



September 6, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts (CMS-1770-P)

Dear Administrator Brooks-LaSure:

On behalf of the American Speech-Language-Hearing Association, I write to offer comments on the calendar year (CY) 2023 Medicare Physician Fee Schedule (MPFS) proposed rule.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 223,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

ASHA's comments focus on several key areas including:

- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section II.D.)
- Valuation of Specific Codes: Caregiver Behavior Management Training (CPT Codes 96X70 and 96X71) (Section II.E.4.29.)
- Methodology for the Proposed Revision of Resource-Based Malpractice (MP) RVUs (Section II.H.2.)
- Non Face-to-Face/Remote Therapeutic Monitoring (RTM) Services (section II.I.)
- Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order (Section II.K.)
- Medicare Shared Savings Program (Section III.G.)
- Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment (section III.J.)
- Updates to the Quality Payment Program (Section IV.)

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

Other Services Proposed for Addition to the Medicare Telehealth Services List

Professional training enables audiologists and speech-language pathologists (SLPs) to provide efficacious services. However, Section 1834(m) precludes Medicare payment for telehealth services provided by audiologists and SLPs. Under 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 federal COVID-19 public health emergency (PHE). Congress also enacted the Consolidated Appropriations Act of 2022 (Public Law 117-103) to enable audiologists and SLPs to continue furnishing services via telehealth for 151 days following expiration of the COVID-19 PHE. Further, the House has passed legislation (H.R. 4040) that would extend this authority through 2024, and other bills (H.R. 2168/S. 3193) have been introduced that would expand Medicare coverage for telehealth services to permanently include services provided by audiologists and SLPs as covered telehealth providers. ASHA remains committed to ensuring Medicare beneficiaries are granted permanent access to audiology and speech-language pathology services provided either in person or via telehealth based on the patient's needs and preferences and the clinician's professional judgment.

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.¹ 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 establishment of the federal COVID-19 PHE, CMS has demonstrated notable ingenuity and dedication to ensuring Medicare beneficiaries maintain access to health care services in ways that mitigate the risk of transmission of 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.

In March 2020, CMS added numerous codes typically billed by audiologists and SLPs to the authorized telehealth services list. However, given the legal limitations of telehealth services at that time, these services could only be billed by a physician or practitioner. With passage of the CARES Act, CMS acted expeditiously to add audiologists and SLPs as authorized providers but that was not finalized until June 2020. The initial list of services was fairly limited—particularly for audiology services—as it included only four Current Procedural Terminology (CPT®) codes associated with cochlear implant programming. CMS further expanded the list of CPT codes billed by audiologists and SLPs in March 2021. As a result, there is limited data around 2020 telehealth utilization for audiology and speech-language pathology services and ASHA anticipates having a clearer picture based on 2021 data.

ASHA recognizes data around utilization, quality, outcomes, and patient satisfaction are critically important to make educated decisions regarding telehealth coverage. Without reviewing the data, it is premature to remove services from the authorized telehealth services list. ASHA was pleased to note that CMS added several audiology and speech-language pathology CPT codes to the authorized telehealth services list through the end of 2023 based on the Category 3 criteria, as outlined in the table below and in Table 8 of the proposed rule.

CPT Code	Descriptor
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92550	Tympanometry and reflex threshold measurements
92552	Pure tone audiometry (threshold); air only
92553	air and bone
92555	Speech audiometry threshold;
92556	with speech recognition
92557	Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)
92563	Tone decay test
92567	Tympanometry (impedance testing)
92568	Acoustic reflex testing, threshold
92570	Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing
92587	Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3-6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report
92588	comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92625	Assessment of tinnitus (includes pitch, loudness matching, and masking)
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); first hour
92627	each additional 15 minutes (List separately in addition to code for primary procedure)

CPT Code	Descriptor
96105	Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, eg, by Boston Diagnostic Aphasia Examination) with interpretation and report, per hour
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour
96113	each additional 30 minutes (List separately in addition to code for primary procedure)
97129	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes
97130	each additional 15 minutes (List separately in addition to code for primary procedure)

Once the federal COVID-19 PHE ends, ASHA recognizes these services would only be reimbursed when provided by a physician, nonphysician practitioner (NPP), or an SLP incident to a physician. ASHA thanks CMS for the additional services that have been added on a Category 3 basis through the end of 2023. ASHA believes the additional time helps gather the evidence necessary to qualify as telehealth services on a permanent basis under the Category 1 or 2 criteria established by CMS.

However, ASHA notes the omission of CPT codes 92603 and 92604, which represent cochlear implant programming and reprogramming, respectively, for patients *over 7 years of age*. ASHA requests CMS include these codes, as they apply to Medicare beneficiaries. ASHA also requests the addition of 92602 for reprogramming for patients under 7 years old as a complement to 92601, for reporting the initial programming for patients under 7 years old.

Ongoing Data Collection and Utilization Review

To ensure appropriate access to telehealth services is maintained, ASHA has committed to identifying a variety of sources of data to understand telehealth utilization as well as the quality and outcomes of care and patient satisfaction with telehealth services. These data include: 1) an analysis by an independent contractor of claims data across payers including Medicare, Medicaid, and private insurers; 2) ASHA registry data; and 3) an ASHA member survey. The data show high patient satisfaction with telehealth services, quality and outcomes that are comparable to in-person services, and additional benefits for patients such as reduced costs and increased access to care.

1. Claims Data Analysis

The claims data analysis secured by ASHA is based on 2020 data since 2021 data is not yet available. However, this preliminary data demonstrates judicious use of telehealth by audiologists and SLPs across all payers.

2. National Outcomes Measurement System

ASHA analyzed utilization and outcomes data from our registry, the National Outcomes Measurement System (NOMS), which has been used by ASHA members for nearly 20 years.² Recently, NOMS underwent a significant redesign and was relaunched in the

second quarter of 2021. As of August 2022, the registry includes data on approximately 16,700 episodes and ASHA estimates about 6,500 of those episodes are Medicare Part B beneficiaries. The preliminary data demonstrates patients who received audiology and SLP services through telehealth had high levels of satisfaction and patient reported outcomes.

Patient-reported satisfaction data in NOMS show that nearly 73% of patients who received at least one telehealth service reported involvement in the development of the plan of care and delivery of treatment. Additionally, 75% of patients reported having a better understanding of their condition or illness and 68% reported improvement in their condition when receiving telehealth services. Approximately 51% of patients who completed the Neurology Quality of Life (Neuro-QOL) scale noted improvement during their episode of care. Clinicians delivering services via telehealth also reported high levels of patient functional improvement associated with spoken language expression, spoken language comprehension, voice, intelligibility, and cognition with many patients experiencing progress of 20% or more from admission to discharge based on the functional communication measures included in NOMS.

