

September 9, 2024

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Attention: CMS-1807-P P.O. Box 8016 Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

On behalf of the American Speech-Language-Hearing Association (ASHA), I write in response to the physician fee schedule proposed rule for calendar year (CY) 2025.

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. Audiologists and SLPs provide critical services to patients in a variety of health care settings that bill for services under the fee schedule and have a vested interest in ensuring that the payment system reflects the value of audiology and speech-language pathology services and supports access to care for Medicare beneficiaries.

ASHA's comments focus on several key areas, including the following:

- Summary of Costs and Benefits (Section I.C.)
- Determination of Practice Expense (PE) Relative Value Units (RVUs) (Section II.B.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Social Security Act (Section II.D.)
- Valuation of Specific Codes (Section II.E.)
- Advanced Primary Care Management Services (Section II.G.)
- Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care with a Physician or NPP Order, and KX Modifier Thresholds (Section II.H.)
- Medicare Shared Savings Program (Section III.G.)
- Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care (Section III.J.)
- Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (Section III.O.)
- Updates to the Quality Payment Program (Section IV.).

Summary of Costs and Benefits (Section I.C.)

CMS estimates a conversion factor (CF) of \$32.3562 for the CY 2025, which reflects a 0.05% positive budget neutrality adjustment. Even with this slight positive adjustment, the CF represents a 2.8% decrease from the \$33.29 CF for CY 2024. We understand that this is due to the expiration of the temporary 2.93% positive adjustment that Congress implemented for 2024 and the federal requirement to maintain a budget-neutral program. **ASHA urges CMS to carefully consider all possible strategies to mitigate the impact of the cuts and to work with Congress and stakeholders on long-term reforms to bring greater stability and equity to the Medicare payment system.**

Determination of Practice Expense (PE) Relative Value Units (RVUs) (Section II.B.)

Adjusting RVUs to Match the PE Share of the Medicare Economic Index (MEI)

ASHA appreciates CMS' decision to continue postponing implementation of updated MEI weights pending the outcome of the American Medical Association's (AMA's) physician practice information survey (PPIS). A group of nonphysician qualified health care professionals are also fielding a clinician practice information survey to collect real-world data that reflects practice expenses for these professionals to share with CMS using the same methodology and contractor employed by the AMA. ASHA is part of this group and is committed to providing CMS with representative data regarding the cost of running audiology and speech-language pathology practices. We strongly believe this is an important effort to ensure Medicare Physician Fee Schedule (MPFS) payments are accurate, which ultimately maintains access to care for Medicare beneficiaries and protects the Medicare trust fund.

PE RVU Methodology: Low-Volume Service Codes

ASHA appreciates CMS' ongoing efforts to improve the stability of PE and malpractice (MP) RVUs for low-volume services. Several low-volume services provided by audiologists have been particularly susceptible to large fluctuations in PE RVUs and, as such, we have indicated our support on the proposed specialty overrides for those services in the following table.

CPT Code	Descriptor	CY 2025 Anticipated Specialty	ASHA Comment
92517	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP)	Otolaryngology	Agree
92518	ocular (oVEMP)	Otolaryngology	Agree
92519	cVEMP and oVEMP	Otolaryngology	Agree
92572	Staggered spondaic word test	Audiologist	Agree
92596	Ear protector attenuation measurements	Audiologist	Agree
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming	Audiologist	Agree
92602	subsequent reprogramming	Audiologist	Agree

CPT Code	Descriptor	CY 2025 Anticipated Specialty	ASHA Comment
92621	Evaluation of central auditory function, with report; each additional 15 minutes	Audiologist	Agree
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour	Audiologist	Agree

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section II.D.)

Requests to Add Services to the Medicare Telehealth List for CY 2025

In the proposed rule, CMS states that it will not permanently add any of the Current Procedural Terminology (CPT®) codes that currently have provisional approval to the authorized telehealth services list until it conducts a "comprehensive analysis" of these services.

ASHA is dismayed by CMS' inaction on telehealth services. The decision to delay adoption of audiology and speech-language pathology codes until completing a "comprehensive analysis" directly contradicts the process CMS established through 2024 fee schedule rulemaking, which was implemented on January 1 of this year. Rather than following the original process CMS defined in its own rulemaking, the Agency is now setting a new requirement for a "comprehensive analysis" that creates an additional, undefined, and unnecessary hurdle to coverage for clinicians and Medicare beneficiaries. This decision is particularly troublesome since CMS has not finalized a coverage policy for provisionally approved codes beyond 2024. This means that if Congress extends telehealth authority beyond 2024—either on a temporary or permanent basis—additional rulemaking may be required, unnecessarily delaying care for Medicare beneficiaries. During the early days of the pandemic, CMS took more than a year to develop the authorized telehealth services policy currently in place. **CMS must act now to maintain continuity of care for Medicare beneficiaries.**

Initially, CMS revised and codified a process by which requests for additions to the authorized telehealth services would be subject in 2024 and beyond. This process requires that interested parties—such as ASHA—submit a letter outlining the services for which they are requesting telehealth coverage along with the evidence and research that supports their inclusion. It then applies the approval criteria CMS developed to these requests. ASHA followed the process and submitted a letter outlining the necessary requirements to support the inclusion of audiology and speech-language pathology services in the authorized telehealth services list. However, it now appears that a "comprehensive analysis" is necessary to approve additions to the authorized telehealth services list.

ASHA is extremely concerned with this additional requirement for a "comprehensive analysis" that CMS has not defined what it entails nor why it is necessary. For example, would a comprehensive analysis include a review of utilization data, audit findings, or other metrics? A report by the U.S. Department of Health and Human Services Office of Inspector General found that 0.2% of telehealth claims submitted in the early part of the federal public health emergency were considered "high risk" for fraud.² This finding reinforces that additional analysis has been conducted and delays in developing a coverage policy are likely unwarranted. As such, we strongly disagree that a "comprehensive analysis" is necessary given the robust approval

process CMS finalized for 2024. However, should CMS finalize that a "comprehensive analysis" is necessary, ASHA requests clarification regarding how the current approval process is insufficient and what changes CMS believes are needed to ensure a robust approval process is in place moving forward. Without these details, stakeholders may not be able to effectively make future requests to add services to the permanently authorized telehealth list.

Stakeholders, including ASHA, spent considerable time developing good-faith requests that they believed complied with CMS' approval process for submission prior to the February 10 deadline. CMS has failed to identify how these requests were insufficient or why they did not comply with Medicare requirements. It is unfortunate that the merits of these requests were not addressed; thereby, creating yet another challenge for stakeholders to improve upon for inclusion on the telehealth services list in future submissions.

