

September 9, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure:

On behalf of the American Speech-Language-Hearing Association, I write to offer comments on the calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS) proposed rule.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 218,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

ASHA members provide health care services to patients under Part B and will be impacted by several provisions of the proposed rule including updates to the Merit-Based Incentive Payment System and telehealth coverage policies. Additionally, ASHA remains concerned that reductions to payments for our members' services to maintain budget neutrality will have a significant negative impact on beneficiary access to care and will further erode the viability of audiology and speech-language pathology practices.

ASHA's comments focus on the following areas:

- Clinical Labor Pricing Update (section II.B.3.D.)
- Telehealth and Other Services Involving Communications Technology (section II.D.)
 - o Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
 - Expiration of PHE Flexibilities for Direct Supervision Requirements
 - o Interim Final Provisions in the CY 2021 PFS Final Rule
- Remote Therapeutic Monitoring-CPT Codes 989X1, 989X2, 989X3, 989X4, and 989X5 (section II.E.4.37.)
- Medicare Shared Savings Program (section III.J.)
- Medicare Provider and Supplier Enrollment Changes (section III.N.1.)
- Updates to the Quality Payment Program (section IV.)
 - MIPS Value Pathways (MVPs)
 - Updates to the MIPS Quality Measures
- Regulatory Impact Analysis (section VII.)

Section II.B.3.D. Clinical Labor Pricing Update (p. 39118)

CMS proposes to update the clinical labor wage rates based on data from the U.S. Bureau of Labor Statistics (BLS). ASHA agrees that the BLS is the most accurate source of wage data. However, ASHA is concerned that because the last update occurred in 2002, dramatic changes in pricing will negatively impact certain specialties. As such, **ASHA recommends that CMS implement a four-year transition to the new clinical labor cost data, similar to what was done with the recent changes to supply and equipment pricing.** Further, ASHA encourages CMS to update pricing data for all inputs on a more frequent and regular schedule to minimize extreme adjustments to future payments. Finally, ASHA notes that the actual increase in clinical labor costs experienced by providers is not acknowledged through an annual update to the conversion factor and asks CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years. Payment reductions during periods of inflationary growth place an undue and disproportionate burden on health care providers; particularly as they address the current public health emergency (PHE).

Section II.D. Telehealth and Other Services Involving Communications Technology

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (p. 39130)

Audiologists and speech-language pathologists (SLPs) effectively provide services by means of telehealth through their professional training. However, ASHA recognizes that Section 1834(m) precludes Medicare payment for telehealth services provided by audiologists and SLPs. Through Section 3703 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136) Congress provided flexibility to allow additional categories of clinicians, including audiologists and SLPs, to be reimbursed for telehealth services during the Public Health Emergency (PHE). Legislation has been introduced in the House of Representatives that would expand Medicare coverage for telehealth services to include services provided by audiologists and SLPs as covered telehealth providers. ASHA remains committed to ensuring Medicare beneficiaries permanently maintain access to audiology and speech-language pathology services provided either in-person or via telehealth based on the patient's needs and preferences.

During the pandemic private health plans dramatically expanded their telehealth coverage as well. Several large national plans, such as UnitedHealthCare and Cigna have established permanent policies covering audiology and speech-language pathology services provided via telehealth. These improvements in telehealth coverage indicate a significant change in the understanding of the effectiveness and efficiency of telehealth services. Medicare beneficiaries deserve access to telehealth services comparable to individuals covered under private insurance.

ASHA's Code of Ethics requires that clinicians use their clinical judgment to determine the most appropriate services for their patients and deliver care via telehealth only if the services are equal in quality to those delivered in person. Delivering care that does not meet the standard for in-person care represents an actionable violation of the ASHA Code of Ethics, which helps ensure patient protection when receiving telehealth services from ASHA certified audiologists and SLPs. An ASHA survey of audiologists and SLPs regarding telehealth services during the PHE found that 38% of audiology respondents and 43% of speech-language pathology respondents do not provide services via telehealth when they have determined those services are not clinically appropriate for individual patients. This demonstrates that ASHA members maintain a commitment to upholding professional ethical standards and only providing

telehealth for clinically appropriate patients when audiology and speech-language pathology services are equivalent in quality to in-person care.

Since the inception of the federally declared PHE, CMS has shown tremendous ingenuity and dedication to ensuring Medicare beneficiaries maintain access to health care services in ways that mitigate the risk of transmission of Coronavirus Disease 2019 (COVID-19). Over the course of a year, CMS developed policies that varied based on the statutory authority available to it at a given time to include a variety of health care settings that bill for Part B services including outpatient clinics, skilled nursing facilities (SNF), and outpatient hospital departments. CMS also established a sub-regulatory process to update the telehealth services list for the purposes of the pandemic on a rolling basis, rather than on an annual basis through the traditional rulemaking cycle. These efforts maintained the quality of and access to care for Medicare beneficiaries and helped clinicians remain employed.

