

December 22, 2020

Alex Azar, Jr., J.D. Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

RE: Regulatory Relief to Support Economic Recovery; Reguest for Information (RFI)

Dear Secretary Azar:

On behalf of the American Speech-Language-Hearing Association, I write to respond to the request for information on regulatory relief to support economic recovery.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 211,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

ASHA appreciates the significant effort that the U.S. Department of Health and Human Services (HHS) has made in response to the federally declared public health emergency (PHE) due to the Coronavirus Disease 2019 (COVID-19). However, ASHA believes there is more HHS may do to protect access to health care services. ASHA's responses to your questions are below.

- 1. Of the regulatory changes that have been made by the HHS in response to the COVID-19 PHE and the pandemic, please identify which changes:
 - a. Have been beneficial to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems, and under what circumstances?

HHS and the Centers for Medicare & Medicaid Services (CMS) developed a variety of regulatory flexibilities within their statutory authority, which included identifying ways to provide virtual services as though they were delivered in person, such as the hospital without walls initiative. ASHA recognizes that initially CMS required additional authorization from Congress before it could implement a robust telehealth policy. ASHA thanks HHS and CMS for using the authority it was ultimately granted under Section 3703 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) to allow audiologists and speech-language pathologists (SLPs) to be reimbursed for select telehealth services during the PHE. This action has been beneficial to both health care providers and patients using audiologists and SLPs. However, the action has not been as beneficial as it could be due to the limited number of telehealth services that CMS allows audiologists and SLPs to bill for.¹ ASHA recommends that CMS include additional services provided by audiologists and SLPs to the authorized telehealth services list to ensure Medicare beneficiaries maintain access to health care services during the pandemic, consistent with congressional intent.²

ASHA disagrees with CMS's decision to preclude telehealth coverage for services such as evaluation and modification of speech-generating devices that private insurers regularly cover

for their beneficiaries. CMS's inaction continues to place Medicare beneficiaries and ASHA members at unnecessary and unacceptable risk of transmitting COVID-19. Medicare beneficiaries with conditions such as Parkinson's disease, traumatic brain injury, and ALS put themselves and their families at risk when seeking face-to-face treatment needed to maintain their ability to communicate medical and personal needs. ASHA urges CMS to act swiftly to expand telehealth coverage to all clinically appropriate services with a specific emphasis on speech-generating services and devices and cognitive evaluation and treatment.³ Beneficiaries and Medicare providers must not be forced to choose between safety and medically necessary care when there is a safe and effective solution available.

Several of the other helpful flexibilities that CMS implemented through rulemaking during the PHE are found in the "Actions" Table of the RFI and include:

- Action 111, which allows SLPs to be reimbursed for communication technology-based services (CTBS). ASHA appreciates that CMS made this ability permanent in the 2021 Medicare Physician Fee Schedule Final Rule. However, ASHA recommends that CMS allow audiologists to be reimbursed for these services as well.
- Action 113, which allows SLPs to bill for telephone evaluation and management services. Unlike several other categories of CTBS, CMS did not extend the ability for SLPs to bill for these services on a permanent basis. ASHA recommends that CMS permanently authorize both audiologists and SLPs to be reimbursed for these services.
- Action 115, which allows the use of telecommunications technology under the Medicare
 Home Health Benefit. Unfortunately, limitations of federal law preclude payment for
 these telehealth services under the home health benefit even during the pandemic.
 Although this flexibility maintained access to care, it did not recognize the cost to home
 health agencies for providing these services. CMS made this authority permanent in the
 2021 Home Health Prospective Payment System Final Rule but for telehealth services to
 be effectively used in this setting, Congress must change the law to allow for
 reimbursement of these services.
- Action 149, which allows CMS to update the authorized telehealth services list through a
 subregulatory process as opposed to formal rulemaking. While ASHA has advocated for
 this list to be expanded, the use of a subregulatory process allows for quicker action
 than formal rulemaking, which is critical during the PHE.
- Action 189, which allows for the use of audio-only technology during the PHE. By temporarily waiving the requirement for a video component, it allowed for timely communication between clinicians and their patients to address immediate health care needs.
- Action 211, which allows clinicians to provide remote evaluations, virtual check-ins, and
 e-visits to both new and established patients. Outside of the PHE, these services can
 only be provided to established patients. The ability to provide these services to new
 patients allows for timely access to health care services for Medicare beneficiaries.
- Action 215, which expands the categories of clinicians authorized as distant site
 providers for telehealth services to include all those eligible to bill Medicare for their
 professional services. This action allows audiologists and SLPs to maintain their
 practices so Medicare beneficiaries can have access to health care services. ASHA
 recognizes that in order for this authority to be permanent, Congress must change the
 law.
- Action 281, which allows Medicare Advantage plans to provide enrollees access to Medicare Part B services in any geographic area and from a variety of places, including

the patient's home. This enhances the availability of health care services in a manner that helps prevent the transmission of COVID-19 by enabling patients to access services virtually rather than in person.

