four years to match the gross revenue in the bundled approach. Most providers foresee this financial “gap” and are quick to dismiss the itemized approach.

Now, assume a patient fit with hearing aids is seen 10 times in the four-years post the initial year, with 2 visits merely for social reasons (although the patient indicated otherwise). In this example, the bundled approach yields a loss of unrealized revenue opportunities because of its inefficient service model. In the itemized approach, two new patients would have been scheduled instead, as the patient previously fit with hearing aids would not have set an appointment and paid for a social visit. With the average US clinic yielding a 50% conversation rate, there is a moderate-to-strong likelihood of one patient moving forward with a hearing aid purchase. This additional purchase results in an increase in total unit output. While the markup is lower in the itemized pricing strategy, the revenue opportunity is expectedly higher because of (i) the potential increase in total units sold and (ii) the ability to generate sustainable revenue streams based on the ongoing patient-provider relationship.

One more comment about itemization: from a professional and financial standpoint, it addresses the public health issue of intervention shortage and yields an increased gross revenue relative to the bundled approach. In my eyes, itemization affords the provider to work smarter, not harder, while effectively and efficiently performing their public health duties.

**Q** *I am a little surprised about the relatively low mark-up ratio of premium devices. Do you think if managers were more cognizant of lowering their cost of goods for these products, like committing to buying all their devices from just one or two manufacturers, we would see an uptick in this ratio?*

**A** To run a successful practice, both revenue and expenses must be considered. I absolutely agree that practices should lower their cost of goods through negotiation and manufacturer-discount offerings. This will yield a larger ratio and an increase in gross revenue. However, I do not believe that expenses should be reduced at the expense of the patient; in our example, by providing a limited selection of product offerings. Today’s consumer wants choices, and having choices enhances practice brand and patient purchasing confidence. Thus, the markup ratio should be used as metric to enhance business decision-making, not as an absolute metric in running your business.

**Q** *What are strategies managers can use to improve their margins?*

**A** Practices must be aware of the dynamic wholesale pricing changes by manufacturers. Relatedly, practices must be willing to adjust their retail prices based on the wholesale pricing changes, while being transparent to patients that the market is not static. Today’s consumer is aware of price fluctuations, for example, gasoline, housing, airline tickets, groceries, and restaurants.

For those practices uncomfortable with rolling wholesale price changes, negotiate a fixed price with the manufacturer. But beware; this activity could be revenue-prohibitive should manufacturers offer lower wholesale prices or a discount.

**Q** *Based on all this data you’ve shared here, what are one or two tactics managers can employ to improve their profitability?*

**A** Three things come to mind, and they are not mutually exclusive. First, negotiate the lowest possible wholesale price with manufacturers. If a particular manufacturer is unwilling to have discussions or if the wholesale price offered is disadvantageous to the practice’s revenue goals, then seek a partnership with another manufacturer. In other words, providers are also consumers. Second, providers and their staff must analyze wholesale and retail prices several times a year, and make adjustments that benefit the practice and its patients. Finally, strongly consider decoupling the product from professional services (i.e., itemize), expanding service offerings and including new and underserved populations. With the proliferation of consumer-electronics companies making products available directly to consumers, the race to the bottom is gaining momentum quickly. That said, the traditional business model is not designed to sustain historic profit results into the future. Embracing these pricing and business strategic tactics increases the likelihood of profitability, and are grounded on (i) itemization, (ii) long-term patient engagement, and (iii) operational effectiveness. ■



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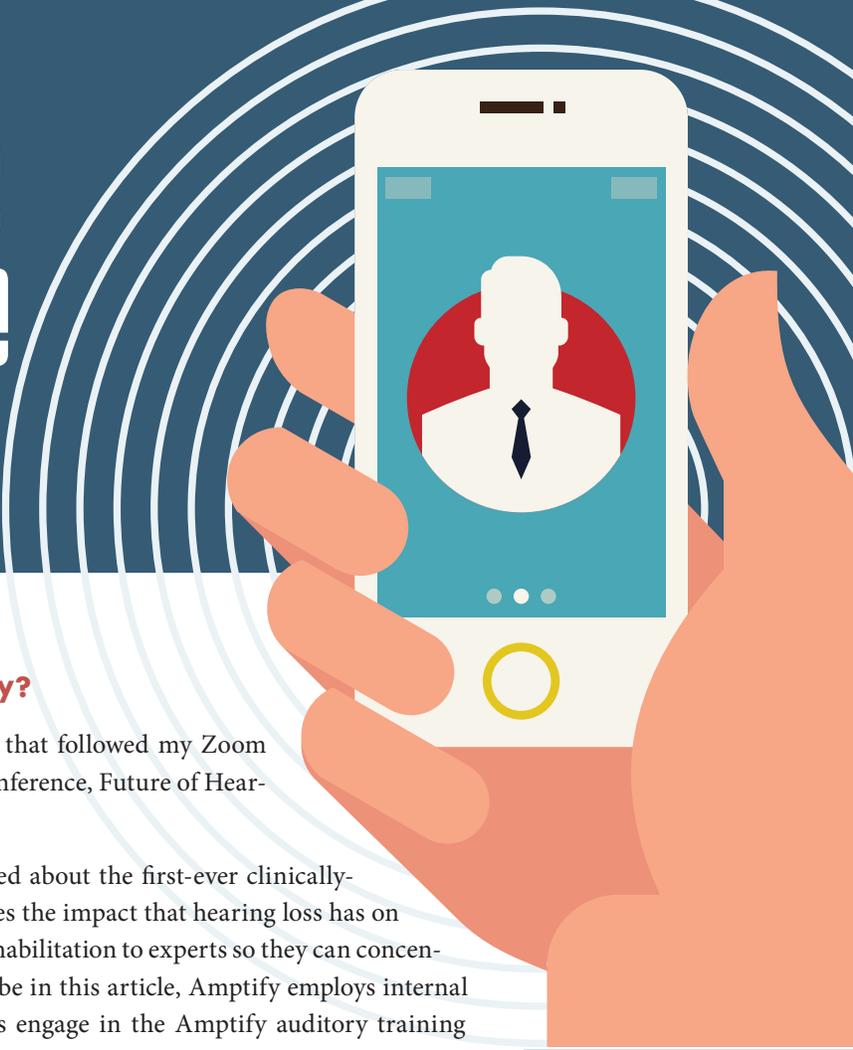
# TOP 20

## Business-related Posts at Hearing Health & Technology Matters

It may not be the NCAA's Top 20 best basketball teams and it's only half the size of Casey Kasem's infamous weekly Top 40 Countdown, but our friends at the HHTM blog have shared their list of the most influential business-oriented posts from the past year.

- 1 In the Virtual World, Humans are Still Needed** <https://hearinghealthmatters.org/innovationsinhearing/2020/audiology-digital-hearing-care/>
- 2 Marketing and the Future of Hearing Healthcare: Reaching the New Consumer** <https://hearinghealthmatters.org/innovationsinhearing/2020/marketing-new-hearing-healthcare-consumer/>
- 3 Customization is the Antidote for Automation** <https://hearinghealthmatters.org/innovationsinhearing/2020/customization-audiology-clinic/>
- 4 Pricing in Hearing Healthcare: Which Race are You Running?** <https://hearinghealthmatters.org/hearingeconomics/2020/pricing-hearing-healthcare-insurance-consumer-demand/>
- 5 The Cost of Free** <https://hearinghealthmatters.org/hearingeconomics/2019/audiology-cost-of-free/>
- 6 The Economic Realities of Tomorrow's Independent Hearing Health Practice** <https://hearinghealthmatters.org/hearingeconomics/2019/economics-independent-hearing-health-practice-1/>
- 7 As Our Profession Evolves, So Should Our KPI's** <https://hearinghealthmatters.org/hearingeconomics/2018/audiology-evolves-so-should-kpis-part-1/>
- 8 Beware: TPAs and HARNs Can be Wolves in Sheep's Clothing** <https://hearinghealthmatters.org/hearingeconomics/2018/audiologist-beware-third-party-administrators-hearing-aid-referral-networks/>
- 9 Trust in Audiology Care: More Important Now Than Ever** <https://hearinghealthmatters.org/hearingeconomics/2020/trust-audiology-care-importance/>
- 10 The Metaphor Monologues: Unhealthy Practices** <https://hearinghealthmatters.org/hearingeconomics/2018/economics-hearing-healthcare-has-a-chronic-disease-part-2/>
- 11 Mistakes Are Inevitable, But Don't Let Them Sink Your Business** <https://hearinghealthmatters.org/hearinprivatepractice/2019/mistakes-inevitable-dont-let-sink-business/>
- 12 What Should Your Practice Post on Social Media?** <https://hearinghealthmatters.org/hearinprivatepractice/2021/what-should-your-practice-post-on-social-media/>
- 13 How to Rank for "Near Me" Google Searches** <https://hearinghealthmatters.org/hearinprivatepractice/2020/how-to-rank-google/>
- 14 How to Deal with a Negative Online Business Review** <https://hearinghealthmatters.org/hearinprivatepractice/2021/how-to-deal-with-a-negative-online-business-review>
- 15 TeleHearing Care Increases Patient Retention** <https://hearinghealthmatters.org/hearinprivatepractice/2020/telehearing-care-increases-patient-retention/>
- 16 Is the Price Really Right? Why Audiology Practices Need to Know Their Breakeven Rate** <https://hearinghealthmatters.org/hearinprivatepractice/2019/audiology-practice-breakeven-rate/>
- 17 Myths and Realities of Audiology Independent Private Practice** <https://hearinghealthmatters.org/hearinprivatepractice/2019/owning-audiology-independent-private-practice-myth-reality/>
- 18 Beginning an Audiology Private Practice** <https://hearinghealthmatters.org/hearinprivatepractice/2019/starting-audiology-private-practice-1/>
- 19 Heed Your Professional Instinct** <https://hearinghealthmatters.org/hearinprivatepractice/2019/heed-your-professional-instinct/>
- 20 Embezzlement in the Office: It Can Happen to You** <https://hearinghealthmatters.org/hearinprivatepractice/2014/embezzlement-office-can-happen/>

# USING DIGITAL THERAPEUTICS TO PROVIDE COMPREHENSIVE HEARING HEALTHCARE



By Nancy Tye-Murray, Ph.D.

