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January 17, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Via E-Mail: Scope of Practice

RE: PATIENTS OVER PAPERWORK: REQUEST FOR RELEVANT INFORMATION TO ADDRESS SCOPE OF PRACTICE/RESTRICTIVE LIMITATIONS ON PRACTICE FOR NON-PHYSICIANS UNDER MEDICARE

Dear Ms. Verma,

The Academy of Doctors of Audiology (ADA), a recognized leader in the advancement of evidence-based clinical practices in the delivery of audiologic and vestibular services, applauds President Donald J. Trump for his commitment to "eliminate regulations that create inefficiencies or otherwise undermine patient outcomes," as outlined in **Executive Order #13890 on Protecting and Improving Medicare for Our Nation's Seniors**, issued on October 3, 2019.

ADA appreciates the opportunity to provide information to advance the Administration's innovative *Patients over Paperwork* initiative through the Centers for Medicare & Medicaid Services (CMS), which seeks to eliminate regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license.

Archaic Medicare regulations impede access to timely hearing and balance health care services for millions of Medicare Part B beneficiaries, create unnecessary office visits and Medicare expenditures, and prevent audiologists from performing the safe, effective diagnostic testing services that they are specifically trained and licensed to provide in all 50 states and U.S. territories for patients of all ages.

Of particular concern is the baseless requirement, exclusive to Medicare Part B beneficiaries, that mandates them to obtain a physician order before seeing an audiologist for medically-necessary diagnostic testing, as a requirement for coverage. By contrast, private insurers, including most Medicare Advantage plans, allow and encourage patients to go directly to audiologists for the provision of covered services. Other federal programs, including the U.S. Department of Veterans Affairs and the Federal Employees Health Benefit Plan, also allow patients to seek diagnostic services directly from audiologists, without the need for a physician order.

Hearing loss is the third most common chronic disorder among adults over 65 years of age, and when left untreated is highly correlated with increased falls risk, cognitive decline, depression, and social isolation.[1,2] Eliminating the physician order requirement will simultaneously improve system efficiencies and reduce delays in treatment that can cause patient harm and reduce quality of life. Audiologists are responsible for determining medical necessity under Medicare, independent of receipt of a physician order for services. Thus, elimination of the physician order requirement for Medicare Part B beneficiaries with suspected hearing or balance problems, will definitively decrease physician office visit claims related to the process of obtaining the order, without any expectation that this action will lead to increased occurrences of improper billing or overutilization of diagnostic audiology services. On the contrary--evidence suggests that when Medicare recipients have direct access to all qualified providers, they choose the most efficient pathway to treatment.[3]

The Administration has already signaled its support for patient choice regarding hearing health decisions as a means of reducing costs and unwarranted delays in treatment. President Trump signed the Over the Counter Hearing Aid Act into law in August 2017, upholding permanently the 2016 decision by the U.S. Food & Drug Administration (FDA) to immediately cease enforcement of regulations requiring adults to receive a medical evaluation or sign a waiver prior to purchasing a hearing aid citing that the regulations offered little to no clinical benefit. The FDA further stated that the medical clearance requirement was eliminated "without prior public comment" because it was a "less burdensome policy that is consistent with public health."[4] The ADA wholeheartedly agreed and issued statements of support for the FDA action and the subsequent enactment of the Over the Counter Hearing Aid Act.[5,6]

Both Congress and the Administration concluded that mandating a physician examination for adult consumers prior to the purchase of a hearing aid is counterproductive. By extension, there is no clinical or administrative justification for requiring Medicare Part B beneficiaries to obtain a physician order as a coverage requirement in order to seek diagnostic services from a licensed audiologist. Audiologists are clinical doctoring professionals, specifically trained to evaluate and treat hearing and balance disorders, and to identify potential medical conditions, and refer patients appropriately when needed. In fact, audiologists are entrusted and instructed to do so by licensure, by evidence-based practice delivery models, and under virtually every other payer construct, except for Medicare Part B.