ASHA strongly urges CMS to reconsider its position that a "comprehensive analysis" is necessary. Instead, CMS should review requests based on the approval criteria finalized for 2024 and on the strength of the research and evidence submitted prior to the February 10 deadline. Based on that analysis, we are confident that audiology and speech-language pathology services would be qualified for continued coverage on a permanent basis. As noted in our February submission, developing a robust benefit is important to ensure a seamless transition should Congress extend coverage of telehealth services to nonphysician clinicians through a change in federal law.

ASHA understands the lack of clarity regarding continuing temporarily authorized telehealth providers beyond 2024 poses implementation challenges for CMS. However, we request that, at a minimum, CMS should clarify the coverage status of audiology and speech-language pathology services provided via telehealth in the final rule issued this fall. We also strongly believe that CMS should ensure that these codes remain on the telehealth services list, either as provisional or permanent, to avoid delays or interruptions in care for patients, should Congress act. In addition, language from the outpatient prospective payment system (OPPS) proposed rule should be finalized as part of the fee schedule rule with modifications to ensure its applicability. Specifically, this language states:

"To the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, we anticipate aligning our Part B policy policies for these services with policies under the PFS and regardless of setting and continueing to make payment to the hospital provider (e.g.; clinician, hospital outpatient department, skilled nursing facility) for these services when furnished by hospital staff-the provider."

By adopting this language in both the fee schedule and OPPS regulations, CMS not only provides uniformity across practice settings billing Part B but also ensures continuity of coverage in the absence of Congressional authority, which might not exist at the time a rule is finalized. Uniformity of coverage policies across practice settings that bill Medicare reduces confusion and ensures equitable access to care for Medicare beneficiaries regardless of the type of practice setting in which the patient accesses these services. In addition, should Congress act in late December, as it often does, to extend Medicare flexibilities such as telehealth, having this language in place will prevent breaks in care because it will clearly state that if there is authority for audiologists and SLPs to serve as distant site providers, they can continue to provide these services.

Beginning in 2024, SLPs have been able to report caregiver training services (CTS) without the patient present when provided under an established, individualized, and patient-centered plan of care. However, CMS did not include CTS on the authorized telehealth services list for 2024.

CMS proposes adding these services to the authorized telehealth services list for 2025 on a provisional basis. ASHA believes this is critically important because caregivers may have logistical challenges that preclude them from participating in caregiver training in person (e.g., lack of transportation, work schedules, or disabilities which make traveling to appointments difficult). While SLPs' ability to continue providing telehealth services is somewhat uncertain in 2025 because Congressional action is needed, if Congress does extend the authority for SLPs to continue to be paid for telehealth services, having these services on the list will maintain continuity of care. Therefore, ASHA recommends CMS finalize its proposal to add CTS to the authorized telehealth services list on a provisional basis in 2025.

Audio-Only Communication Technology to Meet the Definition of "Telecommunications System"

CMS proposes to permanently allow two-way, real-time audio-only communication technology to qualify as a telehealth service furnished to a beneficiary in their home if the clinician is technically capable of using audio and video equipment that enables two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology. To use this flexibility, clinicians in outpatient settings will be required to report modifier "93" (audio-only synchronous telemedicine service) or modifier "FQ" (Medicare telehealth service was furnished using audio-only communication technology) on the claim to verify that these conditions have been met.

ASHA recommends CMS finalize this proposal to allow the flexibility for patients to receive telehealth services in a way that meets their needs and preferences.

Distant Site Requirements

CMS proposes to continue to allow clinicians who are providing telehealth services to Medicare beneficiaries from their homes to use their business address on claims to protect their privacy and security. ASHA agrees this is an important clinician protection and recommends CMS finalize this proposal.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Direct Supervision via Use of Two-way Audio/Video Communications Technology

SLPs are currently allowed to provide services "incident to" a physician with direct supervision. Direct supervision is typically defined as *in the office suite and immediately available to help if needed*. However, as CMS notes in the proposed rule, this definition was relaxed during the COVID-19 public health emergency to allow for telesupervision—supervision via real-time audio and visual interactive telecommunications.

CMS proposes to allow telesupervision through 2025 for physical and occupational therapy and speech-language pathology services. It is our understanding that without additional rulemaking, this flexibility would expire at the end of 2025. ASHA supports CMS' proposal to continue to allow SLPs to be telesupervised by physicians for the purposes of meeting the direct supervision requirement for incident to billing.

However, ASHA requests CMS extend this flexibility permanently because we believe services provided by an SLP incident to a physician meet the proposed criteria outlined in the rule. Specifically, CMS notes it can add a service to the telesupervision incident to policy at any time if it is considered inherently low risk based on the following criteria:

- 1. The service does not ordinarily require the presence of the billing practitioner;
- 2. The service does not require direction by the supervising practitioner to the same degree as other services furnished under direct supervision; and
- 3. The service is not typically performed directly by the supervising practitioner.

ASHA believes speech-language pathology services meet these criteria; however, this is in no way meant to be construed that these codes are provided primarily incident to a physician, thus warranting a change in their status indicator. SLPs in private practice (and in other practice settings, including hospitals and skilled nursing facilities) routinely perform the services within their scope of practice based on their clinical training and expertise and are allowed to do so under state law without physician supervision. In addition, Medicare Part B utilization data demonstrates that the predominant biller of these services are SLPs, not physicians. For example, 2022 Medicare data shows that CPT code 92507 (speech, language, communication treatment, individual) and CPT code 92523 (speech and language evaluation) were both billed by SLPs over 98% of the time.

To be clear, ASHA does not believe that CPT codes related to speech-language pathology services should be modified to a status indicator 5 because that would require the services to be predominantly billed as incident to. That is not the intent of these codes nor the current practice pattern. Rather, we are referring to the criteria against which services will be considered for telesupervision as a whole. As a result, ASHA requests that CMS finalize its telesupervision policy for incident to speech-language pathology services on a permanent basis.

Valuation of Specific Codes (II. E)

(39) Payment for Caregiver Training Services

Caregiver Assessment

ASHA appreciates CMS' work to implement new caregiver training services (CTS) under the 2024 MPFS, including Current Procedural Terminology (CPT®) codes 97550, 97551, and 97552 for caregiver training services under a therapy plan of care established by a physical or occupational therapist (PT, OT) or an SLP. Our members understand that a critical part of providing caregiver training services is determining the risks and benefits associated with caregiver training. Therefore, ASHA supports CMS' decision to emphasize the importance of caregiver-focused risk assessment as a necessary component of caregiver training. Many caregivers who care for Medicare beneficiaries are themselves of advanced age and may also have multiple comorbidities. Caring for a loved one with chronic illnesses, especially the conditions of Alzheimer's disease, dementia, and progressive neurological conditions, often requires significant physical and emotional effort and may lead to risk factors affecting caregiver and patient safety and well-being. Therefore, ASHA agrees that it is important to assess the caregiver's skills and knowledge for the purposes of caregiver training services, when reasonable and necessary.

