May 27, 2025

United States Department of Justice
Anticompetitive Regulations Task Force
950 Pennsylvania Ave. NW
Washington, DC 20530
ATTN: Assistant Attorney General Abigail Slater

RE: Docket ATR-2025-0001

Dear Assistant Attorney General Slater and Members of the Anticompetitive Regulations Task Force,

The Academy of Doctors of Audiology (ADA), a leading national organization dedicated to advancing evidence-based clinical and business practices in the delivery of audiology services throughout the United States, respectfully submits the following comments in response to the March 27, 2025 request from the U.S. Department of Justice (DOJ) Anticompetitive Regulations Task Force to assist in its quest to eliminate "anticompetitive state and federal laws and regulations that undermine free market competition and harm consumers, workers, and businesses."

In 2017, President Trump signed the Over-the-Counter Hearing Aid Act into law, initiating legislative and regulatory changes to increase competition and make hearing aids cheaper and more accessible for consumers with perceived mild-to-moderate hearing loss.[1] ADA proudly endorsed that important initiative, and now commends this administration for seeking additional opportunities to improve competition and democratize healthcare service delivery through meaningful legislative and regulatory reform.

While current state and federal statutory and regulatory climates impose innumerable barriers to competition and consumer access to audiology services, ADA has identified three issue areas that can be readily and immediately addressed through the *elimination* of anticompetitive laws and regulations in order to stimulate competition, reduce costs, and improve access to hearing and balance healthcare for millions of Americans.

1. **Eliminate anticompetitive federal Medicare laws that unfairly restrict beneficiary access to Medicare-covered auditory and vestibular services.**

Immediate action should be taken to reform existing Medicare statutes and regulations governing the delivery of audiology services. Audiology services under Medicare (Part B) are arbitrarily constrained, channeling beneficiaries to a limited number of legacy providers, and requiring beneficiaries to undergo an expensive and time-consuming, multi-step, multi-stop process to meet unfair coverage requirements, just to get the most basic care that they need. Independent audiology clinics are disproportionately impacted by these anticompetitive federal statutes and regulations that limit beneficiary access to Medicare audiology services, when such services are delivered by audiologists.

1. Associated Press. 2017. Hearing Aid Bill Signed into Law: https://apnews.com/article/4470bbb5c7944488886bcb4d219900f0

A. ***Completely eliminate Medicare Part B pre-treatment order requirements for beneficiaries with hearing and balance conditions.***

With few exceptions, Medicare Part B beneficiaries with hearing or balance problems are required to obtain a pre-treatment order from a physician or another provider, prior to obtaining Medicare-covered services from an audiologist, even though no such order requirement exists under the Medicare statute,[2] and even though licensed audiologists are already recognized as qualified Medicare providers, who are responsible for independently determining medical necessity.

- Other federal agencies recognize that a mandatory office visit to obtain an order, for adult patients who suspect that they have a hearing or balance problem, has proven to inflate the cost of care with no meaningful clinical benefit. Federal programs, including, but not limited to, the Veteran's Administration (VA), the Federal Health Benefit Plan (FEHBP), and most Medicaid programs allow patients to seek treatment directly from audiologists, without a pre-treatment order.
- The pre-treatment order requirement for audiology services is contrary to state audiology practice acts that allow consumers direct access to audiologists from birth through end of life.
- The pre-treatment order requirement is inconsistent with private insurance plans, which overwhelmingly allow and encourage beneficiary direct access to audiologists.
- ADA obtained a legal opinion in 2016, supporting the conclusion that CMS has the authority to eliminate the pre-treatment order requirement for coverage (it is not required by statute).
- The Centers for Medicare and Medicaid Services (CMS) has since acknowledged that it has the authority to eliminate the pre-treatment order requirement for coverage.
- CMS updated the pre-treatment order policy in 2023, authorizing beneficiaries to bypass the pretreatment order in very limited circumstances for "non-acute" hearing issues, if the beneficiary has not been seen by an audiologist in the prior 12 months.[3]
- The CMS 2023 limited direct access policy update failed to increase competition or improve access to care—it only served to increase confusion and sow chaos for beneficiaries and audiologists alike.
    - It is practically impossible for an audiologist to determine whether a beneficiary has a "non-acute" hearing condition until the beneficiary has been evaluated and diagnosed. Further, there is no clinical definition, billing code, or objective criteria for the audiologist to rely on for what constitutes a "non-acute" hearing issue.
    - Audiologists have no reliable source to determine whether a patient has been seen by another audiologist within the past 12 months. They must rely solely upon the patient's recollection of the last time they were seen by an audiologist to make a determination of direct access eligibility.
    - Rather than risk coverage denials due to clinical or visit time interval ineligibility, most beneficiaries continue to incur unnecessary office visits to obtain pretreatment orders for audiology services, even for non-acute hearing issues, and/or even if they have not had an audiology visit in the past 12 months.
    - Therefore, this limited direct access policy has been wholly impractical to implement, since its introduction in 2023, and has not improved access to care or decreased wait times for beneficiaries.

