September 6, 2013

The Honorable Marilyn Tavenner, MHA, BSN, RN
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Calendar Year 2014 Proposed Medicare and Medicaid Programs: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, CMS-1600-P

Dear Dr. Tavenner:

The American Academy of Audiology is the world’s largest professional organization of, by, and for audiologists, representing over 11,000 members. The American Academy of Audiology (the “Academy”) promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

Below are the Academy’s comments regarding the Centers for Medicare and Medicaid Services (CMS) Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014 Proposed Rule 1600-P, published in the Federal Register on July 19, 2013. We commend the Agency on its commitment to improving the quality of care for Medicare beneficiaries and appreciate the opportunity to comment on the areas enumerated below.

I. FEE SCHEDULE AND SUSTAINABLE GROWTH RATE (SGR)

While many professions are expected to see minimal or no change in payment based on the 2014 Medicare Physician Fee Schedule proposal, audiology will experience an overall reduction in payment once again this year. It is becoming increasingly difficult and unsustainable for audiology practices to provide hearing and balance services to Medicare beneficiaries. If audiologists cannot afford to provide a reasonable and medically necessary level of care to Medicare beneficiaries, access to care will be limited as audiologists will decide not to participate in the Medicare program as has been evidenced over the last few years. The Academy views this as a distressing situation that is compounded by the ongoing expected increase of enrolled Medicare beneficiaries who will need quality hearing and balance care as they age.

The Academy is also deeply concerned about the greater than 26% decrease in payment rates to professionals providing Medicare services as a result of the flawed Sustainable Growth Rate (SGR) formula. These cuts, scheduled for January 1, 2014, will make it impractical for health care professionals to provide quality services to Medicare beneficiaries. The Academy has offered several comment letters in support of Congressional proposals which seek a
permanent repeal of the SGR and overall payment reform this session. We strongly urge the Agency to continue to work with Congress in establishing a permanent and viable solution to the SGR formula that will result in equitable payment for services provided.

II. PHYSICIAN PAYMENT, EFFICIENCY, QUALITY IMPROVEMENTS—PHYSICIAN QUALITY REPORTING SYSTEM

The Academy is a member of the Audiology Quality Consortium (AQC), comprised of 10 independent audiology organizations that collaborate on Physician Quality Reporting System (PQRS) measure development and member education. In addition, the AQC is the measure owner of two current audiology measures 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. Academy representatives participate in weekly measure owner calls, and have been actively discussing new measure development with CMS and their contractors, including a face-to-face meeting on August 20, 2013 with CMS officials at CMS Headquarters. The Academy’s comments below support and reinforce the comments made independently to CMS by the AQC.

The Academy believes that clinically relevant measures of outcomes and quality can assist Medicare in tracking this data for beneficiaries, provide information to patients about services they receive, and can promote best practices and care coordination within the profession of audiology. Audiologists, however, will likely be unable to achieve the goals of the program due to the paucity of quality measures available for their reporting. The profession remains in an untenable situation in which we are required to participate in PQRS, but do not have a sufficient number of quality measures to do so effectively. Given these circumstances, the Academy appreciates the opportunity to comment on the following PQRS provisions in the proposed rule:

- Retirement of measure #188: referral for otologic evaluation for patients with congenital or traumatic ear deformity;
- The 2014 definition of satisfactory reporting for the incentive payment and 2016 payment adjustments;
- The claims-based reporting option and the qualifications for registry participation.

