

VIA ELECTRONIC SUBMISSION: <http://www.regulations.gov>

August 25, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS- 1631-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

The American Academy of Audiology (the "Academy") is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research. The Academy appreciates the opportunity to offer comments in response to the Centers for Medicare and Medicaid Services (CMS) Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for the CY 2016 Proposed Rule (CMS-1631-P) as published in the *Federal Register* on July 15, 2015. The Academy respectfully submits comments on the areas enumerated below.

I. Valuation of Specific Codes: Vestibular Caloric Irrigation (CPT Codes 9254A and 9254B)

As detailed in the proposed rule for CY 2016, the CPT Editorial Panel deleted CPT code 92543 (Assessment and recording of balance system during the irrigation of both ears) and created two new CPT codes, 9254A and 9254B, to report caloric vestibular testing for bithermal and monothermal testing procedures, respectively. These two newly established codes then went through the rigorous RUC valuation process. They were surveyed by four specialty societies: the American Academy of Audiology (the Academy), the American Speech-Language-Hearing Association (ASHA), the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), and the American Academy of Neurology (AAN). The surveys yielded a robust response, totaling more than the required number of responses and no issues were raised by the RUC regarding the reliability of the data. The specialties recommended to the RUC a work RVU of .80 for 9254A and a work RVU of .55 for 9254B based on the 25th percentile work values identified through the survey process. The specialties also requested pre-facilitation to fully vet our proposal prior to presenting to the full RUC. In the end, the RUC accepted the values proposed by the specialty societies and recommended a work RVU of .80 for 9254A and a work RVU of .55 for 9254B.

The Academy was disappointed to read in the proposed rule that CMS did not accept the RUC recommended values for CPT codes 9254A and 9245B, opting instead to reduce those values and assign work RVUs of .60 and .30 respectively. CMS assigned the work RVU of .60 based on a direct crosswalk to CPT code 97606 (Negative pressure wound therapy, surface greater than 50 square centimeters, per session) to CPT code 9254A. To value CPT code 9254B, CMS simply divided the proposed work RVU for 9254A in half (.30). CMS' stated rationale for rejecting the RUC recommended values was a belief that "the recommendations for these services overstate the work involved in performing these procedures."

The Academy objects to CMS' rationale regarding the valuation of 9254A and 9254B. This rationale ignores the cogent, methodical, and thorough approach utilized by the RUC to review CPT codes. The Academy feels that the RUC-approved work RVUs for 9254A and 9254B were reasonable and appropriate. It is also difficult to understand how directly crosswalking CPT code 97606 to 9254A provides a more appropriate work RVU than a work RVU obtained through the RUC survey process, which entailed extensive preparation and produced a robust survey. This survey was based on expert input from three specialties and adhered to stringent RUC guidelines, as well as review and scrutiny by the objective RUC panel of experts.

The Academy also believes that there are inherent flaws in selecting CPT code 97606 as a direct crosswalk for 9245A. As noted, this CPT code does not accurately capture the work and intensity of the service, and is not reflective of the work RVU supported by the survey data. We also find the direct crosswalk problematic, as CPT code 97606 was last valued in 2003, more than 12 years ago. The survey for this code only yielded 16 respondents, far below the standard set by the AMA and CMS. CPT code 97606 is also not a Multi-Specialty Points of Comparison (MPC) code. Further we find this comparison incongruous, as CPT code 97606 is a low volume code (12,000) compared with the data for CPT code 92543 with much higher utilization (400,000/4=100,000). We suggest using alternative crosswalk codes that more accurately and appropriately reflect the work and intensity of CPT code 9254A. We have provided a list of MPC codes (Table 1) and other reference codes (Table 2) that better support the work, time, and intensity of this service.

Additionally, as reflected in the specialty surveys and as discussed extensively before the RUC panel, the work RVU for 9254B is not accurately characterized as being half of 9245A. We recognize that the code descriptor for this procedure describes the service as having two irrigations as opposed to the four described in 9245A, yet the indication for performing 9245B occurs when a patient is unable to tolerate the more typical four irrigation test (9254A). These patients are more difficult to evaluate because of the severity of the presenting symptoms and the fact that the test exacerbates the patient's state. The comorbidities of the typical patient make them more difficult to evaluate, thus increasing the intensity and complexity of the service. As such, the Academy strongly supports the RUC recommended work RVU of .55 for 9245B, which again was based on the survey's 25th percentile work value. We have provided a list of MPC codes (Table 3) and other reference codes (Table 4) that support the RUC recommended work RVU for CPT code 9254B.