3. ASHA Member Survey

In April 2022, ASHA surveyed its Telepractice Special Interest Group on the quality and outcomes of telehealth as well as the cost of delivering services via telehealth. The vast majority of the survey respondents (68%) noted they provide both in-person and telehealth services and that they have significant annual costs (on average \$2,373) to maintain access to telehealth services for patients including equipment purchases, access to high-speed internet, and the use of secure, HIPAA compliant software. Additionally, 58% of survey respondents report that they provide the same materials (e.g., written materials, evaluation materials, therapy tools) regardless of the service delivery method. Clinicians also reported additional benefits for patients who receive services via telehealth. For example, 50% of clinicians who responded to the survey noted reduced patient costs for time off from work or travel costs, a reduction in missed visits, and prevention of adverse outcomes like hospital readmissions due to timely access to care. Two-thirds of respondents also reported increased patient compliance with the plan of care.

ASHA anticipates that the 2021 data will reinforce the positive trends associated with the quality and outcomes of care, patient satisfaction, judicious utilization, and the additional benefits of telehealth services such as reduced costs to patients. While telehealth services will not replace or eliminate the need for in-person services, **ASHA has determined such data demonstrates the importance of maintaining permanent telehealth coverage for audiology and speech-language pathology services after the conclusion of the federal COVID-19 PHE.**

Services Proposed for Removal from the Medicare Telehealth Services List After 151 Days Following the End of the PHE

In Table 10 of the proposed rule, CMS lists numerous CPT codes used by audiologists and SLPs for removal from the authorized telehealth services list once the federal COVID-19 PHE (and 151-day extension) ends. However, this list appears to contradict several audiology testing codes listed in Table 8 that CMS proposes to include on a Category 3 basis through the end of 2023. Specifically, CPT codes 92550, 92552, 92553, 92555, 92556, 92557, 92563, 92567, 92568, 92570, 92587, 92588, 92601, 92625, 92626, and 92627 should be maintained in Table 8 on a Category 3 basis and removed from Table 10. ASHA also recommends that CMS add CPT

codes 92565 and 96125 to the telehealth services list on a Category 3 basis. These two codes are currently proposed for deletion from the temporary telehealth services list at the end of the federal COVID-19 PHE (and the 151-day extension), but they are both services primarily billed by audiologists or SLPs. ASHA finds it would be incongruous to remove these services while many other audiology and speech-language pathology services remain on the list on a Category 3 basis. In particular, CPT code 96125 describes standardized cognitive performance testing, which is the evaluative component to cognitive function intervention (CPT codes 97129 and 97130), which CMS already proposes to add to the Category 3 list, as outlined in Table 8. ASHA affirms that these codes are appropriate to deliver via telehealth.

Implementation of Telehealth Provisions of the Consolidation Appropriations Acts of 2021 and 2022

CMS proposes to implement provisions of Section 1834(m) of the Act—including the amendments made by the Consolidated Appropriations Acts of 2021 (Public Law 117-103) and 2022 (Public Law 117-103)—that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the federal COVID-19 PHE expires. CMS’s proposals to continue the flexibilities as currently implemented will minimize provider and contractor burden and ensure continued beneficiary access to telehealth services across geographic areas; in a broad range of settings (including the patient’s home); and from a wide array of providers (including audiologists and SLPs). **ASHA supports CMS’s efforts to implement a smooth transition from the federal COVID-19 PHE to the 151-day extension.**

Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID-19

CMS proposes that Medicare telehealth services furnished on or before the 151st day after the federal COVID-19 PHE expires should continue to include modifier “95”, in alignment with policies related to the current telehealth flexibilities. CMS further proposes to continue to allow Medicare providers to use the place of service (POS) code that best reflects where the services would have normally been furnished in person. **ASHA supports both proposals to maintain continuity of claims processing mechanisms that have been in place since early in the federal COVID-19 PHE.**

CMS also proposes to redefine POS “02” as *Telehealth Provided Other than in Patient’s Home* and to add POS “10” for *Telehealth Provided in Patient’s Home*. ASHA understands that once the PHE-related flexibilities end, eligible providers must report POS “02” for allowed Medicare telehealth services, unless they are exempted, such as mental health services furnished via telehealth. **However, ASHA agrees that CMS should adopt both telehealth related POS codes to better align with other payers and lessen administrative burden for providers.**

Valuation of Specific Codes: Caregiver Behavior Management Training (CPT Codes 96X70 and 96X71) (Section II.E.4.29.)

CMS determined that CPT codes 96X70 and 96X71 for caregiver behavior management training without the patient present are not payable under the MPFS because they are services furnished only to caregivers rather than the Medicare beneficiary. CMS cites Section 1862(a)(1)(A) of the Act as the basis for its argument that “Medicare payment is limited to those items and services that are medically necessary and reasonable for the diagnosis and treatment of an individual beneficiary’s illness or injury or that improve the functioning of a malformed body member.” However, ASHA notes that CMS’s interpretation of Section 1862(a)(1)(A) does not account for the well-established evidence that supports the direct benefit caregiver participation

has on patient outcomes and quality of life. **Therefore, ASHA disagrees with CMS's proposal to designate CPT codes 96X70 and 96X71 as not payable.** The Department of Health and Human Services (HHS) itself has identified caregiver involvement as an important component of patient safety as part of its national action plan for adverse drug event prevention.³ ASHA recommends CMS consider this broader perspective on patient care. By allowing payment for caregiver training services without the patient present, CMS can signal its encouragement of the caregiver's critical role in supporting patient care and provide the qualified health care professional with the time and resources to engage caregivers more effectively as part of the individual patient's plan of care.

ASHA reiterates that caregiver training without the patient present can facilitate the caregiver's understanding of the treatment plan; improve their ability to engage in activities with the patient in between treatment sessions; and increase their knowledge of outside resources to assist with patient care. These goals for caregiver training are essential to positive and sustainable outcomes for the patient when provided as a component of a Medicare beneficiary's individualized plan of care to address the primary clinical diagnosis, including direct evaluation and treatment. Improved treatment compliance and quality can also improve outcomes, shorten episodes of care, and reduce costs accordingly. As such, **ASHA strongly recommends CMS to pay for caregiver behavioral management training without the patient present and to use the original RUC recommended work relative value units (RVUs) of 0.43 for CPT code 96X70 and 0.12 for CPT code 96X71.**

Methodology for the Proposed Revision of Resource-Based Malpractice (MP) RVUs (section II.H.2.)

