July 15, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5535-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5535-P)

Dear Administrator Brooks-LaSure:

On behalf of the American Speech-Language-Hearing Association (ASHA), I am writing to offer comments on the proposed rule related to the updates of the alternative payment model (APM) and the Increasing Organ Transplant Access (IOTA) model.

ASHA is the national professional, scientific, and credentialing association for 234,000 members certificate holders, and affiliates who are audiologists; speech-language pathologists (SLPs); speech, language, and hearing scientists; audiology and speech-language pathology assistants; and students.

The Role of Nonphysicians in Value-Based Care Models

ASHA appreciates the ongoing efforts to clarify the roles of nonphysician qualified health care providers in APMs and ensure they can fully participate as the Centers for Medicare & Medicaid Services (CMS) transitions from fee-for-service to value-based payment arrangements.

ASHA supports the quadruple aim of enhancing patient experience, improving population health, reducing costs, and improving the clinician experience. Audiologists and SLPs are uniquely positioned to provide upstream interventions in the areas of hearing, balance, speech, language, cognition, and swallowing that will increase functional independence and decrease downstream costs.

Audiologists are integral members of clinical teams involved in episodes relating to dementia, craniofacial surgery, cytomegalovirus, acquired brain injury, hearing loss, and vertigo, among others. SLPs are members of interprofessional collaborative teams addressing a variety of illnesses and injuries including, but not limited to, acquired brain injury, aerodigestive disorders, head and neck cancer, dementia, craniofacial disorders, and developmental disabilities. Any of these conditions require the knowledge and skills from a range of health care providers for effective management.

Audiologists and SLPs participate, on a limited basis, in quality reporting programs such as the Medicare Merit-based Incentive Payment System (MIPS) and some private value-based care initiatives. However, nonphysician qualified health care providers have had a limited opportunity to meaningfully participate in APMs and other value-based care initiatives to date, and audiologists and SLPs are rarely included in these models. For example, MIPS and APMs currently utilize broad outcome measures (e.g., smoking cessation, BMI) for nonphysician clinicians. In addition, as currently structured, many of the approved APMs and the MIPS Value

Pathways (MVPs) are physician-driven and focused on the entire episode of care. The quality measures often do not capture the services of nonphysicians such as audiologists and SLPs. Therefore, there is no incentive for physicians to incorporate these specialties into the model.

Audiologists and SLPs are not responsible for managing the full range of medical services a patient may need but could rightly be held accountable for the cost of care associated with the types of interventions they provide as a member of a multidisciplinary team participating in an APM. ASHA is committed to moving beyond the use of broad quality measures that do not reflect critical health care services provided by audiologists and SLPs. We are eager to explore, refine, and develop models that create opportunities for nonphysician clinicians to fully participate in the transition from fee-for-service to value-based care. Therefore, we urge regulators to develop models that capture the quality and cost associated with nonphysician services to ensure APMs are achieving their goal of improving the quality of care patients receive while protecting the fiscal health of Medicare.

As models grow to include all health care settings, ASHA encourages Congress, CMS, and the Center for Medicare and Medicaid Innovation (CMMI) to adopt outcome measures that take into account functional domains pertinent to the services provided by audiologists and SLPs, including hearing, communication, balance, swallowing, and cognition. We remain committed to assisting CMS and CMMI in accurately assessing all domains of function to accurately capture patient outcomes, quality of life, and independence.

Outcome measures should include functional measures that are influenced by nonphysician clinicians to avoid a disincentive for physicians referring patients for essential services, including those provided by audiologists and SLPs. If value-based payment models are designed to measure and reward only for the services provided by physicians—while failing to reflect the essential role of nonphysician clinicians on the care team—such models run the risk of underutilizing critical nonphysician services to the detriment of patient health outcomes, quality of life, and overall cost of care to the health system.

General Provisions Related to Innovation Center Models

ASHA generally supports the proposal to expand the applicability of the "General Provisions Related to Innovation Center Models" (42 CFR part 512 subpart A) to all Innovation Center models whose initial performance periods begin on or after January 1, 2025, unless otherwise specified in the models' governing documentation. This support also applies to any Innovation Center models whose initial performance periods begin before January 1, 2025, if referenced in the models' governing documentation. It's important to ASHA that these proposed standard provisions would not affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service. Standardization of provisions across models will decrease administrative burden for providers and simplify understanding of complex models.

IOTA Collaborators

ASHA appreciates the clarity and safeguards around financial arrangements with providers and suppliers making contributions to the IOTA participant's performance across the achievement domain, efficiency domain, and quality domain that would allow the IOTA participants to share monies earned from the upside and downside risk payments.