B. ***Update Medicare statutes to eliminate outdated classifications for audiologists and audiology services.***

Medicare Part B unfairly restricts the classification of audiology services to diagnostic services, statutorily prohibiting beneficiaries from seeking treatment services from audiologists, even though audiologists are licensed in every U.S. state and territory, to provide a wide-range of Medicare-covered treatment services.

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2. Centers for Medicare and Medicaid Services (CMS) Audiology Services Webpage: https://www.cms.gov/medicare/payment/fee-schedules/physician/audiology-services
3. See 2 above.

The classification of audiology services in the Medicare statute limits access and competition. ***To remedy this issue, paragraph (3) of section 1861(ll) of the Social Security Act should be amended to include treatment services, in addition to diagnostic services.***

Additionally, audiologists are the only clinical doctoring professionals, recognized as Medicare providers who are not classified as physicians, practitioners, or therapists under the Medicare statute. Audiologists are subjectively excluded from any appropriate classification under Medicare Part B, creating an artificial market advantage for other providers. *By virtue of their education, training, and qualifications, audiologists should be added to the list of practitioners as defined under Section 1842(b)(18)(C) of the Social Security Act.*

- Private insurers, including most Medicare Advantage plans, by virtue of their coverage policies, encourage beneficiaries to apply their medical coverage when they obtain diagnostic *and* treatment services from audiologists, and allow audiologists to be reimbursed for all of the covered services that they are licensed to provide (both diagnostic and treatment services).
- Audiology is a clinical doctoring profession (the terminal degree is the Au.D.), with training and education commensurate to or greater than that of other practitioners as defined and included in Section 1842(b)(18)(C) of the Social Security Act.
- The exclusion of audiologists from the list of recognized "practitioner" providers under Medicare Part B is blatantly anti-competitive. This discriminatory practice has created an unfair market advantage benefiting competing providers, while hindering the ability of audiologists to practice the full scope of audiology and vestibular services, for which they have been trained and licensed.
- Medicare's inequitable treatment of audiologists contradicts other federal laws, which prohibit health plans from discriminating against entire classes of qualified, licensed healthcare professionals solely on the basis of their provider type. Failure to include audiologists among other "practitioner" providers is detrimental to the provision of safe, efficient, and cost-effective care.
- Adding audiologists to the list of Medicare "practitioners" will ensure that Medicare beneficiaries can obtain hearing and balance services via telehealth and will also foster audiology's inclusion in quality-based payment models that reduce waste and fraud.

The Medicare Audiology Access Improvement Act of 2025, introduced by Representative Gus Bilirakis (R-FL), if enacted, will make these important Medicare reforms.[4] DOJ can work with Congress to prioritize this legislation to improve competition by allowing Medicare beneficiaries to choose from among all qualified providers for Medicare-covered audiology diagnostic and treatment services without financial penalties and extra out-of-pocket costs, and by reclassifying audiologists from suppliers to practitioners under the Medicare statute. Eliminating these restrictive laws will help millions of Medicare beneficiaries get the hearing and balance care that they need, without creating or adding any new reimbursable services to Medicare, or expanding the scope of practice of audiologists.