Steps for Calculating Malpractice RVUs: Impacts of Expanded Data Collection

ASHA supports CMS's work to refine its RVU development process to ensure payment accuracy and equity, including updating the methodology for determining MP RVUs for CY 2023. Specifically, CMS proposes to use premium data to calculate a risk index that is more specialty specific and accurate than the information previously used. However, CMS notes that this new methodology will negatively impact certain specialties, including several nonphysician specialties. Therefore, CMS proposes to phase in the MP RVU reductions over the three years preceding the next update for those specialties that will experience a 30% or more decrease in the 2023 risk index, including audiologists and SLPs. Although ASHA understands that this methodology more accurately captures audiology and speech-language pathology professional liability insurance (PLI) premiums, ASHA is concerned the resulting MP RVU reductions will further negatively impact MPFS payments for audiologists and SLPs. These reductions would be in addition to the nearly 4.5% CF reduction and other payment cuts due to statutory budget requirements. **ASHA appreciates CMS's effort to mitigate the immediate impact of the MP RVU reductions and fully supports finalizing the three-year phase in strategy CMS proposes. ASHA also recommends CMS continue seeking mechanisms within its regulatory authority to mitigate negative impacts to MPFS payment stability, especially for specialties that have been disproportionately affected by the redistributive impact of the 2021 changes to office/outpatient evaluation and management services.**

Steps for Calculating Malpractice RVUs: Low Volume Service Codes

ASHA appreciates CMS's ongoing efforts to improve the stability of practice expense (PE) and MP RVUs for low volume services. ASHA agrees with the proposal to use service-level overrides for low volume services to help mitigate annual fluctuations and provide greater stability in the valuation of these services. Several low volume services provided by audiologists

have been particularly susceptible to large fluctuations in PE RVUs; therefore, **ASHA provides comment on the proposed specialty overrides for those services listed in the following table.**

CPT Code	Descriptor	CY 2023 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
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

Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services (Section II.I.)

ASHA appreciates CMS implementing the family of RTM services (CPT codes 98976, 98977, 98978, 98980, and 98981) under the 2022 MPFS for reporting by physicians and nonphysician qualified health care providers (QHPs), including SLPs. However, ASHA is disappointed that CMS proposes to create four new G-codes because of concern over the clinical labor time included in the existing CPT codes for RTM treatment management services (CPT codes 98980 and 98981). Creating a new family of G-codes that are similar to existing CPT codes creates coding confusion, poses an administrative burden for providers, and does not meet the original intent of the CPT codes.

ASHA is specifically concerned about the structure of proposed codes GRTM3 and GRTM4, which would replace CPT codes 98980 and 98981 for use by nonphysician QHPs under the MPFS. Although CMS proposes to implement the same work RVUs as the current CPT codes, CMS also intends to remove clinical labor time from the G-codes; thereby, significantly decreasing the total RVUs and payment for these services. ASHA understands that certain nonphysician specialties, including SLPs, may not bill for services provided by clinical staff. However, in those cases, the QHP performs the activities, such as patient communications, that would have otherwise been completed by clinical staff. It is inappropriate to remove clinical labor

time from the PE RVUs without redistributing that time and cost to the QHP through the work RVU. This policy would disproportionately impact providers who do not employ clinical staff or who cannot bill for services provided by clinical staff under the MPFS.

In addition to removing clinical labor time from the PE RVUs, CMS also proposes requiring CPT codes 98975, 98976, or 98977 to be billed prior to reporting GRTM3 and GRTM4. This is a new requirement that does not exist with the current CPT codes. The original intent of the family of RTM CPT codes was to allow a provider to bill for the time and work spent on treatment management/assessment services even if they were monitoring data from a device that is not currently represented by a device supply code. CMS's proposal would significantly reduce Medicare beneficiary access to these services, which is in direct contradiction to the original intent of the RTM code family and to CMS's stated goal for creating these new G-codes.

For the reasons stated above, ASHA disagrees with implementation of the new G-codes and strongly urges CMS to continue allowing SLPs and other nonphysician QHPs to report CPT codes 98980 and 98981, as currently structured and valued. However, if CMS maintains that the current structure of the RTM codes is problematic under the MPFS, ASHA strongly urges CMS to address the following issues before finalizing the new G-codes.

- Redistribute any time removed for clinical labor activities—such as conducting patient communications—to the work RVU, since the QHP will perform these activities.
- Remove the requirement to bill CPT codes 98975, 98976, or 98977 prior to reporting GRTM3 and GRTM4.

Without these changes, CMS will again decrease payments to nonphysician QHP providers, who are already sustaining cuts in other areas, and could potentially reduce Medicare beneficiary access to these services.

CMS also seeks feedback about RTM devices that are used to deliver medically reasonable and necessary services, such as information on the types of data collected and the health conditions that may benefit from RTM services. ASHA assumes CMS intends to use this information to guide future policy and code development related to RTM services. However, ASHA reminds CMS that similar work is ongoing through the established American Medical Association (AMA) code development and valuation process. **ASHA encourages CMS to continue engaging the AMA and specialty societies through the code development and valuation process to ensure that all stakeholders are working towards the same goals to develop new codes for RTM devices that are efficacious and medically reasonable and necessary, including those related to audiology and speech-language pathology services as outlined below.**

Audiologists 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 may 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.

SLPs report RTM codes for home-based voice or swallowing training devices that provide biofeedback to the patient and produce objective data for the clinician; thereby, 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.

ASHA is committed to ensuring that audiology and speech-language pathology related services, including RTM services, are appropriately described in the CPT code set when they meet the necessary criteria.

Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order (Section II.K.)

CMS acknowledges in the proposed rule that it has the administrative authority to remove the physician or NPP (e.g., physician assistant, nurse practitioner) order requirement for audiology hearing and balance assessment services and proposes to do so, with limitations. ASHA supports the ability of Medicare beneficiaries to access audiology hearing and balance services without a physician or NPP order and appreciates CMS's effort to clarify this issue. ASHA members also appreciate CMS's role in developing payment policies that balance patient access and safety. **However, as currently structured, the policy articulated in the proposed rule highly curtails beneficiary access to care and creates significant, unnecessary, and unjustified administrative burdens for audiologists.** It also limits robust and accurate utilization data that CMS will need to make effective reimbursement policy moving forward. ASHA remains committed to working with CMS to develop a policy that meets CMS's need to collect data and maintain patient safety that is also clinically appropriate, minimizes administrative burden for audiologists, and enhances beneficiary access to care.

Audiologists and Multidisciplinary Care Teams

ASHA's audiologist members recognize the importance of participating in multidisciplinary care teams—including engagement with the patient's physician or NPP—to ensure patient safety, quality of care, and patient satisfaction with care. ASHA's Code of Ethics specifically addresses care coordination.