The Administration has the authority to correct this outdated paradigm and further its mission to enhance patient choice and access to hearing health care. A 2016 legal opinion by former CMS general counsel, Sheree Kanner, Esq., of Hogan Lovells (enclosed), concluded that the simplest way for CMS to make this much-needed policy change is "for CMS to change its manuals to make clear that audiologists are nonphysician providers for the purposes of ordering diagnostic tests."

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[1] Lin FR, Ferrucci L. Hearing Loss and Falls Among Older Adults in the United States. Archives of internal medicine. 2012;172(4):369-371. doi:10.1001/archinternmed.2011.728.

[2] Iwasaki S, Yamasoba T. Dizziness and Imbalance in the Elderly: Age-related Decline in the Vestibular System. Aging and Disease. 2015;6(1):38-47. doi:10.14336/AD.2014.0128.

[3]Barresi, Barry Joseph, *Demand and Substitution Effects of Expanding Medicare Coverage to Optometrists*, ProQuest NYU, 1991.

[4]Press Release: FDA takes steps to improve hearing aid accessibility: **https://www.fda.gov/news-events/press-announcements/fda-takes-steps-improve-hearing-aid-accessibility.**

[5] https://www.warren.senate.gov/files/documents/2017_04_20_ADA_Support.pdf

[6] https://docs.house.gov/meetings/IF/IF14/20170502/105908/HHRG-115-IF14-20170502-SD013.pdf

Congress has also repeatedly affirmed that the Secretary of Health and Human Services (HHS) has the authority to unilaterally remove the physician order requirement that unjustly forces Medicare Part B beneficiaries to undergo an expensive, time-consuming, multi-step, and multi-stop process to obtain hearing and balance care from a limited number of legacy providers.

A bi-partisan letter from members of the United States House of Representatives and the United States Senate, submitted in April 2019 (enclosed), requested that HHS/CMS take action to update its policies to reflect today's best practices in the delivery of quality hearing and balance services and documenting the need and rationale for removing the physician order requirement to improve patient access and outcomes.

Congress further cemented its position that the Secretary of HHS has the authority to remove the physician order requirement by referencing it specifically in H.R. 4618, The Medicare Hearing Aid Act, which was later added as an amendment to H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act, and passed the U.S. House of Representatives in December 2019. H.R. 4618 Section 4 (report provision) of the legislation specifically states, *"The Secretary of Health and Human Services may promulgate regulations to allow audiologists to furnish audiology services without a referral from a physician or practitioner, consistent with findings submitted to the Secretary pursuant to subsection (a)(2)."*[7]

ADA commends CMS for seeking opportunities to eliminate Medicare regulations that are more restrictive than state laws. As such, ADA respectfully recommends that CMS prioritize the elimination of the physician order requirement for Medicare Part B beneficiaries who have a suspected hearing or balance disorder, thereby allowing them the same direct access to audiologists as the rest of America and thus allowing audiologists to deliver Medicare-covered diagnostic services consistent with their state-defined scope of practice. Please contact Stephanie Czuhajewski at sczuhajewski@audiologist.org for additional information.

Thank you for your thoughtful consideration of this request.

Respectfully,

Debbie Abel, Au.D., President

Enclosure: Legal opinion, Medicare Coverage of Diagnostic Audiology Services, Sheree Kanner, Esq., Hogan Lovells, dated October 14, 2016.

Enclosure: Letter to Seema Verma, Administrator of CMS from members of Congress, requesting regulatory changes to allow streamlined access to audiology services for Medicare beneficiaries, dated April 23, 2019.

cc: U.S. Senator Rand Paul
U.S. Senator Elizabeth Warren
U.S. Representative Tom Rice

[7] https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/AINS%20TO%20HR%204618.pdf

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.

Congress of the United States

Washington, DC 20510

April 23, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

We write today to urge you to allow streamlined access to audiology services for Medicare Part B beneficiaries.