CMS proposes to allow treating practitioners to furnish a caregiver-focused health risk assessment outside the patient's presence, reported with CPT code 96161 (Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit

of the patient, with scoring and documentation, per standardized instrument), to determine the caregiver's skills and knowledge for the purposes of caregiver training services. As proposed, the definition of "caregiver" will be the same for CTS and the risk assessment, and the clinician performing the assessment would need to obtain the patient's or responsible party's consent for caregiver assessment. ASHA agrees with these provisions, as proposed.

However, given that SLPs are allowed to provide and bill for caregiver training services without the patient present (CPT codes 97550-97552), ASHA recommends that CMS broaden the clinical specialties eligible to bill for the caregiver-focused health risk assessment. SLPs assess the caregiver's skills and knowledge as an initial step when performing formal caregiver training to ensure that the caregiver can carry over the learned skills safely. In addition, SLPs are well-positioned to identify signs of caregiver risk factors, as they often spend a significant amount of time with patients and caregivers and can develop a strong rapport during an episode of care. Therefore, ASHA requests CMS allow SLPs and other providers eligible to furnish CTS to report CPT code 96161 for caregiver risk assessment for the purposes of caregiver training services.

Proposed Direct Care Caregiver Training Services

As noted above, SLPs are currently allowed to bill for select caregiver training services reported with CPT codes 97550, 97551, and 97552. ASHA applauds CMS for its continued efforts to recognize the value of caregiver training and expand the caregiver training services available under the MPFS. We recognize that caregiver training is integral to successful treatment outcomes and supports the proposed HCPCS codes GCTD1, GCTD2, and GCTD3, including the proposed valuation by direct crosswalks to 97550-97552. However, it is unclear which treating practitioners would be able to report these codes. Additionally, there is not a clear distinction on how the proposed codes would overlap with existing CTS codes 97550, 97551, and 97552, typically reported by PTs, OTs, and SLPs.

CPT codes 97550, 97551, and 97552 describe caregiver training to provide strategies and techniques to facilitate a patient's functional performance in the home or community. However, there are situations in which caregiver training is required by an SLP but is related to supporting care and reducing complications, rather than supporting functional performance. As such, the proposed G codes could be applicable to critical caregiver training services SLPs provide as members of multidisciplinary care teams delivering targeted interventions. Therefore, ASHA is requesting CMS clarify that these codes can be reported by SLPs.

As requested by CMS, below are examples of situations when SLPs provide medically necessary caregiver training services that fall under the proposed caregiver training codes.

Example 1: Wound, stomal, and tracheoesophageal puncture (TEP) care in laryngectomy patients: SLPs play an integral role in rehabilitation of patients following laryngectomy and placement of a TEP prosthesis. Many laryngectomy patients are unable to independently care for their stoma and/or TEP, especially Medicare beneficiaries who may be of advanced age, have low vision, or have multiple comorbidities. Improper stomal and TEP care can lead to significant negative health outcomes. In these situations, caregivers play a vital role in ensuring proper stomal and TEP care by providing cleaning, humidifying, and monitoring of the sites for granulation tissue, fistula, and leakage to prevent complications and aspiration. Caregivers of these patients may require extensive training on infection control and prevention, stomal and

wound care, functioning of a TEP prosthesis, how to detect signs of a malfunctioning prosthesis, and the need for a new prosthesis.

Example 2: Pain and lymphedema management in head and neck cancer patients: Lymphedema and pain are devastating conditions that frequently follow surgery and/or radiation treatment for head and neck cancer. SLPs play a vital role in rehabilitation of these patients and training of their caregivers. Head and neck lymphedema can affect swallowing, speech, and respiration, and may lead to other complications such as infections or trismus. These patients often rely on their caregivers to monitor lymphedema and prevent complications, such as the need for tracheostomy. Caregiver training that SLPs may provide includes supporting lifestyle modifications, detecting worsening lymphedema, and preventing infection.

Each of these examples could be reported using the proposed G codes, as the skilled caregiver training provided by SLPs in these situations benefits patients who require caregiver training to support their care in areas such as infection prevention and monitoring for potential complications. We believe these activities are distinctly different from CTS described under CPT codes 97550-97552, which specifically address caregiver support of a patient's functional performance and carryover of treatment goals in the patient's natural environment. Therefore, ASHA requests CMS allow SLPs to report the proposed G codes—GCTD1, GCTD2, and GCTD3—when caregiver training without the patient present is provided to support a patient's direct care and to reduce complications.

Patient Consent

CMS proposes to update the CTS requirement for the treating clinician to obtain and document the patient's (or representative's) consent by adding the option to obtain and document verbal consent.

ASHA appreciates that CMS has provided flexibility to obtain and document patient (or representative) consent in ways that work best for all stakeholders. This flexibility prevents undue administrative burden for clinicians and maintains access to care for patients. As a result, ASHA recommends CMS finalize its proposal to allow for verbal consent for CTS.

(40) Request for Information on Services Addressing Health-Related Social Needs

ASHA agrees that social determinants of health (SDOH)—or the nonmedical factors such as where people are born, live, learn, work, play, worship, and age—affect a wide range of health, functioning, and quality-of-life outcomes and risks. The identification, documentation, and intervention of such factors is essential for equitable, high-quality, holistic, patient-centered care. In line with CMS' goal to transition virtually all Medicare and Medicaid beneficiaries into accountable care relationships by 2030, we acknowledge the health equity implications of including SDOH risk assessments to risk adjustment in value-based payment systems.

ASHA supports the practice of early and holistic identification and treatment of upstream factors to improve downstream outcomes and costs. The cost of newly proposed G codes for SDOH risk assessment can be balanced by potential long-term benefits and savings resulting from appropriate holistic interventions that have direct impacts on patient health outcomes and future health care utilization.

Physicians may provide an SDOH risk assessment (G0136) as part of annual wellness visits. This is an important step toward supporting holistic care. However, we believe that other

nonphysician qualified health care professionals, such as audiologists and SLPs, are also strongly positioned through both frequency of patient contact, strong rapport, practice in a variety of settings, and specialization in communication to obtain essential SDOH information that patients may be reticent to share.

Audiologists and SLPs typically see patients for multiple visits during an episode of care. They may treat patients in acute, inpatient, outpatient, skilled nursing, home health, or private practice settings. Many of these settings allow direct observation of nonmedical factors impacting a patient's health. Due to patient communication impairments, SLPs often build strong working relationships with families and caregivers who can provide valuable information for an SDOH risk assessment. During the course of treatment, as communication improves, patients often share personal information about challenges to their recovery, including SDOH risk factors, with their audiologist or SLP. Therefore, ASHA recommends expanding the SDOH risk assessment service and associated G code (G0136) to nonphysician qualified health care professionals who cannot report evaluation and management (E/M) services. This would also reinforce the value CMS places on addressing SDOH, as demonstrated by its adoption in Merit-based Incentive Payment System (MIPS) measures in the audiology and speech-language pathology specialty measure sets.

