

# Within Earshot:

## Overcoming Barriers to Over-the-Counter Hearing Aid Access

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Hannah Garden-Monheit, Bharat Ramamurti, and Emma Freer

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# INTRODUCTION

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**In 2022, the Biden administration** finalized rules permitting hearing aids to be sold over the counter (OTC) to millions of Americans with mild to moderate hearing loss.<sup>1</sup> The rules—which effectuated the bipartisan 2017 Over-the-Counter Hearing Aid Act—led to a significant drop in the price of hearing aids.<sup>2</sup> Before the 2022 rules, prescription hearing aids averaged \$4,744 per pair; today, OTC hearing aids cost a few hundred dollars or less.<sup>3</sup> But despite the sharp drop in price and the widespread availability of OTC hearing aids, consumer uptake has been much slower than anticipated.<sup>4</sup> It appears that deregulating the hearing aid market to allow OTC sales has been a necessary, but insufficient, step toward widespread consumer adoption and the associated health benefits.

This report explores why reforms to date have not produced widespread adoption and what steps policymakers and private actors can take to spur further use. Specifically, it provides an overview of the extremely consolidated hearing aid market; outlines barriers to broader consumer adoption, including consumer concerns about purchasing a medical device without the assistance of a licensed professional, retailer concerns about such consumer reluctance, and a widespread lack of insurance coverage for OTC hearing aids; and recommends policy solutions, including reversing the vertical integration in the hearing industry and eliminating its inherent conflicts of interests while expanding insurance coverage, particularly within Medicare.<sup>5</sup>

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1 Food and Drug Administration, “Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids,” Federal Register, Aug. 17, 2022, <https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids#p-228>.

2 “S.670 - A bill to provide for the regulation of over-the-counter hearing aids,” Library of Congress, introduced March 21, 2017, <https://www.congress.gov/bill/115th-congress/senate-bill/670>.

3 Abram Bailey, “Hearing Aid Price Tracker,” Hearing Tracker, updated April 22, 2022, accessed via the Wayback Machine, <https://web.archive.org/web/20221004104928/https://www.hearingtracker.com/how-much-do-hearing-aids-cost>; Catherine Roberts, “A Complete Guide to Over-the-Counter Hearing Aids,” Consumer Reports, Feb. 11, 2025, <https://www.consumerreports.org/health/hearing-aids/complete-guide-to-over-the-counter-hearing-aids-a3898239010/>.

4 King Chung and Fan-Gang Zeng, “Over-the-counter hearing aids: implementations and opportunities,” *Frontiers in Audiology and Otology*, March 11, 2024, <https://www.frontiersin.org/journals/audiology-and-otology/articles/10.3389/fauot.2024.1347437/full#B2>; “Over-the-Counter Hearing Aids: Information on the New Medical Device category,” Government Accountability Office, May 7, 2024, <https://www.gao.gov/assets/gao-24-106854.pdf>.

5 The authors interviewed more than half a dozen hearing aid market participants, including retailers, manufacturers, and health care professionals.

# MARKET OVERVIEW

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The hearing aid sector exhibits high levels of both horizontal and vertical integration.<sup>6</sup> This market structure has contributed to several anti-competitive harms, including high costs, reduced innovation, and steep barriers to entry.<sup>7</sup>

## THE BIG FIVE

The “Big Five” manufacturers—Sonova, WS Audiology, Demant, GN, and Starkey—control 84% of the U.S. hearing aid product market and 90% of the global market.<sup>8</sup> They are also vertically integrated with both audiology clinics and—except for Sonova—hearing benefit managers (HBMs). Like pharmacy benefit managers, HBMs are middlemen who control health plans’ hearing aid formularies, hearing health care provider networks, and related claims processing.<sup>9</sup> Together, manufacturer-owned clinics and HBMs account for roughly a quarter of the U.S. hearing aid distribution market.<sup>10</sup> Other distributors include the U.S. Department of Veteran Affairs (VA), large retailers like Costco, and independent manufacturers, all discussed below.<sup>11</sup>

Two of the Big Five—Demant and GN Hearing—are also vertically integrated with buying groups. Like group purchasing organizations, these buying groups leverage their members—audiology clinics, ENT and otology practices, and health systems—to negotiate discounts with hearing aid manufacturers, among other services.<sup>12</sup>

The Big Five leverage their market power and vertically integrated business models to charge high prices for prescription hearing aids.<sup>13</sup> Unlike most other consumer electronics,

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6 Esther Landhuis, “Why Aren’t More People Buying Over-the-Counter Hearing Aids,” Undark, Dec. 27, 2023, <https://undark.org/2023/12/27/otc-hearing-aids/>.

7 Letter to President Barack Obama re: hearing aids, President’s Council of Advisors on Science and Technology, October 2015, [https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast\\_hearing\\_tech\\_letterreport\\_final.pdf](https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf).

8 “FACT SHEET: Executive Order on Promoting Competition in the American Economy,” The White House, July 9, 2021, accessed via the Wayback Machine, <https://web.archive.org/web/20210709140541/https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/>; Digby Cook, “The Big Five,” Hearing Loss Journal, Nov. 12, 2024, <https://www.hearinglossjournal.com/the-big-five/>.

9 Hearing health care providers include audiologists; otolaryngologists, or ENTs; and hearing aid dispensers. Sara Sirota, “Why We Should Ban PBM Rebates,” American Economic Liberties Project, February 2024, [https://www.economicliberties.us/wp-content/uploads/2024/02/20240103-AELP-Rebates-Brief\\_Final.pdf](https://www.economicliberties.us/wp-content/uploads/2024/02/20240103-AELP-Rebates-Brief_Final.pdf).

10 “GN Store Nord & Hearing Aids,” In Practise, March 26, 2023, <https://inpractise.com/articles/hearings-care-industry-history-vertical-integration-and-potential-disruption>; “Costco Hearing Aids in 2025 - Models, Features, Prices, and Reviews,” Hearing Tracker, updated May 28, 2025, <https://www.hearingtracker.com/hearing-aids/costco>.

11 Ibid.

12 “Who We Serve,” Audigy, accessed Sept. 23, 2025, <https://www.audigy.com/who-we-serve/>; “Strategic Partnerships,” Fuel Medical Group, accessed Sept. 23, 2025, <https://fuelmedical.com/practice-operations/strategic-partnerships/>; Ann DePaolo, “Buying or Selling an Audiology Business,” The ASHA Leader, September 2008, <https://leader.pubs.asha.org/doi/10.1044/leader.FTR2.13122008.14>; Kim Cavitt, “Looking Behind the Curtain: The Realities of Hearing Aid Pricing,” LinkedIn, Feb. 13, 2023, <https://www.linkedin.com/pulse/looking-behind-curtain-realities-hearing-aid-pricing-kim-cavitt-aud/>.