Access to hearing health services is an integral part of overall health care. An estimated 48 million Americans experience age-related hearing loss, including two-thirds of adults in their seventies.[1] According to the Centers for Disease Control and Prevention, hearing loss is now the third most commonly-reported chronic health condition in the country.[2] Though hearing loss is common, access to hearing health services is not. A minority of Americans in their seventies have had a recent hearing test and only about 14 percent of people with hearing loss use assistive hearing technologies.[3] A recent report by the National Academies of Science, Engineering, and Medicine concluded that hearing health care is "often expensive and underutilized by many of the people who need it."[4]

The Social Security Act defines "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 (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician."[5] These services, which include comprehensive hearing tests and evaluation of hearing, tinnitus, or balance disorders, are covered by Medicare because they are considered diagnostic tests under section 1861(s) of the Social Security Act.[6]

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[1] Frank R. Lin, John K. Niparko, and Luigi Ferrucci. 2011. "Hearing Loss Prevalence in the United States," *Archives of Internal Medicine* 171: 1851-1853 (online at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/).

[2] Centers for Disease Control and Prevention, "New Vital Signs Study Finds Noise-Related Hearing Loss Not Limited to Work Exposure" Press Release (February 7, 2017) (online at: https://www.cdc.gov/media/releases/2017/p0207-hearing-loss.html).

[3] National Academies of Sciences, Engineering, and Medicine. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p. 79, 183.

[4] National Academies of Science, Engineering and Medicine, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p.75.

[5] Section 1861(ll)(3) of the Social Security Act

[6] Section 1861(s)(3) of the Social Security Act authorizes Medicare coverage of diagnostic tests. For treatment of audiology services as diagnostic tests, see Chapter 15 – Covered Medical and Other Health Services, Medicare Benefit Policy Manual, February 2, 2018, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Some types of audiology services are not covered by Medicare. Specifically, "hearing aids or examinations therefor" are excluded from Medicare coverage by Section 1862(a)(7) of the Social Security Act.

Unfortunately, although Medicare covers a range of hearing health services, outdated regulations prevent many Medicare beneficiaries from actually accessing these services. Medicare is an outlier among most federal and private insurance providers in requiring a physician order for coverage of audiology services provided by a qualified audiologist. The Department of Defense, the Veterans Health Administration, and a majority of plans offered through the Federal Employees Health Benefit system allow direct access to covered audiology services without a physician referral.[7] Many private insurance plans and Medicare Advantage plans similarly allow direct access.

In 2006, Congress asked the Centers for Medicare and Medicaid Services (CMS) to provide a "determination as to the legal authority to permit direct access to licensed audiologists under similar terms and conditions used by the Department of Veterans Affairs and the Office of Personnel Management."[8] CMS's conclusion that it did not have clear legal authority to allow direct access was based on Medicare regulations adopted in 1996, which require all diagnostic tests to be ordered by a treating physician in order to be eligible for reimbursement.[9] Yet these regulations also specify that nonphysician practitioners may be treated as physicians for the purposes of ordering diagnostic tests if they are acting within the scope of their authority within State law.[10] Although audiologists are not specifically listed nonphysician practitioners in the part of Medicare regulations dealing with the ordering of diagnostic tests, they are listed as nonphysician practitioners in other parts of the Medicare rules.[11]

Furthermore, it is clear that CMS's refusal to allow Medicare beneficiaries direct access to audiologists is a policy choice, not a requirement under the Medicare statute. No statutory language prohibits Medicare from allowing direct access to audiologists. The 1996 regulations that put in place the requirement for a physician order for diagnostic tests refer only to the statutory prohibition in the Social Security Act against Medicare paying for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[12] However, this language is simply a broad prohibition against paying for unnecessary services and in no way explicitly mandates a physician referral requirement for audiology services.[13]

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[7] National Academies of Sciences, Engineering, and Medicine. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p. 128.

[8] H. Rept. 109-337, Making Appropriations for the Departments of Labor, Health and Human Services, and Education, and Related Agencies for the Fiscal Year Ending September 30, 2006, and for Other Purposes, https://www.congress.gov/congressional-report/109th-congress/house-report/337/1.