## But how will Amptify help me make money?

An audiologist texted me this question during the Q&A that followed my Zoom presentation at the recent Hearing Technology Matters' conference, Future of Hearing Health Care.

Amptify President Chris Cardinal and I had just presented about the first-ever clinically-validated digital therapeutic for hearing loss, which reduces the impact that hearing loss has on patients' lives and allows audiologists to outsource aural rehabilitation to experts so they can concentrate on diagnostics and hearing aid fittings. As I'll describe in this article, Amptify employs internal hearing health coaches who provide support as members engage in the Amptify auditory training games, the Amptify daily interactive curriculum, and the accompanying peer-support community.

I immediately "got" the attendee's question. In 30-plus years of extolling the importance of aural rehabilitation, and the importance of supporting patients beyond the hearing aid fitting, I seemed to have always hit the proverbial brick wall of financial expediency. At the end of the day, audiologists in private practice or in hospital settings need to keep the lights on and the shingle hanging above their doors. Aural rehabilitation is time-consuming and labor-intensive, and admittedly, not a money maker.

So I agreed that the question, *How will Amptify help me make money?* was a legitimate one. Here's the answer, by means of invoking a medical-model analogy:

When a patient has a knee problem, an orthopedic surgeon might diagnose that the knee be replaced. If so, the surgeon performs the implant surgery and then refers the patient to both a physical therapist for follow-up therapy and a pharmacist for a prescription of antibiotics. Although the orthopedic surgeon doesn't generate income with these referrals, making them is all a part of implementing the best standard of care.

To extend this medical model to audiological care, like the orthopedic surgeon, the private practice or hospital audiologist diagnoses a patient's condition (hearing loss) and if appropriate, selects and fits the patient with medical devices (hearing aids). Although in the "old days", best practice might have been for the dispensing audiologist then to provide perceptual training or group aural rehabilitation as part of the treatment plan, it is now possible for the audiologist to make referrals for follow-up care. With the availability of Amptify, the audiologist can hand the patient a brochure (Figure 1) and prescribe a regime of aural rehabilitation. Not only does this not cost the audiologist anything but a couple of minutes added to the counseling session, but importantly, making the referral allows the audiologist to ensure comprehensive hearing healthcare.

And this is the answer to the question of how audiologists profit by making referrals for aural rehabilitation. A downstream benefit of providing comprehensive hearing healthcare is that a clinical practice now distinguishes itself from big box stores such as Costco and Sam's. Whereas these commercial entities truly exist for the sole purpose of generating profit, an audiological practice exists for the purpose of providing comprehensive healthcare services. Making referrals for necessary services that you are unable or unwilling to perform, may not generate income for the practice, but it is the right thing to do and patients are much more likely to leave an office thinking that they have been served by a healthcare provider and less likely to feel as if they have value-shopped at a "store" where one buys hearing aids.

### What exactly is Amptify?

Amptify is the first-ever digital therapeutic designed for hearing health care. A digital therapeutic (DTx) is a software-based intervention for a disease and/or disorder that is clinically validated to drive a specific positive outcome, and is often coupled with a medical intervention such as a drug or medical device. DTxs in the areas of healthcare and education have proven to be highly effective for managing diabetes (Omada), asthma (Propeller Health), weight (Noom), and mental health (Headspace).

The Amptify DTx is a comprehensive tech-enabled hearing health DTx designed to treat hearing loss and its downstream effects. Amptify grew out of our experience with cLEAR (customized learning Exercises for Aural Rehabilitation). cLEAR was a first attempt to allow audiologists to outsource auditory training. Based on what we learned from the feedback of users and clinicians, we developed the next generation of online hearing healthcare, which we call Amptify. The comprehensive program includes the following:

- **Auditory training video games.** The games are professionally crafted to ensure compliance and entertainment through animation and colorful graphic design (Figure 2). The instructional design underlying the games targets the development of speech discrimination skills and exercise for those cognitive skills necessary for discourse comprehension, including auditory attention, processing speed, and word memory. The auditory



Figure 1. The Amptify Patient Brochure

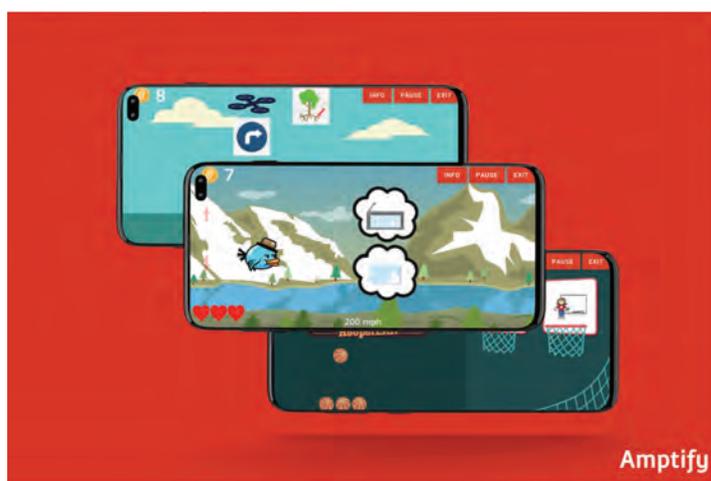


Figure 2. Auditory Training Video Games

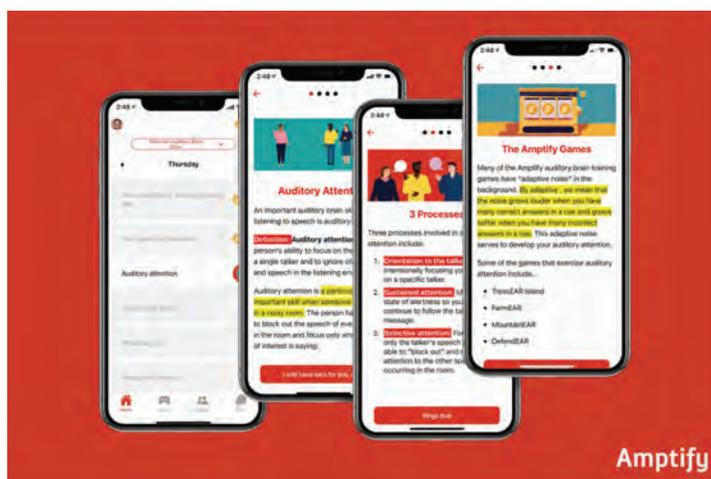


Figure 3. Daily Interactive Curriculum

training games have also been shown to produce positive results in terms of maximizing users' ability to use their residual hearing. Research focused on the games alone has shown that the instructional design that underlies the auditory training games leads to enhanced speech discrimination (Barcroft et al., 2016), reduced perceptual effort (Sommers et al., 2015), increased listening confidence (Tye-Murray et al., 2012), and improvements in those communication situations that patients deem challenging (Tye-Murray et al., 2017).

- **A daily interactive, illustrated curriculum.** The curriculum engages patients through quizzes, tutorials, balance exercises, and social diaries (Figure 3). The 12-to-16 week curriculum includes such topics as preventing and rectifying communication breakdowns, engineering the listening environment to potentiate successful communication, nutritional tips to promote hearing health, tinnitus management, balance exercises, and the link between hearing healthcare and cognitive health. The overall theme of the curriculum is *empowerment*. Patients are given the “tools” for ensuring successful conversations and the tools for mitigating against possible downstream effects of hearing loss, such as social isolation, falls, and cognitive decline. Results from our beta testing with a group of adults with hearing loss underscored the importance of emphasizing self-help content. The beta test results also led us to omit traditionally included content that emphasized managing possible negative correlates of hearing loss; e.g., self-stigmatization; unhelpful conversational behaviors such as aggressiveness or passivity (e.g., see Trychin, 1987; 2002; 2012, for this kind of approach). In finalizing the curriculum, we took to heart the sentiments of one beta tester, who told us (paraphrase): “I want to know what I CAN DO and not what I can't do and I want to come away feeling ENHANCED by having taken proactive steps. My identity is that of someone who just happens to have hearing loss—the hearing loss doesn't define who I am.”
- **An online Amptify hearing health coach.** Starting in the first week, users are paired with a hearing health coach, who provides support, encouragement, and hearing-related information. Over the first two weeks, the coach starts them off with introductory material that supplements the curriculum. In the third week, participants are placed in a group that is led by their coach. Before becoming an Amptify hearing health coach, candidate coaches undergo the in-house Amptify training program and must receive certification. Once they begin practicing as coaches, they are overseen by an in-house audiologist. The audiologist ensures quality-control and is available to answer questions or handle issues that might be technical in nature, as when a member might want to know the details of a hearing aid directional microphone. We discovered from our cLEAR experience that the hearing health coach is an important “secret sauce” of any online aural rehabilitation program. Users respond to positive reinforcement and the accountability of knowing a professional is monitoring them.
- **An online customized social peer support community.** We create communities of users so that each community includes members that are both homogeneous and heterogeneous, and who share the same hearing health coach. The coach leads discussions and promotes conversations. This aspect of the program relates back to traditional group aural rehabilitation and represents a “virtual answer” to the live group experience. Through their online interactions, members can share their experiences, find commonalities, and learn new ways to manage hearing loss through vicarious experiences. Over time, they create a friendship network and sense of empathy and support.

## Does it work?

The short answer is, *Yes*. In addition to enhancing listening performance, as noted above, Amptify enhances the hearing health care experience and facilitates the adjustment to new hearing aids. Under the auspices of an NIH SBIR grant, we recently conducted a study with 28 new hearing-aid users to determine whether Amptify enhanced acclimation to their new devices. Results indicated a very positive response to the program overall and to the curriculum in particular, with the latter receiving a qualitative rating score of 6.1 out of a possible score of 7. Ninety-six percent of the participants reported a positive opinion and one half reported that the program helped them to adjust to their new hearing aids.