13 Matt Stoller, “Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel,” BIG, Oct. 21, 2021, <https://www.thebignewsletter.com/p/silencing-the-competition-inside>.

including computers, smartphones, and televisions, prescription hearing aid prices have barely changed—decreasing \$228 to \$4,672 per pair, or less than 5%, on average—in the last decade, despite limited innovation.<sup>14</sup>

According to interviews with several market participants, manufacturer-owned hearing aid clinics are incentivized to steer patients to their most expensive products and to bundle those products with their professional services, making it harder for patients to shop around or change providers.<sup>15</sup> These clinics are also disincentivized from selling competitors' devices, and, without distribution channels, independent manufacturers struggle to break into the market.

Meanwhile, manufacturer-owned HBMs steer patients with hearing coverage—such as private Medicare Advantage plans that include hearing benefits—to their most expensive products, “benefit[ing] the manufacturer and the provider, not the patient,” as the Academy of Doctors of Audiology explained in a January 2024 letter to the Centers for Medicare and Medicaid Services.<sup>16</sup>

Even if an audiologist works for an independent clinic that isn't affiliated with a hearing aid manufacturer, he or she may steer patients with hearing benefits to products included on a manufacturer-owned HBM's formulary because their coverage makes them more affordable to the patient than models not included on the formulary.

Most individuals with hearing loss who seek care will do so unaware of this vertically integrated business model, in which their audiologist, insurer, and hearing aid manufacturer are linked by conflicts of interest and kickbacks.<sup>17</sup>

Additionally, the Big Five collectively own the for-profit Hearing Instrument Manufacturers' Software Association (HIMSA), which developed and maintains the software standards used by audiologists, including for hearing tests.<sup>18</sup> According to an interview with a hearing aid manufacturer, manufacturers must develop products that are compatible with outdated HIMSA standards or else struggle to break into the market.

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14 Jack Troy, “Inflation explained: Cheaper consumer electronics an outlier among industries,” TribLive, Sept. 30, 2024, <https://triblive.com/local/regional/inflation-explained-cheaper-consumer-electronics-an-outlier-among-industries/>; “Sales Trends in Hearing Care Practices: 2013-2015,” The Hearing Review, June 19, 2015, <https://hearingreview.com/inside-hearing/industry-news/sales-trends-hearing-care-practices-2013-2015>; Abram Bailey, “How much do hearing aids cost in 2025,” Hearing Tracker, Feb. 10, 2025, <https://www.hearingtracker.com/how-much-do-hearing-aids-cost>.

15 The authors conducted half a dozen interviews with OTC hearing aid market participants between late March and April 2025.

16 Letter to CMS Administrator Chiquita Brooks-LaSure re: Medicare Program: Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS-4205-P), Academy of Doctors of Audiology, Jan. 5, 2024, [https://www.audiologist.org/\\_resources/documents/about/academy-docs/2024-CMS-Comment-Letter.pdf](https://www.audiologist.org/_resources/documents/about/academy-docs/2024-CMS-Comment-Letter.pdf).

17 Ibid. at 13.

18 <https://hearingreview.com/practice-building/marketing/setting-the-standard#:~:text=HIMSA%20is%20a,to%20the%20industry.%E2%80%9D>; <https://www.himsa.com/products/all-about-noah-system-4/>

The Big Five also fought efforts to increase competition in the hearing aid market by allowing for OTC products. In a June 2022 report, Sens. Warren and Grassley, who sponsored the bipartisan Over-the-Counter Hearing Aids Act, decried the industry’s use of “astroturf lobbying tactics to influence the [Food and Drug Administration’s (FDA’s)] rulemaking process and weaken the agency’s OTC hearing aid rule.”<sup>19</sup>

Nonetheless, four of the Big Five have since entered the OTC hearing aid market. But prescription products continue to dominate overall sales. For instance, members of the Hearing Industries Association—a lobbying group representing hearing aid manufacturers and distributors—reported that OTC hearing aids comprised just 1% of their sales during the first quarter of 2023.<sup>20</sup>

Below is a brief summary of each of the Big Five and their product offerings:

- **Sonova** is a Switzerland-based hearing aid manufacturer and retailer with an estimated 32% global market share following decades of acquisitions.<sup>21</sup> Sonova manufactures Phonak, the top-selling prescription hearing aid brand, as well as Unitron products, which cost, on average, between \$4,600 and \$4,780 per pair.<sup>22</sup> It acquired Advanced Bionics, the world’s largest cochlear implant manufacturer, for \$489 million in 2010 and Sennheiser’s consumer division for \$200 million in 2022, paving the way for Sonova to announce its first OTC product—under the Sennheiser brand—in 2023.<sup>23</sup> Today, the Sennheiser All-Day Clear OTC hearing aids cost \$1,600 per pair.<sup>24</sup> Sonova counts more than 430 U.S. retail clinics across 20 brands and 35 states.<sup>25</sup>
- **Demant** is a Denmark-based hearing aid manufacturer, retailer, HBM, and buying group with an estimated 24% global market share.<sup>26</sup> Its prescription hearing aid brands include Oticon, whose hearing aids cost, on average, \$5,200 per pair, as

19 “Loud and Clear: Why Americans Want Effective and Affordable Over-the-Counter Hearing Aids—and How Powerful Special Interests are Trying to Undermine Them,” Sens. Elizabeth Warren and Chuck Grassley, June 2022, <https://www.warren.senate.gov/imo/media/doc/FDA%20Hearing%20Aid%20Report.pdf>.

20 Karl Strom, “Hearing Aid Sales Vault Upward by 9% in First Quarter of 2023; OTC Comprises 1% of Sales for Largest Manufacturers,” Hearing Tracker, April 27, 2023, <https://www.hearingtracker.com/pro-news/hearing-aid-sales-vault-upward-by-9-in-first-quarter-of-2023-otc-hearing-aids-make-1-of-sales>.

21 Ibid. at 8; “Investor Presentation,” Sonova, December 2023, <https://www.sonova.com/sites/default/files/2024-01/IR%20Presentation%20Dec%202023.pdf>.

22 Ibid. at 14.

23 “Acquisition of Advanced Bionics completed,” Sonova, April 1, 2010, <https://www.sonova.com/en/acquisition-advanced-bionics-completed>; “Expanding our offering and entering new growth markets – Sonova to acquire Sennheiser Consumer Division,” Sonova, July 5, 2021, <https://www.sonova.com/en/expanding-our-offering-and-entering-new-growth-markets-sonova-acquire-sennheiser-consumer-division>; “Hear, there, and everywhere,” Sonova, June 20, 2023, <https://www.sonova.com/en/media/hear-there-and-everywhere>.