“Principle of Ethics I: Individuals shall honor their responsibility to hold paramount the welfare of persons they serve professionally.

Rule B: Individuals shall use every resource, including referral and/or interprofessional collaboration when appropriate, to ensure that quality service is provided.”⁴

ASHA appreciates CMS's recognition of the value and need to ensure this cooperative care planning continues. When enrolling in or submitting claims to Medicare, audiologists recognize that all services must be medically necessary and require the skills of an audiologist.

Audiologists perform the services that are reasonable and medically necessary based on the clinical history and report of problems provided to the audiologist by the patient (and in some cases, caregiver) as well as any medical records provided to the audiologist by the physician or other clinicians or providers (e.g., skilled nursing facility, hospital) involved in the patient's care.

In the proposed rule, CMS repeatedly stated that only a physician or NPP order can ensure the reasonable and necessary nature of audiologic assessment services despite the ethical, clinical, and legal obligation for audiologists themselves to safeguard these standards. ASHA does not believe an order alone addresses the concerns CMS expressed in the proposed rule. Often, audiologists receive broad orders to evaluate or assess a patient's hearing or balance issue

because physicians and NPPs recognize the audiologist's ability to select the appropriate battery of tests based on the patient's clinical presentation. Audiologists are defined as professionals with specialized education and training in the provision of comprehensive diagnostic and nonmedical treatment services for hearing and balance disorders.^{5,6} ASHA provides this background information to reassure CMS that there are safeguards in place to protect patient safety and program integrity beyond the physician/NPP order.

Balance Billing and ASHA's Code of Ethics

CMS raises concerns with the ability of audiologists to balance bill Medicare beneficiaries as non-participating providers in contrast to practitioners, like physician assistants, who are required to accept assignment. The proposed rule cites this as a rationale for requiring a physician/NPP order for audiology hearing and balance assessments provided by audiologists. A variety of health care providers, including therapists and physicians, are allowed to participate as non-participating providers. **The limiting charge applied to non-participating providers limits beneficiary cost sharing and applies to audiologists—the same as it does to other enrolled Medicare providers when delivering covered services.** ASHA requests that CMS provide additional information so that we may better understand this concern. Assuming that audiologists would be more likely to “balance bill” Medicare beneficiaries at a higher rate than other clinicians who enroll as non-participating providers is not supported by data provided in the proposed rule. In addition, audiologists are not allowed to opt out of the Medicare program in the same way as physicians. As a result, the additional beneficiary liability associated with receiving services from an audiologist, who is non-participating, is lower than the beneficiary liability for services provided by physicians who elect to opt out of Medicare and accept cash directly from Medicare beneficiaries.

Currently, if an audiologist performs a service without a physician/NPP order it is considered a non-covered service and the audiologist may enter into a private pay arrangement with the Medicare beneficiary. In that instance, the charged amount might be higher than the Medicare reimbursement rate. By removing the order requirement, CMS limits the beneficiary's financial exposure and ensures all Medicare rules, such as the limiting charge, apply to the covered services.

CMS raises concerns about audiologists reassigning their benefits to a second entity—such as a private practice—and highlights the difficulty that it creates when tracking utilization and identifying who is providing the service. However, when the audiologist's billing rights are reassigned, the NPI of the rendering provider (in this case the audiologist) and the billing entity are both listed on the 1500 claim form in boxes 24J and 33A, respectively. This reporting should mitigate, if not eliminate, CMS's concerns. Given the program integrity provisions in place, ASHA recommends that CMS exercise its administrative authority to eliminate the physician/NPP order requirement. If CMS has additional questions remaining after the clarification above, ASHA urges CMS to share more information with us.

ASHA's Code of Ethics also addresses the importance of billing appropriately. Specifically, the code states:

“Principle of Ethics I, Rule Q: Individuals shall maintain timely records and accurately record and bill for services provided and products dispensed and shall not misrepresent services provided, products dispensed, or research and scholarly activities conducted.”⁷

Ensuring Patient Safety

CMS indicates patient safety as a rationale for maintaining the physician/NPP order requirement for hearing and balance assessments provided by an audiologist. Understanding the implications for patient safety is critically important to ensure the policy will not have negative unintended consequences on program spending and safety. However, ASHA is not aware of a high volume of liability or malpractice claims against audiologists. In fact, the malpractice expense relative values associated with CPT codes typically used by audiologists are among the lowest of the constellation of clinical providers eligible to bill Medicare. CMS's own data shows that audiologists spend on average \$282 annually on malpractice insurance. Additionally, according to the National Council of State Boards of Examiners for Speech-Language Pathology and Audiology, since 1992, 8 audiologists have had a health plan action taken against them, 14 audiologists have had a judgment or conviction, 72 audiologists have made a malpractice payment, and only 381 audiologists have had a state licensure action imposed on them.⁸ Given this unambiguous evidence, it could be concluded that the services provided by audiologists are often low-risk and present few safety concerns for Medicare beneficiaries.

Conversely, delaying care to obtain the physician/NPP order could have negative unintended health consequences for the patient. Untreated hearing loss contributes to accelerated cognitive decline, social isolation, communication challenges, and mental health challenges.^{9,10,11} However, removing the physician/NPP order requirement has the potential to minimize the occurrence of such negative health outcomes.

Financial Impact

As highlighted in the proposed rule, data analysis has shown the negative financial impact on the Medicare program and beneficiaries by requiring a physician/NPP order for audiology hearing and balance assessment services. Notably, eliminating the physician/NPP ordering requirement for audiology hearing and balance assessment services would result in an estimated savings to Medicare over a 10-year period of approximately \$108 million. Medicare beneficiaries would also see a savings of \$36 million in copayments, further enhancing affordable access to medically necessary care. ASHA appreciates CMS considering this data as it further bolsters the importance of eliminating the physician/NPP order requirement.

Operationalizing the Proposed Policy

ASHA recognizes the need to understand what types of audiology services might be provided without a physician/NPP order and under what circumstances, such as the patient diagnosis. Additionally, ASHA understands that CMS is structuring a limited proposal for removing the physician/NPP order requirement so that it may collect the data necessary to understand the impact on patient safety and utilization. That data may then be used to determine how the policy could be restructured over time to meet our mutual goals of maintaining timely access to medically necessary services for Medicare beneficiaries. However, as written the structure of the proposal creates several logistical and operational issues. ASHA has specific recommendations it hopes will assist CMS in developing a more robust policy in its final rule that would yield useful data for future decision making.

