AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

December 30, 2014

SUBMITTED VIA ELECTRONIC FILING AND REGULAR MAIL

Marilyn Tavenner, RN
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2015

Dear Administrator Tavenner:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Schedule & Other Revisions to Part B for CY 2015" published in the Federal Register as a proposed notice on October 31, 2014. Our comments will address the following issues, in the order in which they appear in the proposed rule: (1) Sustainable Growth Rate (SGR); (2) Resource Based Practice Expense (PE) Relative Value Units (RVUs); (3) Potentially Misvalued Services Under the Fee Schedule; (4) Validating RVUs of Services; (5) Payment for Secondary Interpretation of Images; (6) Physician Compare Website; (7) Electronic Health Records (EHR) Meaningful Use (MU) Incentive Program; (8) Physician Quality Reporting System; and (9) Value Based Payment Modifier and Physician Feedback Program.

1. SUSTAINABLE GROWTH RATE (SGR)

Over the past decade, the AAO-HNS and others in the physician community have repeatedly advocated for the reform and full repeal of the unstable and unsustainable Medicare physician payment formula. The failure to enact permanent reform has created an instability and uncertainty that undermines the ability of physicians to plan for the future, to provide for their employees, and to make investments to improve the quality and efficiency of the care they provide. In the proposed rule, the Centers for Medicare & Medicaid Services (CMS) estimates that under current law, the conversion factor (CF) for CY 2015 would be reduced, beginning on April 1, 2015, by more than 20 percent. The CF for the first three months of the year is $35.8013 (compared to the CY 2014 conversion

factor of $35.8228), but emphasizes that the Agency is committed to working with Congress to permanently reform the SGR methodology for MPFS updates.

The Academy applauds CMS for recognizing that the SGR formula must be eliminated, and we appreciate CMS' commitment to work with Congress to resolve the issue. The Academy continues to advocate for permanent repeal of the SGR formula and submitted numerous comments to Congress supporting its legislative reform proposal in the 113th Congress (H.R. 4015/S. 2000). To access the Academy's comments on SGR repeal visit: http://www.entnet.org/content/permanent-repeal-sgr-formula. We hope lawmakers will continue to prioritize this on the 114th Congressional agenda and welcome efforts by CMS to work with Congress to achieve full repeal of the SGR formula prior to the April 1, 2014 expiration of the current SGR patch.

2. RESOURCE BASED PRACTICE EXPENSE (PE) RELATIVE VALUE UNITS (RVUS)

A. Review of CPT Codes Captured by the RUC OPPS CAP Screen

As CMS is aware, the Academy responded to a RUC issued screen that was issued in response to concern expressed by CMS in 2014 rulemaking related to services whose practice expense RVUs were higher, and therefore were paid more, in the office setting than the hospital outpatient setting. Of the 211 CPT codes identified by CMS, 14 of those codes were services provided by practicing Otolaryngologists. In an effort to be responsive to CMS' concerns, the Academy indicated interest in reviewing the practice expense for these codes, and did so, during the April 2014 RUC meeting. We would note that CMS did not recognize these efforts in any manner within the 2015 final MPFS. During an AMA briefing on the payment sections of the final rule, our staff was able to confirm with CMS staff responsible for the practice expense sections of the MPFS, that these PE recommendations submitted by the AMA RUC would be discussed in future rulemaking. ***The Academy appreciates CMS' consideration of the revised PE direct inputs for these 14 CPT codes in future rulemaking and we look forward to your decisions related to these efforts. As you know, the Academy was one of only a few specialty societies who undertook the substantial work and expense of reviewing these codes, and we sincerely hope this addresses CMS' concerns related to the practice expense inputs for high cost supplies and equipment as it relates to these services.***

B. Using OPPS and ASC Rates in Developing PE RVUs

Within the final rule, CMS revisits their CY 2014 proposed policy to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. CMS adds that it is not proposing a similar policy for the CY 2015 PFS and that if it did do so in the future rulemaking, it would consider all of the comments received previously. CMS notes, however, that it continues to believe that there are various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated. CMS adds that section 220(a)

of PAMA, Publ. L. 113-93, provides them with the authority to explore ways of collecting better and updated resource data from physician practices, including those that are provider-based, and other non-facility entities paid under the PFS, and that using this information does not detract from the statutorily required "relativity" of the MPFS. CMS says that such efforts will be challenging given the wide variety of practices and likely impose some burden on EPs. CMS notes that through a validation contract, it has been gathering time data directly from physician practices, from which it has learned much about the challenges of gathering data directly from physician practices.