24 “All-Day Clear,” Sennheiser, accessed June 20, 2025, <https://www.sennheiser-hearing.com/en-US/p/all-day-clear-hearing-aids/>; “Sennheiser All-Day Clear Bluetooth OTC Hearing Aids,” Target, accessed June 10, 2025, [https://www.target.com/p/sennheiser-all-day-clear-bluetooth-otc-hearing-aids-rechargeable-self-fitting-1-count/-/A-1003414570?sid=&TCID=PDS-20993325566&gad\\_source=1&gad\\_campaignid=20993325566&gbraid=OAAAAAD-5dfZ\\_XSzxuX5lJn7\\_rMkhEdZT-&gclid=CjwKCAjwr5\\_CBhBIeiwAzfwYuMrpKBgtlvmDVVURcSqQ5uDDV6KON9-PtKsCo4nz-HEhplcLE\\_pdxoCVhMQAvD\\_BwE&gclsrc=aw.ds](https://www.target.com/p/sennheiser-all-day-clear-bluetooth-otc-hearing-aids-rechargeable-self-fitting-1-count/-/A-1003414570?sid=&TCID=PDS-20993325566&gad_source=1&gad_campaignid=20993325566&gbraid=OAAAAAD-5dfZ_XSzxuX5lJn7_rMkhEdZT-&gclid=CjwKCAjwr5_CBhBIeiwAzfwYuMrpKBgtlvmDVVURcSqQ5uDDV6KON9-PtKsCo4nz-HEhplcLE_pdxoCVhMQAvD_BwE&gclsrc=aw.ds).

25 “AudioNova US,” Sonova, accessed June 10, 2025, <https://www.sonova.com/en/audionova-us>.

26 Ibid. at 8; “Sounds of Success,” Gabelli, Nov. 6, 2023, <https://gabelli.com/research/sounds-of-success/>.

well as Bernafon, Phillips, and Sonic.<sup>27</sup> Demant also manufactures diagnostic instruments used by audiologists and otolaryngologists. Demant counts more than 600 HearingLife retail clinics across the U.S.<sup>28</sup> It also encompasses an HBM, Birdsong, and a hearing provider network, Your Hearing Network.<sup>29</sup> In May 2024, Demant acquired the remaining 51% of the shares of the buying group Fuel Medical for an undisclosed amount, making it the sole owner of its “long-time distribution partner.”<sup>30</sup> Demant is the only one of the Big Five that does not offer OTC hearing aids.<sup>31</sup>

- **WS Audiology (WSA)** is another Denmark-based hearing aid manufacturer, retailer, and HBM with an estimated 23% global market share.<sup>32</sup> Its brands include Rexton, Signia, and Widex, whose prescription hearing aids cost, on average, between \$2,688 and \$5,344 per pair.<sup>33</sup> WSA also partnered with Sony in 2024 to launch OTC hearing aids; today, a pair costs between \$600 and \$900.<sup>34</sup> Meanwhile, in 2022, WSA united its 28 U.S. retail brands under HearUSA, which now counts more than 360 locations across the country.<sup>35</sup> The company also includes the online hearing aid retailer Hear.com and HBMs Hearing Care Solutions and TruHearing.<sup>36</sup>
- **GN Hearing** is a third Denmark-based hearing aid manufacturer, retailer, HBM, and buying group with an estimated 12% global market share.<sup>37</sup> Its prescription hearing aid brands include Beltone, Jabra, and ReSound. Beltone and ReSound prescription hearing aids cost, on average, between \$4,812 and \$5,220 per pair.<sup>38</sup> Jabra also offers OTC products, which cost between \$995 and \$1,695 per pair.<sup>39</sup> There are roughly 1,500 Beltone-branded hearing clinics across the U.S.<sup>40</sup> GN also

27 Ibid. at 14.

28 “About HearingLife,” HearingLife, accessed June 10, 2025, <https://www.hearinglife.com/why-hearinglife>.

29 “About,” Birdsong Hearing Benefits, accessed June 10, 2025, <https://birdsonghearing.com/>; “About,” Your Hearing Network, accessed June 10, 2025, <https://yourhearingnetwork.com/>.

30 “Annual Report,” Demant, Dec. 31, 2024, <https://regnskaber.cvrapi.dk/xhtml/19216772/amNsb3Vkc2ovLzAzLzJlZmdmLzkwLzhlL2UzOGUtNDBjNC04MDc1LTliYWExYzllNGU5NA.pdf>; Albert Rønning-Andersson, “Demant secretly acquires long-term distribution partner,” MedWatch, July 5, 2024, [https://medwatch.com/News/hearing\\_health/article17084901.ece](https://medwatch.com/News/hearing_health/article17084901.ece).

31 Demant CEO Søren Nielsen explained this decision in a 2022 letter to investors: “While we fully support expanding the access to hearing healthcare, we remain convinced that the involvement of an expert between a person with hearing loss and the appropriate treatment is the best solution for treating hearing loss most efficiently.” “CEO letter,” Demant, accessed June 10, 2025, <https://www.demant.com/investor-relations/annual-report-2023/ceo-letter>; *ibid.* at 4.

32 Ibid. at 8 and 26.

33 Ibid. at 14.

34 “Sony and WSA Launch New OTC Hearing Aid,” The Hearing Review, Aug. 27, 2024, <https://hearingreview.com/hearing-products/hearing-aids/otc/sony-and-wsa-launch-new-otc-hearing-aid>; “All OTC Hearing Aid,” Sony, accessed June 10, 2025, <https://electronics.sony.com/more/otc-hearing-aid/c/all-otc-hearing-aid>.

35 “About Us,” HearUSA, accessed June 10, 2025, <https://www.hearusa.com/about-us/>.

36 “What are OTC hearing aids,” TruHearing, accessed June 10, 2025, <https://www.truhearing.com/hearing-aids/>; “About,” Hearing Care Solutions, accessed June 10, 2025, <https://www.hearingcaresolutions.com/>; “WS Audiology Postpones Plans for Hear.com IPO,” The Hearing Review, May 17, 2022, <https://hearingreview.com/inside-hearing/industry-news/ws-audiology-postpones-plans-for-hear-com-ipo>.

37 Ibid. at 8 and 26.

38 Ibid. at 14.

39 “Hearing aids,” Jabra Enhance, accessed June 10, 2025, <https://www.jabraenhance.com/product>.