In summary, it is now possible to provide aural rehabilitation without incurring additional time or cost on the part of a patient's audiologist. In addition, Amptify can reduce in-clinic time with patients because the online Amptify hearing health coach is able to answer simple questions about hearing aid use, such as those about battery life or device handling. Ultimately, the audiologist accrues profits by not only reducing in-clinic visits but also by creating patient loyalty through gold-star service.

Amptify was made available for general use on March 21, 2021. Enrollment is easy. Amptify provides brochures to clinics and a “cheat sheet” about how to describe the program. They can enroll patients either by referring them to [www.Amptify.com](http://www.Amptify.com) so they can self-pay or they can sponsor their patients via their own clinic’s Amptify portal. The Amptify app can be accessed on iOS, Android, or at [app.Amptify.com](http://app.Amptify.com).

The future of hearing healthcare entails digital therapeutics for hearing loss—you can bet money on it. ■

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# ADA's Practice Resource Catalog: The Tools You Need for Your Practice



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*An Interview with  
Dakota Sharp, Au.D.*

# ARE WE RUNNING OUT OF PUNS?

The Rise of  
Podcasting  
in Audiology





Although podcasting, a popular application of on-demand audio, has been around for more than 15 years, over the past year or so, it has really picked up steam. These days, it seems, everyone has a podcast. The profession of audiology is no exception. A recent check of the Apple podcast app (or any of the other assorted ways to download podcasts), reveals dozens of audiology-related podcasts on myriad subjects. Even some of the Audiology Old Guard, so to speak, have podcasts, including *AudiologyOnline*, *Audigy* and the *Hearing Journal*. In addition, there are several great podcasts, carefully curated by individuals. Below is a sample of those podcasts. As you peruse them, one wonders, have these podcasters exhausted all the ear and hearing puns?

- The Hear Me Out Podcast with Mark Truong
- All About Audiology with Lilach Saperstein
- EmpowEar Audiology with Carrie Spangler
- Hearing Matters Podcast with Gregory Delfino and Blaise Delfino
- Audiology Talk with John Coverstone
- The Business of Hearing with Phil M Jones and Oli Luke
- FuturEar Radio with Dave Kemp
- The Unbundled Audiologist with Erica Person

Together, these podcasts cover a range of subjects within our profession. One podcast that covers an assortment of interesting topics is *On the Ear*, created by Dakota Sharp. Audiology Practices managed to catch up with Dakota. Here is our interview with him.



**AP** Tell us what motivated you to become an audiologist.

**DS** After graduating high school, I was on track to become an elementary school teacher. I have a passion for education, and I love working with children. During my undergraduate orientation I took an Intro to CSD course, on the off chance that I might be interested in speech-language pathology (SLP), and learned about audiology. As the grandson/family member who is always called when someone needs help with a new computer or piece of technology, audiology felt like the perfect blend of technology, serving others, and the opportunity to work with children!



**AP** Where did you earn your AuD and who were some of your biggest influences while training to become an audiologist?

**DS** I completed both my Bachelor's degree and Au.D. at James Madison University (Go Dukes!!). Highly recommend a visit to the Shenandoah Valley for anyone who hasn't had the chance. I was fortunate to have a LOT of influential educators and clinical supervisors in my training. A few that come to mind: Dr. Sara Conrad for showing me the importance of compassion as a clinician, Dr. Brenda Ryals for sparking curiosity and teaching me how to better read journal articles, and Dr. Kelly Murphy for being a hilarious and brilliant mentor. Outside of direct contacts, Dr. Jane Madell was an early hero of mine, and helped cement my goal to improve pediatric audiology services for all children with hearing loss in any way I can. I am the clinician I am today thanks to the fantastic guidance I received from so many amazing audiologists, researchers, and educators.



**AP** Where are you currently practicing?

**DS** I am currently a Clinical Assistant Professor at the University of South Carolina, where I see patients in the on-campus clinic and teach Master's SLP students the Introduction to Audiology course. It is truly my dream job—part clinic, part classroom.



**AP** As a clinician, researcher or teacher, what are some of your biggest challenges and rewards?

**DS** Working with students in the clinic and classroom is what makes my job so special but can also lead to the biggest challenges. While seeing patients, you're not only mentally focused on the patient and their needs, but also the performance of the student, their needs, and feedback for them to share at the end of the appointment. It's a lot of mental juggling, and when you're in the midst of a screaming 3 year old with a scared parent and wild sibling, it can feel like a lot. But to see a student implement what they've been learning, take charge, and serve patients well? There's no better feeling.



**AP** Again, putting on your clinician, researcher or teacher hats, what are some of your biggest interests?

**DS** I see a pretty good mix of cochlear implant and hearing aid patients, from birth to adults. My passion is for pediatrics, though, and when I first started at my current clinic, we did not have a pediatric hearing aid program, and did not work with the state newborn hearing screening program. I was able to establish our pediatric hearing aid

program within the first year, and working with our state NBHS program, obtained ABR equipment to start seeing babies for natural sleep ABRs. My favorite appointments are ABRs and pediatric hearing aid fittings/follow-ups!



### **AP** What prompted you to get into podcasting?

**DS** While in grad school, I hosted a weekly pub trivia at a local brewery, and it was always my favorite night of the week. I've also emceed a few school dances and weddings—I just love to host. I've also been an avid podcast listener for years, and so starting a podcast of my own was always a goal. A former student of mine connected me with Michelle Dawson, SLP, host of the First Bite podcast, where I was invited as a guest. Our conversation was so much fun, and after asking her about what it takes to get started, I decided to take the plunge! There were no other audiology podcasts eligible for CEU credit, so it felt like a great opportunity to do something I'd always wanted to try and learn a lot in the process.



### **AP** Tell us about the process of creating a podcast. What goes into planning and set-up?

**DS** Because the podcast is eligible for CEUs, it takes a bit of planning! My first few guests were friends, mentors, and colleagues who I knew were fun and knowledgeable experts. Since then, I have made connections through previous guests and through social media to find new voices. As a young clinician, I don't really have a long list of contacts, so this podcast has seriously helped me meet so many fantastic clinicians and researchers. For the more technical aspect of things, I work with a fantastic company called SpeechTherapyPD.com. They make sure everything is edited, hosted, and manage the CEUs. I take suggestions for episode topics and guests through the podcast's Facebook and Instagram pages, and record new episodes every other week.



### **AP** I'm curious how other audiologists learn about your podcast. Do you market? Is it strictly word of mouth on social media?

**DS** It's all word of mouth. Honestly managing the social media is the most time-consuming aspect of the podcast. There are a lot of good tools for creating and planning content out there, but it's so hard to stay ahead of it. The feedback from audiologists on social media has been great, and there's a surprising number of AuD students who are avid listeners. I'm still working on how to reach more new listeners, but the best thing fans can do is leave a review or share on their favorite social media platform.



### **AP** Who are some of your most memorable guests on the podcast?

**DS** That's a tough one. I sincerely believe each guest has been fantastic, so new listeners should just find a topic that interests them and give it a listen. I received a lot of great feedback after Episode 10 – The Power of Conversation: Racial Disparities in Hearing Healthcare with my friend Dr. Logan Faust. She shared her experiences as a biracial audiologist, and her story is really powerful. Another popular episode is Episode 7 – Navigating Unilateral Hearing Loss as an Audiologist with SSD with another friend of mine, Dr. Sofia Roller. Sofie is hilarious and brilliant and her blend of personal stories and clinical experiences is great.



### **AP** Let's look at the future of audiology. What advice would you give graduate students?

**DS** I learned a lot from Dr. Ashley Hughes and Dr. Natalie Nelson in a recent episode (#15)—those extra skills you have, like creating graphics for Instagram, understanding social media algorithms, using Photoshop, etc. They can be useful in the workplace. Put those skills on your resume and negotiate with them. I'd also say that your 4th year externship is extremely important. Consider locations all over the country, and find a site that will give you the most well-rounded experience possible.



### **AP** How do you think the practice of audiology is likely to evolve over the next decade or so?

**DS** This is a great question. I hate to keep doing this, but we have a recent episode for that, haha. I don't consider myself much of a predictor, but Dave Kemp specializes in this. In episode #16 he breaks down how hearables are changing the hearing aid industry and audiology in general, and I am convinced. I really think the capabilities of things like AirPods will expand to be "communication enhancers" for people with mild hearing losses, as they're clearly already tracking toward. I think it's important that audiologists really embrace their full scope of practice and be willing to adapt to what people actually need.



### **AP** What future hearing device technology are you most excited about and why?

**DS** The more I learn about Bluetooth LE Audio, the more excited I am. I think we will soon see a new, tidal wave of acceptance and accessibility for listeners with hearing loss that will really benefit everyone.



### **AP** Any final thoughts on podcasting or the future of audiology?

**DS** I've been overwhelmed with the positive reaction to *On the Ear*. I truly enjoy making it, so hearing how it is impacting clinical practice, clinician attitudes, and the education of future clinicians is mind-blowing. The most important thing for any clinician to maintain is a love of lifelong learning. If audiologists can be trained to be curious and compassionate, our profession will no doubt continue to grow and benefit patients, families, and our society as a whole.



You can find the **On the Ear** podcast wherever you download your favorite podcasts.

Dakota Sharp, Au.D. can be reached at [ds24@mailbox.sc.edu](mailto:ds24@mailbox.sc.edu). ■



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# State Laws and Hearing Aid Sales: Home Field Advantage or House of Cards? Federal Preemption, Disruptive Innovation, and Implications for Audiology Practices

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## INTRODUCTION

State laws dictate who can practice audiology, what services licensed audiologists can perform, and where, when, and how audiology services *may* or *must* be delivered. However, when it comes to the sale of hearing aids, federal laws generally supersede state statutes and regulations. Conflicting laws cause confusion and create a conundrum for practicing audiologists, especially when conditions are new, uncertain, or controversial.