2. Eliminate anticompetitive state laws that impose unfair barriers to telepractice and mobile audiology service delivery.

Audiology and hearing aid dispensing services in the United States are governed by state laws and regulations for licensure and service delivery. Many states require in-person, face-to-face patient visits, the use of standardized test batteries and procedures, and specific equipment for hearing assessments as conditions for sale for prescription hearing aids. These traditional mandates, while originally designed to protect consumers and foster quality patient care, now serve to prop up and reinforce outdated paradigms that stymie innovation, competition, and access.

4. Medicare Audiology Access Improvement Act: https://www.congress.gov/bill/119th-congress/house-bill/2757

Today, telehealth and mobile audiology offer powerful alternatives to traditional brick and mortar clinics, enabling audiologists to reach more patients—especially those in rural, underserved, or mobility-limited communities. Yet, outdated regulations often prevent audiologists from leveraging these technologies fully. For example, some states still require that hearing tests be conducted only in soundproof booths, even though remote and mobile technology can provide reliable results using validated protocols and calibrated equipment. Other laws insist on specific test batteries or procedures that may not be necessary or practical for every remote patient encounter.

Audiologists are bound by their code of ethics, state licensing provisions, and other consumer protections that enforce minimum standards of clinical care, regardless of the service delivery channel. Eliminating archaic laws that unduly restrict telehealth and mobile audiology services will improve patient access, competition, and clinical outcomes, without undermining necessary consumer protections.

3. **Eliminate anticompetitive state laws that improperly restrict occupational licensing for audiologists, create unfair subsidies, and support tying arrangements for professional societies.**

ADA is a strong proponent of the Audiology and Speech-Language-Pathology (A-SLP) Interstate Compact, adopted by more than 30 states[5], to allow audiologists and speech language pathologists licensed in their home state to obtain a privilege to practice in other participating states across the nation. Once it becomes fully functional, the A-SLP Compact will undoubtedly result in expanded interstate audiology service delivery, increased competition, and improved access for consumers. However, there are fundamental state licensing concerns that must be resolved to ensure its success.

State audiology licensing laws were created to provide consumer protection and foster a culture of patient safety. Unfortunately, today, many state audiology practice acts and state licensing regulations contain provisions that are designed merely to profit associations at the expense of licensees and consumers.

State laws that require an audiologist to be certified by the American Speech-Language-Hearing Association (ASHA) or the American Board of Audiology (ABA), as either a condition for licensure, or as an easier pathway to licensure, coerce audiologists into paying high fees to subsidize associations in exchange for a license to practice. This "certification tax" offers absolutely no benefit to the public. On the contrary, it unnecessarily increases the cost of services delivered. ***State statutes and regulations compelling ASHA or ABA certification should be eliminated.***

- State licensing laws governing audiology in all 50 states, territories, and the District of Columbia already include rigorous academic and clinical standards. States whose licensing laws reference certification requirements, particularly for ASHA certification, are effectively holding a profession hostage to a certification that is supposed to be voluntary. ASHA annual certification maintenance fees are $446[6] for non-member audiologists and ABA annual certification fees for non-members of the American Academy of Audiology (AAA), of which it is a wholly owned subsidiary are $200.[7]
    - Most universities strongly recommend that students obtain ASHA certification at the time of graduation from their clinical Au.D. programs—not because it offers additional training or rigor—but because it will ensure that students don't face barriers to licensure. In fact,