[9] 42 CFR 410.32; Centers for Medicare and Medicaid Services, "Report to Congress: Direct Access to Licensed Audiologist Under the Fee for Service Medicare Program," 2007, https://www.audiology.org/sites/default/files/advocacy_files/CMSDirectAccessReporttoCongress2.pdf.

[10] 42 CFR 410.32

[11] For instance, the part of the Medicare regulations laying out screening levels for Medicare providers at 42 CFR 424.518 defines nonphysician practitioners as a group "including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists."

[12] Section 1862(a)(1)(A) of the Social Security Act

[13] Memorandum from Sheree Kanner, Hogan Lovells, to Academy of Doctors of Audiology, "Medicare Coverage of Diagnostic Audiology Services," October 14, 2016.

Medicare's requirement for physician order for audiology services creates an unnecessary barrier that prevents patients from accessing important hearing health services. Research suggests that the convenience of accessing hearing health care, appointment wait times, and the distance to services are key factors that can affect patient utilization of hearing health care and the choice of a hearing intervention.[14] Allowing Medicare beneficiaries direct access to audiologists in their community could reduce the number of appointments and referrals needed before a patient receives needed health care, speed access to care, and could also offer beneficiaries more choices of local hearing health providers.

Eliminating the requirement for a physician order for audiology services would improve access to hearing health care without compromising the health and safety of Medicare beneficiaries. Opponents of audiology direct access for Medicare beneficiaries argue that "bypassing a physician evaluation and referral can lead to misdiagnosis and inappropriate treatment."[15] However, the prevalence of ear disorders in the Medicare beneficiary population is low; a 2010 analysis published in the *Journal of the American Academy of Audiology* concluded that "under the most conservative assumptions, greater than 89% of Medicare beneficiaries complaining of hearing loss would not be expected to have active otologic disease or medically treatable conditions affecting hearing."[16]

Moreover, evidence indicates that audiologists appropriately evaluate and treat older adults, including making appropriate decisions about whether to refer a patient to a medical doctor when necessary. The same 2010 study, which reviewed records of Medicare-eligible patients complaining of a hearing impairment to compare assessment and treatment plans developed by audiologists and otolaryngologists, found that audiology treatment plans "were not substantially different from otolaryngologist plans for the same condition," that "there was no definitive evidence that audiologists were likely to miss significant symptoms of otologic disease," and that "there was strong evidence that audiologists referred to otolaryngology when appropriate." The study authors concluded that "direct access for patients complaining of hearing problems would not pose a risk to Medicare beneficiaries."[17]

The Food and Drug Administration (FDA) reached similar conclusions in December 2016 when it eliminated the requirement – originally enacted out of concern that individuals with undetected medical conditions would bypass needed health care – that individuals receive a medical evaluation or sign a waiver before purchasing hearing aids. In taking this step, the FDA cited a report by the National Academies of Sciences, Engineering, and Medicine that concluded that after "weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver,"

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[14] Margaret Barnett et al., "Factors Involved in Access and Utilization of Adult Hearing Healthcare: A Systematic Review," *Laryngoscope*, May 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5322257/. Ariane Laplante-Leveseque et al., "Factors Influencing Rehabilitation Decisions of Adults with Acquired Hearing Impairment," International Journal of Audiology, 2010, https://www.ncbi.nlm.nih.gov/pubmed/20528667.

[15] Letter from James C. Denny III, Executive Vice President and CEO, American Academy of Otolaryngology-Head and Neck Surgery and Theodore P. Mason, President, Massachusetts Association of Otolaryngology to Senator Elizabeth Warren, March 28, 2018.

[16] David A. Zapala et al., "Safety of Audiology Direct Access for Medicare Patients Complaining of Impaired Hearing," *Journal of the American Academy of Audiology*, 2010, https://www.ncbi.nlm.nih.gov/pubmed/20701834.