CPT codes 9254A and 9254B were created to replace CPT code 92543 and represent the culmination of efforts spanning nearly seven years to correct the flawed valuation of vestibular procedures 92541-92545. This flawed valuation dates back to 2009, when clinical staff time was removed from the practice expense of vestibular procedures, including CPT code 92543 (now 9254A and 9254B), without being reviewed or evaluated through the RUC survey process and appropriately added to the work component. The reduction in practice expense in 2009 should have occurred in conjunction with a work survey to appropriately capture professional work, since audiologists' time was removed from practice expense with the assumption that this change would be captured as part of the work RVU. However, no work survey occurred and CPT code 92543 was left with decreased practice expense and no valuation of professional work, time and effort in the work RVU. Since that time, the profession of audiology, in conjunction with other specialties and the AMA, has worked to remedy this issue and secure fair valuation for this series of vestibular codes. Finalizing CPT codes 9254A and 9254B was one of the remaining steps in correcting this flawed valuation formula that has negatively impacted these procedures since 2009.

The Academy disagrees with CMS' decision not to accept the RUC recommendation for CPT codes 9254A and 9254B and asks that CMS reconsider this decision within final rulemaking for CY 2016. This recommendation was based on a rigorous, detailed and systematic review by the RUC. Given the history of these codes, the solid

multi-specialty survey data, and the well-reasoned rationale provided for these values, we urge CMS to revisit its decision to not accept the RUC recommended values for these codes.

Table 1: Comparison to MPC codes for CPT code 9254A

CPT Code	Descriptor	RVW	IWPUT	Total Time	PRE	INTRA	POST
93015	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report	0.75	0.031	26	2	20	4
92012	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient	0.92	0.047	25	5	15	5

Table 2: Additional Reference Codes for CPT code 9254A

RUC Reviewed	CPT Code	Descriptor	RVW	IWPUT	Total Time	PRE	INTRA	POST
2007	95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming	0.80	0.026	32	3	24	5
2011	95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs	0.86	0.021	40	10	20	10

Table 3: Comparison to MPC codes for CPT code 9254B

CPT Code	Descriptor	RVW	IWPUT	Total Time	PRE	INTRA	POST
93923	Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more levels), or single level study with provocative functional maneuvers (eg, measurements with postural provocative tests, or measurements with reactive hyperemia)	0.45	0.020	16	3	10	3
76536	Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation	0.56	0.038	4	10	4	18

Table 4: Additional Reference Codes for CPT code 9254B

RUC Reviewed	CPT Code	Descriptor	RVW	IWPUT	Total Time	PRE	INTRA	POST
2011	92588	Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report	0.55	0.025	22.5	3	16.5	3

2013	77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)	0.60	0.022	27	7	15	5
2010	76881	Ultrasound, extremity, nonvascular, real-time with image documentation; complete	0.63	0.027	25	5	15	5

II. CY 2016 Refinement Panel Proposal

In keeping with the concerns expressed above, the Academy also wishes to offer comments on CMS' proposal to permanently eliminate the refinement panel beginning in CY 2016. The Academy supports the new process for publishing proposed values for interim final codes in the proposed, rather than final payment rules for the upcoming calendar year. The Academy believes that having two opportunities to comment on proposed values will contribute to overall accuracy and applauds CMS' commitment to transparency by having those comments publicly available at www.regulations.gov. However, as noted in our comments regarding the valuation of CPT codes 9245A and 9254B, the Academy also values the opportunity for review and consideration by a refinement panel composed of representatives from multiple specialties who can review and discuss the work involved in each procedure, much like the RUC. We believe that the existence of a refinement panel brings further transparency to this valuation process. CMS cites multiple methods for determining appropriate valuation and assessing RUC recommended values, yet aside from a brief explanation in the proposed/final rule, little is understood as to how CMS actually makes their decisions regarding valuation. Maintaining the refinement panel ensures some possibility for systematic review by a transparent and objective panel of multispecialty experts.

III. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

The Academy appreciates the steps taken by CMS to ensure that qualified individuals continue to provide incident to services to Medicare beneficiaries in a manner consistent with Medicare statute and regulations. We share CMS' position that billing practitioners should take a personal interest in, and responsibility for, furnishing services for which they are billing as an incident to their own professional services. We support CMS' proposal in the proposed rule to require the physician or other practitioner who bills for the incident to service to be the physician or other practitioner who directly supervises the service. The Academy believes that this policy will further promote appropriate incident to billing practices among health care providers.