40 “Services,” Beltone, accessed June 10, 2025, <https://www.beltone.com/en-ca/services>.

has an HBM, Great Hearing Benefits.<sup>41</sup> In July 2016, GN Hearing completed its acquisition of the Audigy Group—a buying group with more than 250 members at the time—for \$151 million.<sup>42</sup>

- **Starkey** is an U.S.-based hearing aid manufacturer, retailer, and HBM with an estimated 7% global market share.<sup>43</sup> Its prescription hearing aid brands include Audibel and Starkey, the latter of which cost, on average, \$5,348 per pair.<sup>44</sup> The company “reluctantly” released an OTC device, Start Hearing One, in October 2022 under its HBM brand, Start Hearing.<sup>45</sup> Start Hearing One OTC hearing aids cost \$899 per pair.<sup>46</sup> Starkey also counts more than 3,700 retail clinics across the U.S.<sup>47</sup>

MANUFACTURER	PRESCRIPTION HEARING AID BRAND(S)	OTC HEARING AID BRAND(S)	HBM(S)	BUYING GROUP	RETAIL CLINIC CHAIN
<b>Sonova</b>	Phonak, Unitron	Sennheiser			AudioNova
<b>Demant</b>	Oticon, Bernafon, Phillips, Sonic	None	Birdsong, Your Hearing Network	Fuel Medical	Hearing Life
<b>WSA</b>	Rexton, Signia, Widex	Sony	Hearing Care Solutions, TruHearing		HearUSA
<b>GN Hearing</b>	Beltone, Jabra, and ReSound	Jabra	Great Hearing Benefits	Audigy Group	Beltone
<b>Starkey</b>	Audibel, Starkey	Start Hearing	Start Hearing		Various names

41 “Great Hearing Benefits,” Great Hearing Benefits, accessed June 10, 2025, <https://greatearingbenefits.com/>.

42 “GN Completes Acquisition of Audigy Group,” The Hearing Review, July 5, 2016, <https://hearingreview.com/inside-hearing/industry-news/gn-completes-acquisition-audigy-group>; “GN ReSound Announces Plans to Purchase Audigy Group,” The Hearing Group, May 16, 2016, <https://hearingreview.com/hearing-products/accessories/components/gn-resound-announces-plans-purchase-audigy-group>.

43 Ibid. at 8 and 26.

44 Ibid. at 14.

45 Lucile Perreau, “Starkey to launch an OTC hearing aid ... reluctantly, and without conviction,” Audiology Worldnews, Oct. 11, 2022, <https://www.audiology-worldnews.com/world-news/market/4590-starkey-to-launch-an-otc-hearing-aid-reluctantly-and-without-conviction/>.

46 Ibid.

47 “Locations,” Starkey, accessed June 10, 2025, <https://locations.starkey.com/>.

## OTHER OTC MANUFACTURERS

Beyond the Big Five, notable OTC hearing aid manufacturers include:

- **Apple:** After years of speculation about whether Apple would enter the hearing aid market, the FDA approved the company’s “Hearing Aid Feature,” available with its AirPods Pro 2 earbuds, in September 2024.<sup>48</sup> The feature, which became available the following month, allows users to take a five-minute at-home hearing test and then adjust their sound settings according to the results.<sup>49</sup> The \$249 price tag is much lower than most OTC options, and many interviewees expressed enthusiasm that AirPods may significantly disrupt the market. In particular, several interviewees expressed hope that the feature will provide an easy way for users to discover the benefits of sound amplification—for example, by experimenting with AirPods without the larger expense or stigma associated with purchasing a traditional hearing aid. However, one interviewee noted that some hearing-impaired patients may be reluctant to use AirPods as their primary hearing aid device because they may find in-ear devices more comfortable for all-day use. Another interviewee reported that some patients worry that they’ll be misperceived as rude if they wear AirPods around others who may not realize the AirPods have a medical function.
- **Concha Labs:** Concha Labs’ OTC hearing aids cost \$1,299 per pair.<sup>50</sup> They are designed by individuals with hearing loss and personalized to each user based on its patented self-fitting technology, which improves upon conventional hearing tests to account for factors such as background noise.<sup>51</sup> Based in California, Concha Labs has also published a peer-reviewed clinical trial, which found “statistically significant improvements” compared with clinician-fitted outcomes.<sup>52</sup>
- **hearX Group:** Based in South Africa, hearX includes the self-described #1 U.S. OTC brand Lexie Hearing, which partners with Bose on self-fitting products that cost between \$400 and \$850 per pair.<sup>53</sup> In March 2025, hearX merged with another OTC manufacturer, Eargo, which was “[c]ontending with the fallout of a Department of Justice investigation” into allegations of insurance fraud, to form

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48 Ibid. at 4; Juliana Kim, “FDA approves some Apple AirPods to be used as hearing aids,” NPR, Sept. 14, 2024, <https://www.npr.org/2024/09/14/nx-s1-5112400/fda-airpods-hearing-aids-software-update>.

49 Christopher Null, “Review: Apple AirPods Pro 2 With Hearing Aid Feature,” Wired, Oct. 21, 2024, <https://www.wired.com/review/apple-airpods-pro-2-with-hearing-aid-feature>.

50 “Product,” Concha Labs, accessed Sept. 22, 2025, <https://conchalabs.com/products/concha-sol-hearing-aids>.

51 “Home,” Concha Labs, accessed Sept. 22, 2025, <https://conchalabs.com/>.

52 Lucas Baltzell et al., “Validation of a Self-Fitting Over-the-Counter Hearing Aid Intervention Compared with a Clinician-Fitted Hearing Aid Intervention: A Within-Subjects Crossover Design Using the Same Device,” Trends in Hearing, March 25, 2025, <https://journals.sagepub.com/doi/10.1177/23312165251328055>.

53 “Compare Products,” Lexie, accessed June 10, 2025, <https://lexiehearing.com/us/compare-hearing-aids>.

LXE Hearing.<sup>54</sup> Patient Square Capital, a private-equity firm that took Eargo private in 2024, invested \$100 million in LXE, a sign of its “confidence in the direct-to-patient hearing market.”<sup>55</sup>

- **Lucid Hearing:** Based in Texas, Lucid makes both prescription and OTC hearing aids under the Liberty, Engage, and Fio brands, as well as hearing protection gear.<sup>56</sup> The company is also vertically integrated, with more than 500 retail centers located inside Sam’s Club locations, with prescription hearing aids ranging from \$1,300 to \$4,150 per pair, and OTC devices from \$200 to \$1,300.<sup>57</sup>

## OTC RETAILERS

Beyond Apple and Sam’s Club, major OTC hearing aid retailers include online marketplaces, big-box stores, and pharmacies.