In addition, as the national association with a vision of "making effective communication, a human right, accessible and achievable for all," we recognize communication as not only a critical health outcome, but also an SDOH impacting the effectiveness of other health interventions and a range of health care, economic, and social factors.

Z Codes

ASHA strongly supports the use of Z codes on claims to accurately capture factors influencing patients' health status and health-related needs. Care planning, prevention, and intervention to achieve the best possible outcomes requires all providers across settings to share a comprehensive understanding of the patient's big picture of health. Z codes aid individual clinicians in data sharing with their interprofessional care team while also facilitating the population health and cost analytics necessary for the transition from fee-for-service to value-based payment models.

Z codes, which offer a powerful mechanism to capture SDOH to address health disparities, are currently underutilized.³ Allowing qualified nonphysician health care providers, including audiologists and SLPs, to be reimbursed for SDOH screening would incentivize capturing these essential data elements that address health disparities, identifying community needs, supporting quality measurements, and improving overall health outcomes.

ASHA requests that CMS undertake provider education on the benefits and reimbursement impact of Z codes to incentivize their use and ensure consistent reporting.

Advanced Primary Care Management (APCM) Services (HCPCS codes GPCM1, GPCM2, and GPCM3) (Section II.G.)

We support CMS' efforts to advance primary care through its proposal to add advanced primary care management (APCM) services reported with new HCPCS codes GPCM1, GPCM2, and GPCM3. The proposed rule indicates that APCM services incorporate elements of virtual checkin services (HCPCS codes G2251 and G2252); SLPs can report HCPCS code G2251 under the MPFS.

Although CMS anticipates a reduction in utilization of communication technology-based services (CTBS) due to the newly proposed APCM codes, it does not indicate that this will impact the value and payment for CTBS codes when separately reported by nonphysician qualified health care professionals. However, upon review of Addendum B, we note that the non-facility and facility PE RVUs for G2251 show a significant reduction from 0.15 to 0.00. **ASHA would like to bring this to CMS**' attention and seeks clarification on whether this is a data entry error or an intentional change related to the proposed APCM codes. If this update is intentional, we respectfully request CMS provide a rationale for the reduction in PE RVUs for G2251. ASHA believes that the PE RVU for G2251 should be restored to the original value of 0.15, as it should remain separately reportable when a virtual check-in is not associated with APCM services.

Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care with a Physician or NPP Order, and KX Modifier Thresholds (Section II. H.)

Supervision of Outpatient Therapy Services in Private Practices

For 2025, CMS proposes a regulatory change to allow for general supervision of physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) by PTs in private practice (PTPPs) and OTs in private practice (OTPPs) for all applicable physical and occupational therapy services. ASHA supports this change because we believe it is important to apply consistent policies across practice settings to reduce confusion and administrative burden, whenever possible. Given the current staffing shortages across clinical specialties, this flexibility has the potential to decrease patient wait times and ensure timely access to care.

Certification of Therapy Plans of Care With a Physician or NPP Order

For 2025, CMS proposes amendments to the certification of the plan of care regulations to reduce the administrative burden for therapists and physician/nonphysician practitioners (NPPs). These changes, if finalized, would provide an exception to the physician/NPP signature requirement on the therapist-established treatment plan for purposes of the initial certification. This exception would apply in cases where a written order or referral from the patient's physician/NPP is on file and the therapist has documented evidence that the treatment plan was transmitted to the physician/NPP within 30 days of the initial evaluation.

ASHA appreciates CMS' consideration of our long-standing recommendation to modify the initial certification of the plan of care regulations. We believe this policy will reduce the administrative burden for SLPs and their staff who report to us that the cost of complying with this requirement is untenable, both financially and in terms of time wasted. We also believe it reduces the burden for physicians who field requests for a signature on the plan of care, which is duplicative when they have already provided an order.

CMS is also soliciting comments on the need for a regulation addressing the amount of time during which the physician/NPP who has written an order for therapy services could make changes to the therapist-established treatment plan by contacting the therapist directly. ASHA agrees that timely feedback from the physician is critically important to ensure the patient's needs are being met and that SLPs are not placed at undue financial risk for noncoverage if the physician ultimately disagrees with the SLP's treatment recommendations. It is unreasonable for a physician to request changes to a plan of care weeks after it was initially transmitted to them, given the nature of speech-language pathology services. SLPs often initiate treatment soon after the initial evaluation, and these services can often be furnished two or more times a week. If a physician returned a plan of care to the SLP two or more weeks after the initiation of

treatment, it would throw the overall episode of care into disarray and jeopardize coverage for numerous treatment sessions that may have been provided during that time.

However, we do not believe that setting a specific time frame, such as 10 business days or 30 calendar days, is appropriate. What is more consequential is ensuring that any services provided between the time the plan was transmitted to the physician and when the physician provides feedback or alters the plan of care will be covered and not at risk for recoupment. It is important to provide the physician the opportunity to ensure the plan of care reflects their feedback, but it is unreasonable for the therapist to be at risk for recoupment for services provided in the interim.

Medicare Shared Savings Program (Section III.G.)

Proposal to Require Shared Savings Program ACOs to Report the APM Performance Pathway (APP) Plus Quality Measure Set

ASHA supports aligning quality measures across CMS programs and the stated goals of the APP Plus Quality measure set—reducing reporting burden and encouraging alternative payment model (APM) participation. Of the proposed additional five measures—Breast Cancer Screening (to be added PY 2025), Colorectal Cancer Screening (to be added PY 2025), Initiation and Engagement of Substance Use Disorder Treatment (to be added PY 2026), Screening for Social Drivers of Health (to be added PY 2028), and Adult Immunization Status (to be added PY 2028)—only the SDOH measure is applicable to qualified nonphysician health care providers like audiologists and SLPs. While we understand the goal of streamlined reporting, we encourage adding measurement of functional status, as it is a strong predictor of mortality.⁴

ASHA encourages CMS to expand measure concepts to include functional status—such as improvement or maintenance of communication, cognition, and swallowing function. It is critically important to ensure Medicare beneficiaries are receiving quality care and achieving the outcomes they require in all areas of function—including mobility, self care, communication, cognition, and swallowing—to safely and effectively move on to the next level of care.

Health Equity Benchmark Adjustment

We support CMS' proposed Health Equity Benchmark Adjustment (HEBA) applicable to accountable care organizations (ACOs) in agreement periods beginning on January 1, 2025, and in subsequent years. ASHA appreciates the commitment to meaningful incorporation of health equity into MSSP. The proposed HEBA, which incentivizes health care providers to serve patients with dual eligible status through the upward adjustment of an ACO's historical benchmark, addresses *cherry-picking* and *lemon-dropping*, which are unintended consequences of many value-based care models.