CMS further notes that section 220 of PAMA provides authority to use alternative approaches to establish PE RVUs, including the use of data from other suppliers and providers, and that the agency is exploring how best to exercise this authority. They note that they continue to believe that there are various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated. They feel that OPPS cost data is routinely updated and is an auditable source of cost information submitted contemporaneously by a wide array of providers across the country, and therefore, is a valid reflection of ''relative'' resources and could be useful to supplement the resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year. They note that their own experience has shown that is difficult to obtain invoices for supply and equipment items that we can use in pricing direct PE inputs. Many specialty societies also have noted the challenges in obtaining recent invoices for medical supplies and equipment. Further, PE calculations rely heavily on information from the Physician Practice Expense Information Survey (PPIS) survey, which, as discussed earlier, was conducted in 2007 and 2008. When we implemented the results of the survey, many in the community expressed serious concerns over the accuracy of this or other PE surveys as a way of gathering data on PE inputs from the diversity of providers paid under the PFS. They note that the OPPS pricing information could be as a means to validate or, perhaps, in setting the relative resource cost assumptions within the PFS PE methodology.

The Academy has some concerns in response to CMS' inquiries related to the use of hospital data to compare costs for direct practice expense inputs to that of the RUC database or society presented PE direct input data/invoices. Specifically, that hospitals have much greater buying and negotiating power as compared to physician practices given that hospitals are often purchasing equipment and supplies in larger quantities, and more frequently, than physician practices or solo-practitioners. This affords them leverage in negotiating prices with manufacturers and industry partners that is not available to physician practices purchasing equipment once every few years, or in single quantities. Thus, we would caution that CMS only use hospital cost data submitted to them under the Hospital Outpatient Prospective Payment System (OPPS) as a comparator for invoices submitted via the RUC process by physician practices and specialty societies, and not as a measuring tool or concrete cost data for setting supply and equipment rates under the direct input portion of PE within the PFS.

C. Collecting Data on Services Furnished in Off-Campus Hospital Provider-Based Departments

Within the final rule CMS continues to seek a better understanding regarding the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments. CMS adds that as more physician practices become hospital-based, it is difficult to know which PE costs typically are actually incurred by the physician, which are incurred by the hospital, and whether Medicare's bifurcated site-of-service differential adequately accounts for the typical resource costs given these relationships. CMS finalized two policy changes within the final rule to address these concerns.

1) Two new place of service (POS) codes (one for outpatient services furnished on-campus, remote, or satellite locations of a hospital, and a second to identify services furnished in off-campus hospital provider-based outpatient department) to replace POS 22 (Hospital outpatient). There will be no voluntary reporting period for these codes, but CMS intends to do education prior to their release and expects them to be available after July 1, 2015.

2) For hospital claims they are creating a HCPCS modifier that must be reported with every code for outpatient hospital services furnished in an off-campus PBD of a hospital. This is not required for remote locations or satellite facilities of a hospital, or for services furnished in an ED. The modifier will be available as of January 1, 2015 with the label "PO". Reporting of the modifier will be voluntary for one year and required beginning on January 1, 2016.

We have commented previously in support of the development of a new place of service (POS) code for "off-campus departments" to be used on the 1500 claim form as the best of the alternatives aimed at tracking the site of service in which providers are rendering services to Medicare beneficiaries. Given that providers already have to select a POS code for the 1500 claim, simply adding a new option to denote an "off-campus department" will not place any additional burden on the physicians or their billers, and therefore, we support this finalized policy by CMS.

3. ESTABLISHING RELATIVE VALUE UNITS (RVUS) FOR CY 2015

Within this section of the final rule, CMS first addresses comments received on the 2014 final MPFS and the outcome of refinement panels convened during 2014 related to these comments.