Definition and Parameters for Non-Acute Classification

ASHA is requesting CMS to define or clarify what constitutes an acute or non-acute hearing assessment service. Clinically, this concept does not seem to align with how CPT codes are structured or with how audiologists view service delivery. In addition, the International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) does not classify hearing loss as "acute" or "non-acute". In the proposed rule, CMS identifies 36 services that an

audiologist could provide without a physician/NPP order. ASHA presumes that CMS considers that the services captured by these CPT codes are typically used in non-acute circumstances. However, it is not explicitly clear in the proposed rule how CMS defines non-acute. Additional information is needed to determine how a non-acute hearing assessment is defined and what parameters are set. *For example, would the setting where the service is provided—outpatient setting (e.g., clinic) or private practice vs. an acute-care hospital—impact the classification? Would it be based on the patient’s diagnosis?* A CPT code could be used in a variety of practice settings and for a variety of diagnoses in both ambulatory and emergent situations.

Clinically, when a patient presents with hearing loss, the audiologist must assess the patient to determine what is causing the hearing loss and determine if that hearing loss presents a threat to the patient’s health that requires immediate coordination with the physician or NPP. In other words, without assessing the patient, it is difficult to know if the patient’s condition is acute or non-acute. Delineating that a service can only be provided without a physician/NPP order in non-acute circumstances makes the structure of the proposal difficult to navigate for providers and beneficiaries.

Restrictions on Billing within 12-Month Period

CMS restricts the billing of non-acute audiology assessment services to once per beneficiary per 12-calendar months. However, there are circumstances when a non-acute hearing service could be provided multiple times within a 12-month period. CPT code 92603 represents diagnostic analysis and programming of a cochlear implant and 92604 is for subsequent reprogramming for patients over 7 years old. Often a patient with a cochlear implant requires multiple reprogramming visits as demonstrated by the public 2020 Medicare physician/supplier procedure summary files. In 2020, CPT code 92603 was billed approximately 2,800 times but 92604 was billed approximately 24,000 times. This data shows that a non-acute hearing assessment could be performed more than once every 12 months. The clinical standard of care for cochlear implant reprogramming is to see the patient at 3-, 6-, and 12-months post-implantation with additional visits as necessary. A surgeon is not typically involved in the programming and maintenance of the cochlear implant unless there are concerns for device migration and/or failure. These issues are often first identified by the audiologist performing the programming and reprogramming who immediately refers the patient back to the surgeon to determine next steps.

Audiologists may see cancer patients multiple times in a year for ototoxic monitoring as they experience changes in hearing during their treatment. A physician/NPP order for each visit is not necessary and would be administratively burdensome for the physician/NPP, patient, and audiologist. The requirement is also unnecessarily costly for the Medicare program and the beneficiary as a physician visit might be conducted multiple times to obtain the requisite order. ASHA appreciates that CMS is proceeding with caution; however, restricting hearing assessments provided without a physician/NPP to once every 12 calendar months is not always clinically appropriate.

Additional Details on Proposal Timeline

ASHA requests that CMS outline its process for refining this proposal over time so that stakeholders would be able assist it to ensure it meets the needs of patients, physicians/NPPs, audiologists, and the Medicare program. Based on the limited information provided, stakeholders are left with unanswered questions.

- *How many years will CMS collect data on the delivery of non-acute hearing assessments by audiologists?*

- *How much data does CMS need to make effective policy choices?*
- *How will CMS utilize this data in its engagement with the American Medical Association Relative Value Update Committee?*
- *How often will CMS update or refine this proposal moving forward (e.g., annually through rulemaking, every 5 years)?*

In order to effectively refine the proposal over time to ensure it is meeting Medicare beneficiary needs, these types of policy questions require answers.

ASHA understands that CMS is limiting its proposal to hearing assessment services out of an abundance of caution because it is concerned balance assessments require a degree of physician or practitioner coordination in order to maintain patient safety. However, there are circumstances in which a balance assessment could be provided safely without a physician/NPP order and the typical communication between an audiologist and the physician/NPP would continue, as illustrated in the following example.

A patient comes to the audiologist for a hearing evaluation reporting hearing loss in one ear that has been slowly diminishing as well as dizziness that has progressively gotten worse. The patient has not yet seen his physician because the patient wants to get his hearing tested first. The audiologist performs a full audiometric evaluation (92557 and 92570). Since the patient presented with an asymmetrical sensorineural loss, the audiologist plans to refer the patient to the physician because the audiologist suspects that the asymmetrical hearing loss and dizziness is acoustic neuroma. The audiologist wants to provide as much clinical information as possible to assist the physician and, therefore, performs videonystagmography (VNG) with bithermal caloric irrigations. If the audiologist could perform the **hearing and balance assessment** prior to referring the patient to the physician, it could reduce the patient's wait time and more effectively facilitate care coordination on behalf of the patient between the members of the multidisciplinary team.

ASHA welcomes the opportunity to discuss the evolution of this policy that would expand beyond select hearing assessment services.

New G-Code Proposal

CMS proposes to create a new G-code, GAUDX, to be used when 36 non-acute hearing assessment services (as represented by CPT codes) are provided without a physician/NPP order. In the proposed rule, CMS does not outline the various policy options that were considered before choosing the GAUDX methodology, making it challenging for ASHA to provide effective policy alternatives. ASHA has determined that there are more effective and accurate ways to collect and analyze this data. In addition, ASHA is concerned that the G-code, as described in the proposed rule, would create a significant administrative burden for audiologists; limit the granular claims data CMS receives; undercut the structure of the overall CPT code set; and jeopardize beneficiary access to care. **ASHA strongly recommends that services captured under GAUDX are instead reported and paid based on the CPT codes already available, with a modifier appended to the claim form, when provided by an audiologist without a physician/NPP order.**

ASHA's Recommendation for Using Current CPT Code with Modifier

Although ASHA notes that all hearing and balance assessment services can be safely and appropriately provided without an order, it recognizes CMS's desire to gradually implement this policy. Under ASHA's recommendation, CMS could still restrict the types of services or CPT codes that could be billed without a physician/NPP order while allowing equitable payment of hearing services based on the actual value of the CPT code. For example, if CMS finalized the list of codes in Table 29, it could clearly state that these are the only CPT codes that may be provided without an order and may be billed with the modifier. Instructions would need to be provided to CMS contractors to initiate claims processing edits that require claims to have the correct combination of CPT code and modifier on the same date of service. Additionally, billing would be restricted to once during a distinct time period (e.g., calendar year, 12-calendar months) per beneficiary. This recommendation would ensure billing for services without the physician/NPP order would be limited and not applicable to all Medicare-covered hearing and balance assessment codes, which respects CMS's need to ensure this policy evolves over time in a way that maintains both patient safety and program integrity.