One example of an innovative approach to telehealth flexibilities during the PHE is the ability for outpatient hospital departments to register a patient's home as a temporary extension site through the Regional Office and to consider services provided via audiovisual technology as inperson services. A second example is allowing services provided via audiovisual technology through the window of a SNF resident or in a second location within the SNF to be considered in-person, not telehealth, services. In these instances, the use of modifier 95 (synchronous telemedicine service) is not required. Therefore, based on the claim alone, it is not clear that the services were provided via audiovisual technology rather than in-person without a review of the medical record documentation. ASHA supports the permanent application of using audiovisual technology as in-person services, particularly in outpatient hospital departments and SNFs.

However, one potential challenge that these varied policies has created is a lack of complete data or understanding of the use of audiovisual technology in service delivery during the pandemic. While CMS notes that it saw a sustained increase in use of telehealth associated with mental health services, it is possible that the use of audiovisual technology to deliver a variety of services is more significant than claims data might reflect given the flexibilities outlined above. Therefore, ASHA recommends that CMS consider adding additional services to the telehealth services list under the Category 3 approval criteria that may enable stakeholders to gain an additional understanding of using telehealth across clinical specialties and better inform reimbursement policies.

Through the collaborative efforts of CMS and ASHA, an expanded list of audiology and speech-language pathology Current Procedural Terminology (CPT ®) codes were authorized for Medicare reimbursement when provided via telehealth over the course of the PHE. Many of these codes are only authorized for the duration of the PHE while some other codes will be covered through the end of the year in which the PHE ends when provided incident to a physician. ASHA respectfully requests that the following codes be covered through the end of the year in which the PHE ends under the incident to policy established in the CY 2021 Medicare Physician Fee Schedule final rule. The inclusion of these codes is critical to ensure that CMS and clinicians may gather the requisite experience and data to guarantee appropriate coverage when Congress changes the law to include ASHA members and the services they provide. The information collected will also help prepare CMS to implement a more robust telehealth benefit more efficiently and effectively.

ASHA notes that several of the codes we request for inclusion when provided incident to a physician are representative of audiology diagnostic services. Once the PHE ends, telehealth services provided by audiologists will be statutorily noncovered and such services may only be

billed incident to a physician when provided by an audiologist. However, ASHA maintains that audiologists should be reimbursed when providing diagnostic services via telehealth incident to a physician. Based on the existing telehealth approval criteria established by CMS, covering these codes offers a critical opportunity for both CMS and clinicians to collect the requisite experience and data necessary to request inclusion on a permanent basis in the future.

Code	Short Descriptor	Status
92508	Speech/hearing therapy	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 4/30/20
92526	Oral function therapy	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92607	Ex for speech device rx 1hr	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92608	Ex for speech device rx addl	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92609	Use of speech device service	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92610	Evaluate swallowing function	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92626	Eval aud funcj 1st hour	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92627	Eval aud funcj ea addl 15	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
96105	Assessment of aphasia	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
96125	Cognitive test by hc pro	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
97129	Ther ivntj 1st 15 min	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
97130	Ther ivntj ea addl 15 min	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92550	Tympanometry & reflex thresh	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92552	Pure tone audiometry air	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92553	Audiometry air & bone	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92555	Speech threshold audiometry	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92556	Speech audiometry complete	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92557	Comprehensive hearing test	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92563	Tone decay hearing test	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92565	Stenger test pure tone	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92567	Tympanometry	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21

Code	Short Descriptor	Status
92568	Acoustic refl threshold tst	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92570	Acoustic immitance testing	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92587	Evoked auditory test limited	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92588	Evoked auditory tst complete	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 5/10/21
92601	Cochlear implt f/up exam <7	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 4/30/20
92602	Reprogram cochlear implt <7	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 4/30/20
92603	Cochlear implt f/up exam 7/>	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 4/30/20
92604	Reprogram cochlear implt 7/>	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 4/30/20
92625	Tinnitus assessment	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92626	Eval aud funcj 1st hour	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21
92627	Eval aud funcj ea addl 15	Temporary Addition for the PHE for the COVID-19 Pandemic—Added 3/30/21

Finally, ASHA requests that CMS add CPT codes 92651, 92652, and 92653 to the PHE telehealth services list. These codes replaced CPT codes 92585 and 92586 effective January 1, 2021. ASHA has previously requested the inclusion of 92585 and 92586, and even with the change in coding to better clarify the type and level of testing provided, these services have not changed and are ethically, safely, and effectively provided via telehealth. These tests evaluate hearing in patients who cannot complete typical audiometric testing or may be used to evaluate neural conduction to identify site of lesion of the auditory nerve or brainstem nuclei. Audiologists can conduct testing for auditory evoked potentials (AEPs) using remote access software to connect with a computer-based auditory brainstem response (ABR) testing system at the originating site. A trained facilitator at the originating site acts as an extension of the audiologist and performs very specific tasks at the audiologist's direction, such as applying electrodes on the patient.

Although AEP testing may require the patient to leave the home to access ABR testing equipment, there are practices equipped to provide these services via telehealth, and Medicare beneficiaries should not be precluded from accessing these tests when other standard audiologic tests are currently covered under the temporary telehealth list.