Reimbursement for telehealth services during the PHE and beyond is critical to ensure continued access to health care services while allowing clinicians to remain in business while slowing the transmission of COVID-19. However, CMS has failed to exercise its full authority as conferred by Congress and has limited telehealth reimbursement to audiologists and SLPs to a narrow subset of Current Procedural Terminology (CPT®) codes typically billed to reflect their services. This narrow action is in stark contrast to the actions taken by many states, private payers, and State Medicaid Agencies, many of which have given broader authorization for telehealth services when provided by audiologists and SLPs.

The limitation of CPT codes allowed has had a negative impact on our nation's seniors and individuals with disabilities who need timely access to audiologists providing evaluation services to prevent isolation and depression due to hearing loss or to identify balance issues that could lead to falls and serious injuries. Limiting reimbursement for speech-language pathology telehealth services places patients at risk of unidentified swallowing disorders that could lead to aspiration pneumonia. ASHA has provided detailed evidence and clinical vignettes demonstrating the efficacy and effectiveness of audiology and speech-language pathology telehealth services on numerous occasions but, to date, CMS has not acted on this information.

Therefore, ASHA recommends that CMS expand upon its existing efforts to develop telehealth regulatory flexibilities to include a more comprehensive list of CPT codes for services provided by audiologists and SLPs during the PHE. And, at such time when Congress modifies section 1834(m) of the Social Security Act, ASHA recommends that CMS include audiologists and SLPs as authorized telehealth providers.

b. Have been detrimental to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems, and under what circumstances?

ASHA is gravely concerned by CMS's decision not to approve new CPT code 99072 for separate payment to help defray the cost of additional personal protective equipment (PPE), cleaning supplies, and clinician or clinical staff time needed to safely provide in-person services during the PHE. Although CMS recognizes the increased market-based pricing associated with certain PPE supply items—namely surgical masks, N95 masks, and face shields—this provides little relief to financially struggling audiologists and SLPs because the CPT codes they commonly report do not include these items in their practice expense component.

Access to appropriate PPE is especially critical for audiologists and SLPs due to their limited ability to provide Medicare telehealth services to the full extent of their scope of practice and benefit category. As such, ASHA strongly urges CMS to approve CPT code 99072 for separate payment; thereby, allowing clinicians and practices a small measure of financial relief and supporting their efforts to protect themselves, their staff, and the patients they serve.

- 2. Of the regulatory changes that have been made by the Department of Health and Human Services in response to the COVID–19 PHE and the pandemic, please identify which changes:
 - b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent

ASHA recognizes that Congress must modify Section 1834(m) of the Social Security Act to allow audiologists and SLPs to be reimbursed for telehealth services after the PHE ends. ASHA supports bipartisan legislation, the Expanded Telehealth Access Act (H.R. 8755), which would provide permanent telehealth authority for audiologists and SLPs under Medicare. Given the benefit to patients of improved access to services, especially in rural and medically underserved areas, ASHA maintains that audiologists and SLPs should be reimbursed for telehealth services permanently and encourages HHS to work with Congress to enact this change.

In addition, the policy that would allow SLPs to provide select telehealth services incident to a physician, as finalized in the 2021 Medicare Physician Fee Schedule Final Rule, has limited practical utility. Providing these services incident to a physician would require the SLP to have established clinical and financial relationships with physicians in order to meet the supervision and claims submission requirements or to develop such relationships with limited notice based on the timing of the final rule released. Therefore, the ability for direct reimbursement for telehealth services on a permanent basis is critical to ensure timely access to services for Medicare beneficiaries.

Additional Considerations/Recommendations

Fee Schedule Reduction in 2021 to Maintain Budget Neutrality

In order to maintain the benefit of the actions CMS has taken during the PHE, the imposition of fee schedule reductions effective January 1, 2021, must be addressed. These reductions, estimated to result in an aggregate 6% and 9% reimbursement reduction for audiologists and SLPs respectively, result from budget neutrality requirements related to payment increases for outpatient evaluation and management services largely provided by primary care and other office-based physicians. ASHA questions whether imposing such significant payment reductions can be justified at this time while the nation's health care system battles an ongoing and worsening global pandemic. Audiologists, SLPs, and other Medicare providers already face significant financial losses due to the pandemic. To compound these losses with payment reductions threatens their ability to maintain their businesses and jeopardizes beneficiary access to care. CMS must delay implementation of these reductions or implement other strategies, such as a phase-in of the reductions over several years, to mitigate the negative impact these reductions will have on Medicare providers, beneficiaries, our health system as a whole and the U.S. economy.