However, if implementing this policy for all 36 CPT codes with a new modifier would prove administratively challenging for CMS and its contractors, ASHA would first recommend using a smaller list of CPT codes (for which an order may not be required) in conjunction with a modifier. Under this scenario, **ASHA recommends the limited list include only the following six CPT codes outlined in the table below.**

CPT Code	Descriptor
92550	Tympanometry and reflex threshold measurements
92557	Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)
92567	Tympanometry (impedance testing)
92570	Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing
92587	Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3-6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report
92588	comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report

Audiologists frequently furnish these tests, which are foundational hearing assessments that can provide the necessary information to recommend further testing, audiologic intervention, or medical referral. However, because a range of policy options were not presented in the proposed rule, ASHA recognizes that there may be reasons why the use of the CPT code with modifier is not possible.

GAUDX Comments

ASHA reiterates its strong concerns that the use of a G-code, as opposed to the CPT code with a modifier, continues to restrict CMS's ability to develop meaningful utilization data and undermines the relativity of the payment system and the RUC process. **Using the CPT code and associated modifier should be viewed as ASHA's recommendation and preferred methodology.** The following comments are offered if CMS provides a clear, objective, data-driven, and evidence-based reason for why the CPT code and associated modifier is somehow not feasible under any circumstance.

If CMS cannot implement the CPT code and modifier option under any circumstance and elects to finalize its proposal to use GAUDX, then ASHA recommends that the codes captured under GAUDX should be significantly restricted to the six codes listed above. This is not because ASHA believes an order is medically necessary for any audiology services, but because the value of GAUDX is structured in a way that has problematic financial implications for beneficiaries and audiologists. Specifically, it would increase beneficiary liability in many cases or grossly underpay audiologists in other scenarios.

ASHA considers the only services that would be appropriate to “bundle” under GAUDX are CPT codes 92550, 92557, 92567, 92570, 92587, and 92588, as outlined earlier. At a minimum, services related to cochlear implant programming/reprogramming and pre- or post-implant auditory function evaluation (92601, 92602, 92603, 92604, 92626, and 92627) should be removed because the reimbursement value of GAUDX ranges from approximately \$30-\$100 less than the value of each implant-related service and would have a disproportionate negative financial impact on cochlear implant centers and the beneficiaries they serve.

Typographical Error: ASHA notes that the final three codes listed in Table 29 (Proposed Codes for Tests that can be Encompassed by HCPCS Code GAUDX...) are transcribed incorrectly. The correct codes related to auditory evoked potential (AEP) testing are CPT codes 92651, 92652, 92653. They are incorrectly listed on the table as 92561, 92562, and 92563. ASHA requests CMS correct this typographical error if it finalizes its proposal without adopting ASHA’s earlier recommendations.

By using GAUDX, CMS eliminates its own ability to identify what types of hearing services are being provided without an order and under what circumstances. It also skews its own utilization and practice expense data. For example, without accurate utilization data of services provided by audiologists, ASHA is concerned that the regulatory impact of future rulemaking on audiologists may not be accurately represented, or that it could impact CMS’s ongoing practice expense refinement efforts. In addition, using GAUDX could make it difficult to apply correct coding initiative (CCI) edits when processing claims for code pairs that include one or more of the 36 CPT codes, especially from an institutional provider submitting claims for multidisciplinary services. This skewing of the data and established program-integrity mechanisms has implications beyond Medicare and precludes other payers, such as Medicaid and private insurers, from understanding overall utilization of the audiology code set. Using the CPT code with a modifier would allow CMS to understand what is happening in real time to Medicare beneficiaries to refine and update this policy over time.

Under the proposal, GAUDX could be used once every 12 calendar months per Medicare beneficiary for non-acute hearing assessments identified in Table 29 of the proposed rule. Once GAUDX is used in the 12-month period, audiologists would need to secure an order for these services and use the CPT code that reflects the service. Tracking the use of GAUDX based on 12 months rather than the calendar year makes this proposal challenging for both audiologists and their patients who will have to remember when the last audiology visit occurred. Additionally, restricting the provision of audiology hearing assessments to once a year might place a small portion of Medicare beneficiaries in a position where they will have to delay care while waiting for a physician/NPP order. While once a year might be appropriate in some circumstances, for patients who have experienced a change in hearing due to a new medical event (e.g., stroke, fall, head injury), requiring the beneficiary to wait for an appointment to obtain an order from a physician/NPP unnecessarily delays care impacting the patient’s quality of life. While ASHA recommends CMS remove this requirement, we appreciate CMS would like

to implement a limited proposal initially. If it maintains a time restriction, ASHA recommends that utilization be reset on January 1 of each year.

ASHA recommends CMS clarify the beneficiary liability related to the use of GAUDX. For example, in March a patient sees Audiologist A in Florida for a hearing assessment and the audiologist bills GAUDX. The patient then suffers a stroke in November and sees Audiologist B in New Hampshire. Audiologist B asks the patient and/or caregiver if the patient has seen an audiologist for any reason in the last 12 months and they say they do not know or remember. Audiologist B reviews the medical records that were provided by the hospital and physician and does not see mention of another audiology visit. Audiologist B then bills GAUDX, and the claim is rejected. *In this scenario, would Audiologist B be able to bill the patient for this service? If so, would they need a mandatory or voluntary advanced beneficiary notice (ABN) on file?* Tracking based on a distinct time period (e.g., 12 months) will require developing a mechanism, such as the interactive voice response system or the common working file, that would allow an audiologist to check if GAUDX has already been billed within the set time period.

CMS proposes a payment value for GAUDX based on two CPT codes typically used by audiologists—92557 and 92567—that in many cases would skew the cost of providing non-acute hearing assessments to patients. In some cases, GAUDX would overpay for the visit and in other cases GAUDX would underpay for the visit. The proposed 2023 national non-facility rate for GAUDX is \$51.93. Upon reviewing the CPT codes listed in Table 29 that GAUDX would replace, several key examples of the impact on beneficiary liability and Medicare payments can be anticipated. For example, the proposed 2023 national rates for CPT codes 92550 and 92588 are \$21.83 and \$33.41, respectively, leading to a significant overpayment and higher beneficiary cost sharing for these services when replaced with GAUDX. CMS has made a commitment to addressing health disparities and improving health equity with a particular focus on disadvantaged populations, including those who are at a socioeconomic disadvantage. However, increasing beneficiary cost sharing runs counter to CMS's efforts and may lead to socioeconomically disadvantaged patients delaying or forgoing care; thereby, placing them at higher risk for additional medical complications.