Expiration of PHE Flexibilities for Direct Supervision Requirements (p. 39149)

CMS seeks comment on the permanent application of a change in the definition of direct supervision as temporarily allowed under the PHE to allow the supervising professional to be immediately available through virtual presence using real-time audiovisual technology, instead of requiring their physical presence. This would allow physical and occupational therapists to provide direct supervision of assistants virtually as well as physicians to provide direct supervision virtually when supervising a physical or occupational therapist or speech-language pathologists for the purposes of incident to billing.

ASHA maintains this flexibility is critically important both within and outside the context of the PHE, particularly for Medicare beneficiaries who live in rural or medically underserved areas or those who have challenges accessing care due to a physical impairment or lack or transportation or childcare. However, ASHA notes there should be transparency in the delivery of incident to services and, therefore, encourages CMS to consider a mechanism, such as a modifier, that would be appended to claims whenever a therapy service is provided incident to a physician.

Interim Final Provisions in the CY 2021 PFS Final Rule (p. 39150)

ASHA appreciates CMS's efforts to provide Medicare beneficiaries with broader access to audio-only services both during and beyond the PHE. ASHA agrees with the CMS proposal to permanently adopt coding and payment for HCPCS code G2252 for extended audio-only virtual check-in services for providers who can report evaluation and management (E/M) services. However, ASHA is disappointed that CMS did not also propose a mechanism for providers who cannot report E/M services under the MPFS—including audiologists and SLPs—to report an extended virtual check-in. This is counter to CMS's recent actions to allow additional qualified nonphysician health care professionals (QHPs) permanent access to certain communication technology-based services (CTBS), as well as its current policy allowing telephone assessment and management services (98966-98968) provided by certain nonphysician QHPs—including SLPs—during the PHE. In addition, Medicare beneficiaries will likely lose access to audiology and speech-language pathology telehealth services at the conclusion of the PHE. As such, CTB services—including those conducted via audio-only—will play an even greater role in helping providers and Medicare beneficiaries mitigate a potential resurgence of the virus beyond the PHE.

Therefore, ASHA urges CMS to establish a new G-code for an extended audio-only virtual check-in by a QHP who cannot report E/M services and allow audiologists, SLPs, and other qualified nonphysician providers to report these services. CMS created a similar structure by finalizing two new codes specifically for use by providers who cannot report E/M services—G2250 (remote evaluation of patient videos/images) and G2251 (brief virtual check-in)—in the CY 2021 interim final rule with comment period. Creating a G-code based on this precedent supports CMS's efforts to ensure Medicare beneficiaries who may not have access to audiovisual technology avoid unnecessary office visits and receive timely and appropriate care.

ASHA also firmly maintains that CTBS codes fall within the scope of the audiology diagnostic benefit category and recommends that CMS allow audiologists to bill Medicare for these services, including extended audio-only virtual check-ins. Audiologists provide audiologic testing under the Medicare diagnostic benefit category. They may provide virtual assessments as diagnostic services for patients when a physician or nonphysician practitioner orders an assessment of hearing and/or balance that requires a battery of tests. We understand that the statutorily established Medicare benefit classifies audiology services as diagnostic tests. However, the examples provided in ASHA's comments in response to the CY 2021 NPRM describe services that appropriately involve the referring physician and stay within the Medicare diagnostic benefit, allowing Medicare beneficiaries timely access to care and avoiding potential overutilization of in-person visits.²

Section II.E.4.37. Remote Therapeutic Monitoring-CPT Codes 989X1, 989X2, 989X3, 989X4, and 989X5 (p. 39173)

ASHA supports CMS's proposal to implement five new codes for remote therapeutic monitoring (RTM), including the proposed practice expense (PE) refinements. However, ASHA disagrees with CMS's assessment that these codes may not be reported by providers other than physicians or nonphysician practitioners (NPPs)—such as physical and occupational therapists, audiologists, or SLPs—due to application of the "incident to" policy. CMS notes that most nonphysician specialties may not report "incident to" services. However, ASHA asserts that the "incident to" policy does not apply to the RTM codes and should not be used to preclude specialties from reporting these services. For example, when conducting remote monitoring services, audiologists and SLPs would personally furnish the clinical labor activities included in the direct practice expense inputs because they cannot bill for services provided by auxiliary personnel or assistants. In addition, occupational and physical therapists (OTs and PTs) would supervise assistants or aides when providing RTM services, which is allowable under the Medicare benefit for occupational and physical therapy services. As such, ASHA recommends that CMS implement the new RTM codes as general medicine codes—without restrictions on the provider types that can provide these services—including audiologists and SLPs. ASHA also requests CMS to clarify that clinical labor activities are billable when personally performed by clinicians or by assistants/aides under the direct supervision of an OT or PT.

If CMS maintains that the current structure of the RTM codes prevents audiologists, SLPs, OTs, PTs, and other nonphysician QHPs from reporting these services, **ASHA requests CMS to establish G-codes that would allow providers who are not physicians or NPPs to report and receive comparable payment for these services.** It is critical for CMS to allow audiologists and SLPs to report these new G-codes because audiologists and SLPs may conduct remote monitoring services for a variety of conditions and patients.

ASHA offers the following recommendations for structuring the new G-codes and examples of typical RTM services provided by audiologists and SLPs.