- **Amazon’s** best-selling OTC hearing aids range in price from \$100 to \$400, and the e-retailer’s overall selection includes Lexie, Lucid, Oticon, and Phonak, among other brands.<sup>58</sup> As in other product categories, the e-retailer emphasizes customer reviews and fast delivery options.
- **Best Buy** offers an online hearing assessment and OTC hearing aids from nearly a dozen brands, ranging from \$100 to \$2,700 per pair.<sup>59</sup> According to an interview with a hearing aid manufacturer, in-store availability of OTC hearing aids at Best Buy has declined since fall 2022, when the retailer began selling them.<sup>60</sup>
- **Costco Wholesale** has a long history of seeking to disrupt the hearing aid market, having launched its first in-store prescription hearing aid center in 1989.<sup>61</sup> According to an interview with a hearing aid retailer, Costco should have quickly cornered the market because of its lower price point. Instead, Costco has experienced slow but steady growth, emerging as the largest hearing aid retailer

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54 Nick Paul Taylor, “Eargo, Hearx merge into one OTC hearing aid firm, receive \$100M boost,” MedTech Dive, April 3, 2025, <https://www.medtechdive.com/news/otc-hearing-aid-eargo-hearx-merge/744043/>; “Hearing Aid Company Eargo Inc. Agrees to Pay \$34.37 Million to Settle Common Law and False Claims Act Allegations for Unsupported Diagnosis Codes,” Department of Justice, April 29, 2022, <https://www.justice.gov/archives/opa/pr/hearing-aid-company-eargo-inc-agrees-pay-3437-million-settle-common-law-and-false-claims-act>.

55 Ibid.

56 “Lucid Hearing,” LinkedIn, accessed June 10, 2025, <https://www.linkedin.com/company/lucid-hearing/>.

57 “Hearing Aids,” Sam’s Club, accessed June 10, 2025, <https://www.samsclub.com/b/hearing-aids/1710103?rootDimension=Prescription%20or%20Over-the-Counter%3APrescriptionpipsymbPrescription%20or%20Over-the-Counter%3APrescription;OTC%20hearing%20aids>, Lucid Hearing, accessed June 10, 2025, <https://lucidhearing.com/shop/>.

58 “Best Sellers in Hearing Aids,” Amazon, accessed June 10, 2025, <https://www.amazon.com/Best-Sellers-Hearing-Aids/zgbs/hpc/8626361011>.

59 “Over-the-counter (OTC) hearing aids,” Best Buy, accessed June 10, 2025, <https://www.bestbuy.com/site/health-wellness/hearing-solutions/pcmcat1630355900545.c?id=pcmcat1630355900545>.

60 Indeed, Best Buy offered 47 OTC hearing aid products in July 2023 compared with 34 in June 2025. <https://web.archive.org/web/20230714093929/https://www.bestbuy.com/site/hearing-aids-amplifiers/hearing-aids/pcmcat1616614505031.c?id=pcmcat1616614505031>; “Hearing Aids,” Best Buy, July 14, 2023, accessed via the Wayback Machine, <https://www.bestbuy.com/site/hearing-aids-amplifiers/hearing-aids/pcmcat1616614505031.c?id=pcmcat1616614505031>.

61 “Exploring Costco Hearing Aids: Models and Features,” Nearity, May 22, 2024, [https://www.nearity.co/blog/exploring-costco-hearing-aids-models-and-features?srsId=AfmBOoqb5X7zsWn3gCKxf8qE75PgQghjRZTBAA9r16rEQ5\\_Ybx94Z4XL](https://www.nearity.co/blog/exploring-costco-hearing-aids-models-and-features?srsId=AfmBOoqb5X7zsWn3gCKxf8qE75PgQghjRZTBAA9r16rEQ5_Ybx94Z4XL).

in the U.S., with an estimated 16% market share.<sup>62</sup> In addition to prescription hearing aids, Costco briefly sold Sonova-made OTC hearing aids for \$1,400 under its private label, Kirkland Signature. Sonova discontinued sales in November 2022, citing “the decision to focus the distribution of our Phonak brand with strategic channels and eliminate our offering in certain large retail chains.”<sup>63</sup> Today, Costco sells Apple AirPods Pro 2 and an OTC Lexie model for \$980.<sup>64</sup>

- **Drugstores:** Both CVS and Walgreens sell OTC hearing aids in store and online. CVS customers can take a two-minute screening test to gauge the kind of products they require; options range from \$250 to \$1,100 per pair.<sup>65</sup> Walgreens’ OTC offerings fall within a similar range.<sup>66</sup> Smaller drugstore chains and independent pharmacies also offer OTC hearing aids. According to an interview with an independent pharmacist, consumer demand spiked in the immediate aftermath of the FDA issuing its final rule but has remained modest overall.
- **Soundly** is an online hearing aid marketplace that launched in 2022 and sells both prescription and OTC products. For the latter, Soundly promises prices that “match what you will find in other retail locations like Amazon but come with additional benefits,” including a “guided setup service.”<sup>67</sup>
- **Walmart** started offering OTC hearing aids in October of 2022. Today, the big-box store sells a wide variety of brands both in store and online, with prices ranging from \$100 to \$1,900 per pair.<sup>68</sup>

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62 Ibid. at 10.

63 Abram Bailey, “Costco’s Kirkland Signature 10.0 Hearing Aid – KS10,” Hearing Tracker, Nov. 15, 2022, <https://www.hearingtracker.com/hearing-aids/kirkland-signature-costco-10>.

64 “Lexie Hearing Assisted Hearing Aids,” Costco, accessed June 10, 2025, [https://www.costco.com/assisted-hearing-devices.html?refine=Brand\\_attr-Lexie%2520Hearing%257C%257Citem\\_program\\_eligibility-Shiplt](https://www.costco.com/assisted-hearing-devices.html?refine=Brand_attr-Lexie%2520Hearing%257C%257Citem_program_eligibility-Shiplt).

65 “Hearing Aids,” CVS, accessed June 10, 2025, <https://www.cvs.com/shop/home-health-care/hearing-aids-accessories/hearing-aids>.

66 “Hearing Aids & Assistance,” Walgreens, accessed June 10, 2025, <https://www.walgreens.com/store/c/hearing-aids-and-assistance/ID=364027-tier3>.

67 “About,” Soundly, accessed June 10, 2025, <https://www.soundly.com/about>.

68 “OTC Hearing Aids,” Walmart, accessed June 10, 2025, [https://www.walmart.com/browse/health-medicine/otc-hearing-aids/976760\\_1005860\\_8870874?sort=price\\_high](https://www.walmart.com/browse/health-medicine/otc-hearing-aids/976760_1005860_8870874?sort=price_high).