Conversely, the national average rates for CPT codes 92584 and 92603 are \$111.14 and \$149.51, respectively, which would result in significant underpayments to the audiologist if they billed GAUDX. It is unlikely that everyone would essentially “break even” by the end of the 12 calendar months considering the significant difference between the value of the CPT codes and the value CMS has developed for GAUDX. This example further reinforces the utility of an approach that requires the billing and payment of the CPT code at the established MPFS rate with a modifier indicating an order is not on file.

ASHA firmly asserts that the implementation of GAUDX based on the blended work and practice expense of two existing CPT codes contradicts the well-established MPFS valuation process, including input from the American Medical Association's Relative Value Update Committee (RUC) and Health Care Professionals Advisory Committee (HCPAC). Proposing an alternate value to replace 36 unique CPT codes is not resource based, fundamentally damages relativity across the MPFS, ignores the collaborative process among specialty societies, the AMA RUC/HCPAC, and CMS, and has far-reaching implications for the valuation of audiology services. Any future work to assess and value audiology services will be based on inaccurate data regarding utilization of services, including tracking of codes frequently billed together, primary place of service, rendering providers, and practice expense costs.

Finally, as structured, the proposal yields very little clinical, financial, or administrative benefit. ASHA is concerned that many audiologists would elect not to use GAUDX and continue securing a physician/NPP order because the administrative challenges of billing GAUDX exceed the challenges of obtaining an order as currently required for all Medicare covered services audiologists provide. Such a practical response from audiologists would not indicate they feel they require a physician/NPP order to provide services, but rather that the administrative burden CMS created to eliminate that requirement exceeds the burden of obtaining the order itself. Refining the proposal would allow audiologists to take advantage of this opportunity by demonstrating to CMS the efficacy of eliminating the physician/NPP order requirement and inform the evolution of the policy over time to ensure patient access and safety.

In summary, ASHA:

1. Commends CMS for identifying it has the administrative authority to remove the physician or practitioner order requirement for hearing and balance assessments provided by audiologists who are clinically educated and trained to perform hearing and balance evaluation and treatment services.
2. Encourages CMS to consider if select balance assessments could also be included in this policy.
3. Requests CMS clarify key issues, such as the difference between acute and non-acute hearing assessment services, as well as the process for updating this policy over time.
4. Recommends that CMS not implement GAUDX and instead track these services via the CPT code with a modifier.
5. Recommends that if CMS cannot under any circumstance utilize the CPT code with modifier, then it should limit the services covered without an order with the CPT code and modifier or under GAUDX, to the subset of the six CPT coded ASHA suggested, to avoid significant fluctuations in reimbursement and to minimize beneficiary and audiologist financial liability.
6. Suggests CMS to not restrict this proposal to once every 12-calendar months. However, if it maintains this provision, ASHA recommends CMS structure any limitations around the billing for hearing and balance assessment services provided without a physician or practitioner order based on the calendar year beginning January 1, and develop a tracking mechanism to ensure audiologists do not inadvertently bill for this service more than once a year.
7. Urges CMS to use the program integrity tools at its disposal to ensure patient safety.
8. Suggests CMS consider how the policy could be restructured to ensure the flexibility it is proposing could be practically adopted by audiologists.
9. Recommends CMS clarify beneficiary liability for GAUDX, if finalized.
10. Stands ready to assist CMS in developing a proposal that would eliminate the physician/NPP order requirement in a way that maintains access to timely, medically necessary services for Medicare beneficiaries while safeguarding patient safety, collaborative interprofessional practice, and the Medicare trust fund.

Medicare Shared Savings Program (Section III.G.)

ASHA supports CMS's goal to drive health system transformation to achieve equitable outcomes through high-quality, affordable, person-centered care for all beneficiaries. Therefore, ASHA supports advancing equity within the Medicare Shared Savings Program (MSSP), using

advance investment payments to accountable care organizations (ACOs) with low revenue, those new to risk-based models, and those that reach underserved populations.

ASHA supports strengthened financial incentives and adjustments to benchmarking methodology that make serving high-risk and high dually eligible populations more favorable from a business standpoint. ASHA supports the proposal to implement a health equity adjustment to an ACO's quality performance category score to recognize high quality performance by ACOs with high underserved populations.

ASHA recognizes that CMS intends to decrease administrative burden by proposing to remove the requirement for an ACO to submit certain narratives when applying for the SNF 3-day rule waiver. However, ASHA would like to ensure that the replacement proposal—a requirement that an ACO submit an attestation that it has established the narratives and will make them available to CMS upon request—protects program integrity and beneficiary access to care. In other words, ASHA believes that a request for a waiver to the SNF 3-day rule must be supported in the medical record and that this important protection remains in place on a permanent basis.

CMS requests comment on eliminating the APM entity level qualified professional (QP) determination and instead will calculate threshold scores and QP determinations at the individual clinician level for eligible clinicians in Advanced APMs and Other Payer APMs. As a professional organization representing non-physicians, very few of ASHA's members are eligible to participate in the MSSP. Those who are eligible typically qualify through their affiliation with larger health systems. ASHA is concerned that a change of QP determination to the individual provider level could increase administrative burden while further inhibiting our members from participating in the program. **Therefore, ASHA suggests that it would be premature to move to individual determinations from entity determinations.**

Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment (Section III.J.)

Currently, CMS has the authority to deny or revoke a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, if the provider or supplier is excluded by the OIG. In the proposed rule, CMS would expand the categories of parties listed within these denial and revocation provisions to include managing organizations and officers and directors of the provider or supplier if the provider or supplier is a corporation. ASHA supports the inclusion of managing organizations as well as officers and directors.

Further, the proposed rule stipulates that if a revocation or denial, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, the revocation or denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation or denial notification. ASHA supports this provision because it allows for the opportunity to demonstrate a good faith effort to comply with Medicare requirements.

CMS has the authority to utilize levels of screening by which it and the Medicare Administrative Contractors (MACs) review initial applications, revalidation applications, and applications to add

a practice location. These screening categories and requirements are based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category. While all applicants go through a standard level of screening, applicants considered moderate or high risk are also subject to a site visit and fingerprint background checks for most individuals with an ownership interest. At this time, only four types of providers are subject to increased scrutiny, including home health.