Coding Considerations

ASHA urges CMS to consider the follow factors when developing new G-codes for remote monitoring.

- Unlike OTs and PTs, audiologists and SLPs cannot bill for services provided by auxiliary
 personnel or assistants. Therefore, any time typically associated with clinical labor
 activities—such as greeting the patient or device setup—should be considered as part of
 the work RVU, since the QHP will perform those activities.
- It may be necessary to create distinct G-codes for providers who can bill for services
 provided by assistants, such as OTs and PTs, versus those providers who cannot, such
 as audiologists and SLPs. For example, initial device setup and patient training
 conducted by an audiologist or SLP should not be a PE-only code because all this time
 is spent by the QHP instead of the clinical staff.
- CMS should consider a similar structure to the current RTM codes with codes for initial device setup and patient education (989X1); codes for device-specific supplies and monitoring (989X2, 989X3) over a calendar month; and codes for reviewing and integrating the data and interaction with the patient (989X4, 989X5) over a calendar month.

However, CMS should also consider additional codes specific to different Medicare benefits, as outlined in the following discussion regarding audiology services.

Audiology Remote Monitoring Services

Audiologists can provide remote monitoring services to assess and adjust hearing aid or implant functionality, monitor device usage, and collect data on the patient's functional hearing ability in real-world situations to inform an auditory rehabilitation plan of care. They can also use home-based systems for treatment of vestibular (balance) disorders; thereby, allowing remote monitoring of a patient's progress and the adjustment of exercises based on objective data.

However, ASHA understands the limitations of the Medicare diagnostic benefit and recommends that CMS create specific G-codes to allow specialties that fall under this benefit category—such as audiologists—to report remote monitoring services that collect data regarding device function rather than data for monitoring therapeutic activities. For example, ASHA maintains that under the Medicare diagnostic benefit, audiologists could use remote software to collect data on hearing implant device function to determine the need for device troubleshooting or adjustments to device programming. It may be necessary for CMS to distinguish between remote monitoring codes for specific these purposes versus those designed for monitoring of treatment adherence and progress. CMS should consider creating create a Gcode specifically to monitor hearing implant devices, such as cochlear implants or auditory osseointegrated devices. Because audiologists cannot bill for auxiliary personnel or assistant services, any time typically associated with clinical labor activities should be considered as part of the work RVU since the audiologist will perform those activities. Therefore, ASHA recommends that CMS consider specific G-codes for remote monitoring and review of diagnostic data for auditory implant devices, which may be structured like 989X4 and 989X5, except for removal of clinical labor time from direct practice expense inputs. The purpose of the service would be to monitor device functionality to allow audiologists to provide troubleshooting or assess the need for further programming of the device.

Clinical Example

A Medicare beneficiary with a cochlear implant device—a surgically implanted device to help with severe to profound hearing loss—has been participating in device programming/reprogramming sessions with an audiologist. The patient is provided with and trained to use a mobile application for remote monitoring of the implant device. Using a secure portal, the audiologist can remotely monitor device connectivity and wearing time of the external speech processor. The audiologist can also customize and adjust the remote monitoring activities based on the patient's needs, including standard questionnaires, a customized battery of automated hearing tests, and impedance checks. Once activities are determined and sent to the patient's remote monitoring application, the patient may complete the activities at their own pace. When activities are completed by the patient, the application automatically transmits the results to the audiologist through a secure portal. The automated hearing tests provide objective data about the patient's hearing ability with the device, such as the softest level the patient can hear with the implant (thresholds) and the patient's ability to listen at different levels of background noise. The impedance check allows the audiologist to assess whether the electrodes in the implant device are functioning correctly, and the questionnaires allow the patient to provide feedback regarding their functional hearing abilities when using the device. The comprehensive data collected through objective measures and patient selfreport allows the audiologist to monitor whether the device is functioning properly. provide troubleshooting to optimize the patient's use of the device, and assess the need for further programming of the device. The audiologist will contact the patient/caregiver to discuss results of the data gathered, provide guidance on how to troubleshoot certain challenges with the device, and advise whether an appointment to adjust the

programming of the implant is required for better hearing function. A report may also be forwarded to the patient's physician and other patient care providers.

Speech-Language Pathology Remote Monitoring Services

SLPs may report RTM codes for home-based voice or swallowing training devices that provide biofeedback to the patient and produce objective data for the clinician, allowing the clinician to provide ongoing adjustments to training exercises and informing the plan of care and treatment goals. SLPs may also conduct remote monitoring through mobile applications or computer-based software used to design a personalized home training program supplementing speech, language, and/or cognitive treatment and allowing the clinician to collect objective data regarding the patient's functional performance and progress.