# BARRIERS TO OTC HEARING AID USE

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According to interviews with market participants and industry experts, there are several barriers preventing further purchase and use of OTC hearing aids. They fall into four general categories:

- **Consumer concerns:** Unlike reading glasses or other medical devices available for purchase in retail locations, OTC hearing aids are more complicated, with a potentially months-long adjustment period, and a strong majority of consumers worry about purchasing them without the assistance of a trained medical professional, according to a May 2024 analysis from the Government Accountability Office (GAO).<sup>69</sup> In fact, the same analysis found that many consumers who have previously seen an audiologist say that their audiologist recommended against buying an OTC product.<sup>70</sup> Some consumers also report being unsure how to gauge their level of hearing loss and therefore their fitness for buying OTC hearing aids, which are approved only for people with mild to moderate hearing loss. Based on interviews with industry participants, the proliferation of competitors in the space has also contributed to consumer confusion, as potential purchasers feel overwhelmed by the choices available and unsure how to pick among them. The emergence of very low-cost OTC options that may not deliver high-quality service has further complicated the purchasing experience for consumers. Although the introduction of the Apple AirPods Pro 2 with hearing aid functionality has helped ease some consumer concerns and increased awareness of OTC options, consumer hesitation to go with an OTC option remains a significant barrier to uptake.
- **Retailer concerns:** Although OTC hearing aids are available at thousands of retail locations across the country, some retailers have cut back on options—or eliminated OTC options entirely—for business reasons. Market participants report that OTC hearing aids have a high “return rate,” meaning that quite a few consumers who purchase a product end up returning them within a few weeks. That has dampened retailer enthusiasm. Many retailers also incur substantial expense to offer OTC hearing options—since many dedicate one or more employees to providing full-time assistance to potential purchasers—which makes it harder to achieve profitability. Research also shows that pharmacists, despite feeling that OTC hearing aids “fit logically within [their] existing physician

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<sup>69</sup> Ibid. at 4.

<sup>70</sup> Ibid. at 4.

workflow,” reported “frustration with the complex nature of these devices” and limited engagement in selling them.<sup>71</sup>

- **Lack of insurance coverage:** An average pair of high-quality OTC hearing aids costs roughly \$1,000.<sup>72</sup> Although that is nearly 80% cheaper than the average pair of prescription hearing aids, it is still quite expensive for many people to cover out of pocket. And most health plans, including traditional Medicare, Federal Employees Health Benefits (FEHB), TRICARE, and VA insurance, as well as most Medicaid and private coverage, do not cover OTC hearing aids. By contrast, many private insurance plans, TRICARE, and VA insurance cover prescription hearing aids, and Medicaid provides uniform coverage for prescription hearing aids for children. This disparity in coverage helps push consumers towards more expensive prescription hearing aids rather than OTC options.
- **Steering concerns:** As noted above, the hearing aid market is vertically integrated, with most of the leading hearing aid manufacturers also operating the leading hearing benefit managers (HBMs) and audiology clinics. This creates an inherent conflict of interest in which the HBM and clinic are incentivized to push products that are made by their affiliated manufacturer, rather than more affordable products, including OTC devices. In addition, some audiologists use loans from hearing aid manufacturers to finance their clinics, given challenges accessing capital elsewhere.<sup>73</sup> According to an interview with an audiologist, many banks that offer small business loans are unfamiliar with the audiology clinic business model. But manufacturer financing introduces new conflicts, including minimum purchase terms that require the borrower to purchase up to 90% of the clinic’s hearing aid units from the manufacturer lender and “create an expectation that audiologists will refer [patients to the manufacturers’ products] based on the purchase requirement rather than using their own professional judgment.”<sup>74</sup>

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71 James Wheeler et al., “Sounding off – Pharmacist insights on over-the-counter hearing aids: A qualitative focus group study,” *Journal of the American Pharmacists Association*, July-August 2025, [https://www.japha.org/article/S1544-3191\(25\)00080-9/abstract?rss=yes](https://www.japha.org/article/S1544-3191(25)00080-9/abstract?rss=yes).

72 Paula Span, “Hearing Aids Are More Affordable, and Perhaps More Needed, Than Ever,” *The New York Times*, Oct. 30, 2023, <https://www.nytimes.com/2023/10/30/health/hearing-aids-dementia.html>.

73 Brandon Pauley, Ashley Watson, and Kim Cavitt, “Lend Me Your Ears: Legal and Compliance Issues Impacting Audiology Practice-Manufacturing Loan Agreements,” Brennan, Manna & Diamond, July 26, 2022, [https://audiologist.org/\\_resources/documents/webinars/2022/2022-07-26-Lend-Me-Your-Ears.pdf](https://audiologist.org/_resources/documents/webinars/2022/2022-07-26-Lend-Me-Your-Ears.pdf).

74 Ibid.

# RECOMMENDATIONS

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Federal and state policymakers can and should take additional steps to improve uptake of OTC hearing aids and promote competition in the highly consolidated hearing sector. However, many of these policy recommendations would require adequate staffing and funding of federal agencies, many of which—including the Department of Health and Human Services (HHS)—have instead seen their resources slashed by the Trump administration via the Department of Government Efficiency.<sup>75</sup>

## CONGRESS

- **Break up the Big Five:** Removing red tape by making hearing aids available over the counter lowered one barrier to entry for new market participants, but the vertically integrated market structure of hearing aid manufacturers, HBMs, and retail chains continues to be a significant barrier to free and fair competition. To eliminate these conflicts of interest, Congress should prohibit hearing aid manufacturers from offering hearing benefit insurance products and from advertising hearing aid clinics as if they are independent clinics, rather than as a storefront for a particular manufacturer. The bipartisan Patients Before Monopolies Act, which would eliminate similar conflicts of interest in the vertically integrated prescription drug supply chain, provides a template for this kind of structural separation legislation. Congress should also prohibit hearing aid manufacturers and HBMs from misleadingly marketing device discounts as insurance products. At a minimum, Congress should investigate whether HBMs—whose growing role in the hearing health marketplace raises significant concerns about competition and consumer choice—are violating federal antitrust laws.
- **Strengthen anti-kickback provisions and protect audiologist independence:** Some hearing aid manufacturers offer audiologists bonuses, commissions, rebates, or other financial perks to recommend their products, creating a conflict of interest that can undermine patient trust and lead to unnecessary spending on premium devices. Congress should prohibit manufacturers from paying audiologists to steer patients to a particular manufacturer's products. These payments may not be covered by the existing Anti-Kickback Statute, which prohibits only inducements for services or items payable by federal health care programs, which generally do not cover hearing

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<sup>75</sup> "HHS Announces Transformation to Make America Healthy Again," Department of Health and Human Services, March 27, 2025, <https://www.hhs.gov/press-room/hhs-restructuring-doge.html>.

aids.<sup>76</sup> Where an audiologist is an employee of a particular manufacturer—such as when a direct-to-consumer hearing aid company provides audiology support services—that company should be required to disclose that it is a retailer only of that manufacturer’s devices and is not an independent audiology practice.