In the proposed rule, CMS cites numerous Government Accountability Office (GAO) and Office of Inspector General (OIG) reports highlighting examples of patient abuse as well as payment fraud and abuse associated with the SNF industry. Additionally, as ASHA has reported to CMS in meetings and in comments, many SLPs working in this sector are subject to administrative mandates, which removes their ability to utilize their clinical judgment to develop plans of care for their patients based on patient needs. Some examples include limiting the number of minutes for a treatment session and inappropriately precluding therapy for patients based on diagnosis or other factors. This jeopardizes access to care for Medicare beneficiaries in SNFs. As a result, CMS proposes to move initially enrolling SNFs into the high-level of categorical screening and revalidating SNFs would be subject to moderate risk-level screening. For the reasons identified by CMS as well as additional factors, such as ASHA member reports, **ASHA supports moving SNFs into the high-risk category as an important trust fund and patient protection mechanism.**

Updates to the Quality Payment Program (Section IV.)

Updates to the Specialty Measure Sets

In the proposed rule, CMS makes changes to the quality specialty measure sets for audiology and speech-language pathology. Specifically, CMS would include two new measures for the audiology specialty measure set including Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling; and Screening for Social Drivers of Health. ASHA recognizes that these are important drivers of improving health care quality and patient outcomes and support their inclusion in the audiology measures set.

However, ASHA does not support the removal of Measure 261; Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness. This measure is a critical element of care for patients with hearing loss and has the potential to prevent potentially avoidable negative health outcomes, such as falls, which could lead to hospital admissions or fractures. CMS notes that it is considering removing this measure because of the “limited patient population and the measure does not allow for the creation of benchmarks to provide a meaningful impact on quality improvement.” ASHA recognizes that the measure is reported at low rates, but this is, in part, a result of the limited number of audiologists who are required to report to Merit-Based Incentive Payment System (MIPS) based on the construction of the low-volume thresholds. While ASHA does support the low volume threshold as constructed, it has implications for reporting measures. In other words, low reporting is not an indication of a measure’s lack of importance or utility in improving patient care but rather a construct of the limited number of providers required to report such a measure under the current eligibility requirements. ASHA recommends that CMS maintain this measure.

CMS also proposes to add the Screening for Social Drivers of Health to the speech-language pathology specialty measure set. ASHA supports the inclusion of this measure to improve

patient care and because it provides SLPs with a robust measure set that meets CMS's minimum reporting requirements associated with this performance category.

Promoting Interoperability Performance Category

Historically, audiologists and SLPs have been exempt from the promoting interoperability performance category since their initial inclusion in MIPS in 2019. ASHA has supported this exemption because of the structure of this performance category. Specifically, audiologists and SLPs are not authorized through their scopes of practice or state license to e-Prescribe medications, and they would not typically report immunizations or select conditions to public health registries. Including nonphysician specialties in this performance category would add a level of reporting complexity as it would require CMS to delineate which of the categories measures a nonphysician would be exempt from reporting. However, CMS notes that it will eliminate the exemption for reporting associated with promoting interoperability for audiologists and SLPs after the 2023 performance/2025 payment years.

While ASHA contends it is not appropriate to include audiologists and SLPs in this performance category, it recognizes CMS has developed an exemption process. According to the program requirements outlined in the 2022 Promoting Interoperability User Guide, clinicians who write fewer than 100 permissible prescriptions during the performance period can apply for an exemption to this category. However, audiologists and SLPs will likely never be in a position to order prescriptions for their patients due to state licensing laws. Therefore, ASHA recommends CMS develop a blanket exception to these elements of the promoting interoperability category for all non-prescribing providers to minimize the administrative burden to nonphysician clinicians.

CMS bases its proposal on reporting rates associated with the promoting interoperability performance category for 2019 through 2021 for audiologists, SLPs, and dietitians. This is a broad category of providers that encompasses approximately 16,000 Medicare-enrolled clinicians according to the most recent Medicare enrollment data. CMS notes these clinical specialties reported data associated with the promoting interoperability category approximately 19% of the time in 2019, not at all in 2020, and nearly 7% in 2021. However, CMS does not indicate if the data was simply reported or if it was reported successfully. This is an important distinction because audiologists and SLPs likely did not report this data accurately or successfully due to the construction of this performance category. Additionally, to assume that such small reporting numbers indicate a readiness on the part of these clinical specialties to participate in this performance category fails to acknowledge that successful participation requires the use of certified technology and there are no audiology or speech-language pathology specific electronic health record or registry product recognized by CMS. The lack of a discipline-specific certified electronic health record or registry means that non-physicians, such as audiologists and SLPs, would need to utilize a product with more functionality than required or with functionality that does not translate readily to the needs of non-physicians. These products tend to be more expensive because of the broad functionality and impose an unreasonable burden on non-physicians utilizing them. Without certified technology, these categories of clinicians would not be able to effectively participate in the promoting interoperability category.

Therefore, ASHA does not support CMS's proposal to eliminate the exclusion from the promoting interoperability performance category after the 2023 performance/2025 payment year. Several of the measures required under this performance category could not legally be reported by audiologists and SLPs. Furthermore, additional work would need to be

done by CMS and stakeholders to determine how the performance category could be modified to practically include nonphysician clinicians.

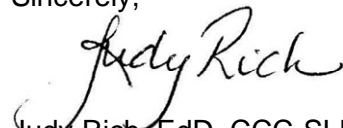
MIPS Value Pathways

ASHA remains committed to robust participation in the Quality Payment Program (QPP) including MIPS, APMs, and MIPS Value Pathways (MVPs). Under MIPS, ASHA members cannot effectively participate in the promoting interoperability performance category because they cannot report on specific measures such as e-Prescribing or the cost category because there is not an applicable cost measure. Additionally, the specialty measure sets for audiology and speech-language pathology are not as robust as needed and include many generic measures, such as medication reconciliation. While efforts have been made to be included in additional quality measures, ASHA has had difficulty gaining approval from measure stewards.

These challenges may carry over to MVPs making it challenging to determine how ASHA members could effectively participate in this track in the future. Of the five new proposed MVPs, ASHA identified Optimal Care for Patients with Episodic Neurological Conditions MVP, and Supportive Care for Neurodegenerative Conditions MVP for potential participation by audiologists and SLPs. Because CMS requires reporting of all four performance categories under MVPs, non-physicians, such as audiologists and SLPs, will not be able to participate unless CMS modifies MVP requirements. In addition, ASHA expects that MVP developers would be hesitant to include ASHA members as MVP participants—the same reluctance measure stewards have—which further reinforces our challenges in successfully participating in MVPs. CMS has expressed an interest in transitioning from MIPS to MVPs as early as 2028 but given these challenges such a transition might be premature. ASHA stands ready to assist CMS in the development of an MVP structure that supports all clinicians.

Thank you for the opportunity to comment on this proposed rule. If you or your staff have any questions, please contact Sarah Warren, ASHA's director of health care policy for Medicare, at swarren@asha.org.

Sincerely,



Judy Rich, EdD, CCC-SLP, BCS-CL
2022 ASHA President

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