A. *Results of 2014 Refinement Panels*

The Academy is appreciative of CMS' decision to increase values for CPT code 43233 in accordance with the recommendations of the refinement panel convened in CY 2014 for this service. We believe the final values approved by CMS for the other two codes reviewed during that refinement panel, CPT 43204 and 43205, continue to be inappropriate and would encourage CMS to revisit the values recommended for these services by the AMA RUC and/or the refinement panel.

B. *Rigid Transoral, Flexible Transoral, and Flexible Transnasal (TNE) Esophagoscopy CPT Codes*

The Academy is extremely appreciative of CMS' decision to modify the work RVUs for CPT codes 43191-43198 based on Academy comments on the 2014 final MPFS. We believe these services are now more accurately valued and show the appropriate differentiation in work across the family of rigid transoral, flexible transoral, and flexible transnasal esophagoscopy services.

Related to CMS' changes to practice expense RVUs for CPT 43198, we appreciate CMS' agreement that biopsy forceps should be included in the equipment for this code. We also acknowledge CMS' comment that they will price that input at $0 until a paid invoice is received. ***As such, we are attaching a paid invoice for this item to this comment letter, in hopes you will assign a value accordingly through future rulemaking.***

C. *Speech Evaluation Codes*

CMS did not modify the final values for speech evaluation codes (92521-92524) as requested by the Academy and other audiology specialty societies. In response to comments that these services were undervalued by CMS in the 2014 final rule CMS stated: "We believe that our interim final work RVU is most appropriate for these services. In the HCPAC recommendation for CPT code 92523 the affected specialty society stated that its survey results were faulty for this CPT code because those surveyed did not consider all the work necessary to perform the service. **The commenters did not provide any information that demonstrates that our valuations fail to fully account for the intensity, work, and time required to perform these services. Therefore, we are finalizing our CY 2014 interim final values for CY 2015. We did not refer these codes to refinement because the request did not meet the criteria for refinement**."

4. Potentially Misvalued Services Under the Physician Fee Schedule

A. *CMS Retraction of Potentially Misvalued Code High Expenditure Screen for CY 2015*

Within the 2015 NPRM, CMS proposed a new screen which captures approximately 65 codes listed below as potentially misvalued codes as a prioritized subset of codes that account for the majority of spending under the physician fee schedule. Specifically, they note that within their usual identification process for capturing potentially misvalued codes it is possible to miss certain services that are important to a segment of Medicare practitioners and beneficiaries because the specialty that typically furnishes the service does not have high volume relative to the overall PFS utilization. To capture such services in developing this list, they began by identifying the top 20 codes by specialty in terms of allowed charges. They excluded codes from our proposed potentially misvalued list reviewed since CY 2009, with fewer than $10 million in allowed charges, and that describe anesthesia or E/M services. ***Within the final rule, however, CMS rescinded this screen as a result of their decision to finalize the transition of all codes to 000 globals by 2018. Rather, they directed that the RUC should focus their efforts on how to operationalize that policy change, and delayed this screen and review of associated codes to a time***

uncertain. The codes relevant to Otolaryngology that were captured in this screen are listed below. Review of codes in red has been cancelled, or postponed, based on the delay of the screen.

14060 Tis trnfr e/n/e/l 10 sq cm/<
31575 Diagnostic laryngoscopy
31579 Diagnostic laryngoscopy
92557 Comprehensive hearing test
95004 Percut allergy skin tests
95165 Antigen therapy services

The Academy understands, and appreciates, CMS' decision to delay this screen for future rulemaking to allow specialties and the RUC to focus on how best to implement the global surgery transition policy. ***We continue, however, to have concerns related to this type of CMS screen.*** Specifically, while we support efforts in regards to identifying potentially misvalued codes within the PFS in an effort to conserve resources across the RBRVS payment system we have concerns about the use of a blanket "high expenditure" screen without thought towards why a code may be high volume or high expenditure. Specifically, for diagnostic screening tools used by one or multiple specialties, we think it is vital that CMS take into consideration the downstream costs saved by performing the initial diagnostic study. Given the usefulness of these diagnostic exams, we believe CMS should exempt services that are high volume or high expenditure from these screens unless they have not been RUC reviewed (also known as Harvard valued) and/or if they have not been RUC surveyed in the past 10 years. This will ensure that high volume / high expenditure diagnostic services remain accurately valued, but are not subject to multiple screens on a yearly basis, due solely to the fact that they are high volume or high expenditure, without the acknowledgement that they are medically necessary and save downstream health care costs by being performed initially to fully evaluate the patient.