### **Initiative to Repeal Florida Hearing Aid Laws Causes National Controversy, Warrants Further Inquiry**

A controversial 2021 Florida legislative proposal, if enacted, will dismantle state-mandated minimum testing requirements and fitting procedures tied to the sale of hearing aids to adult consumers, repeal Florida's ban on mail order hearing aid sales, and introduce a medical examination requirement that could be waived by adult consumers for religious or personal reasons. The proposed statutory changes, shepherded by a private equity firm on behalf of its start-up remote hearing care venture, have received significant public opposition from incumbent firms, providers, and legacy networks that rely heavily on traditional delivery channels. The legislation was introduced in the Florida Senate as Committee Amendments 302884 and 286824 to Senate Bill SB 700, Telehealth, by Senators Ana Maria Rodriguez and Aaron Bean respectively, in February 2021.<sup>1</sup>

The internal policy analysis, conducted by the Academy of Doctors of Audiology (ADA) concluded that the proposed amendments to SB700 align with U.S. Food & Drug Administration (FDA) regulations covering professional and patient labeling and conditions for sale of hearing aids, raising questions about the validity of requirements contained in the Florida statutes in light of conflicting federal regulations.<sup>2,3</sup>

Given the significance of the legislative initiative to ADA members in Florida, the potential for broad applicability for other U.S. states and jurisdictions, and the complex nature of the legal issues involved, ADA sought a legal opinion from a licensed Florida attorney with relevant healthcare expertise. The legal opinion, drafted by Christine C. Whitney, Esq., along with subsequent research, uncovered several facts that are both important and urgent for audiology practice owners and dispensing audiologists to fully understand.<sup>4</sup>

### **LEGAL DETERMINATION: EXISTING FLORIDA STATUTES ARE NON-BINDING AND LIKELY UNENFORCEABLE**

According to the Whitney determination, *“any requirements for the fitting or selling of hearing aids that are different from, or in addition to, the federal Food and Drug Administration (FDA) requirements are subject to federal preemption. This means that if a Florida court is asked to enforce Florida regulations for the fitting or selling of hearing aids that add*

*any requirements or contain different requirements not found in the FDA rules, the court could, and, in my view would, declare the Florida regulations to be federally preempted and unenforceable.”*

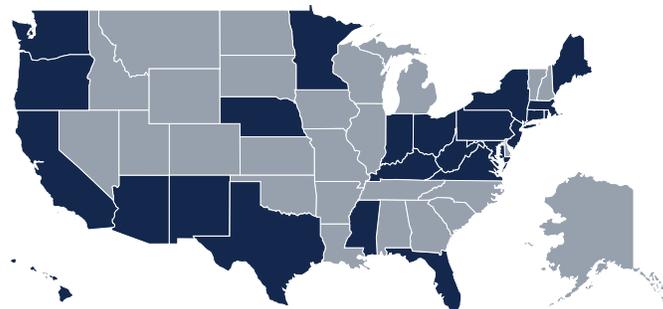
Further, as currently written, many of the minimum testing and fitting procedures are conditional because they are followed by the phrase, “when indicated,” which leaves the decision about whether and when to perform them to the discretion of the professional. The full legal determination, *ADA Florida Bill re Hearing aids and Audiologists SB 700 and two amendments proposed by the Committee on Health Policy*, are available at [audiologist.org](http://audiologist.org).

### **MDA, FDA, Federal Preemption, and Hearing Aid Sales Requirements**

As Whitney's determination noted, the U.S. Constitution declares federal law as the supreme law of the land. The preemption doctrine prohibits state governments from interfering with the exercise of the federal government's constitutional powers and from assuming any functions that are exclusively entrusted to the federal government.

The Medical Device Amendments (MDA) of 1976 established a three-class, risk-based classification system for all medical devices (including hearing aids) and provided the FDA with broad regulatory authority.<sup>5</sup> The statute contained an express preemption in section 21 U.S.C. § 360k(a), clearly prohibiting states from establishing any requirement “different from, or in addition to” a federal requirement that relates “to the safety or effectiveness” of a medical device.<sup>5,6</sup>

The law also outlined a mechanism and process for states to formally request exemptions from federal preemption, where state laws were more restrictive, but could be justified by public interest or protection. The FDA has addressed federal preemption exemption requests by 22 states over the past 42 years. The vast majority of FDA decisions regarding state preemption exemption requests were published on Friday, October 10, 1980.<sup>6</sup> Most preemption requests were denied. View the *ADA Compendium of State Preemption Requests and FDA Decisions in the table located on pages 41-42*.



## The FDA Does Not Prohibit the Sale of Direct-To-Consumer Hearing Aids

The FDA does not prohibit the sale of direct-to-consumer (DTC) hearing aids, nor has any state been granted an exemption authorizing it to prohibit the sale of hearing aids through the mail or over the internet. Hearing aids are not designated by the FDA as prescription devices. Specifically:

- Prescription devices, bear the label *Rx only* and are defined as, “A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared”<sup>8</sup>...
- Hearing aids are classified as restricted devices—and are only restricted by the conditions for sale and labeling requirements.<sup>3,4</sup> Consumer information, published by the FDA on its website states, “**Buy your hearing aid either direct-to-consumer, or from a licensed hearing healthcare professional** (audiologist, a hearing aid dispenser, or an ear, nose, and throat physician).”<sup>9</sup>

## The FDA Denied Requests for State Preemption Exemptions Requiring Medical or Audiologic Evaluations for Adults

The FDA has repeatedly denied federal preemption exemption requests from states seeking to mandate an audiologic evaluation for adult consumers prior to the purchase of a hearing aid and those seeking to prohibit adult consumers from waiving a medical evaluation for religious or personal reasons.<sup>10</sup> The agency has provided the following rationales:

- *Regarding mandatory audiologic evaluation requirements for adults: “After reviewing the conflicting information in the public record regarding the predictive value of audiological testing in determining whether a patient would benefit from a hearing aid, FDA has concluded that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. There is no evidence that audiological evaluation reduces or eliminates any risk to health presented by a hearing aid.”*
- *Regarding the medical evaluation waiver for adult consumers: “The agency believes that examination by a physician is necessary to ensure that the organic causes of hearing loss are diagnosed and treated properly. The agency also believes, however, that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the requirement.”*

While the FDA has universally denied exemption requests for states imposing additional examination requirements on the sale of hearing aids to adult consumers, the FDA has consistently granted exemption requests from states imposing stricter audiologic and medical examination requirements for children under 18 years of age than federal law requires.<sup>10</sup>

The FDA has also granted exemption requests for states requiring additional written disclosures be provided to consumers purchasing hearing aids. The last FDA exemption determination occurred in 1988.<sup>7</sup>

## Medical Evaluation and Waiver: Not Enforced but Not Repealed

In December 2016, the FDA issued updated guidance for conditions for sale for air-conduction hearing aids, stating, “FDA does not intend to enforce the medical evaluation (21 CFR 801.421(a)) or recordkeeping (21 CFR 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.”<sup>11</sup> The FDA has not issued a proposed rule repealing the regulation. Therefore, state laws with similar medical evaluation mandates are likely not vulnerable to federal preemption at this time. The FDA could elect to begin enforcing the rule again at any time. ADA speculates that the medical evaluation and waiver requirement was added as part of the proposed amendment to Florida’s SB 700 precisely to avoid a conflict with existing FDA regulations.

## Applicability of Whitney Opinion to Hearing Aid Sales Laws in Other States

Regardless of whether SB700 and its proposed amendments make their way successfully through the Florida legislature and into law, or existing Florida statutes are tested through the courts, the legal precedents outlined in the Whitney determination are broadly applicable to all U.S. states, territories, and the District of Columbia—and have implications for audiologists practicing nationwide. Courts have consistently held that federal hearing aid sales regulations preempt state laws that mandate minimum testing or fitting requirements for adults and state laws that prohibit internet or mail order sales.<sup>4</sup>

## IMPLICATIONS OF WHITNEY DETERMINATION FOR STATES, AUDIOLOGISTS, AND AUDIOLOGY PRACTICES

The Whitney determination confirms concerns that many state audiology licensing boards and audiologists have been operating under a false set of assumptions about the validity and enforceability of their state laws related to the sale of hearing aids.

### An Opportunity to Enhance Enforceability, Transparency, Access, Equity, Flexibility, and Competition

Exposing federal preemption vulnerabilities should prompt states to do the following:

- Align state laws with federal requirements,
- Apply state laws equitably for audiologists and other hearing aid dispensers,
- Increase transparency regarding available consumer protections, and
- Fortify existing laws by seeking exemption from federal preemption in areas where it is likely to be granted,

such as for state hearing aid dispensing laws that have consumer disclosure requirements and/or that require audiologic evaluations for children which are “different from” or “in addition to” FDA mandates, but where the FDA has previously granted similar exemptions.

State and federal laws do not mandate the actions that an adult consumer must take to purchase hearing aids. They only mandate the actions that manufacturers, distributors, and dispensers must take to sell them. Audiologists practicing in states where hearing aid sales laws go beyond the federal requirements are quite literally playing by a different, more difficult set of rules than their competitors. Upstart firms, organized to sell DTC hearing aids and associated services, are keenly aware of the doctrine of federal preemption and are exploiting state law vulnerabilities in Florida and elsewhere.<sup>12,13</sup> So too are incumbent manufacturers and networks, some of whom already offer products for distribution through DTC and hybrid channels.

Removing antiquated (and likely unenforceable) state laws that prescribe minimum testing and treatment procedures beyond the FDA mandates will help level the playing field for audiologists and will not prohibit audiologists from performing those tests and treatments when they are indicated. It will simply authorize audiologists to employ their training and clinical judgment to evaluate each patient and each situation independently, and to deliver the course of treatment that is most appropriate, under a given set of circumstances. Had the federal preemption doctrine and its implications for state laws been brought to light sooner, audiologists may have been able to deliver more essential, clinically appropriate services during the height of the COVID-19 pandemic when practices were shuttered, and patients were isolated.

Audiologists, unlike online out-of-state dispensers, are already bound by extensive state-imposed ethical, legal, and educational requirements to obtain and maintain a license to practice audiology. They are also accountable for medical errors as measured against the reasonable standard of care. Taking the clinical decision-making process out of the hands of the state and putting it into the hands of licensed audiologists is prudent, responsible, and pro-competitive.