IV. Physician Compare

In the proposed rule, CMS discusses its ongoing efforts to expand public reporting on Physician Compare by making a broader set of quality measures available for publication on the website in CY 2016. These broader measures include all 2015 PQRS measures for individual eligible providers collected through a registry, EHR or claims, as well as and group-level measures reported across all group reporting mechanisms available for public reporting in 2016. To support CMS in these efforts, the Academy respectfully requests that its representative experts continue to advise CMS to ensure that audiologists are meaningfully represented and can be easily identified by other professionals and patients on Physician Compare. The Academy also has a

number of resources and expert representatives available to review the audiology measures under considerations for public reporting.

The Academy would like to offer comments regarding CMS' proposal to include "Board Certification" to the Physician Compare website, specifically the American Board of Optometry (ABO) and American Osteopathic Association (AOA) certifications. The Academy applauds CMS' efforts to equip consumers with expanded information to make informed health care decisions. To further promote informed decision-making by consumers, the Academy notes that many specialties, including the profession of audiology, have multiple, voluntary certification options. Audiologists have the option of pursuing certification through the American Board of Audiology (ABA) and/or a Certificate of Clinical Competence in Audiology (CCC-A) from ASHA. As CMS looks to add Board Certification to Physician Compare, the Academy urges the Agency to consider multiple certifications within a specialty and to develop a tool for Medicare beneficiaries and other health care consumers to view a comparison of the multiple certifications on the site. Additionally, at present there is no category for specialized certifications for non-physician professionals under Physician Compare, as such, the Academy requests the opportunity to provide input should such a category be under consideration.

V. Physician Quality Reporting System (PQRS)

The Academy is a member of the Audiology Quality Consortium (AQC), comprised of ten independent audiology organizations that collaborate on PQRS measure development and member education. In addition, the AQC is the measure owner of one current audiology measure in the PQRS program. Since it was founded in 2008, the AQC has worked diligently toward developing, establishing, and reviewing the PQRS measures for the profession of audiology. Still, audiologists are among a small number of provider types who are limited in the number of measures available for PQRS reporting. Audiologists currently may report on three PQRS measures:

- **#261:** Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness
- **#130:** Documentation and Verification of Current Medications in the Medical Record
- **#134:** Screening for Clinical Depression and Follow-Up Plan

Due to the limited nature of current PQRS measures available for audiologists, the Academy urges CMS to maintain these measures as they further define the quality measures performance category of the Merit-based Incentive Payment System (MIPS).

Proposed Changes to the Requirements for Qualified Clinical Data Registries (QCDRs)

The current Medicare regulatory definition places audiologists in the "Other Diagnostic Procedures" benefit classification, which is limited to the exclusive diagnostic only areas of hearing and balance healthcare. Developing measures of quality and outcomes for this narrowly defined benefit classification, as well as participating in interdisciplinary measures that require outcomes or treatment management of the patient has been challenging within these regulatory confines. The Academy believes that QCDRs offer expanded opportunities for specialties like audiology to develop, utilize, and report on more specialty specific measures that may extend beyond Medicare's definition of their services. QCDRs also allow specialties to develop measures that are clinically relevant in order promote best practices and improve performance.

In exploring this quality reporting option, the Academy asks that CMS continue to clarify, streamline, and simplify requirements related to reporting via QCDRs. The Academy asks CMS to consider modifications or

alternative options to meeting the 50% threshold of reporting on all patients across all payers. This 50% threshold may deter some providers from participation, and may cause unnecessary burden to providers, especially with regard to the development of and reporting on patient reported outcome measures. The Academy understands that other specialties currently reporting via QCDRs find this threshold difficult to meet and burdensome for individual providers.

Definition of satisfactory reporting/satisfactory participating

The Academy strongly supports the Agency's continued application of the Measure-Applicability Validation (MAV) process for audiologists and other eligible professionals with fewer than 9 PQRs measures. The MAV process offers protection to these providers from a PQRs payment penalty when current circumstances require they report on fewer than 9 measures. At the same time, the MAV process can be confusing and may require professionals to engage in a multiple-step analysis to determine if they meet the requirements of satisfactory PQRs reporting. The Academy requests that CMS continues to work to provide less complex, step-by-step educational products for eligible professionals to engage in the MAV analysis, and consider a continuation of the MAV process or the application of a similar process for the Merit-Based Incentive Payment System (MIPS) where appropriate.