Additionally, we encourage CMS to consider different types of screens to achieve their goals of identifying misvalued codes in scenarios, such as the one outlined above, where a code will always be high volume because it is useful diagnostic tool and saves downstream costs. In these cases, we believe a screen for codes that have increased a certain percentage over a set period of time (e.g. codes that have increased more than 30% over five years) should be captured, not just codes that are over a certain total utilization. This would identify areas of growth in high volume codes, rather than repeatedly capturing the same high volume codes, and requiring their re-review, when in many cases the high volume may be entirely appropriate.

B. Improving Valuation of the Global Surgical Package – Concerns with 010 and 090 Globals

We strongly urge CMS to rescind the policy in the 2015 Final Medicare Physician Fee Schedule Rule to transition 10– and 90–day global period codes to 0-day global period codes in 2017, and 2018, respectively. At a minimum, we encourage CMS to refrain from implementing the transition of 10- and 90-day global codes to 0-day global codes until they have issued a methodology, and allowed for appropriate notice and comment on that

methodology, that has been endorsed by the medical specialty societies whose procedures will be affected and that has been tested to ensure there is no negative impact on patient care and access.

The policy to transition 10- and 90-day global codes to 0-day has a number of potential consequences that should be well understood before implementation:

Detracts from quality of care, impedes patient access, complicates patient copays

Under the 10- and 90-day global codes, patients typically pay one copay related to all the services covered under the 10- or 90-day global code. If 10- and 90-day global codes are transitioned to 0-day global codes, patients will pay copays on other services as well, including each of the follow-up visits. This could considerably increase the administrative burden on patients, or worse, discourage them from coming back for follow-up care.

In the hospital critical care setting, the global payment structure allows the surgeon to oversee and coordinate care related to the patient's recovery. Without the global, care will be fragmented and providers will likely be forced to compete for the opportunity to see patients and bill for the care they provide.

Unintended Consequences

Removing post operative visits and simply substituting with the general E/M office visit codes will have unintended negative consequences to surgical specialties given that current post operative visits include direct practice expense inputs specific to that specialty. For example, a typical ENT office may have an exam chair, SMR cabinet, xenon light, etc. built into the post operative visit because this equipment is typical in the ENT office and used in all post operative visits. The regular E/M visits of course, do not include these specific pieces of equipment. Thus, in reporting the E/M visit codes, affected specialties will no longer be able to cover the costs of their office supplies and equipment for the direct practice expense inputs unless a higher paid E/M code set is created, or modifiers are utilized to denote the higher cost practice expense items commonly utilized by surgical specialties.

Although CMS has repeatedly stated that reimbursement should not be different between surgical specialists and primary care practitioners for E/M type visits, however, the reality is that the equipment and supplies utilized in a typical surgeon's office are different from that of a primary care practice, and therefore, should be reimbursed differently. It is unfair and punitive for CMS to discount the need for the differentiated equipment based on the practice patterns of surgical specialists, and we strongly encourage CMS to reconsider their position on this issue. Specialties such as Otolaryngology and Ophthalmology are among those that would be significantly harmed. Failure to do so will result in inadequate reimbursement for specialists which may result in practice closures and impede patient access to care if Medicare rates do not appropriately cover practice's overhead expenses.

Undermines the current SGR legislation and other Medicare reform initiatives

CMS initiatives for payment are all moving towards larger bundled payments. Deconstruction of the current payment structure for physicians is counterintuitive to the end goal of providing more comprehensive and coordinated care for the patient. Additionally, current bipartisan, bicameral legislation, to repeal and replace the flawed sustainable growth rate formula calls for a "period of stability" in physician pay to allow physicians to transition to alternative payment models. This proposal intends to introduce new complexities into an already flawed system and stymie that progress.

Increases administrative burden

The administrative burden on surgical practices and CMS (and its contractors) will be significant. The American Medical Association estimates that eliminating the global package will result in 63 million additional claims per year to account for post-surgical evaluation and management services. Clearly, this will add unnecessary costs to the claims processing system.