### **OTC Hearing Aid Act—Clarity or Confusion?**

The Over-the-Counter Hearing Aid Act, signed into law in 2017, directs the FDA to make certain hearing aids available for sale over-the-counter (OTC) to consumers with a perceived mild-to-moderate hearing loss. The law contains an express federal preemption superseding state laws requiring the *“supervision, prescription, or other order, involvement, or intervention of a licensed person.”*<sup>14</sup>

Designed to provide consumers with greater access, affordability, and choice when purchasing hearing aids, passage of the OTC Hearing Aid Act may have inadvertently reinforced misconceptions about the enforceability of current state laws related to the sale of hearing aids, by implying that provider involvement is required for the purchase of traditional

hearing aids. The FDA has not released proposed regulations for OTC hearing aids, missing the Congressionally-mandated August 2020 deadline. The timing of the release of proposed regulations remains uncertain, as does their potential impact on current regulations. In the meantime, DTC disruptors are already filling the void.

### **DTC Disruptors May Redistribute Power Centers Ahead of OTC**

The hearing industry has long been characterized by high consumer costs, inadequate access to services across populations, incremental technological advances, significant barriers to entry for new competitors, high variability in perceived quality, and slow industry growth. Over the past decade, industry consolidation, together with intensified vertical integration between manufacturers, distributors, third-party administrators, and affiliated clinics has deepened power imbalances and blurred the lines between the sale of a device and the practice of audiology.

Corporations have been selling hearing aids directly to consumers (legally) for more than 50 years.<sup>15</sup> A staff report released by the Federal Trade Commission’s Consumer Protection Bureau, in 1978 states:

*“Lloyd’s has sold over 100,000 hearing aids by mail in the 15 years since its founding, at prices up to 50% less than the prices charged by traditional sellers for comparable aids, and has for over 10 years allowed its customers a completely free trial of their hearing aids (TR6556). Hearing aids are manufactured according to Lloyd’s specifications and sold under the Lloyd brand name (TR6576). Since Lloyd’s sells by mail, it obviously does not test the hearing of its customers although it sometimes receives their audiograms (TR 6577–78).”*<sup>15</sup>

Early DTC efforts were largely ignored and often discredited by incumbent firms. Most manufacturers were unwilling to distribute products through DTC channels. Substitute products were not readily available and consumer reach was limited by high advertising costs and the association between mail order and low-quality products. Disruptive innovations require technological or business model advantages that can be sustained upmarket. While the hearing industry has been ripe for disruption for many years, suitable disruptors did not emerge until very recently.

Advances in technology and changing consumer attitudes shifted the DTC hearing aid paradigm and attracted relevant innovators. Today, respected companies such as United Healthcare (UHC) are dispensing DTC hearing aids supplied by well-known hearing aid manufacturers and delivering hearing healthcare services using virtual, hybrid, and physical models, customized to patient preferences.<sup>16</sup> These models are becoming readily normalized and widely adopted. Legacy firms, big retailers, and reputable start-ups are entering the virtual and hybrid hearing care space, armed with big data and big plans to democratize healthcare delivery.

Will industry disrupters upend predicted OTC implementation and impact – and if so, could it result in greater benefits for audiologists and consumers? That remains to be seen, but audiologists should act now to prepare for the future.

## RECOMMENDATIONS FOR AUDIOLOGISTS: POLICY, PREEMPTION, PATIENT CARE, AND PANDEMONIUM

New technologies and new applications of existing technologies have aligned with new markets. Quality care cannot be sustained by the execution of a one-size-fits-all set of processes, and excellence will not be defined merely by the presence of a physical location. Consumer demand for alternative hearing healthcare models is accelerating. Audiologists can use the information contained in the Whitney determination to transform audio-vestibular care and improve the lives of the patients they serve using the following recommendations:

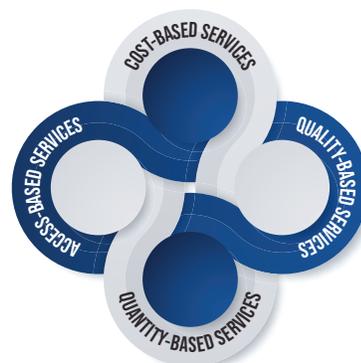
1. Audiologists should seek a legal opinion to determine if their state audiology statutes and regulations “are different from, or in addition to” federal requirements for the sale of hearing aids or are otherwise vulnerable to federal preemptions that may impact the practice of audiology. Audiologists may be able to combine resources and obtain a single determination applicable to practices throughout the state by working through their state audiology association.
2. Audiologists should petition their state to seek preemption exemptions to fortify state laws that require audiologic evaluations for children and that require disclosures to consumers that are more expansive than federal regulations.
3. Audiologists should petition their state government to eliminate laws that are vulnerable to federal preemption when the FDA has consistently denied similar state requests for exemptions. Doing so will promote transparency, consumer choice, patient access, and provider flexibility.
4. Audiologists should assert their professional sovereignty and advocate to prevent industry interests from interfering in the clinical practice of audiology. It is inappropriate for medical device manufacturers, distributors, and representative trade groups to lobby the government to impose minimum procedure requirements on licensed providers as a condition for sale of non-prescription medical devices, particularly when many of those same industry stakeholders are themselves selling or allowing the sale of the same devices through other channels without such requirements.
5. Audiologists should redesign their services to meet the needs of current patients and unserved markets. Audiologists should seek upmarket opportunities that maximize the value of their doctoral education and training. Activities and services that can be delivered effectively by less qualified staff, should be. Services can

be differentiated by cost, access, quality, and quantity:

- Cost-based services (standardized processes, high-volume).
  - Access-based services (hours of operation, geography/telehealth, technology).
  - Quality-based services (complex, comprehensive).
  - Quantity-based services (depth, breadth, scarcity/unique).
6. Audiologists should decouple clinical services from devices. The hearing aid is a commodity and can be readily substituted. There is no equal substitute for audiologists who provide professional, unique, accessible, and valuable services.
  7. Audiologists should contact hearing aid manufacturer and network suppliers and request their DTC distribution policy in writing. It is important for audiologists to have a clear understanding of supplier protocols for segment and channel-level distribution policies that impact audiology practices, particularly in such a tightly regulated, highly consolidated industry, where suppliers sometimes compete with downstream customers.
  8. Audiologists should adopt the ADA practice accreditation standards in their clinics to signify their commitment to deliver exceptional, patient-centered care. The most effective way to differentiate the profession of audiology from available substitutes for the sale, dispensing, and fitting of a hearing aid is by consistency in the delivery of high-quality hearing and balance services that improve the health and quality of life for all patients served.

## CONCLUSION

Existing Florida statutes, banning hearing aid sales through the mail and mandating testing requirements and fitting procedures, are likely vulnerable to federal preemption and, thus, unenforceable. The legal determination, obtained by ADA, has applicability to other state and territorial jurisdictions and broad-reaching implications for audiologists practicing throughout the United States. Audiologists and audiology practice owners, empowered with this knowledge, should seek legal advice, specific to their state and situation, which can be used to inform clinical and business decisions and advocacy initiatives that benefit and protect their patients, practices, and the public.



## ADA Compendium of State Preemption Requests and FDA Decisions

| Exemption Request Description Under 21 CFR 808   | Date                                 | States Requesting   | FDA Exemption Decision | Rationale   |
|--|--------------------------------------|---|------------------------|---|
| State laws that require the disclosure of certain information to hearing aid purchasers that goes beyond what FDA requires (for example, whether a hearing aid is refurbished, new, used). | October 10, 1980                     | Massachusetts, New York, Ohio, Oregon, Texas, Washington, California, Maine, District of Columbia | Granted                | These requirements are more stringent than the Federal requirements. However, FDA believes that the additional information required by these State provisions may be useful to the consumer and will not impose a significant burden on the hearing aid dispenser or manufacturer. Therefore, FDA is granting exemption from preemption for these requirements. To ensure uniformity, the agency is requiring that the States apply the Federal definition of "used hearing aid" (21 CFR 801.420(a)(6)) in enforcing their disclosure requirements. |
| State laws that require hearing aid dispensers to advise prospective purchasers in writing to consult with a physician if any of eight specified medical conditions are found to exist.    | October 10, 1980, September 13, 1988 | Connecticut, New Jersey, Washington, West Virginia  | Granted                | These requirements are more stringent than the FDA regulation because they require the dispenser to advise the prospective purchaser in writing. This requirement places only a slight additional burden on the dispenser and does not conflict with the FDA requirement. Therefore, the agency is exempting these requirements from preemption. FDA's requirements with respect to medical evaluation and waiver still apply in these states.  |
| State law requires that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid (for adults).   | October 10, 1980                     | Massachusetts   | Denied                 | Informed adults are not required to undergo medical exam or hearing test evaluation.  |
| State laws that prohibit advertising of any drug or device represented to have an effect on disorders of the ear.  | October 10, 1980                     | California  | Denied                 | The law prohibits not only false and misleading advertising but also truthful representations that hearing aids have an effect on hearing loss. This puts a burden on interstate commerce.  |
| State laws that require a hearing test evaluation for persons 18 years of age or older.  | October 10, 1980, August 14, 1985    | Massachusetts, West Virginia, Rhode Island, Hawaii  | Denied                 | FDA believes that an informed adult should be permitted to waive a medical evaluation.  |
| States laws that prohibit a waiver of medical evaluation for persons over 18 years of age, when certain medical conditions are observed in or disclosed by the prospective purchaser.      | October 10, 1980                     | Florida, Pennsylvania, Maine, Nebraska, Minnesota   | Denied                 | FDA believes that an informed adult should be permitted to waive a medical evaluation even if one of these conditions is present. The existence of such a condition does not necessarily mean that the individual could not safely benefit from using a hearing aid.  |
| State laws prohibiting the sale of a hearing aid unless the purchaser has been examined by a licensed physician and has received an audiological evaluation within the past 90 days.       | October 10, 1980                     | Kentucky, New York, Pennsylvania, District of Columbia  | Denied                 | FDA requires medical evaluation within six months of hearing aid purchase (waiver permitted). Audiological evaluation should not be required, even if a waiver is permitted, because it has not been shown that evaluation by an audiologist is necessary to ensure the safety or effectiveness of hearing aids. Requirement may erect an unnecessary barrier to the purchase of a hearing aid by leading people to believe that audiological evaluation is as important as medical evaluation.   |