Cherry-picking refers to carefully selecting a caseload of mostly healthy, uncomplicated, and socially advantaged patients who are the most likely to have good outcomes with the least amount of intervention. There is a perverse incentive for providers to maximize their quality and financial rewards primarily by choosing only the ideal candidates for treatment.

Lemon-dropping is the opposite. Patients with chronic conditions, multiple comorbidities and disabilities, and those in underserved populations or communities with less access to preventive health care often require more services, increasing the total cost of care. Without an HEBA, a health care provider's quality scores might be inappropriately reduced, or they may be

incentivized to avoid patients to maintain higher quality scores and lower costs. As a result, these patients risk being dropped by providers and could have difficulty finding care without a HEBA.

ASHA supports the proposed HEBA based on the number of beneficiaries an ACO serves who are dually eligible or enrolled in the Medicare Part D Low-Income Subsidy (LIS). This will align incentives with CMS' goal of protecting complex patients with a high prevalence of health—related social needs to advance health equity.

Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care (Section III. J.)

We appreciate the significant effort CMS is making to ensure that quality reporting programs improve care for Medicare beneficiaries, protect the Medicare trust fund, and comply with the requirements of the law. While we recognize MIPS is imperfect and applaud CMS' efforts to transition to advance alternative payment models (A-APMs), we remain concerned that MVPs do not solve many of the existing problems nonphysician qualified health care professionals (QHPs), such as audiologists and SLPs, have in participating in A-APMs. Specifically, nonphysician QHPs are seen as "collaborators" in A-APMs, meaning they are downstream participants rather than "convenors"—those considered accountable for the results of the A-APMs. Consequently, quality metrics are often limited and rarely reflect the clinical value audiologists and SLPs bring to the A-APM team, and their overall engagement or inclusion in these models remains limited. Even when nonphysician QHPs are included in these models, the incentive structure is often centered on the physician, which provides limited opportunities for nonphysician QHPs to earn bonus payments. **Therefore, ASHA believes it is premature to build a bridge to A-APMs via MVPs.**

In addition, MVPs require cost measure reporting. There is currently no cost measure for audiologists or SLPs. This is despite consistent engagement in technical expert panels (TEPs) convened by CMS and its contractors. Most recently, an ASHA member served on a TEP to develop a measure associated with movement disorders such as Parkinson's. Without a cost measure, our members cannot successfully participate in MVPs. Therefore, we urge extreme caution in fully sunsetting MIPS. Without MIPS, MVPs, or A-APMs inclusive of audiologists, SLPs, and other nonphysician QHPs, sunsetting MIPS entirely could jeopardize the ability of these clinicians to get the annual 0.25% or 0.75% payment adjustment prescribed under law. Therefore, ASHA recommends CMS consider relaxing the requirements of MVPs in instances where a cost measure is not available or maintaining MIPS to ensure all clinicians paid under the fee schedule maintain a path for annual payment updates.

We have provided the following responses to many, but not all, of the questions posed in the request for information (RFI) for CMS' consideration.

1. How should CMS identify single specialty and multispecialty groups while accounting for regular clinician turnover? Which data sources and methodology should CMS use to consider identifying specialists and sub-specialties that could potentially participate in an ambulatory specialty model?

CMS should consider the clinical specialties that might be engaged in patient care and what quality measures exist or need to be developed to ensure that all aspects of the patient's care are delivered with quality and outcomes in mind. ASHA also recommends CMS review clinical practice guidelines for the clinical conditions to determine the best practices, including the types of clinical specialties that should be involved.

2. Should CMS consider different identification approaches to identify individual clinician specialist type versus practice- or group-level specialty types? If so, how?

Using the rulemaking process, requests for information, and/or other mechanisms to engage a broad cross section of stakeholders to ensure the types of clinical specialties or services patients might need, will be important to ensure MVPs are comprehensive and adequate.

3. Are there certain characteristics of clinicians or practices or both that may warrant additional policy flexibilities or exemption from participation in a mandatory ambulatory specialty model? What flexibilities should CMS consider for these participants?

Unfortunately, MVPs require reporting a cost measure, and there are no cost measures applicable to most nonphysician QHPs such as audiologists and SLPs. CMS should consider if these types of clinicians should be exempt from reporting a cost measure. Alternatively, CMS may not be able to sunset traditional MIPS for nonphysician QHPs. Without a MIPS or MVP reporting option, nonphysician QHPs would not be eligible to receive the 0.25% payment update allowed under law, leaving their payments permanently stagnant.

4. How should CMS collect unbiased comparison group data on quality and costs for evaluation purposes? Would mandating a control group to report MVPs be appropriate for model evaluation?

CMS should establish robust risk adjustment methodologies for both the control and participant groups. This should include matching groups based on demographic factors such as race and gender, diagnoses, and SDOH. CMS should also pull cost data from MVP participating sites that have achieved a specific threshold of clinical outcomes set by CMS as another point of information regarding the cost to achieve the desired outcomes.

5. How can CMS support a multispecialty group's ability to successfully participate in MIPS and the model if a portion of its clinicians are reporting separate measures pursuant to the model? What steps could CMS take to reduce any added administrative burden that might arise from such separate reporting?

ASHA believes it is important to capture quality measures across the range of clinical specialties a patient might encounter based on their diagnoses to ensure quality and continuity of efficient care. As a result, you could have a variety of clinical specialties reporting on discipline-specific measures, including primary care physicians, specialty physicians such as surgeons or oncologists, and nonphysician QHPs like audiologists and SLPs. Quality measure reporting is going to be required based on clinical specialty regardless of the form of the quality reporting program (e.g., MIPS, MVPs, A-APMs), so minimizing burden will admittedly be challenging.

The primary consideration should be to select meaningful measures reported by the clinicians delivering the care to ensure it accurately reflects what is happening with that patient over the course of the episode. If clinicians feel like the data they are reporting and analyzing is useful to improve patient care, administrative burden becomes less of a concern. If they're reporting on generic measures or measures they do not believe are correlated to patient care, the burden seems more significant.

6. If CMS were to reduce the number of measures and activities in an MVP for clinicians participating in the model to those measures and activities most relevant to a specified specialty or subspecialty, how should CMS select the measures and activities? Consider the following prioritization approaches: (a) measures with a performance gap; (b) measures with meaningful benchmarks that can be applied; (c) measures that are reliable in the model context given the expected sample size; (d) measures that are evidence-based and either strongly linked to outcomes or an outcome measure; (e) measures that capture an adequate number and representativeness of the clinicians intended by a possible ambulatory specialty model; (f) measures that drive specialty integration with primary care and meaningful involvement with accountable entities. Are there other measure selection principles that should be prioritized when narrowing measuring in an MVP?