Obstructs clinical registry data collection and quality improvement

If patients forgo follow-up treatment or seek it from other providers, this policy would have a deleterious effect on surgeons' ability to collect information on patient outcomes in clinical registries, undermining many of the most meaningful quality improvement initiatives.

Because this policy will have a wide-ranging negative impact on patients, physicians, hospitals, third-party payers, and CMS, we recommend that CMS refrain from implementing this policy until the concerns of the affected specialties have been thoroughly evaluated.

C. CMS' Proposal to Modify the Rulemaking Process for Establishing Interim Values for Services

In the CY 2012 rulemaking process, CMS proposed and finalized consolidation of the five-year review and the potentially misvalued code activities into an annual review of potentially misvalued codes. Under this process, CMS issues interim final RVUs for all revaluations and new codes in the PFS final rule with comment period and payments based on those values during the CY covered by the final rule. CMS considers it appropriate to establish interim values for new, revised and potentially misvalued codes because of the timing incongruities between the PFS rulemaking cycle and the release of codes by the AMA CPT Editorial Panel and the RUC review process.

CMS notes that their recent revaluation of several code families have raised concerns from stakeholders with the existing process based on the reductions in payment for those services. Specifically, that they did not receive notice of the possible reductions before they occurred, CMS notes that stakeholders should be aware of changes because either CPT has made changes or CMS has identified the codes as potentially misvalued, and representatives of the affected specialties are participating in the RUC meetings. Commenters have asserted, however, they are not aware of RUC recommendations, they have no opportunity to respond to RUC recommendations and not all suppliers are

permitted to participate in the RUC process. Additionally, some stakeholders objected to interim final decisions because they do not have an opportunity to meaningfully comment before the values are implemented in the next year's final rule.

In response to these concerns, CMS issued several proposals to modify the process of finalizing values for new and revised services via rulemaking each year. Based on comments received, CMS has finalized the following:

- 2016 will be a transition year during which they will propose values for new, revised, and potentially misvalued codes that they receive RUC recommendations in time for inclusion in the 2016 NPRM. For all others, they will establish interim final values in the 2016 final rule as they have historically done.
- In 2017, CMS will include proposed values for all codes for which CMS has complete RUC recommendations by February 10th of the preceding year. This will allow for stakeholder comment on the proposed values within the proposed rule notice and comment period, annually. For codes where CMS does not receive a RUC recommendation by the deadline, CMS will use G-codes in order to facilitate continued payment for certain services (those with predecessor codes) for which we do not receive RUC recommendations in time to propose values; and adopt interim final values in the case of wholly new services, for which there are no predecessor codes or values, and for which we do not receive RUC recommendations in time to propose values.

Overall, the Academy is supportive of CMS' proposals to make the assignment of RVUs for new and revised services more transparent via the rulemaking process. Specifically, we support, and have been supportive via sign on letter efforts earlier this year, the concept of publishing the revised RVUs for services within the NPRM rather than within the final rule each year. This gives the public an opportunity to comment in advance of the final rulemaking by CMS, and also allows specialties time to educate their members and the general public when services are anticipated to receive a substantial reduction in reimbursement for the coming calendar year. ***We appreciate CMS' decision to modify their proposal based on comments received from the Academy and other specialty societies to better collaborate with the AMA RUC and CPT cycles. We believe the finalized policy is a fair compromise in this regard and will achieve the intended goal of increased transparency.***

We continue to have concerns related to the use of G codes for revised codes which do not make the NPRM as it essentially duplicates the CPT codes and will unnecessarily add to the administrative burden of physicians, non-physician practitioners, and providers who would be tasked with having to learn and implement new codes to be replaced within a relatively short period. When this applies to large families of codes, the burden is even greater, as is the risk for coding errors. Further, we are concerned that in the event private payers do not implement G codes consistent with Medicare, this will cause even greater confusion for providers in reporting their services. We hope that CMS' estimation is correct that the number of codes captured by this policy will be minimal, and that we are able to plan accordingly with the AMA RUC to allow the majority of CPT

codes to be submitted to CMS by the February 10th date to avoid the need for G codes on an interim basis.