## ADA Compendium of State Preemption Requests and FDA Decisions

| Exemption Request Description Under 21 CFR 808  | Date                               | States Requesting  | FDA Exemption Decision | Rationale   |
|---|------------------------------------|--|------------------------|---|
| State laws permitting the parent or guardian of a child under 18 years of age to waive the medical evaluation requirement   | October 10, 1980                   | Arizona, Ohio, Oregon, Washington, Mississippi, Texas  | Denied                 | The laws are less stringent than the FDA regulations and permit the sale of hearing aids to children without a medical evaluation by a licensed physician.  |
| State laws that allow the mandated evaluation for persons younger than 18 years of age to be performed by an audiologist.   | October 10, 1980                   | Maine, Minnesota, New York, District of Columbia   | Denied                 | These laws are less stringent than the FDA regulations because they permit the sale of a hearing aid to children on the recommendation of an audiologist, without a medical evaluation by a licensed physician.   |
| State laws requiring children under 18 years of age to undergo physical exam by an otolaryngologist or a physician and an audiologist; requirements that are more comprehensive than those prescribed by FDA.                               | October 10, 1980,<br>July 29, 1985 | California, Connecticut, District of Columbia, Massachusetts, Nebraska, New Jersey, New Mexico, Washington, Hawaii | Granted                | Comments from physicians, audiologists, and hearing aid dealers supported FDA's proposal to exempt from preemption State requirements of audiologic evaluation for children. Audiologists are specially qualified to assist in the language development and educational and social growth of a child with hearing loss. Consequently, mandatory audiologic or otologic evaluation of a minor will serve an important public health purpose. |
| State law provisions that require that a prospective hearing aid user with a significant air bone gap or apparent unilateral sensorineural hearing loss receive an audiologic evaluation, although they permit a waiver of this requirement | October 10, 1980                   | Arizona  | Denied                 | Such a requirement places audiologic evaluation on a par with medical evaluation and that this is inconsistent with the position of FDA. An audiologic evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids.  |
| State law requiring that hearing examination be conducted in an environment that meets or exceeds the American National Standards Criteria for Background Noise in Audiometer Rooms (A.N.S.I. S3.1 - 1971).                                 | October 10, 1980                   | New Jersey   | Denied                 | The requirement that the testing be conducted in an environment that meets the A.N.S.I. standard is unnecessarily restrictive because it has not been shown that such an environment is necessary for proper testing.   |
| State laws requiring that the physician's written recommendation and any signed waiver statements be kept on file for 7 years.  | October 10, 1980                   | Pennsylvania, West Virginia  | Granted                | FDA is also granting exemption from preemption for section 507(2), which requires that the physician's written recommendation and any signed waiver statements be kept on file for 7 years.   |

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# Call to Action from the Audiology Quality Consortium

BY KIM CAVITT, Au.D.

The profession of Audiology has an opportunity to demonstrate the importance and quality of our services to our patients, policy makers and payers. We need your help to achieve this.

As previously announced, The Audiology Quality Consortium, representing 9 member organizations, has collaborated with healthcare analytics firm Healthmonix, to create new audiology-specific measures for use in the CMS Merit-Based Incentive Payment System (MIPS).

Now is the time to participate. Your critical input, needed before June 30, 2021, may impact our future reimbursement.

Please participate in the testing of these quality measures in your facility. We are in need of data from a variety of practice settings. The cost to participate starts at \$289 per provider per year. For more information on pricing, see: <https://healthmonix.com/audiology-pricing/>.

*See AQC's FAQ for more information about this testing and how to participate.*

## What Is the Merit-Based Incentive Payment System?

The Merit-based Incentive Payment System (MIPS) was established by the Medicare Access and CHIP Reauthorization Act of 2015, with implementation in January 2017. MIPS reflects the consolidation of the Centers for Medicare and Medicaid Services (CMS) previous quality programs: the Physician Quality Reporting System (PQRS), the Value-based Payment Modifier (VBPM), and Meaningful Use (MU). MIPS also adds a new performance category, called Improvement Activities (IA).

MIPS ties payment incentives and penalties to defined quality, cost savings, electronic data exchange, clinical practice improvement, and outcome measures and metrics. Audiologists were added as eligible clinicians for MIPS participation beginning in January 2019. Audiology is measured by two metrics: Quality (including patient outcomes), and clinical practice improvement (IA).

For more information about value-based payment, see: [www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs).

For more information on MIPS and to determine if you are required to report under MIPS, visit the CMS Quality Payment Program (QPP) portal at: [www.qpp.cms.gov](http://www.qpp.cms.gov).

## What Is a Qualified Clinical Data Registry?

A Qualified Clinical Data Registry (QCDR) is a CMS-approved vendor in the business of improving healthcare quality. The vendors specialize in the creation, tracking, and submission of healthcare quality and clinical improvement measures and metrics. Such vendors may assist medical professionals, like audiologists, in developing, operationalizing, tracking and reporting quality measures and metrics.

## What Is a Qualified Clinical Data Registry Measure?

These are test measures designed to 1) measure an individual's outcomes following audiology evaluation and treatment, and 2) show the value, efficacy, and utility of a measure prior to being included in the MIPS reporting system. These measures can also be used to track a practice's own internal quality, performance, patient satisfaction, outcomes measures, and metrics.

QCDR measures are not like other MIPS or Clinical Quality Measures (CQM). You can only report them through a QCDR that has permissions from the measure steward. You cannot report or track a QCDR measure via claims reporting, EHR reporting, registry reporting, or any other reporting mechanism. Currently, Healthmonix is the only vendor that offers a QCDR registry for audiology.

## How Were the Audiology Quality Measures Developed?

For the development of the audiology MIPS quality measures, the Audiology Quality Consortium (AQC) worked with Healthmonix to create QCDR measures for 2022. The next step in this process is to test the measures. Healthmonix, the Audiology registry vendor, will also assist with measure testing. After testing and acceptance by CMS, these MIPS Quality measures will be available for reporting by audiologists who are required to participate in MIPS, for those who choose to opt-in to try to earn a payment incentive, or for audiologists who wish to voluntarily report. NOTE: Healthmonix is one vendor that offers software systems and integrations that allow for the reporting of current MIPS quality measures, clinical improvement activities, and meaningful QCDR measures. An annual per provider fee is charged to utilize the registry, report to CMS and track outcome measures.

## Why Should Audiologists Want to Participate in Quality Reporting?

- The measures and activities demonstrate audiologists' value to consumers and the healthcare system.
- The activities differentiate audiology from over the counter (OTC)/direct to consumer (DTC) entities, big box retailers, and hearing aid dispensers in the marketplace.
- These activities illustrate the evidence-based, patient-centric practice of audiology.
- The profession needs to obtain data and metrics on the quality and value of audiology evaluation and treatment services to patients and the healthcare system. The profession of Audiology needs to utilize these clinical data in legislative, regulatory, and advocacy initiatives as well as individual clinic improvement activities.
- Audiologists are one of the providers acknowledged by CMS for MIPS reporting and need to remain in parity with other doctoral-level health care providers to improve quality and optimize payment options afforded to the profession.

## How Can You Help?

We need participants from a variety of practice settings to help implement our new Quality measures. Provider participants reporting to MIPS will receive performance feedback that can lead to improved patient outcomes and ultimately contribute to demonstrating the value of audiology services in the healthcare delivery model. You also will be eligible to be included in the Medicare Care Compare Doctors & Clinicians profile pages and in the Provider Data Catalog.

If you are interested or want to learn more, please contact: Kim Cavitt, Au.D. at [kim.cavitt@audiologyresources.com](mailto:kim.cavitt@audiologyresources.com). ■

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*Dr. Kim Cavitt was a clinical audiologist and preceptor at The Ohio State University and Northwestern University for the first ten years of her career. Since 2001, Dr. Cavitt has operated her own Audiology consulting firm, Audiology Resources, Inc. She currently serves on the State of Illinois Speech Pathology and Audiology Licensure Board. She also serves on committees through AAA and ASHA and is an Adjunct Lecturer at Northwestern University.*



# HAVE YOU HEARD?

## Senators Warren, Paul, Grassley, Shaheen, Brown, and Sinema Introduce Medicare Audiologist Access and Services Act

On May 19, 2021, U.S. Senator Elizabeth Warren (D-MA) introduced the Medicare Audiologist Access and Services Act (MAASA) of 2021 (S. 1731), along with Senators Rand Paul (R-KY), Charles Grassley (R-IA), Jeanne Shaheen (D-NH), Sherrod Brown (D-OH), and Kyrsten Sinema (D-AZ). Representatives Tom Rice (R-SC) and Matt Cartwright (D-PA) introduced identical legislation (H.R. 1587) in the House of Representatives. Since its introduction on March 3rd, the House bill has already picked up 32 bipartisan cosponsors.

MAASA will make three important updates to Medicare coverage policies:

1. Remove the physician order requirement for coverage so that Medicare beneficiaries will have direct access to audiology services;
2. Authorize Medicare to reimburse audiologists for the Medicare-covered services that they are licensed to provide; and
3. Reclassify audiologists from suppliers to practitioners within the Medicare system.

MAASA will make much-needed improvements to Medicare statutes to remove red tape, better deploy audiologists within the Medicare system, and streamline access to audiologic care for seniors.

"It seems to me that the COVID-19 pandemic has forced us all to reconsider bureaucratic limitations to health care—including hearing care. So, I believe that the Senate should prioritize the passage of our bill to help seniors get the care that they need," said Senator Warren.

ADA applauds Senators Warren and Paul for their leadership in advancing this important legislation in Congress. For more information, visit [www.chooseaudiology.org](http://www.chooseaudiology.org).