Clinical Examples

Patient with aphasia: A Medicare beneficiary with aphasia—a language disorder caused by brain injury—has been receiving language treatment under a speechlanguage pathology plan of care. The patient/caregiver is provided with and trained to use a mobile application that allows the SLP to create a customized plan for the patient to work on language-based and communication activities at home, between visits. The mobile application guides the patient through interactive activities and exercises to implement the skills and strategies learned during treatment in real-world communication contexts. The application automatically adapts to the patient's skill level as they progress through the activities and provides feedback to the patient regarding their performance. Data are automatically transmitted to the SLP through a secure portal, allowing the SLP to remotely monitor the patient's adherence to treatment, review objective data regarding the patient's functional progress, and adjust the activities and exercises based on the patient's current needs. Using the data gathered, the SLP can contact the patient/caregiver to review the results and discuss the patient's adherence and progress between sessions. The SLP also uses the data to inform and modify ongoing treatment goals, as needed. A report may also be forwarded to the patient's physician and other patient care providers.

Patient with dysphagia: A Medicare beneficiary with dysphagia—a swallowing disorder—has been receiving dysphagia treatment under a speech-language pathology plan of care. The patient is provided with and trained to use a remote monitoring and biofeedback system that allows the patient to continue retraining swallowing physiology at home, between sessions. The system typically consists of a mobile application and a wireless device placed under the patient's chin. The system allows the SLP to create a customized plan for the patient to perform swallowing exercises at home. The mobile application guides the patient through exercises while sensors on the wireless device under the patient's chin monitor muscle contractions. The system provides real-time biofeedback regarding length and strength of muscle contractions, allowing the patient to adjust their swallow effort or change swallow strategies to successfully complete the individualized exercises. Data are automatically transmitted to the SLP through a secure portal, allowing the SLP to remotely monitor the patient's adherence to treatment, review objective data regarding the patient's functional progress, and adjust the exercises based on the patient's current needs. Using the data gathered, the SLP can contact the patient/caregiver to review the results and discuss the patient's adherence and progress between sessions. The SLP also uses the data to inform and modify ongoing treatment goals, as needed. A report may also be forwarded to the patient's physician and other patient care providers.

Section III.J. Medicare Shared Savings Program (p. 39261)

CMS seeks comments and recommendations on how accountable care organizations (ACOs) can utilize their resources to ensure that patients, regardless of racial/ethnic group, geographic location and/or income status, have access to equal care and how ACOs can improve the quality of care provided to certain communities, while addressing the disparities that currently exist in health care. ASHA appreciates CMS's efforts to identify ways to eliminate health disparities and improve access to and the equity of health care. ASHA members are committed to improving health equity as well. While access issues associated with race, ethnicity, geography, and income must be addressed, ASHA also recommends ACOs address equity associated with the following:

- Ability to communicate: An inability to communicate because of hearing loss, a
 cognitive or speech impairment, articulation, and/or inability to comprehend clinical
 instructions impact a patient's overall ability to participate in the care planning process
 and benefit from skilled interventions. Effective communication represents the core and
 foundation of patient-centered care and without it, patients will be less satisfied, less
 enabled, and may demonstrate more symptoms, higher rates of readmission, and
 greater use of resources.
- Insurance coverage (including lack thereof): Health insurance coverage has been identified as a key social determinant of health domain and is one of the largest barriers to health care access. Lack of health insurance contributes to health disparities. For example, patients who are underinsured or uninsured may forgo or delay necessary care, which impacts the quality and outcomes of care they receive.
- Access to technology (e.g., broadband internet access or tablets): Patients without
 access to technology and digital literacy may not be able to receive timely and clinically
 appropriate care via telehealth; thereby, delaying care and adversely impacting
 outcomes and quality of care.
- Forms of economic insecurity such as, but not limited to, housing or food insecurity: Patients with one or more forms of economic insecurity may have to choose between medical care and responding to other financial demands. The stress of such choices adversely impacts the overall physical and mental health of the individual. When forced to choose, medical care may be a lower immediate priority despite the significant financial impact delaying care can have on an individual's overall economic security.
- Availability of caregiver support: Lack of caregiver support creates access challenges that may reinforce health disparities.
- Health literacy: The patient's ability to obtain, process, and understand basic health information and services needed to make appropriate health decisions and follow instructions for treatment needs to be assessed. Health literacy is not restricted to only a person's ability to read and write.⁴ If a person also has a communication disorder, it can increase their difficulties with processing and using health information. Other factors that play a role in how well someone understands health information that they receive through hearing, seeing, and reading include:
 - o experience with the health care system,
 - cultural and linguistic factors,
 - the format of materials, and
 - how information is communicated.

CMS also seeks comments and recommendations on how to encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives, including whether any adjustments should be made to quality measure benchmarks to consider ACOs serving vulnerable populations. One improvement would be to ensure ACOs include a variety of clinical specialties, including audiologists and SLPs, and quality metrics associated with their services. Too many ACOs overlook the full range of services and care coordination needed by the patients they serve and in doing so exclude important episodes of care.

Section III.N.1. Medicare Provider and Supplier Enrollment Changes (p. 39311)

CMS proposes to modify its authority to deny or revoke a provider's enrollment based on an Office of Inspector General (OIG) Exclusion to include excluded administrative or management services personnel who furnish services payable by a federal health care program, such as a billing specialist, accountant, or human resources specialist. While ASHA recognizes the importance of program integrity, the proposal will increase provider burden, particularly for small practices. ASHA urges CMS to mitigate the impact of these changes to the extent practicable.