5. VALIDATING RVUS FOR SERVICES

Under the ACA, the Secretary is directed to validate a sampling of RVUs for services identified by the seven categories listed above. In the CY 2013 proposed rule CMS informed the public of their intent to, "enter into a contract to assist them in validating RVUs of potentially misvalued codes that will explore a model for the validation of physician work under the PFS, both for new and existing services." Both contracts will extend over a 2 year period. More details were released regarding these contracts in the 2015 NPRM, including the first interim report from the Urban Institute. The RAND Corporation will use available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design will be informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and AMA RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND will consult with a technical expert panel on model design issues and the test results. Urban Institute will focus on the central role of time in establishing work RVUs and the concerns that have been raised about the current time values. A key focus of the project is collecting data from several practices for services selected by the contractor. The data will be used to develop time estimates. Urban Institute will use a variety of approaches to develop objective time estimates, depending on the type of service, which will be a very resource-intensive part of the project. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a range of specialties to review the new time data and their potential implications for work and the ratio of work to time. Additional detail on both projects can be found here. CMS notes that they are not making any policy surrounding this issue in the 2015 final rule, but they anticipate that a interim report on the RAND project will be available by the end of the year.

Given the initial difficulties outlined by both contractors during the beginning phases of their validation projects, the Academy would urge CMS to consider other methods by which they might be able to validate services within the PFS moving forward. Specifically, we would urge CMS to consider the use of specialty society registries, or collaboration with specialty societies to create a more robust general registry should CMS find that more beneficial, to review and analyze practice patterns and intensity/complexity of services across medical specialties. The Academy, like many other specialties, is currently exploring registry options, however, due to the large upfront cost; this is a somewhat daunting task. If CMS or CMMI were willing to contribute funding to support specialties in registry development, we believe this could be a partnership opportunity that would benefit both specialty societies and the Agency as a whole.

6. PAYMENT FOR SECONDARY INTERPRETATION OF IMAGES

Within the final rule, CMS says that questions have arisen as to whether and under what circumstances it would be appropriate for Medicare to permit payments under the PFS

when physicians furnish subsequent interpretations of existing radiology images. Under current policy, Medicare can pay for a second interpretation (which is billed using modifier -77) under "unusual circumstances (for which documentation is provided)." CMS sought comment on the proposed rule to assess whether there is an expanded set of circumstances under which it would be appropriate to allow more routine Medicare payment for a second professional component for radiology services, and whether such a policy would be likely to reduce the incidence of duplicative advanced imaging studies. CMS also stated in the NPRM based on comment received, it will consider whether any further action is appropriate, such as proposing under future rulemaking to allow for payment of subsequent interpretations of advanced diagnostic images in lieu of duplicative studies.

Within the final rule CMS thanked commenters for their helpful feedback, but neglected to make any policy changes within this rule. They note that any changes to the current policy on allowing physicians to more routinely bill for secondary interpretations of images will be addressed in future rulemaking.

The Academy would reiterate our comments on the NPRM as CMS continues to consider policy making in this regard:

- For which radiology services are physicians currently conducting secondary interpretations, and what, if any, institutional policies are in place to determine when existing images are utilized?

The services for which physicians are conducting secondary interpretations within the otolaryngology community are: CT temporal bone, neck, sinus; MRI neck, ultrasound of the neck, and IAC/brain. At this time we are not aware of written institutional policies to determine when existing images are utilized. It is the opinion of our imaging experts, who hold experience and training from large quaternary medical centers and tertiary centers, that the delivery of care in tertiary facilities receiving patients who arrive with existing, available images, focus on high quality care and place the needs of the patient first. The integrity and professionalism of physicians caring for the patient in these settings prevents additional, unnecessary imaging from being performed. If the existing images are of sufficient quality and provide the necessary information, they are used. If imaging is not of sufficient quality or is poor quality, they are repeated as needed.

Our experience suggests that physicians are not ordering duplicative images upon receiving patients transferred from outside hospitals in order to bill for primary interpretation of imaging. Rather, if high quality images are available, they review the images, seek out prior documentation and document the E/M services as an appropriately higher service level.