Retirement of Measure #188

CMS proposes the retirement of Measure #188, referral for otologic evaluation for patients with congenital or traumatic deformity of the ear. In the rationale for retirement, it is erroneously noted that the measure “lost measure owner support.” AQC comments for the 2013 proposed rule state that the AQC supported “…consideration of the retirement of Measure #188 in lieu of Measure #190 (sudden or rapidly progressive hearing loss).” The Academy understands that the audiology measures used by CMS did not meet NQF endorsement standards and could eventually be retired for use. We also agreed that measures requiring a referral for further evaluation may indicate care coordination, but do not necessarily capture quality or outcomes. Comments in response to the Measures Application Partnership (MAP) recommendation for retirement indicated low utilization and clinical relevance of the measure for the Medicare population. While the measure owners (the AQC) agreed with the MAP, the AQC did not actively pursue retirement of Measure #188. The Academy requests that the rationale set forth in the Final Rule for retirement of Measure #188 reference the MAP recommendations for retirement, rather than lack of measure support from the measure owners.
Definition of satisfactory reporting/satisfactory participating

The Academy has significant concerns regarding the dramatic increase in reporting requirements in 2014. The increase from 3 measures to 9 measures covering at least 3 of the National Quality Strategy (NQS) domains, or if less than 9 measures apply, report 1-8 measures “for which there is Medicare patient data” seems an excessive expectation when previous reporting requirements were 3 measures for 50% of the eligible patients for the incentive. Furthermore, to avoid the payment adjustment, the current requirement states that an audiologist must report 1 measure, 1 time for 1 patient. While intended to demonstrate a broader picture of the quality of care furnished by the eligible professional, reporting on measures that are not clinically relevant or are too broad does not improve patient care. The Academy requests establishment of a gradual, scheduled increase of satisfactory reporting requirements with a tiered reporting option that allows for quality reporting by professionals with a limited number of measures. This would allow input from stakeholders regarding the most appropriate measures to include, and allow time for measure development or modification of existing measures.

The Measure-Applicability Validation (MAV) process may represent a form of a tiered reporting option. However, the specific language used by the Agency, “for which there is Medicare patient data”, is of concern and requires clarification. It is unclear from this language whether the MAV process is being redesigned or if the roles of the generalized measures are changing. The Academy requests clarification of the MAV process concerning the generalized (non-discipline specific) measures and the proposed 9 measure increase. Further, the Academy respectfully requests that a MAV process be continued for the foreseeable future to allow audiologists and other eligible professionals with fewer than 9 measures to participate in PQRS.

Audiologists are among a small number of provider types who are limited in the number of measures available for reporting by virtue of the statutory definition that limits the profession to diagnostic hearing and balance procedures. It has been challenging for the profession of audiology to develop outcome measures of quality for a limited scope of practice as well as to participate in interdisciplinary measures that require outcomes or treatment management of the patient. With the time, resources, and processes required for measure development and NQF endorsement, it is not feasible for the AQC to attain the 9 measure minimum in the short-term. This situation is further complicated by the retirement of two audiology measures last year (Measure #189: Referral for Otologic Evaluation for Patients with a History of Active Drainage From the Ear Within the Previous 90 Days and Measure #190: Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss), and the current proposal for retirement of Measure #188. As expressed earlier, we recognize that measures of referral are not sufficient for measuring quality, and acknowledge that retirement of #188 and #189 were reasonable given the low utilization and the limited Medicare beneficiaries that present to an audiologist with active drainage or ear deformities that are not already under the care of a physician. It was disappointing, however, when Measure #190 was eliminated for 2013 reporting, as sudden or progressive hearing loss is a common condition seen by audiologists in the Medicare population and this was reflected in the high utilization rate among audiologists reporting on this measure. In light of the limited measures available and the proposed increase to a 9 measure threshold, the Academy urges CMS to reinstate Measure #190 for reporting in 2014 and in future years, while the AQC continues to develop measures which meet NQF endorsement standards.