VI. Value Based Payment Modifier (VM)

The Academy agrees with CMS' position that it would not be appropriate to apply the VM to any non-physician providers who are not physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs) and certified registered nurse anesthetists (CRNAs) for the CY 2018 payment adjustment period. As the VM becomes integrated into the quality measure performance category of the MIPS, the Academy requests that CMS work to provide sufficient education and training for audiologists and other non-physician practitioners on the VM and other components of this category to ensure timely and appropriate application and reporting. The Academy requests that CMS consider opportunities and incentives for audiologists that do satisfactorily report PQRs measures.

VII. The Merit-Based Incentive Payment System (MIPS)

As defined in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and further outlined by CMS, MIPS will be comprised of four performance categories including quality measures, resource use measures, clinical improvement activities, and Meaningful Use of EHR. We offer the following comments in response to CMS' request for public input on provisions related to the creation of the MIPS.

Determination of Composite Performance Score for EPs

CMS has stated that features of PQRs, the VM, and the EHR Meaningful Use will be included in the MIPS. The Academy has long advocated for and continues to seek meaningful, reasonable, and appropriate inclusion of audiologists in these programs, yet as previously stated audiologists have limited measures within the PQRs program, will not have the VM applied to them for CY2018, and were statutorily excluded from Meaningful Use of EHR. As CMS develops their methodology for determining composite performance scores, the Academy requests that the Agency recognize there are a number of specialties that have limited participation in existing programs. The Academy would like to see multiple, inclusive options for participation in MIPS that take into consideration such factors.

Clinical Practice Improvement Activities

The Academy is encouraged by the opportunities for participation proposed as part of clinical practice improvement activities. The Academy believes that many providers currently engage in the activities defined under this category, and see benefits to incentivizing such efforts. In reviewing the list of suggested clinical practice improvement activities, the Academy would like to note that many of these activities vary across practice setting. We encourage the creation of a diverse list of activities to ensure robust participation across practice settings and specialties. The Academy also suggests that CMS include use of EHR to the list of clinical practice improvement activities. This would provide an opportunity for audiologists who use EHR in their practices to voluntarily report on some of these activities. EHR also serve as an important component of quality reporting, especially through mechanisms such as QCDRs.

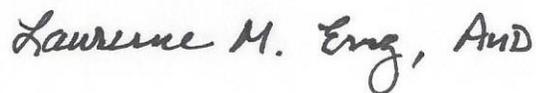
Resource Use Measures

As CMS looks to develop resource use measures and seeks to identify areas of quality improvement and cost savings, the Academy urges the Agency to consider the current trends for the diagnosis and management of dizzy patients. Vestibular testing is an objective and sensitive battery of tests using voluntary and involuntary eye movements (known as nystagmus) to assess the peripheral and central vestibular systems. Most information obtained through vestibular testing cannot be obtained by other means. Additionally, diagnosing a benign vestibular disorder often safely rules out a worrisome stroke or brain lesion. Due to highly problematic changes in payment policies related to vestibular testing (discussed in the first section of this letter), we have seen a marked decrease in patient access to and utilization of vestibular testing since 2008. At the same time, we have seen an increased use of neuro-imaging in the assessment of dizzy patients. For example, cranial CT scans were ordered on 39 percent of dizzy patients in 2011. The Academy believes decreased access to vestibular testing has led to an increased use of neuro-imaging with more patients visiting the emergency room (ER) for complaints of dizziness. With the increased use of neuro-imaging, the estimated costs for ER services are estimated at \$4 billion per year as of 2011. It is estimated that with policy changes and education, these services could be reduced by \$1 billion per year. The Academy strongly encourages CMS to consider the diagnostic testing of dizzy patients when engaging in the future development of resource use or cost savings measures. The Academy would be happy to provide in depth resources and supporting data to assist CMS in these efforts.

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The Academy appreciates the opportunity to comment on this proposed rule. Please contact Kate Thomas, director of payment policy and legislative affairs, by phone 703-226-1029 or via email at kthomas@audiology.org should you have any questions regarding the Academy's comment letter.

Sincerely,



Lawrence M. Eng, AuD
President, American Academy of Audiology