[17] David A. Zapala et al., "Safety of Audiology Direct Access for Medicare Patients Complaining of Impaired Hearing," *Journal of the American Academy of Audiology*, 2010, https://www.ncbi.nlm.nih.gov/pubmed/20701834.

there was "no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit."[18]

Finally, there is little indication that increased access to hearing health services already covered by Medicare would substantially increase Medicare costs. Since 2008, CMS has assigned audiologists responsibility for determining the medical necessity of diagnostic testing for Medicare beneficiaries, meaning audiologists are already charged with preventing improper utilization of covered Medicare services.[19] Analyses have also repeatedly estimated Medicare cost savings from the implementation of direct access to audiology services.[20] The most recent analysis estimated that Medicare could save more than $173 million over a decade by eliminating unnecessary and duplicative services if Medicare beneficiaries had direct access to audiologists.[21] The authors suggested that direct access could save as much as $240 million over ten years if access to audiologists prevented medical costs in beneficiaries who currently go untreated for hearing loss, dizziness, and vestibular conditions – even accounting for a potential 30% increase in utilization of audiology services covered by Medicare.

CMS has the authority to allow Medicare beneficiaries streamlined access to audiology services by updating the Medicare policy manual or pursuing regulatory changes. Evidence indicates that this change would improve access to critical hearing health care services, would not pose increased risk to Medicare beneficiaries, and could result in cost savings to the Medicare program.

We urge CMS to take action to improve hearing health for seniors and people with disabilities covered by the Medicare program. Please contact Julia Frederick in the office of Senator Elizabeth Warren, Agnes Rigg in the office of Senator Paul, or Walker Truluck in the office of Congressman Tom Rice with any questions related to this letter.

Sincerely,

Elizabeth Warren
United States Senator

Rand Paul
United States Senator

Tom Rice
Member of Congress

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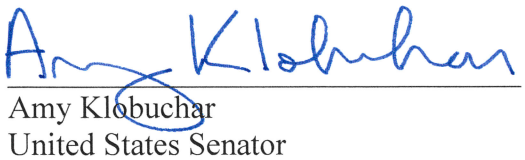
[18] Food and Drug Administration, "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids Guidance for Industry and Food and Drug Administration Staff, December 12, 2016, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995.pdf; National Academies of Sciences, Engineering, and Medicine. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p. 103.

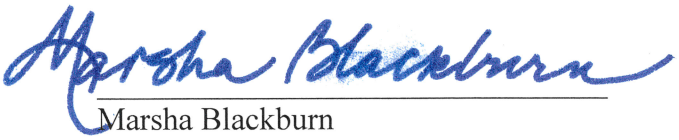
[19] Centers for Medicare and Medicaid Services, "Pub 100-02 Medicare Benefit Policy," February 29, 2008, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R84BP.pdf.

[20] Gene Bratt et al., "The Audiologist as an Entry Point to Healthcare: Models and Perspectives," *Seminars in Hearing*, 1996. Barry A. Freeman and Brandon S. Lichtman, "Audiology Direct Access: A Cost Savings Analysis," *Audiology Today*, 2005, https://www.audiology.org/sites/default/files/advocacy_files/freeman_lichtman.pdf.

[21] Dobson DaVanzo and Associates, "Determining Potential Medicare Savings by Streamlining Beneficiary Access to Audiology Services," 2012, https://www.audiology.org/sites/default/files/documents/DobsonDAFinalReport.pdf.



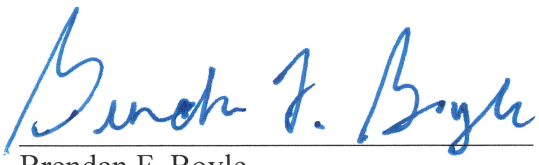
Amy Klobuchar
United States Senator



Marsha Blackburn
United States Senator

Mark Meadows
Member of Congress

Jamie Raskin
Member of Congress



Brendan F. Boyle
Member of Congress

Ralph Norman
Member of Congress