5. ASLP Interstate Compact website: https://aslpcompact.com/
6. ASHA Certification Website: https://www.asha.org/certification/slpcertification/?srsltid=AfmBOoqZ1x9OEdncseReNL5G4iL32DxlzxJ5iRLzHXCgGHHk6JzFyAez
7. ABA Certification Website: https://www.audiology.org/american-board-of-audiology/aba-certification/recertify/

holding ASHA certification is so important to the graduates' perceived ability to become licensed that universities consistently require graduate students to sign a waiver if they elect not to obtain ASHA certification.
    - Many long-practicing clinical audiologists continue to maintain ASHA certification solely because they supervise (precept) clinical audiology graduate students seeking ASHA certification (as they are compelled to do). Certification candidates are required to have a certified preceptor to obtain certification. So, not only are audiology licensure certification requirements unfairly taxing licensees to subsidize ASHA, but they are effectively, unfairly excluding other qualified, licensed audiologists from serving as preceptors to train audiology students.
    - Still other long-practicing clinical audiologists maintain ASHA certification solely as a means of licensure reciprocity should they decide to move to another state. There is a justifiable fear that licensure will be impeded, despite holding a license in a state with similar requirements.
- ASHA and ABA certification can be readily obtained by entry-level audiologists. Neither represents a meaningful board certification in the traditional sense, and both can be maintained merely by paying an annual fee and obtaining a certain number of continuing education credits, which often mirror what states already independently require for licensure maintenance.
- There is no data to support that audiologists holding ASHA and/or ABA certification have better clinical outcomes or enhanced performance in any way compared with audiologists who do not hold certification.
- ASHA further unfairly ties its membership and certification by making it totally implausible for practicing clinical audiologists to hold ASHA membership without also purchasing its certification. ASHA's Code of Ethics reads, "ASHA members who do not hold the Certificate of Clinical Competence may not engage in the provision of clinical services; however, individuals who are in the certification application process may provide clinical services consistent with current local and state laws and regulations and with ASHA certification requirements."[8]
- State laws should not further exacerbate ASHA's tying scheme by forcing audiologists to become certified as a condition of or a means to obtain licensure. Professionals who have already met high standards elsewhere should not be forced to duplicate requirements, or face additional hurdles impeding their ability to serve patients and increasing costs for both providers and patients.

Eliminating state licensure laws that require certification by ASHA and/or ABA as a condition for licensure or as a means of creating an easier pathway to licensure will improve competition and reduce cost of care. State licensure already ensures that audiologists meet minimum standards for education, clinical experience, and ethical practice. Professional certification, while valuable, is not necessary for state licensure and should remain voluntary, allowing providers to choose the credentials that best fit their practice.

ADA further encourages DOJ to evaluate the elimination of state licensing laws that hinder professional mobility by creating arduous occupational licensure requirements. Establishing automatic licensure reciprocity for states with similar (often identical) licensing requirements would increase provide portability, and allow for improved access, particularly along state borders and via telehealth.

Recommendations

ADA appreciates the opportunity to provide input to the DOJ Anticompetitive Regulations Task Force to assist in the identification of state and federal laws that should be eliminated to improve competition,

8. American Speech Language Hearing Association Code of Ethics: https://www.asha.org/policy/code-of-ethics

consistent with free markets to benefit consumers, workers, and businesses. ADA recommends the DOJ take swift action to eliminate the following anticompetitive laws and regulations in order to foster accessible, affordable audiology care in the United States:

- Eliminate anticompetitive federal Medicare laws that unfairly restrict beneficiary access to Medicare-covered auditory and vestibular services.
- Eliminate anticompetitive state laws that impose unfair barriers to telepractice and mobile audiology service providers.
- Eliminate anticompetitive state laws that improperly restrict occupational licensing for audiologists, create unfair subsidies, and support tying arrangements for professional societies.

ADA stands ready to assist DOJ in implementing reforms to address these issues so that consumers can readily access the care that they need and audiologists can deliver care more flexibly and innovatively, improving access, affordability, competition, and quality of care for a broader population.

Please contact me at sczuhajewski@audiologist.org if I can answer any questions or assist you in any way. Thank you for your attention and consideration of these important recommendations.