**ADA leaders and South Carolina audiologists toast Representative Tom Rice and Representative Jaime Herrera-Beutler and their support of the Medicare Audiologist Access and Services Act.**

## **ADA Members and Leaders Host Dinner to Honor Representative Tom Rice**

On May 7th, ADA leaders and member audiologists hosted a dinner to honor Representative Tom Rice (R-SC) in his home district of Myrtle Beach, South Carolina. Representative Rice, a longstanding advocate for improved access to audiology services for Medicare beneficiaries and the lead sponsor of H.R. 1587, the Medicare Audiologist Access and Services Act (MAASA), in the U.S. House of Representatives, was joined by special guest, Representative Jaime Herrera-Beutler (R-WA). Audiologists from South Carolina and around the country joined in person and via Zoom to recognize Representative Tom Rice and to thank him for his support of MAASA.



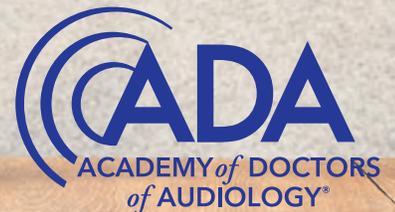
**Representative Tom Rice (Center) with Dr. Victor Bray (Left) and Dr. Jonette Owen (Right).**



**Representative Tom Rice (Left) and Dr. Kristin Davis (Right)**

# Contact Your Legislators!

Urge them to support the **Medicare Audiologist Access and Services Act**  
(H.R. 1587 and S. 1731)



The Medicare Audiologist Access and Services Act of 2021 (H.R. 1587 and S. 1731) will remove unnecessary barriers, allowing patients to receive appropriate, timely, and cost-effective audiologic care. This legislation can improve outcomes for beneficiaries by allowing direct access to audiologic services and streamlining Medicare coverage policies so that audiologists can provide the full range of Medicare-covered diagnostic and treatment services that

correspond to their scope of practice. The legislation would also reclassify audiologists as practitioners, which is consistent with the way Medicare recognizes other non-physician providers, such as clinical psychologists, clinical social workers, and advanced practice registered nurses.

## **Support the future of audiology!**

Contact Congress today and express your support for H.R. 1587 and S. 1731.

Visit [chooseaudiology.org/support](https://chooseaudiology.org/support) and contact your congressperson today!

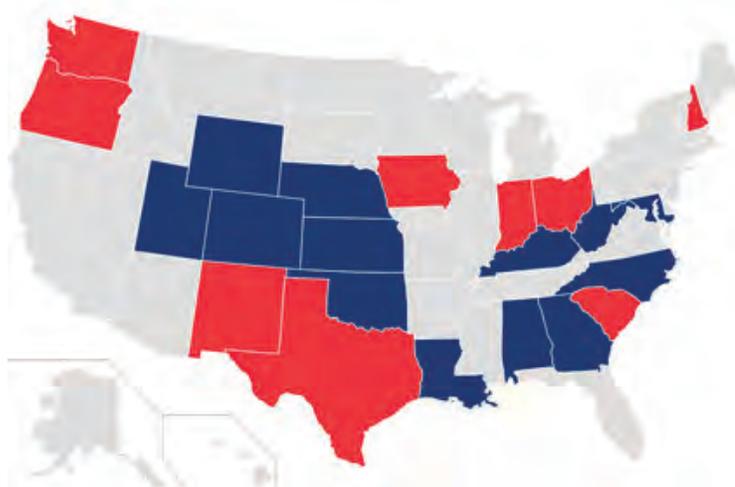
## Mobilize to Make MAASA Move

MAASA has great momentum in the 117th Congress already—but it will take grassroots efforts to get it passed and enacted. Mobilize and take action today—it is **easy as 1,2,3**.

1. Contact your legislators. Use the Congressional Connect tool. Follow up frequently by calling legislators to voice your support for H.R. 1587 and S. 1731. Contact Adam Haley at [ahaley@audiologist.org](mailto:ahaley@audiologist.org) to set up a virtual meeting with your members of Congress or their legislative staffs.
2. Donate to the Eric N. Hagberg Advocacy Fund to support ADA's advocacy efforts through professional legislative strategists. Visit [www.chooseaudiology.org/donate](http://www.chooseaudiology.org/donate).
3. Tell your friends, colleagues, patients, and family members to contact their legislators to share their personal stories about why MAASA matters.

## ADA Applauds Passage of the Audiology Speech-Language Pathology Interstate Compact in 10 States

On March 31st Governor Pete Ricketts (R-NE) signed into law the Audiology Speech-Language Pathology Interstate Compact (ASLP-IC) making Nebraska the 10th state to enact the law, formally beginning the process of enacting the compact in the member states. Nebraska joins Alabama, Kansas, Kentucky, Louisiana, North Carolina, Oklahoma, Utah, West Virginia, and Wyoming in being among the first 10 states to enact the ASLP-IC. Georgia has also since enacted the legislation and it has been introduced in nine additional states.



With passage of the ASLP-IC, the process now moves to implementation, with audiologists and speech language pathologists from the participating states coming together as a commission to write the regulations that will govern the compact and provide oversight of providers. The commission will soon convene to establish rules and bylaws and implement the shared interstate licensure data system that will allow for instant verification of good standing. This setup process typically takes 12 to 14 months, meaning the Commission could begin issuing privileges to practice by summer 2022.

States will continue to license practitioners on their own, but now those providers who maintain an active and unencumbered license in their home state can obtain a privilege to practice in participating member states. Providers will be required to practice to the standard of the state in which they are practicing and can be subject to disciplinary action that will be shared with their home state's licensing board. This helps ensure that the compact will provide access to high-quality care for audiology patients and offer a high degree of patient safety protections across state lines.

The Academy of Doctors of Audiology (ADA) is excited to support this initiative and has been working with the American Academy of Audiology (AAA), the American Speech-Language-Hearing Association (ASHA), and state audiology associations across the country to help enact this legislation. For more information about the ASLP-IC, contact ADA Director of Public Policy Adam Haley, at [ahaley@audiologist.org](mailto:ahaley@audiologist.org)

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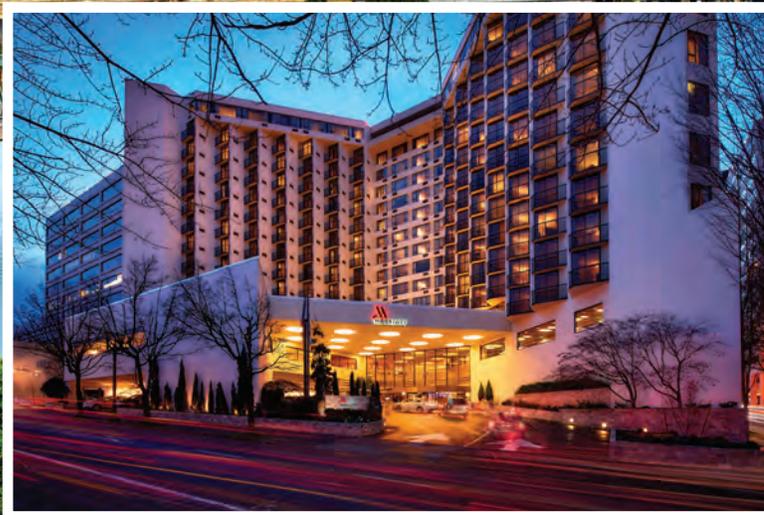
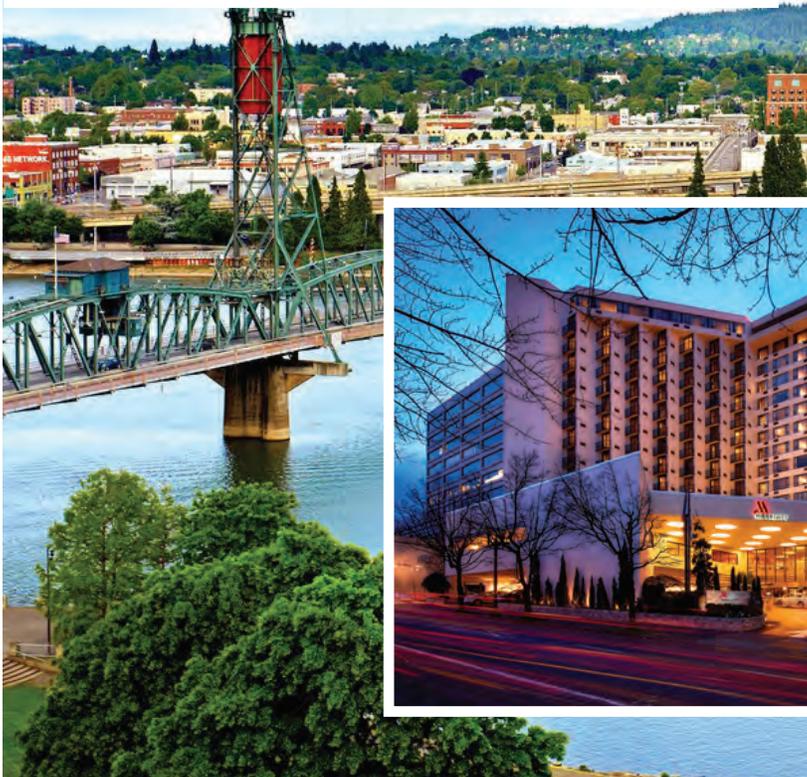
# AuDACITY 2021

AUDIOLOGY UNLEASHED

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## AuDacity 2021: Audiology Unleashed, October 25-27 in Portland, OR

Unleash your potential along with outstanding education, networking opportunities, and fun at **AuDacity 2021: Audiology Unleashed!** The excitement begins on October 25th at the Portland Marriott Downtown Waterfront in Portland, Oregon. For questions and general information, please contact Brian Doty at [bdoty@audiologist.org](mailto:bdoty@audiologist.org).