For example, some solo and small practices hire a third-party vendor to submit claims on their behalf. As part of that contractual relationship, the clinicians expect that the vendor has performed the requisite background check to determine if the individual performing the claims submission, as the vendor's employee, has not been excluded from the program. In some instances, the vendor may not have performed the necessary background checks, and this would be difficult or impossible for the clinician to know. If finalized as proposed, the rule will require clinicians to update their contracts with vendors to ensure that in instances when the vendor has not met its obligation to perform an accurate and comprehensive background check, that the clinician themselves would be held harmless and the vendor will bear the financial responsibility.

In summary, while the proposal is important for the purposes of program integrity, CMS should understand and mitigate to the extent practicable the administrative burden associated with it.

Section IV. Updates to the Quality Payment Program

MIPS Value Pathways (MVPs) (p. 39351)

ASHA recognizes that CMS has made a significant effort—since the inception of the Merit-Based Incentive Payment System (MIPS)—to ensure that it achieves the intended outcomes of improving the quality of care for Medicare beneficiaries and protects the Medicare trust fund in the transition to a value-based payment system, including the development of MIPS Value Pathways (MVPs). However, ASHA remains concerned that the development of the Quality Payment Program (QPP), including MIPS, MVPs, and Advanced Alternative Payment Models, continues to focus on physicians at the detriment and exclusion of nonphysicians such as audiologists and SLPs. Despite ASHA's involvement in technical expert panels tasked with developing cost measures, no measures have been approved to address our members' services and needs.

The measures in the quality performance category remain fairly generic process measures. ASHA has requested that measure stewards include our members' services in specific MIPS quality measures to develop a more discipline-specific and robust specialty measure set. These efforts have often been rebuffed because the stewards, understandably, have designed the measures with their specialty in mind and are concerned that participation by clinicians outside the specialty may inappropriately skew the data. The Physician Technical Advisory Commission

(PTAC) has made little headway in approving alternative payment models and those that have been recommended to CMS do not include (or include on a very limited basis) nonphysician services. Despite the continued exclusion of nonphysicians from these processes, the proposals associated with MVPs would require nonphysician clinical specialty groups that develop an MVP to include physicians without imposing a complementary burden on physicians to include nonphysicians. If nonphysician clinicians continue to be a secondary consideration in the evolution of the QPP, it is unlikely CMS will achieve its goal of improving the quality and coordination of care for Medicare beneficiaries.

In addition to our overall concerns about the evolution of the QPP, ASHA worries about the applicability of MVPs to audiologists and SLPs, the potential transition to MVPs (and associated elimination of MIPS) as early as 2028, and the utility of the MVP concept to our members and the Medicare beneficiaries they serve. It is ASHA's understanding that CMS designed MVPs to help clinicians identify which metrics within each of the performance categories (i.e., quality, improvement activities, cost, promoting interoperability) most directly apply to their clinical practice and patient populations to streamline reporting requirements. While ASHA supports these goals, it remains unclear how MVPs would ease the reporting burden associated with MIPS and how they apply to nonphysician clinicians—such as audiologists and SLPs—who are not eligible for two of the four performance categories.

Specifically, audiologists and SLPs cannot participate in the cost or promoting interoperability categories for MIPS. ASHA appreciates CMS's continued exclusion of our members from these categories and will support their exclusion until these categories are modified to reflect the needs of nonphysicians. Audiologists and SLPs do not control the total cost of care in the same way as physicians. They are also not subject to many of the reporting requirements of the promoting interoperability category (e.g., e-prescribing) because of scope of practice exclusions under state law that preclude them from prescribing medications or other services. Audiologists and SLPs were also ineligible for meaningful use incentive payments under a previous incentive program. Therefore, application of promoting interoperability essentially would be an unfunded mandate on nonphysicians. For these reasons, MVPs for audiologists and SLPs would only include two performance categories—quality and improvement activities. This seems to contradict CMS's expectations for MVPs. ASHA urges CMS to clarify if audiologists, SLPs and other nonphysicians would be eligible to participate in an MVP if they do not report on all four performance categories, and under what program requirements and exceptions.

In addition, CMS recommends MVPs include 10 quality measures and 10 improvement activities. Under the proposals of this rule, audiologists would have eight potentially applicable measures and SLPs would have five potentially applicable measures in 2022, and few of these measures are discipline specific. ASHA continues to monitor the development of quality measures approved for addition to the MIPS quality measure set to determine their applicability potential to our members and we are also considering the development of a qualified clinical data registry and associated measures for MIPS purposes in a future year. The expectation to include 10 quality measures in an MVP is challenging at best for ASHA members given the potential lack of measures available. **ASHA urges CMS to clarify that the development of or participation in an MVP may be possible for specialties with fewer than 10 applicable quality measures and whether a measure applicability validation process would be applied.**

It is ASHA's understanding that an MVP must be open to any eligible clinician and this raises concerns about improving care within a specialty. Specifically, ASHA has developed a registry

known as the National Outcomes Measurement System (NOMS) for use by audiologists and SLPs. Similarly, many other clinical specialties have developed discipline-specific registries and/or quality measures. In the future, ASHA may submit NOMS to CMS for approval as a qualified clinical data registry along with associated quality measures for the purposes of MIPS or MVPs. The measures would be performed and reported by audiologists or SLPs and it is unclear what impact it would have on the data and the development of future measures if other clinical specialties were also reporting these measures. The cost associated with incorporating and maintaining data reported by clinicians other than audiologists and SLPs into NOMS must also be considered. If CMS's intention is to improve care at a specialty-level, then requiring an MVP to be open to "any willing participant" makes achieving this goal more challenging. The proposal also contradicts the historical trajectory of MIPS, which was founded on the concept of specialty measure sets.