In the short-term, Measure #190 is clinically relevant and will offer audiologists the ability to report a measure on a common condition needing immediate intervention. However, one of the long-term objectives for audiology quality measure development by the AQC is to comply with the standards of PQRS and NQF. In order to best accomplish this, the Academy requests that CMS assign a contractor to assist the AQC with measure development for the PQRS program, ensuring measures meet the scientifically rigorous criteria set by CMS and NQF. The
resource burden in terms of sheer financial cost and staffing for the endeavor of measure development to comply with PQRS is unmanageable for smaller professional associations. The Agency has a responsibility to ensure that eligible professionals who are subject to the program have the tools necessary to participate without penalty. Without the assistance of the Agency, through an assigned CMS contractor to develop audiology measures that meet NQF and CMS standards, audiologists will be unable to participate in PQRS beginning in 2017 under these proposed rules. **CMS has precedent for assigning the CMS contractor, Quality Insights of Pennsylvania, and the Academy requests similar consideration for the profession of audiology in CY 2014.**

**Reporting options**

The proposed rule cites that, according to 2011 PQRS data, approximately 72% of eligible providers used the claims-based reporting option. The Academy appreciates that claims-based reporting is a mechanism that has a higher error rate and is burdensome for data collection. However, claims-based reporting is the only viable option currently available for audiologists to participate in PQRS. At this time, audiologists are not mandated electronic health record (EHR) participants and systems that are available for audiologists are generally not integrated with PQRS. Audiologists do not have the resources available to participate in PQRS through any other method except claims-based reporting.

If CMS were to eliminate the claims-based reporting option by 2017, it is doubtful that an audiology-based registry would be available for continued participation. As noted in the proposed qualifications for current registries and the proposed newly defined clinical data registry, a registry must have available 9 measures covering 3 NQS domains and include a minimum of one outcome measure. Currently audiologists have 1 measure; referral for otologic evaluation for patients with acute or chronic dizziness, and they are able to participate in measure #130, documentation of current medications in the medical record and measure #134; screening for clinical depression and follow-up plan. Although the AQC is diligently pursuing development of audiology measures, it is highly unlikely that nine measures will be available for reporting by 2017, even in the most optimal conditions, and the concurrent development of an independent audiology registry would not be feasible. **The Academy requests that the claims-based reporting option continue for audiologists and other health care professionals who are diligently engaging in measure development and do not have meaningful, alternative non-proprietary options for reporting.**

Finally, the proposed clinical data registry requirements include several qualifications that are complex and costly, requiring significant resources to establish, including: the ability to capture data on other payers outside of Medicare, the inclusion of protected health information and patient-specific data that would require business agreements with all participants, validation and risk-adjustment strategies, data privacy and security requirements for storage, transmission, and reporting, and public reporting of individual participants. Additionally, the timeline proposed is not feasible for health care professionals lacking previously established registries. With the requirement that the registry have 100 participants and be established for one year prior to application, in order to be ready for 2017 participation, the 9 measures and the registry would need to be finalized by January 1, 2016. **If no other option exists besides phasing out claims-based reporting, CMS must consider the fact that audiologists would prefer to move to an EHR-based reporting system prior to a registry reporting system.** Many audiologists will need to be educated on EHR-based reporting methodology and will need to undertake the significant cost of purchasing such a system.
III. PHYSICIAN COMPARE WEBSITE

In 2013, CMS launched a full redesign of the Physician Compare website offering significant improvements, including a complete overhaul of the underlying database and a new "Search" feature. Academy staff and volunteer experts worked closely with CMS and were asked to review the website for the profession of audiology, including providing key words to be included in the search criteria and identifying improvements with the search engine and its ability to identify audiologists across the nation. CMS proposes to continue to refine these detailed search criteria in 2014, as well as to implement the next phase of publicly documenting a professional's PQRS performance regarding quality measure reporting on Physician Compare. The Academy respectfully requests that its representative experts continue to advise CMS as the Agency redesigns the Physician Compare website to assure that audiologists are meaningfully represented and can be easily identified by other professionals and patients.

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The Academy appreciates the opportunity to comment on this proposed rule. Please contact Sharmila Sandhu, Esq., Director of Regulatory Affairs at 202.544.9337 or via email at ssandhu@audiology.org should you have any questions regarding the Academy’s comment letter.

Sincerely,

Bettie Borton, Au.D, FAAA
President, American Academy of Audiology