## AuDacity 2021 to Feature Keynote Addresses By Kevin Franck and Claudia Gordon



**Kevin Franck, Ph.D., MBA** is Senior Vice President, Strategic Marketing and New Product Planning at Frequency Therapeutics, where he leads pre-commercial strategy and launch planning for the company's clinical pipeline. His prior experience includes serving as Director of Audiology for Massachusetts Eye and Ear. Dr. Franck previously served as Head of Marketing for Bose Hear, a division of Bose Corporation, where he led new product management and channel marketing of an emerging category of business focused on hearing loss. Dr. Franck co-founded Ear Machine, a startup funded by the National Institutes of Health before it was acquired by Bose in 2014. He is the incoming Board Chair of the Hearing Loss Association of America.



**Claudia L. Gordon** is Director of Government and Compliance with T-Mobile Accessibility, a Business Unit within T-Mobile that offers communication products and services to reduce or eliminate communication barriers for customers with disabilities. Claudia was a member of the Obama Administration from December 2009 to January 2017 initially serving as Special Assistant to the Director of the U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP), and then as OFCCP's Chief of Staff. From July 2013 to March 2014, Claudia was assigned to the White House Office of Public Engagement where she served as the liaison to the disability community and advised on disability policies. Prior to DOL, she was a Senior Policy Advisor with the U.S. Department of Homeland Security's Office for Civil Rights and Civil Liberties. She is a former staff attorney with the National Association of the Deaf Law and Advocacy Center and has also worked as a consulting attorney with the National Council on Disability.

### Agenda Highlights Include:

#### Monday, October 25, 2021

Preconference Workshops  
Concurrent Sessions beginning 1:00 p.m.  
Keynote presentation by Kevin Franck, Ph.D., MBA  
Opening Reception in Exhibit Hall

#### Tuesday, October 26, 2021

General Sessions featuring the following:  
Breakfast Symposium on Telehealth  
Keynote speaker Claudia Gordon, Esq.  
Exhibits and Networking

#### Wednesday, October 27, 2021

ADA Student Business Plan Competition  
Concurrent Sessions  
ADA Member Meeting

Visit [audiologist.org/2021](https://audiologist.org/2021) for more information.



## PRESIDENT'S MESSAGE

*Continued from page 5*

community that live and/or work within a Congressional House district. Write a joint letter to your U.S. representative asking for a meeting to discuss MAASA and the legislator's co-sponsorship of the legislation. Attach to your letter copies of the endorsements from your state academy/association.

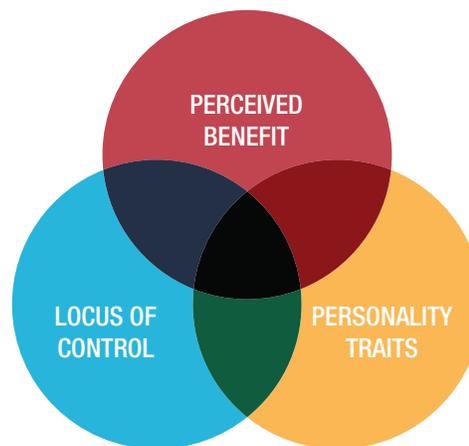
Another reason to get involved in your state audiology association is because your scope-of-practice (SOP) is defined by your state licensure act, not by federal statute, and not by your national professional organization. Is your SOP to diagnose and treat hearing and balance disorders or the more limiting 'nonmedical' diagnosis and treatment of hearing and balance disorders? Does your SOP allow cerumen management, or do you work in a state where cerumen management is considered a semi-invasive medical procedure and not within the SOP of an audiologist? Does your SOP allow telehealth for audiologists (tele-audiology) or does it prohibit any audiology interactions that are not face-to-face? All of these issues are important today and will be more important with the passage of MAASA. While MAASA will make much needed Medicare coverage updates for the diagnosis and treatment of audiological and vestibular conditions, cerumen management, and tele-audiology, you will not be able to provide these services if they are not allowed under your state SOP! Membership and active state advocacy efforts are essential for advancing your professional goals and the goals of the profession!

ADA strongly supports your membership in your state audiology association. ADA encourages all members to join and be active in state audiology associations. To show our support, ADA will discount its fellow and associate membership dues for first-time members by the amount of their paid 2021 state dues, and ADA will discount AuDacity conference registration fees by the amount of paid 2021 state dues for all renewing fellow and associate members.

Think Globally to achieve MAASA for the nation-- and Act Locally to secure MAASA from your Members of Congress, and to protect your SOP and bring it into alignment with MAASA's components.

## EDITOR'S MESSAGE

*Continued from page 7*



**Three interconnected traits related to hearing aid uptake, all independent of price.**

Finally, the authors state, "we believe that personality traits and LOC are intimately intertwined and have an undeniable influence on hearing aid uptake, independent of the price tag." For clinicians who interact with persons with hearing loss every day, many of which are often in serious need of amplification, the insights from this paper suggests many non-audiological characteristics are critical in the treatment planning and goal setting process and well worth the time trying to better understand prior to recommending hearing aids, regardless of their retail price tag. ■

► **Please contact Stephanie Czuhajewski at [sczuhajewski@audiologist.org](mailto:sczuhajewski@audiologist.org) for more information about ADA, ADA membership, and opportunities for advancing your audiology career through involvement with ADA.**

# New considerations for recommending a cochlear implant evaluation

## New information for guiding your patients along their hearing journey.

Every patient's hearing loss journey is unique, and each patient may require a different treatment option. The continuum of care for hearing loss isn't a linear pathway so being aware of all technologies to manage your patient's hearing loss can help you find the best solution for them.

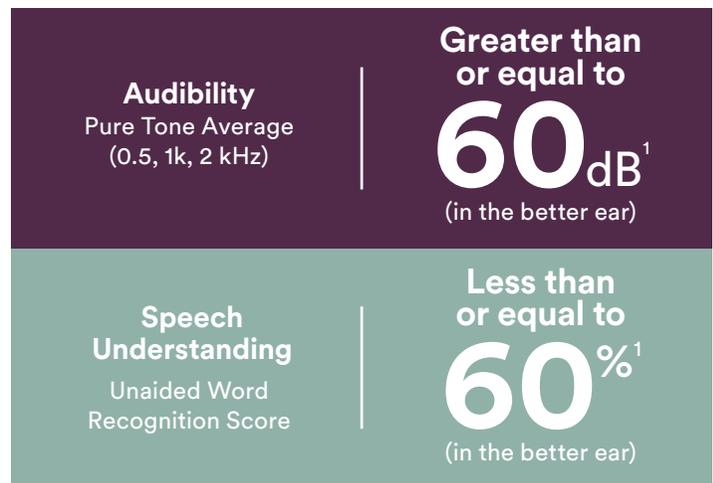
Hearing loss is seen by many to be a communication disorder, it is now known to have much wider-ranging consequences that can significantly impact a person's quality of life. Age-related hearing loss has been shown to also lead to increased accidental falls, hospitalizations, loneliness and social isolation.<sup>1</sup> A multi-faceted approach to the treatment of hearing for patients is needed from a collaborative network of providers to meet the needs of your patients.

Innovations in hearing health care have made the way for over-the-counter (OTC) hearing devices and personal sound-amplification products (PSAPs) enabling patients access outside of the traditional clinical practice. However, hearing care providers are the best professionals to speak to the different hearing solutions for their patients.

As a hearing care provider, you have the unique ability to differentiate your practice by counseling on all hearing loss treatment options and providing comprehensive services to support optimal performance.

If hearing aid technology is not providing your patient the ability to hear and understand speech, a cochlear implant may be the next step. Traditionally, cochlear implants have been considered a treatment option as a last resort and only for those who have lost all of their hearing. Health benefits and improved hearing outcomes<sup>2</sup> support the need to shorten the duration of hearing loss and consider cochlear implantation before hearing loss progresses to profound. For patients with hearing losses greater than or equal to 60 dB HL (pure tone average 0.5, 1k, 2kHz) and speech understanding less than or equal to 60%,<sup>3</sup> referral for a cochlear implant evaluation should be pursued.

## When to Consider a Cochlear Implant Evaluation for Adults\*



Many adult cochlear implant users continue to wear a hearing aid on their non-implanted ear, commonly referred to as bimodal hearing. A bimodal configuration can provide your patients a richer and more natural hearing experience.<sup>4</sup> If you recognize there is an opportunity to treat patients bimodally, there is value offered in patient experience and an opportunity to expand business. Offering cochlear implants can not only expand your business but can be a differentiator. Cochlear implant manufacturers can provide reimbursement information about their technology when billing for services like evaluations, programming and follow-up care.

The Cochlear Provider Network (CPN) enables independent dispensing audiology/ENT practices to expand their services to include cochlear implants and become part of a medical network that helps people with hearing loss achieve optimal outcomes.

To learn more about the Cochlear Provider Network visit [www.cochlear.com/us/ADA](http://www.cochlear.com/us/ADA)

1. Deal JA, Reed NS, Kravetz AD, et al. Incident Hearing Loss and Comorbidity: A Longitudinal Administrative Claims Study. *JAMA Otolaryngol Head Neck Surg.* 2019;145(1):36–43. doi:10.1001/jamaoto.2018.2876.
2. Derinsu U, Yüksel M, Geçici CR, Çiprut A, Akdeniz E. Effects of residual speech and auditory deprivation on speech perception of adult cochlear implant recipients. *Auris Nasus Larynx.* 2019 Feb;46(1):58–63. doi: 10.1016/j.anl.2018.06.006. Epub 2018 Jun 23. PMID: 29945747.
3. Zwolan TA, Schwartz-Leyzac KC, Pleasant T. Development of a 60/60 guideline for referring adults for a traditional Cochlear implant candidacy evaluation. *Otol Neurotol* 2020;41:895–900.
4. Gifford R, Dorman M, McKarns S, Spahr AJ. Combined electric and contralateral acoustic hearing: word and sentence recognition with bimodal hearing. *J Speech Lang Hear Res.* 2007;50:835–843.

\*This provides a recommendation of when an adult may be referred for a cochlear implant evaluation, but does not guarantee candidacy based on indications. For the approved Cochlear Nucleus Indications, please refer to the important information booklet or physician's guides.

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