ASHA applauds CMS' acknowledgement that many providers and suppliers, other than the IOTA participants, furnish related services to attributed patients during a model performance period. We agree that, for purposes of the anti-kickback statute safe harbor for CMS-sponsored model

arrangements (42 CFR part 1001.952(ii)), it is essential to include the proposed settings and provider types that capture speech-language pathology services as IOTA collaborators:

- ESRD facility
- Skilled nursing facility (SNF)
- Home health agency (HHA)
- Long-term care hospital (LTCH)
- Inpatient rehabilitation facility (IRF)
- Nonphysician practitioner
- Therapist in a private practice
- Comprehensive outpatient rehabilitation facility (CORF)
- Provider or supplier of outpatient therapy services
- Physician group practice (PGP)
- Hospital
- Critical access hospital (CAH)
- Nonphysician provider group practice (NPPGP)
- Therapy group practice (TGP).

However, ASHA strongly recommends including audiologists, in addition to therapists, in the list of IOTA collaborators. Audiologists are professionals qualified in the education, prevention, identification, diagnosis, and treatment of hearing loss and balance disorders. As such, participating in CMS quality initiatives is important to demonstrate the quality care provided by audiologists to Medicare beneficiaries. For example, individuals with chronic kidney disease (CKD) on hemodialysis, those who receive kidney transplants, and those with mild CKD are all at an increased risk for hearing loss.[1]

While audiologists are trained and licensed to provide both assessment and treatment for hearing and balance disorders, the current Medicare regulatory definition places audiologists in the “Other Diagnostic Procedures” benefit classification (Section 1861(s)(3) of the Social Security Act[2]), which is limited to the exclusive diagnostic-only areas of hearing and balance health care. Unlike other allied health professionals, audiologists are not designated as practitioners under Medicare regulations. Developing measures of quality and outcomes for this narrowly defined benefit classification, as well as participating in interdisciplinary measures that require outcomes or treatment management of the patient, is challenging within these current restrictive regulatory confines. ASHA-supported legislation—the Medicare Audiology Access Improvement Act (H.R. 6445/S. 2377)—has been introduced that would rectify this problem, which we urge Congress to pass as soon as possible.

The term “IOTA collaborator,” used to refer to providers and suppliers, indicates that such individuals and practices are not full participants in the model and are, therefore, dependent upon full participants to gain access to risk-based financial incentives. While we appreciate the clarity about how nonphysician qualified health providers could be paid in APMs, ASHA is concerned that sharing arrangements are optional and are left to the discretion of the full model participants. ASHA encourages adopting a payment system that affords nonphysician qualified health providers the option to fully participate in value-based payment models or a guarantee that they may participate as collaborators in such models.

ASHA is in favor of strong sharing-arrangement protections (i.e., must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between IOTA participants and IOTA collaborators do not negatively impact beneficiary protections under the model) that ensure services—such as audiology and speech-language pathology—that improve quality of care and ensure a patient's quality of life are not reduced or eliminated in an effort to cut costs.

ASHA encourages CMS to consider measures that capture important aspects of quality of life, including communication, swallowing, cognition, hearing, balance, and functional independence. Options include:

- Quality of Communication Life Scale (ASHA QCL)[3]
- International Outcome Inventory for Hearing Aids (IOI-HA)[4]
- Quality of Life in People with Hearing Loss Questionnaire (HL-QoL)[5]

Finally, ASHA wishes to ensure that collaborators are held responsible only for that which they can reasonably impact through their services and are not held responsible for the outcomes and cost of the entire episode of care over which they have minimal control.

Thank you for the opportunity to comment on the APM update and IOTA model and for working to ensure all members of the multidisciplinary care team receive appropriate compensation for their clinical interventions. If you have additional questions, please contact Rebecca Bowen, ASHA's director of health care policy, value, and innovation, at rbowen@asha.org.

Sincerely,

Tena L. McNamara, AuD, CCC-A/SLP
2024 ASHA President

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[1] Greenberg, D., Rosenblum, N. D. and Tonelli, M. (2024, January 29). *The multifaceted links between hearing loss and chronic kidney disease.* Nature Reviews Nephrology. 20, 295–312 (2024). https://doi.org/10.1038/s41581-024-00808-2

[2] Social Security Administration. (n.d.). *Compilation Of The Social Security Laws, Part E—Miscellaneous Provisions.* https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

[3] Paul, D. R., Frattali, C. M., Holland, A. L., Thompson, C. K., Caperton, C. J., and Slater, S. C. (2004). *Quality of Communication Life Scale*. Rockville, MD: American Speech-Language-Hearing Association. https://apps.asha.org/eWeb/OLSDynamicPage.aspx?Webcode=olsdetails&title=Quality+of+Communication+Life+Scale+(ASHA+QCL)

[4] Cox, R.M. and Alexander, G.C. (2002). *The International Outcome Inventory for Hearing Aids (IOI-HA): psychometric properties of the English version.* Int J Audiol. 41(1):30-5. doi: 10.3109/14992020209101309. PMID: 12467367. https://pubmed.ncbi.nlm.nih.gov/12467367/

[5] Illg, A., Amann, E., Koinig, K. A., Anderson, I., Lenarz, T., and Billinger-Finke, M. (2023, June 21.) *A holistic perspective on hearing loss: first quality-of-life questionnaire (HL-QOL) for people with hearing loss based on the international classification of functioning, disability, and health.* Front. Audiol. Otol. https://doi.org/10.3389/fauot.2023.1207220