We recommend that CMS prioritize measures accordingly:

- a. measures that drive specialty integration with primary care and meaningful involvement with accountable entities
- b. measures that capture an adequate number and representativeness of the clinicians intended by a possible ambulatory specialty model
- c. measures that are evidence-based and either strongly linked to outcomes or an outcome measure
- d. measures with a performance gap
- e. measures with meaningful benchmarks that can be applied
- f. measures that are reliable in the model context given the expected sample size.
- 7. Are there specific measure focus areas or objectives that should be prioritized across MVPs (such as equity, population health measures, or patient-reported outcome-based performance measures [PRO-PMs] and patient-reported experience measures)?

ASHA recommends prioritizing clinician-reported function measures, as well as all of the areas CMS has identified.

8. To support improvements in primary and specialty care integration, an ambulatory specialty model could initially focus on specialty types eligible to become rostered specialty care partner clinicians in the MCP model, which include general cardiologists and physical medicine and rehabilitation clinicians. Accordingly, which measures within the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVP might be subset to apply to general cardiology and physical medicine and rehabilitation, respectively?

In reviewing the measures associated with the Advancing Care for Heart Disease and Rehabilitative Support for Musculoskeletal Care MVPs, only three measures could be reported by audiologists and SLPs, if they were ultimately included—body mass index, SDOH, and falls plan of care. Again, this raises concerns about the ability to effectively transition many nonphysician QHP specialties to MVPs and eliminate MIPS.

It is critically important to consider a patient's function across MVPs, including their physical and cognitive function. Physical function includes the domains of communication and swallowing. Without understanding a patient's ability to function in their environment, MVPs will fail to improve the quality and outcomes of care for patients.

9. Similar to how other Innovation Center models may test new measures during their implementation (for example, the Comprehensive Joint Replacement model [80 FR 73358 through 73382 and 86 FR 23543 through 23549] and the Guiding an Improved Dementia Experience [GUIDE] Model612), what role could an ambulatory specialty model have in testing potential new measures, such as relevant PRO-PMs, by gathering data for consideration in future MVP measure sets?

The models CMS cited do not currently capture metrics associated with the services audiologists and SLPs provide to these patients. For example, SLPs play a role in improving cognitive function for dementia and transplant patients, addressing swallowing issues that arise for head and neck cancer patients, and treat patients in post-acute care settings such as skilled nursing and inpatient rehabilitation facilities that might participate in the BPCI Advanced model. As CMS builds out an MVP, it could be instructive to consider the absence of measures that reflect the communication, swallowing, and cognitive function of patients associated with these current models.

10. What kinds of strategies could be tested to obtain patient and family feedback on how they experience care coordination between primary care and specialty care for the clinical focus areas of the model?

It is critically important to capture patient experience with care coordination across their multidisciplinary care team; we applaud CMS for seeking feedback on how to do this. CMS could consider adding a section to the Consumer Assessment of Healthcare Providers and Systems Patient Experience Surveys and Guidance as an option to capture this type of feedback.

12. How could a model for applicable specialists improve the comparison of similar specialists to determine future Medicare Part B payment adjustments?

Such a model could help establish baseline costs as opposed to quality outcomes, assuming the groups are appropriately matched for patient demographics, diagnoses, and SDOH.

13. What range of upside and downside risk (as measured by the range of possible payment adjustments to future Medicare Part B claims) could incentivize increased and meaningful participation of specialists in APMs, care transformation, and strengthened integration between primary and specialty care?

Because the vast majority of audiologists and SLPs operate under fee-for-service models, many are unfamiliar with or unaccustomed to alternative payment models such as episode-based payment models. CMS can support providers through initial investments of capital to establish the technological and care coordination equipment and processes essential to success in value-based care. Alternatively, a ramp-up period in which providers can participate in upside-risk-only arrangements would encourage new providers to explore value-based care in a financially responsible way prior to transitioning to full-risk arrangements.

Given our current payment environment in which Medicare payments have consistently declined since 2021 due to various statutory budget control mechanisms, low incentives with upside-only risk would likely be the most effective to secure widespread participation in the immediate future.

14. What model design features should CMS consider in designing an ambulatory specialty care model that increases risk over time to potentially qualify the model for Advanced APM (AAPM) status under the Quality Payment Program (see § 414.1415)?

ASHA believes the most important design features of an ambulatory specialty care model that increases risk over time that would ultimately qualify as an A-APM are:

- a. Selection of appropriate quality measures
 - Ensure all participants can impact measures with the services they provide.
 - Ensure referrals to specialists such as audiologists and SLPs aren't eliminated because their outcomes aren't measured.
- b. Initial investment of capital
 - Establish the technological and care coordination equipment and processes essential to success in value-based care.
- c. Fair division of incentive payments
 - Tie the incentive amount each A-APM participant receives to outcomes they have the ability to impact and time spent treating the patient. The allocation of earned bonuses should not be determined arbitrarily.
- d. Address ratchet effect
 - To deliver higher-value care, providers need a margin to keep making improvements. The better they do, the less they earn in the future.
- e. Address patient adherence
 - Outcomes are strongly tied to treatment, but in cases where patients do not comply with the plan of care, providers need a way to indicate such and not be penalized for what they can't control.
- 15. Are there model design features not discussed here that would incentivize primary care and specialty care providers to improve how beneficiaries experience care coordination?

One challenge shared by ASHA members, particularly SLPs, is productivity challenges where they are expected to generate a certain amount of revenue within a working day. These standards usually only account for direct patient care, despite the fact that time spent documenting and participating in multidisciplinary care team planning could improve the quality and efficiency of care. APM design should take into consideration how activities that do not necessarily involve direct patient care should still be incentivized or valued because of the overall impact they can have for the patient.

16. How can CMS best encourage specialist clinicians and accountable care entities to collaborate to establish clear care pathways and protocols that optimize patient outcomes while ensuring efficient resource utilization?

ASHA cannot emphasize enough that there must be measures that reflect the services of all members of the multidisciplinary care team with equal opportunities to earn bonus payments. In addition, these payments must be substantial enough to truly drive behavior change on the part of clinicians.

17. How may CMS identify specialists who are most engaged in care management, care coordination, and care improvement activities with an accountable care entity?

CMS should consider what elements of an episode of care a particular clinical specialty can actually control and focus on tying incentives to individuals within the model rather than the model as a whole. Considering the amount of time a specialist spends with the patient and the outcomes and quality of care by specialty might help ensure equitable distribution of incentives.

19. What characteristics should CMS consider in the design of this model to account for variations between ACOs, such as whether the ACO is physician-owned versus hospital-owned (or a low-revenue ACO versus a high-revenue ACO), whether or not an ACO identifies as an integrated delivery system (IDS), and differences in regional health care landscapes and local dynamics? What other characteristics should we consider?

CMS should consider the population served and the cost of treating populations with different health-related social needs.

20. How can the model proactively address concerns related to increased consolidation, ensuring that integration efforts do not lead to reduced competition and potential negative impacts on health care quality and costs?