- **Pass the bipartisan, bicameral Medicare Audiology Access Improvement Act (MAAIA):** Sponsored by Sen. Warren and Rep. Gus Bilirakis (R-FL), the MAAIA would expand Medicare coverage for wrap-around audiology services, including through telehealth. Medicare currently reimburses audiologists only for “hearing and balance assessment services,” which CMS interprets to exclude “prescribing, fitting, or changing hearing aids.”<sup>77</sup> By expanding reimbursement to cover treatment services, the MAAIA would help patients access professional guidance when choosing, fitting, adjusting, or adapting to their hearing aids. In addition to improving the rate of successful adoption, reimbursing such services could make audiology practices less reliant on hearing aid manufacturers for financing and revenue—an entanglement that further entrenches the Big Five.<sup>78</sup> Furthermore, the MAAIA would provide permanent authorization for telehealth audiology services, which expired for Medicare patients in September 2025.<sup>79</sup> Providing greater market certainty about telehealth reimbursement could potentially foster innovative business models that provide remote professional support for OTC devices. Finally, the MAAIA would eliminate requirements that Medicare patients generally must receive a referral from a physician to see an audiologist—reducing burdensome red tape.
- **Add Medicare coverage for hearing aids:** While the MAAIA would expand Medicare coverage for audiology services, additional legislation is needed to provide Medicare coverage for hearing aid devices themselves. Traditional fee-for-service Medicare provides no coverage for hearing aids—whether prescription or OTC. Providing Medicare coverage would not only eliminate cost as a barrier to access for millions of older Americans, but it could also be an important “demand pull” strategy. Namely, Medicare coverage would provide a steady stream of customers at much lower customer acquisition costs than new entrants currently face. This could encourage more companies to enter the market, which could in turn lower prices through competition. Providing hearing coverage in traditional Medicare would also level the playing field between traditional Medicare and

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76 “Question and Answer: Self-Referral/Stark Law And Anti-Kickback Regulations,” American Speech-Language-Hearing Association, accessed June 10, 2025, <https://www.asha.org/practice/reimbursement/medicare/qas/?srsltid=AfmBOorpwNyn1AReon46wafXvKJrw5f5FkXyqBCKcaTwOnE7dZpnZySb#a9>.

77 42 U.S.C. 1395x §(l)(3); 42 C.F.R. 411.15(d).

78 Ibid. at 73.

79 “Congress Extends Medicare Telehealth Authority Through September,” American Speech-Language-Hearing Association, March 17, 2025, <https://www.asha.org/news/2025/congress-extends-medicare-telehealth-authority-through-september/>.

privatized Medicare Advantage plans. Currently, older Americans may be enticed to enroll in Medicare Advantage with promises of supplemental hearing (as well as dental and vision) benefits that are unavailable in traditional Medicare, even though MedPAC data shows that utilization of Medicare Advantage hearing benefits is low and private Medicare Advantage plans often cost taxpayers more than traditional Medicare without improving quality.<sup>80</sup>

## FEDERAL AGENCIES

- **Strengthen enforcement of antitrust laws:** In addition to Congress strengthening anti-kickback provisions, the Federal Trade Commission (FTC) should act on its June 2022 policy statement, in which the Commission pledged to “use its full authority under the FTC Act” to “challeng[e] healthcare industry conduct that may raise prices and stifle innovation.”<sup>81</sup> Specifically, the FTC should scrutinize whether hearing aid manufacturers’ and their affiliated HBMs’ use of kickbacks to audiologists violate antitrust laws, including the FTC Act’s prohibition on unfair methods of competition and the 1936 Robinson-Patman Act, which prohibits price discrimination. Depending on its findings, the FTC should sue the Big Five hearing aid manufacturers, similar to the Commission’s ongoing lawsuit against the “Big Three” PBMs for allegedly engaging in an illegal rebate scheme to artificially inflate the price of insulin.<sup>82</sup>
- **Give federal employees the option of OTC hearing aids:** The FEHB, TRICARE, and VA programs provide coverage for hearing aids under specific clinical and administrative conditions, but none allows beneficiaries to use this coverage for OTC hearing aids. Specifically, many FEHB plans provide reimbursement—often up to \$2,500—every few years for medically necessary, professionally fitted devices; TRICARE offers hearing aids to active-duty service members and eligible dependents who meet certain audiometric criteria; and the VA provides full coverage of prescription hearing aids and ongoing support. To promote affordability and flexibility, these programs should give beneficiaries the option to apply existing benefits toward OTC hearing aids. This could save

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<sup>80</sup> Stuart Hammond, “Assessing the utilization and delivery of Medicare Advantage supplemental benefits,” MedPAC, April 10, 2025, <https://www.medpac.gov/wp-content/uploads/2025/04/Tab-E-MA-supplemental-April-2025.pdf>; “Special Report: The Real Impact of Medicare Advantage for Beneficiaries and Medicare Funding,” Center for Medicare Advocacy, July 18, 2024, <https://medicareadvocacy.org/report-real-impact-of-medicare-advantage/>.

<sup>81</sup> “Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products,” Federal Trade Commission, June 2022, [https://www.ftc.gov/system/files/ftc\\_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf).

<sup>82</sup> “FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices,” Federal Trade Commission, Sept. 20, 2024, <https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices>.

taxpayer dollars if beneficiaries choose OTC hearing aids over more expensive prescription devices. And as with Medicare, coverage for these populations could provide a “demand pull” incentive for more device manufacturers to enter the market, which could further lower costs. FEHB coverage of OTC hearing aids could also provide a useful pilot for broader coverage, creating an opportunity to identify best practices for when patients can safely and effectively use OTC hearing aids—including the degree of support needed. Federal employee plans could also measure and publicly report any savings (from both lower device costs and any health improvements among beneficiaries), which could spur the commercial insurance market to adopt OTC hearing aid coverage.

- **Facilitate apples-to-apples comparison shopping:** Lack of standardized terminology among manufacturers makes it difficult for consumers to compare devices without professional assistance. Unlike eyeglasses, where prescriptions and measurements are standardized, hearing aids are marketed with a wide range of inconsistent language to describe core features like amplification levels, noise reduction, directionality, and Bluetooth capabilities. To facilitate apples-to-apples comparison shopping, the FDA should adopt a standardized labeling system that clearly defines and discloses key hearing aid features—including clinical Speech-In-Noise results—across all manufacturers in plain language.<sup>83</sup> The FDA could also create an online dashboard for comparison shopping, similar to its Care Compare website for health care providers. Other models include the Consumer Financial Protection Bureau’s Explore Credit Cards comparison tool and the Department of Transportation’s Airline Customer Service Dashboard.<sup>84</sup>
- **Ban bundled pricing:** Bundled pricing of hearing aids and audiology services—where the costs of the device, fitting, and follow-up care are combined into a single opaque fee—makes it difficult for patients to evaluate the true cost of each component and obtain only the products or services they actually need. To address this, the FTC could adopt a rule under its existing unfair or deceptive practices rulemaking authority to prohibit bundled pricing in the hearing aid market, requiring providers to offer consumers the ability to purchase devices and services à la carte. The FTC has precedents for such action: its eyeglass and contact lens rules helped unbundle eyeglass and contact lens prescriptions from retail sales to promote competition, and its junk fee rule prohibits hidden

83 Curtis Billings et al., “Speech-in-Noise Testing: An Introduction for Audiologists,” *Seminars in Hearing*, Sept. 11, 2023, <https://pmc.ncbi.nlm.nih.gov/articles/PMC10872656/#:~:text=As%20many%20as%2070%25%20of,in%20age%20and%20hearing%20status>.