ASHA is concerned that other specialties might not include audiologists or SLPs in their registries for the purposes of MVP participation due to the cost and administrative burden of including measures specific to audiology or speech-language pathology. For those MVP sponsors who do choose to incorporate audiologists and SLPs and those discipline-specific measures, it raises concerns about the cost of securing that data for the purposes of quality improvement and access to that data. For example, if a physician registry incorporated audiology-specific measures, it would create a need for the development of a data use agreement between the physician registry and ASHA. Consideration must be given for the challenges of collecting data for another specialty, which would likely create administrative and financial burdens not only for the physician registry but also ASHA, and the individual audiologist providing services. MVP sponsors might include the more generic MIPS measures currently approved for audiologists or SLPs, but inclusion of these measures calls into question whether MVPs would then achieve CMS's intended goal of meaningfully improving the quality of care delivered by all clinical specialties treating Medicare beneficiaries.

For these reasons, ASHA recommends that CMS allow for MVPs to truly focus on specific clinical specialties. This will facilitate the development of MVPs for nonphysicians and improve the quality of care for Medicare beneficiaries. Providers would report discipline-specific measures and more often outcomes, rather than process measures.

Finally, most audiologists and SLPs remain excluded from MIPS based on the low-volume threshold. Many of those who do report do so on a voluntary or on an opt-in basis. CMS proposes that voluntary reporters would not be eligible to participate in an MVP, which would further reduce the ability of audiologists and SLPs to participate in MVPs and make successful transition from MIPS to MVPs even harder.

Without access to an MVP, audiologists, SLPs and other nonphysicians would not have a reporting option and would automatically be subject to a 9% payment reduction if CMS eliminated MIPS in the future (e.g., 2028). Therefore, ASHA recommends that CMS delay the transition from MIPS to MVPs until it may be modified to include nonphysicians. CMS must more actively partner with nonphysician groups to overcome the challenges associated with MIPS participation to ensure every clinician, regardless of clinical specialty, may successfully participate to ensure the program improves the quality of care for Medicare beneficiaries.

MIPS Performance Category Measures and Activities (p. 39386)

CMS proposes to update the measure specifications for Measure 182: Functional Outcomes Assessment to include the concept of swallowing, hearing, and balance function. The specifications are updated to include the EAT-10: Swallowing Screening Tool, the Health Partners Hearing Assessment, and the Tinneti Performance Oriented Mobility Assessment as eligible assessment tools. The proposed rule also updates the definition of functional outcome deficiencies to include the "impairment or loss of function related to speech or language capacity, included but not limited to swallowing, hearing, and balance disorders." **ASHA appreciates the collaborative efforts of the measure developer and CMS and supports these revisions to the measure specifications.**

However, ASHA asserts this measure should continue to be reported on claims. As noted above, audiologists and SLPs were not eligible for meaningful use incentive payments and are not subject to the promoting interoperability performance category. Many audiologists and SLPs work in small practices where the adoption of an electronic medical record system remains cost prohibitive. As a result, removing the ability to report this measure via claims limits the ability of nonphysicians to report this measure and effectively participate in MIPS. Eliminating claims-based reporting would lower their score in the quality performance category and the MIPS score overall, potentially leading to an unfortunate and undeserved payment penalty. For these reasons, ASHA opposes CMS's proposal to remove this as a claims-based measure.

Section VII. Regulatory Impact Analysis (p. 39528)

CMS published specialty-level payment impacts for CY 2022 in Table 123, based on policies contained in the proposed rule. However, because CMS calculated the estimated 2022 conversion factor (CF) as though the one-year 3.75% increase to the 2021 CF had never been applied, Table 123 does not reflect the full impact of the payment changes providers could experience in 2022, should policies be finalized as proposed. ASHA understands that, per the Consolidated Appropriations Act, 2021 (Public Law 116-260), CMS cannot take the increase into account when determining payment rates for following years. However, we firmly maintain that providers must have access to impact data that provides a clear and complete picture regarding payment changes to reduce potential confusion, help make informed business decisions regarding their practices, and ensure continued patient access to medically necessary care. As such, ASHA requests that CMS provide greater clarity in all future rulemaking regarding actual payment impacts when there are mitigating factors—such as the temporary 3.75% payment adjustment—in addition to the standard regulatory impact analysis (RIA).