CMS should carefully consider antitrust issues. Value-based care often involves establishing provider networks or ACOs to coordinate care delivery. The formation of these networks may require complex contractual arrangements that require compliance with federal and state laws, including antitrust regulations and state insurance laws.⁵ Coordination with the Federal Trade Commission and clarity from CMS on acceptable waiver use would assuage provider concerns that may inhibit adoption of value-based payment models.

21. How might risk categorization of ACOs influence the design of incentive structures of model participants engaging with ACOs, and what adjustments might be necessary to accommodate different risk levels?

ASHA believes that a larger risk leading to a larger reward seems like a reasonable approach. Lower-risk ACOs would likely have more participants, necessitating smaller rewards, while high-risk ACOs would draw a smaller pool, allowing larger payouts and making the APM's investment more reasonable.

22. What specific issues should CMS consider when determining whether additional requirements and objectives may be necessary beyond those currently specified in the MVP framework around the use of health IT by specialists participating in a potential model?

CMS should consider what ways it can help offset the initial upfront investments required to facilitate the data analysis necessary to be successful in ACOs.

23. What investments in health IT or information exchange would be most beneficial to helping specialists succeed in such a model?

It is important to remember that not all elements of interoperability can be applied equally across clinical specialties. For example, audiologists and SLPs do not prescribe medications, so e-prescribing is not an applicable interoperability metric.

In addition, larger health systems can more easily absorb the cost of certified electronic health record technology than solo practitioners or small private practices. CMS should

determine if there are ways to provide financial assistance to clinicians like audiologists and SLPs who were not eligible for meaningful use incentive payments.

24. What is your experience with the integration of health IT systems? Please highlight any inoperability issues or opportunities for seamless data exchange between different systems, such as electronic health records (EHRs) and telehealth platforms.

There are not many EHR systems designed for nonphysician QHPs and for audiologists and SLPs in particular. This means that considerable investment in time and money must be made to modify an "off the shelf" product to meet the unique needs of audiology and speech-language pathology practice. There is also the cost of training staff, fixing errors that are made as staff learn to use the product, and routine maintenance of the system to reflect changes in treatment and diagnosis coding or regulatory requirements.

25. How should CMS structure the model and any health IT and data sharing requirements to align with, build upon, and otherwise leverage advances in Federal interoperability policy (for example, USCDI and USCDI+ or FHIR; TEFCA)?

Alignment across programs minimizes clinician burden and facilitates a collection of data in a standardized way that allows for the comparison of that data across the spectrum. CMS should consider using the standards established in the prior authorization and interoperability final rule.

26. What data or metrics or both are important to clinicians in terms of monitoring performance and improving patient outcomes? What data or metrics or both should CMS share publicly to help inform beneficiaries of clinician performance?

CMS should focus on collecting information related to the patient's *experience of* (not satisfaction with) care. A patient might not have the desired outcome, but the focus should be on the effort of the clinician to achieve the right outcomes. In addition, monitoring functional progress throughout an episode of care can help ensure proper referrals are made earlier in care episode. Finally, publicly reported data should be a manageable set of data that actually helps a patient make informed choices regarding their care.

27. What additional resources or support mechanisms could CMS provide to help clinicians make sense of the data, enhancing the data's usability, effectiveness, and frequency of updates, so that clinicians acquire actionable insights for improving patient care and experience? And to enable data-driven referrals?

Whenever possible, quarterly reporting with a clear dashboard of metrics—including visual representations of trends and the ability to dive down into the specialty type—should be provided. Annual data or data with significant lag times between when it is submitted by the provider and when it is publicly reported slows progress toward improving care.

28. What supports can this new model provide for decreasing the burden of data collection and measure reporting?

ASHA remains concerned that transitioning to MVPs from MIPS does not provide the level of burden reduction CMS envisions. All four performance categories must still be reported. The primary burden reduction appears to be a defined set of quality measures specific to the MVP design rather than the laundry list of MIPS measures providers must weed through to meet the minimum reporting requirements.

29. Similar to how other Innovation Center models may offer financial and technical supports to certain qualifying clinicians (for example, safety net clinicians) as part of a model's health equity strategy (for example, the GUIDE model619), how might CMS support the participation of clinicians in an ambulatory specialty model that may serve a higher proportion of underserved patients (for example, small practices or clinicians in rural areas)?

We remain committed to ensuring models reflect the unique needs of nonphysician QHPs, including audiologists and SLPs, as they are developed. These clinicians contribute to the outcomes and cost of care; however, metrics and incentives that recognize this remain unadopted, particularly as it relates to the development of cost measures. In addition, many nonphysician QHPs work in solo or small practices and may not be using an EHR. They will likely need technical assistance to ensure their successful integration into these models.

30. How could an ambulatory specialty model support participant efforts to identify health disparities within their practices, identify actionable equity goals, and design and implement strategies to improve identified disparities?

CMS should consider requiring reporting of quality measures that capture data on SDOH and Z codes for diagnosis of these factors. Incentives should also exist for identifying and modifying service delivery to accommodate these risk factors.

31. How could an ambulatory specialty focused model work synergistically with other primary care focused models to improve health disparities?

CMS should identify ways to incentivize specialty providers such as audiologists and SLPs to encourage their participation in these models. Additionally, as CMS works with stakeholders to build MVPs, it should identify ways to incentivize physicians to refer to specialty services when they improve the cost and outcomes of episodes of care.

32. How could an ambulatory specialty model encourage clinicians to collect and use (HRSN) screenings and follow-up data collected on patients attributed to the model?

CMS should consider requiring the use of an HRSN screen in all MVPs and have an improvement activity around the use of that data to improve health outcomes.

33. How can measure stratification among patient subgroups or use of composite health equity measures improve how participants identifies and quantifies potential disparities in care and outcomes related to ambulatory specialty care?

Ensuring granular data collection on patient demographics will help stratify outcome measures in a variety of ways to capture multiple facets of health equity. For better or worse, what's measured is what's managed. By allowing providers to see outcome disparities among their patient population and incentives to achieve health equity, providers will be able to perform a root cause analysis and facilitate changes in practice patterns.

34. Are there opportunities to reduce clinician burden between this model, other CMMI models, and beyond through multi-payer alignment, in areas such as performance measurement, quality measurement, and data/reporting requirements?

ASHA appreciates CMS' efforts to develop the Universal Foundation in an attempt to align quality measures across CMS programs. But we are not aware of any efforts to expand this foundation to private payers, which we recognize would be challenging. One area where CMS might have leverage is to apply the foundation to Medicaid managed care

organizations and Medicare Advantage plans, particularly given so many of these beneficiaries have transitioned to managed care from the government-managed programs.

35. How could this model align with value-based care approaches in the Medicare Advantage, Medicaid, and commercial payer space that focus on specialty integration? What model components and payment incentives can be aligned with other payers to support improvement goals?

We are particularly concerned that private payers have taken an extremely narrow approach to value-based care focused on utilization management (e.g., prior authorization) and low utilization rather than adoption of quality measures that drive quality and alternative payment models that improve the value of care.