84 “Explore credit cards for your situation,” Consumer Financial Protection Bureau, accessed June 10, 2025, <https://www.consumerfinance.gov/consumer-tools/credit-cards/explore-cards/>; “Airline Customer Service Dashboard,” Department of Transportation, updated Dec. 10, 2024, <https://www.transportation.gov/airconsumer/airline-customer-service-dashboard>.

mandatory fees in certain other consumer transactions.<sup>85</sup> Alternatively, Congress could enact legislation banning bundled pricing directly, or it could waive the additional procedural burdens imposed on FTC consumer protection rulemakings; either approach would speed implementation of this consumer protection measure.

- **Increase enforcement against fraudulent, low-quality devices:** The marketing of personal sound amplification products or other unapproved devices that don't meet FDA safety standards as OTC hearing aids creates a confusing, cluttered marketplace for consumers, who generally lack the technical knowledge to evaluate product legitimacy. To protect consumers from deception and create a level playing field for honest businesses that play by the rules, the FDA and FTC should prioritize enforcement actions against bad actors who falsely label or illegally market low-quality, noncompliant devices.
- **Increase awareness among pharmacists and physicians:** Access to hearing aids—including OTC options—could be significantly improved if health care providers beyond audiologists, particularly primary care providers and pharmacists, played a more proactive role in supporting patients' hearing health. These providers are often the first point of contact for adults experiencing hearing difficulties, yet many lack the knowledge or resources to help patients navigate their options, including OTC hearing aids. To expand access and ensure informed decision-making, HHS should promulgate guidance and toolkits for primary care providers and pharmacists on counseling patients about OTC hearing aids, including when professional referral is warranted. Additionally, HHS should work with medical and pharmacy schools to incorporate hearing health education into their curricula, with a focus on identifying signs of hearing loss and understanding the range of device options available. For example, HHS grants could require or incentivize the inclusion of hearing health modules in curricula. HHS could also publish model curricula modules. Trade associations such as the American Medical Association and the American Pharmacists Association should likewise take an active role in educating their members about OTC hearing aids and integrating hearing health into standard patient care protocols.
- **Reimburse pharmacists for helping Medicare patients navigate OTC hearing aids:** To improve access to hearing care and support the successful adoption of OTC hearing aids among older adults, Medicare should reimburse pharmacists for providing counseling and support services that help older Americans navigate their OTC hearing aid options. Pharmacists

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85 "Eyeglass Rule," Federal Trade Commission, accessed June 10, 2025, <https://www.ftc.gov/legal-library/browse/rules/eyeglass-rule>; "Contact Lens Rule," Federal Trade Commission, accessed June 10, 2025, <https://www.ftc.gov/legal-library/browse/rules/contact-lens-rule>; "FTC Rule on Unfair or Deceptive Fees to Take Effect on May 12, 2025," Federal Trade Commission, May 5, 2025, <https://www.ftc.gov/news-events/news/press-releases/2025/05/ftc-rule-unfair-or-deceptive-fees-take-effect-may-12-2025>.

are important providers of medication counseling and management, as well as immunizations and rescue medications, especially in rural communities, where they might be the only health care professional.<sup>86</sup> They are well positioned to offer guidance on device selection, usage, and when to seek audiologic care, with appropriate training. To ensure quality and consistency, Medicare should pair this new reimbursement policy with evidence-based training modules and clinical guidance. This approach would empower pharmacists to become effective front-line resources in hearing health, reduce barriers to hearing aid adoption, and help fulfill the public health promise of the FDA's OTC hearing aid framework.

- **Increase consumer awareness and reduce stigma:** Lack of consumer awareness about OTC hearing aids remains a significant barrier to broader uptake, and many who would benefit from hearing aids are deterred by stigma. HHS should launch a national consumer education campaign to raise awareness and combat the assumption that hearing aids are only for the old or infirm. By normalizing hearing health as part of routine preventive care and promoting OTC hearing aids as a modern, tech-savvy option, HHS can empower millions of Americans to improve their quality of life and long-term health outcomes.

## STATE LEGISLATURES

- **Break up the Big Five:** Like Congress, state lawmakers should outlaw the vertically integrated market structure of hearing aid manufacturers, HBMs, and retail chains given competition concerns. Some states have already taken steps to eliminate similar conflicts of interest in the vertically integrated prescription drug supply chain. For instance, in April 2025, Arkansas Gov. Sarah Huckabee Sanders signed into law House Bill 1150, which prohibits PBMs from owning pharmacies and serves as a template for future structural separation reform legislation targeting Big Ear.<sup>87</sup>

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86 Samantha Valliant et al., "Pharmacists as accessible health care providers: quantifying the opportunities," *Journal of Managed Care + Specialty Pharmacy*, January 2022, <https://pmc.ncbi.nlm.nih.gov/articles/PMC8890748/>; Devi Shastri, "Rural pharmacies fill a health care gap in the US. Owners say it's getting harder to stay open," *Associated Press*, June 7, 2024, <https://apnews.com/article/pharmacy-rural-drugstore-access-closures-425c785b5f244115543d54001311ef33>; Sagar Dugani et al., "Rural Independent Pharmacies Sustainability Strategy," *National Rural Health Association*, December 2024, <https://www.ruralhealth.us/nationalruralhealth/media/documents/advocacy/policy%20brief/nrha-policy-brief-independent-retail-pharmacy-final.pdf>.

87 "Sanders Signs Legislation to Ban Anti-Competitive PBM Practices," *Arkansas Gov. Sarah Huckabee Sanders*, April 16, 2025, [https://governor.arkansas.gov/news\\_post/sanders-signs-legislation-to-ban-anti-competitive-pbm-practices/](https://governor.arkansas.gov/news_post/sanders-signs-legislation-to-ban-anti-competitive-pbm-practices/).

## CONCLUSION

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The Over-the-Counter Hearing Aid Act, and the subsequent rulemaking by the FDA, helped bring OTC products to mainstream retailers' shelves and improve consumer access to hearing loss treatment. However, there remain a variety of complex and wide-ranging barriers to their uptake, including the Big Five's anti-competitive business practices, lack of insurance coverage, and consumer reticence.

For this deregulatory action to live up to its promise, policymakers must address these issues. Congress should work to dismantle the vertical integration among manufacturers, insurers, and providers as well as pass the MAAIA to enable Medicare hearing aid coverage. At the same time, federal agencies should focus their energy on increasing consumer awareness, facilitating comparison shopping, eliminating bundled pricing, and enabling OTC hearing aid access for federal employees.

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