Sincerely,

Stephanie Czuhajewski, MPH, CAE
Executive Director

Enclosure: October 14, 2016, Memo Hogan Lovells on Medicare Coverage of Diagnostic Audiology Services

October 14, 2016 DRAFT
Privileged and confidential

MEMORANDUM
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TO Academy of Doctors of Audiology

FROM Sheree R. Kanner **TELEPHONE** (202) 637-2898

DATE October 14, 2016

SUBJECT Medicare Coverage of Diagnostic Audiology Services

You requested our views on whether the Centers for Medicare & Medicaid Services (CMS) has authority to allow audiologists to furnish Medicare-covered diagnostic audiology services[1] without first obtaining a physician order. You further asked that, if we conclude audiologists are permitted to provide such diagnostic services without a physician's order, we articulate the legal theory and mechanism for so doing.

We conclude that CMS possesses authority to allow audiologists to furnish diagnostic audiology services without a physician's order. Our analysis and the mechanism for achieving this result follow.

Requiring a physician order for diagnostic audiology tests is a policy choice and, as such, CMS can change its policy to eliminate the physician order requirement.

1. Statutory background

The Medicare statute does not require that diagnostic tests be referred by a physician. Diagnostic tests are included in the statutory definition of "medical and other health services,"[2] which is a category of Medicare benefits.[3] By virtue of being in a Medicare benefit category, diagnostic

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1 We are assuming that all such services would be furnished within the audiologist's scope of practice under state law.

2 Social Security Act (SSA) § 1861(s)(3).

3 *See* SSA § 1832(a)(2)(B).

tests are covered unless they are excluded from coverage by virtue, for example, of not being reasonable and necessary.[4]

Similarly, the Medicare statute does not require a physician order for audiology services. Rather, the statute defines the term "audiology services" as "such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law . . .), as would otherwise be covered if furnished by a physician."[5] CMS considers audiology services to be diagnostic tests.[6] As such, as explained above, they are covered by Medicare unless otherwise excluded.

2. Regulatory history

Absent a statutory requirement that diagnostic tests or audiology services be ordered by a physician, or a prohibition on such tests or services being provided without a physician order, CMS possesses discretion to permit audiologists to furnish diagnostic audiology services without a physician order.

The history of the regulation requiring a physician order for diagnostic tests confirms this conclusion. The requirement for a physician order for diagnostic tests appears in a regulation stating that diagnostic tests "must be ordered by the physician who is treating the beneficiary . . . ."[7] CMS adopted this requirement through a regulation promulgated in 1996, *more than 30 years after enactment of the Medicare statute*.[8] While this time gap alone strongly suggests that the physician order requirement is an exercise of CMS's discretionary authority rather than a statutory mandate, what CMS said in the rule-making process cements this conclusion.

In the preamble discussion to the proposed rule amending the Medicare regulations to require that diagnostic tests be ordered by the treating physician, CMS did not cite to a specific statutory provision as the source. Rather, CMS explained that it was relying on a manual provision, which provided

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4 *See* SSA § 1862(a).

5 SSA § 1861(ll)(3).

6 *See, e.g.*, CMS Program Memorandum, Payment for Services Furnished by Audiologists, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/B0134.pdf.

7 42 C.F.R. § 410.32(a) (2016).

8 Prior to promulgation of the 1996 regulation requiring that all diagnostic tests be ordered by the treating physician, Medicare rules addressed the level of supervision required for diagnostic x-rays and the types of entities that could provide diagnostic laboratory tests. The rules did not require or even mention a physician order for those tests. *See* 42. C.F.R. § 410.32 (1996).