Direct Access to Audiology Services

Currently, Medicare beneficiaries, under 42 CFR 410.32, must first obtain a physician order to see an audiologist for coverage of diagnostic hearing and balance tests. A physician order is not required under any state or District of Columbia audiology licensure law prior to an individual being allowed access to the care of an audiologist. The Department of Defense, the Veterans Health Administration (VHA), and a majority of plans offered through the Federal Employees Health Benefit Program allow direct access to covered audiology services without a physician referral.⁴ In addition, most private insurance plans and Medicare Advantage plans allow direct access. The VHA implemented its audiology direct access policy in 1992. In a letter from then VHA Acting Deputy Under Secretary for Health Michael Kussman, MD to Senator Charles Grassley in 2004, he states that the VA direct access policy "provides high-quality, efficient and cost-effective hearing care." Dr. Kussman goes on to state that requiring all veterans with hearing loss complaints to see ENT physicians would result in unnecessary medical care, inefficient use of VA resources, and longer wait times for veterans who need the specialized

care of ENT physicians. "The [direct access] policy is cost-effective because an unnecessary clinic visit is avoided." In addition, Dr. Kussman states that "the VA has not experienced patient complaints or problems as a result of the direct access policy." ⁵

There is no statutory language that prohibits Medicare from allowing direct beneficiary access to audiologists' services. The retention of this requirement—generally cited as a policy provision requiring a physician order for a diagnostic test—was designed solely to limit payment for possible unnecessary services. As audiologists are already responsible for determining medical necessity, allowing Medicare beneficiaries to apply coverage when seeking direct access to audiologists' services would reduce unnecessary physician visits and improve beneficiary access to services, perhaps staving off the harmful downstream effects of untreated hearing loss such as falls and expedited cognitive decline. Direct access would not expand the scope of practice of audiology nor diminish the important role played by physicians and other primary care providers.

Audiologists could also be added to the list of certain nonphysician providers currently able to administer diagnostic tests without a physician order under 42 CFR 410.32(a)(2)(2016). HHS could also effect this change by amending the requisite Medicare manuals clarifying that audiologists are included in the list of nonphysician providers under 42 CFR 410.32(a)(2)(2016).

Therefore, ASHA recommends that CMS eliminate the physician order requirement for audiology services.

Certification and Recertification of the Therapy Plan of Care (Medicare Benefit Policy Manual, Chapter 15, Section 220.1.3)

Currently, Medicare requires a physician involved in the patient's care to certify the SLP developed plan of care within 30 days of its development and recertify the plan periodically as necessary. The same certification and recertification requirements apply to physical therapists and occupational therapists. While a plan of care is important for the purposes of care planning and documentation, certification is unnecessary. ASHA strongly encourages CMS to eliminate this burdensome requirement.

The certification/recertification requirement does not add value or improve the quality of care for Medicare beneficiaries. Rather, it is a "check the box" requirement that adds an administrative burden on SLPs and physicians. If SLPs cannot get the plan of care signed, the payment consequence is applied to them instead of the physicians who must often be reminded to provide certification. The certification requirement also fails to recognize the clinical graduate education and expertise of the SLP. In practice, the SLP develops the plan of care independently and the physician rarely modifies or even thoroughly reviews the plan. CMS does not require a physician order and no state licensure laws specifically require a physician order for speech-language pathology services. Further, SLPs complete an accredited master's program and are licensed in every state. Finally, ASHA's Certificate of Clinical Competence (CCC) demonstrates that the SLP has voluntarily met rigorous academic and professional standards that often go beyond the minimum requirements for state licensure.

For these reasons, ASHA requests the elimination of the certification requirement for therapy plans of care and instead recommends that CMS replace certification with a requirement that the treating physician receive a copy of the plan of care to enhance effective interdisciplinary practice and care coordination.

December 22, 2020 Page 6

Thank you for your consideration of our recommendations. If you or your staff have any questions, please contact Sarah Warren, ASHA's director for health care policy for Medicare, at swarren@asha.org.

Sincerely,

Theresa H. Rodgers, MA, CCC-SLF

2020 ASHA President

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¹ Centers for Medicare & Medicaid Services. (2020). *CMS-1744-IFC. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.* https://www.cms.gov/files/document/covid-final-ifc.pdf.

² U.S. House of Representatives. (2020). *Letter to CMS Administrator Seema Verma*. https://axne.house.gov/sites/axne.house.gov/files/10092020%20Axne-Fitzpatrick%20Audiology%20and%20SLP%20Letter%20to%20CMS.pdf

³ American Speech-Language-Hearing Association. (2020). ASHA Comments Regarding CMS-5531-IFC (Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program). https://www.asha.org/siteassets/uploadedfiles/asha-comments-cms-covid-ifr2-060320.pdf.

⁴ The National Academies of Sciences, Engineering, and Medicine. (2016). *Hearing Health Care for Adults*. http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx.

⁵ https://www.audiology.org/sites/default/files/advocacy_files/DeptofVeteranAffairs.pdf