As many Medicare providers—including audiologists and SLPs—brace for the scheduled expiration of the 3.75% payment adjustment and the return of significant payment cuts due to the 2021 changes to office/outpatient E/M services, ASHA again requests CMS to consider the far-reaching implications of this policy. ASHA recognizes that CMS cannot change the underlying budget neutrality mandate that necessitated the payment reductions. However, we remain extremely concerned about the negative impact this policy has had on many specialties that cannot report E/M services—including audiology and speech-language pathology—especially given the prolonged impact of the current PHE on the health care system and Medicare beneficiaries.

CMS notes the actual negative impact on total revenue for individual providers is less than outlined in the RIA due to revenue from non-Medicare patients or from other Medicare payment systems. However, other payers tie their fee schedules directly or indirectly to the Medicare

Physician Fee Schedule (MPFS). Many private contracts, as well as the Department of Veterans Affairs' Community Care, the Department of Defense's TRICARE, workers compensation programs, and state Medicaid agencies reference the MPFS in their payment rates. As such, this policy not only negatively affects Medicare providers and beneficiaries, but also impacts revenue generated from non-Medicare patients, including veterans, TRICARE enrollees, and commercially insured and self-pay patients.

Other Medicare payment reductions, such as sequestration, the multiple procedure payment reduction (MPPR), and the assistant payment differential compound the reductions. Although the rule points to other Medicare payment systems, such as the Quality Payment Program (QPP), as a means to offset the cuts, there is little potential for meaningful relief under this program, which must also remain budget neutral, providing a net-zero increase for participating providers. Audiologists, SLPs, and other nonphysician providers have limited opportunities for payment adjustments under MIPS and few pathways for participation in Alternative Payment Models.

Therefore, ASHA requests that CMS continue to consider any regulatory options to mitigate the long-term impact of the E/M coding and payment changes finalized in 2021. Actions undertaken by CMS can provide greater stability to providers—independent of additional congressional action taken to mitigate the cuts. For example, a potential long-term strategy to reduce the impact of the E/M policy is cancellation of the policy implementing payment for Healthcare Common Procedure Coding System (HCPS) add-on code G2211 (visit complexity inherent to evaluation and management associated with medical care services). This would allow CMS to apply the savings to the budget neutrality calculation and lessen the negative impact to affected providers. As such, ASHA requests that CMS cancel implementation of HCPCS add-on code G2211 before the suspension of payments for this code mandated by Public Law 116-260 expires in 2024. ASHA also urges CMS to seek other opportunities to mitigate the cuts, such as finding savings from past over-estimates of spending or positively revaluing additional services that are analogous to office/outpatient E/M visits.

Finally, ASHA notes that Table 123 does not include specific impact data for speech-language pathology, which is currently included in calculations for physical/occupational therapy. ASHA does not consider it accurate or appropriate to include SLPs in this category, as speech-language pathology billing and utilization patterns are not analogous to physical or occupational therapy services. For example, most CPT codes reported by SLPs are untimed, which changes how MPPR adjustments impact payment in contrast to reimbursement for multiple timed codes billed per encounter by OTs and PTs. In addition, unlike OTs and PTs, SLPs cannot bill Medicare for services provided by assistants and, as such, payments for speech-language pathology services are not affected by the assistant payment differential.

Medicare providers must have access to accurate estimated impact data specific to their specialty, especially given the ongoing potential for significant payment reductions due to the E/M coding and payment changes. Without this data, SLPs and other providers face a distinct disadvantage as they attempt to prepare for the impact of the CY 2022 and future coding and policy changes. As such, ASHA urges CMS to separate speech-language pathology from the physical/occupational therapy category. In addition, ASHA requests that CMS continue to include specific specialty-level impact data for all specialties—including SLPs—in all future rulemaking. This practice will ensure equitable access to information for all Medicare providers and aligns with CMS's ongoing commitment to transparency.

Conclusion

The 2022 MPFS proposed rule contains several provisions of significant importance to audiologists and SLPs in the areas of telehealth, coding and payment policy, as well as quality reporting. Thank you for your attention to our comments. If you or your staff have questions regarding telehealth or the Quality Payment Program, please contact Sarah Warren, MA, ASHA's director of health care policy for Medicare, at swarren@asha.org. For questions about coding, relative value units, or remote therapeutic monitoring, please contact Neela Swanson, ASHA's director of health care policy for coding and reimbursement, at nswanson@asha.org.

Sincerely,

A. Lynn Williams, PhD, CCC-SLP

a. Lynn William

2021 ASHA President

¹ American Speech-Language-Hearing Association. (2016). Code of Ethics. https://www.asha.org/Code-of-Ethics/

² American Speech-Language-Hearing Association. (2020). *Comments in Response to CY 2021 Medicare Physician Fee Schedule Notice of Proposed Rule Making (CMS-1734-P)*. https://www.asha.org/siteassets/uploadedfiles/asha-2021-mpfs-nprm-comments-100520.pdf

³ Healthy People.gov. (n.d.). *Access to Health Services*. https://www.healthypeople.gov/2020/topicsobjectives/topic/social-determinants-health/interventions-resources/access-to-health#3.

⁴ American Speech-Language-Hearing Association. (n.d.). *Health Literacy*. https://www.asha.org/slp/healthliteracy/.