> that for a diagnostic test to be covered, the service must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. . . . The results of the test were to be used to treat the patient or refer him or her for treatment. It has come to our attention . . . that, in some cases, the intent of this instruction has been frustrated. We have heard of instances in which a physician . . . has no relationship to the beneficiary, and it is highly likely that tests by this physician would not be medically necessary. We believe this practice generates unnecessary diagnostic tests and places Medicare beneficiaries at needless risk both medically and financially. We propose to further clarify this long-standing manual instruction requirement that tests be ordered by a physician by specifying that the physician ordering the test must be the physician treating the patient. This proposed policy would link the ordering of the diagnostic test to the physician who will use the test results to treat the patient.[9]

This discussion confirms that the requirement for a physician order is not a statutory one; rather, CMS chose to require that diagnostic tests be ordered by a physician "to assure that beneficiaries receive medically necessary services and to prevent patterns of abuse . . . ."[10]

Moreover, although the discussion in the preamble to the 1996 proposed rule demonstrates that the statute does not require a physician order for a diagnostic test, the preamble discussion to the 1997 revision of the rule provides additional proof. In explaining revisions to the physician order requirement in 1997, CMS stated:

> [C]ommenters have asked about the statutory basis for denial of claims under the ordering rule adopted in the 1996 physician fee schedule final rule. We have determined that tests are not demonstrably reasonable and medically necessary unless they are ordered by the patient's physician who will employ the tests to manage the patient's care. Thus, we are clarifying in § 410.32(a) that the denials are based on the exclusion in section 1862(a)(1)(A) of the Act, and contained in § 411.15(k)(1), that is, the services "are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member."[11]

The language CMS employed in amending the text of the regulation was: "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) . . .)."[12] The regulatory citation is to what is commonly referred to as the "reasonable and necessary" requirement for Medicare coverage. As noted above in CMS's

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9 61 Fed. Reg. 34,614, 34,622 (July 2, 1996).

10 61 Fed. Reg. 59,490, 59,497 (Nov. 22, 1996). Indeed, the regulation ultimately adopted stated: "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who treats the beneficiary, that is, the physician who is actively furnishing a consultation or treating a beneficiary for a specific medical problem(s) and uses the results in the management of the beneficiary's specific medical problem(s)." 42 C.F.R. § 410.32(a) (1997).

11 62 Fed. Reg. 59,048, 59,057 (Oct. 31, 1997).

12 *Id.* at 59,098.

discussion of the 1997 rule, that requirement is derived from a statutory *prohibition* on Medicare paying for items or services "not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ."[13] The fact that the requirement for a physician order is based on a *general prohibition* against paying for services that are not reasonable and necessary, rather than on explicit statutory text, establishes that CMS made a policy choice in concluding that diagnostic tests must be ordered by treating physicians.

3. Changing the policy

Because CMS made a policy choice to require a physician order, it could change its policy to permit audiologists to furnish diagnostic services without a physician order. That is, CMS could change its view and conclude that it is reasonable and necessary for diagnostic audiology services to be furnished by an audiologist without a physician order.

Indeed, CMS has already reached this conclusion for certain nonphysician practitioners. The regulations requiring a physician order for a diagnostic test contain two exceptions, one of which is for nonphysician practitioners.[14] That exception provides:

> Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.[15]

Even though this regulation does not specifically list audiologists as nonphysician practitioners, CMS has treated audiologists as nonphysician practitioners in the past.[16] Hence, it would be reasonable for CMS to conclude that audiologists should be included in the nonphysician practitioner exception to the physician referral requirement. There are several ways this might be accomplished.

The fastest and simplest way for audiologists to be able to provide diagnostic tests to Medicare beneficiaries without a physician order would be for CMS to change its manuals to make clear

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13 SSA § 1862(a)(1)(A).

14 42 C.F.R. § 410.32(a)(2) (2016).

15 *Id.*

16 *See, e.g.*, 42 C.F.R. § 424.518(a)(i), which designates certain providers and suppliers as low risk for Medicare enrollment screening purposes ("Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and **audiologists**) and medical groups or clinics." (Emphasis added.)).

that audiologists are nonphysician practitioners for purposes of ordering diagnostic tests. If, however, the agency were to determine that a change in regulations is needed to allow audiologists to furnish diagnostic services without a physician order, it could undertake rulemaking explicitly to include audiologists among the practitioners excepted from the physician order requirement. CMS could do this either by expanding the list of nonphysician practitioners in 42 C.F.R. § 410.32(a)(2) to include audiologists or by establishing an additional exception to the physician order requirement.