36. How can CMS align with other payer approaches to equity and disparity reduction? This could include alignment on definitions, methods, and requirements for equity-related data collection, etc.

ASHA believes that the preponderance of work in driving quality, value, and equity in health care is a result of CMS' hard work, and little of this has translated to or been adopted in the private health insurance marketplace. We have seen some modest progress where plans have piloted the use of community health workers and implemented programs focused on LGBTQ+ health.

37. What technical assistance can CMS provide to support alignment and reduce burden?

To reduce burden, ASHA recommends CMS offer provider-facing resources on measures per program, mandatory and voluntary reporting opportunities, and allow paper or electronic submission based on the size and resources of the practice. CMS should also provide a technical assistance center for clinicians to answer questions.

Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (Section III.O.)

In the proposed rule, CMS highlights the substantial statutory, legal, and regulatory history for implementing a requirement of the Patient Protection and Affordable Care Act (P.L. 111-148) that requires a clinician or provider to report and return an overpayment within 60 days of its identification or the date a cost report is due, as applicable. However, CMS proposes to suspend the deadline for reporting and returning overpayments to allow the clinician or provider to investigate and calculate overpayments if:

- 1. A person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and
- 2. The person actually conducts a timely, good-faith investigation to determine whether related overpayments exist. If the requirements for a suspension of reporting and returning overpayments are met, the deadline for reporting and returning the initially identified overpayment and any related overpayments that arise from the same or similar cause or reason as the initially identified overpayment will remain suspended until the earlier of the date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated, or the date that is 180 days after the date on which the initial identified overpayment was identified.

We believe this flexibility is important to ensure the Medicare trust fund is protected while still allowing clinicians and facilities reasonable time to do their due diligence to report and return any and all overpayments as required by federal law. Therefore, ASHA recommends CMS finalize this proposal.

Updates to the Quality Payment Program (Section IV.)

Merit-Based Incentive Payment System (MIPS)

Improvement Activities Performance Category Changes

CMS is proposing two changes to the traditional MIPS improvement activities reporting and scoring policies for the CY 2025 performance period/2027 MIPS payment year:

- 1. Eliminate the weighting of activities
- 2. Reduce the number of activities to which clinicians are required to attest to achieve a score in the improvement activities performance category.

ASHA supports these changes and encourages CMS to finalize them as proposed.

Quality Performance Category Changes

In 2023, we submitted a letter to CMS and its contractor requesting the addition of several quality measures from the existing MIPS measure set to the speech-language pathology specialty measure set.⁶ Several of those measures were added to the 2024 performance year/2026 payment year specialty measure set. CMS proposes to add the remaining measures ASHA requested to the specialty measure set for the 2025 performance year/2027 payment year. These measures include:

- 1. **Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
- Dementia: Functional Status Assessment: Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.
- 3. **Dementia:** Safety Concern Screening and Follow-Up for Patients With Dementia: Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
- 4. **Dementia:** Education and Support of Caregivers for Patients With Dementia: Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
- 5. Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: Percentage of patients diagnosed with ALS who were offered assistance in planning for end-of-life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, hospice) or whose existing end-of-life plan was reviewed or updated at least once annually or more frequently as clinically indicated (i.e., rapid progression).

ASHA appreciates CMS following up on our request and proposing to add these remaining recommended measures. We recommend CMS finalize this proposal.

Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs Request for Information

ASHA applauds CMS' efforts to elevate the patient voice in health care. We offer the following responses to the questions posed in the RFI for CMS' consideration.

 Are the aforementioned guiding principles outlined comprehensive, or are there additional guiding principles and considerations we should consider for the selection and implementation of PROMs and PRO-PMs?

ASHA recommends that the principle of accessibility be expanded beyond clinical and care team accessibility to account for the needs of individuals with disabilities, including those with communication disabilities. Considerations of web accessibility standards, plain language accessibility principles, and the use of a proxy when responding to patient-reported outcome measures (PROMs) will allow accurate data collection on a more comprehensive swath of the population.

 How can CMS support making PROMs broadly accessible without limiting both innovation and resources committed to developing new tools? Are there other examples (beside PROMIS) of currently existing PROMs/PRO-PMs repositories that make their tools widely available to clinicians and health care systems?

We suggest using established PROMs such as those included in ASHA's National Outcomes Measurement System (NOMS) data registry. These include:

- Cognitive Function PRO (Neuro-QOL)
- Communication PRO (CPIB)
- Swallowing PRO (EAT-10)
- Cognitive Function PRO (Neuro-QOL Pediatric)
- Communication PRO (ASHA Communication)
- Swallowing PRO (PEDI-EAT-10)
- Hearing Handicap Index PRO
- Tinnitus Handicap Inventory PRO
- How should CMS balance the use of broad PRO-PMs that might be applicable across multiple clinical contexts compared to condition-specific PROMs and PRO-PMs that can be more tailored to a given clinical situation but lead to a greater number of tools in use across measures and health care providers?

ASHA encourages the use of PROMs that accurately reflect the outcomes of the services provided. This may require a combination of both broad and narrow measures depending on the providers and services involved in a patient's care. If provider payment is to be linked to quality outcomes, including PROMs, it is essential that providers have the ability to impact the factors that their performance is measured by. Use of the International Classification of Functioning, Disability and Health (ICF) Framework philosophy, structure, and classification system can be beneficial for guiding the development, use, and interpretation of PROMs.⁷

Thank you for considering ASHA's comments. For questions regarding the Quality Payment Program, the Medicare Shared Savings Program, SDOH, and health equity, please contact Rebecca Bowen, MA, CCC-SLP, ASHA's director for health care policy for value and innovation, at rbowen@asha.org. For questions regarding valuation of specific codes, please contact Inoka Tennakoon, MA, CCC-SLP, ASHA's director for health care policy for coding and payment, at itennakoon@asha.org. For all other inquiries, please contact Sarah Warren, MA, ASHA's director for health care policy for Medicare, at swarren@asha.org.

Sincerely,

Tena L. McNamara, AuD, CCC-A/SLP

2024 ASHA President

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² U.S. Department of Health and Human Services. Office of Inspector General. (2 Sept. 2022). Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks. https://oig.hhs.gov/oei/reports/OEI-02-20-00720.asp

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⁶ American Speech-Language-Hearing Association. (2023, February 9). ASHA recommendations to CMS on Merit-based Incentive Payment System Specialty Measure Sets. https://www.asha.org/siteassets/advocacy/comments/asha-recommendations-to-cms-on-mips-specialty-measure-sets-rfi-020923.pdf

⁷ Threats, T. T. (2012, December 1). Use of the ICF for Guiding Patient-Reported Outcome Measures. *Perspectives on Neurophysiology and Neurogenic Speech and Language Disorders*. <u>https://doi.org/10.1044/nnsld22.4.128</u>