Therefore, we believe it is important to allow for payment for a secondary interpretation of imaging, where medically necessary. Tertiary radiologists and neuroradiologists frequently read/re-read such images from outside hospitals, as previously discussed. This is the most common example our imaging experts see in their practices. We believe radiology input is

essential, and thus, their work should be compensated. Should another specialist make the second reading, they too should be compensated.

- Should routine payment for secondary interpretations be restricted to certain high-cost advanced diagnostic imaging services?

The Academy does not believe secondary interpretations should be restricted to specific high-cost advanced diagnostic imaging services. Two interpretations of any imaging can be helpful for patient care. Given that the specialist is responsible, and held liable, for such secondary interpretations, we believe it is reasonable they be compensated for this work and time in interpreting all images.

- How should the value of routine secondary interpretations be determined? Is it appropriate to apply a modifier to current codes or are new HCPCS codes for secondary interpretations necessary?

In response to this inquiry, we defer to radiology in cases where the secondary read of images is performed by a radiologist. In cases where a surgeon is re-reading the image, we would agree that appending a modifier to indicate the secondary interpretation is reasonable as a method of tracking these trends by physicians.

- Is there a limited time period within which an existing image should be considered adequate to support a secondary interpretation?

We feel it is difficult to define a set time period within which an image could be considered "adequate" and do not support the use of generic time frames in this regard. We believe these decisions should be left to the independent clinical judgment of the physician and will vary based on clinical condition and specialty.

- Would allowing for more routine payment for secondary interpretations be likely to generate cost savings to Medicare by avoiding potentially duplicative imaging studies?

We are concerned that this question presumes that many additional studies are ordered merely to generate a bill for interpretation, and therefore, are not medically necessary. While we understand CMS' concern in this regard, and support their efforts to eliminate unnecessary medical imaging, we urge CMS not to implement generic guidelines that will hamper independent clinical judgment as it relates to critically important diagnostic imaging tools. We believe the decision as to whether a prior MRI brain or sinus CT scan was appropriate, and whether correct anatomy was imaged, is a critical piece of this discussion. In order for secondary interpretation to be valuable, rapid review of images and reports would need to be available. Currently, mechanisms to do this are often inadequate and delay timely diagnosis and delivery of care.

- What operational steps could Medicare take to ensure that any routine payment for secondary interpretations is limited to cases where a new imaging study has been averted while minimizing undue burden on providers or Part B contractors (such as restricting physicians' ability to refer multiple interpretations to another physician that is part of their network or group practice, requiring physicians to attach a physician's order for an averted imaging study, or requiring physicians to identify the technical component of the existing image supporting the claim)?

1650 Diagonal Road, Alexandria, Virginia 22314-2857 U.S.A. 1-703-836-4444 1-703-683-5100 fax www.entnet.org

We suggest the requirement of including a single line within the dictation/documentation in the medical report stating: "the secondary interpretation is done with the benefit of EITHER averting a new imaging study; OR is necessary for specialized patient care, in which case a description of the lesion/pathology reviewed is provided".

7. PHYSICIAN COMPARE

The Academy fully supports providing patients and beneficiaries with information that allows them to make the best decisions possible regarding their clinical care. However, information publicly posted, like that published on Physician Compare, must be presented in the manner that not only is easily understood by patients, but also is derived from sources that adequately and appropriately demonstrate the quality of care provided. ***Given the complexity of data derived from CMS' quality initiative programs, we urge CMS to reconsider publishing specific performance data derived from CG-CAHPS, PQRS, and other reporting initiatives, as patients are highly unlikely to be aware of the variances, potential inaccuracies, and other key issues associated with the programs as they currently stand.***[1]

A. CG-CAHPS versus S-CAHPS Survey Information

As we mentioned during our NPRM comments, the CG-CAHPS survey does not appropriately capture patient experience associated with surgical procedures, yet this data is published for certain group practices reporting CG-CAHPS. To ensure patients are provided with the most accurate and relevant data, we encourage CMS to allow surgeons to utilize the AHRQ approved Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey (S-CAHPS) to evaluate the patient experience associated with surgical care for purposes of posting this information on the Physician Compare website. We believe the use of the S-CAHPS survey will further CMS' goal to obtain more accurate and meaningful quality data to share with patients because it more closely assesses the relevant patient experience during surgical care. The publishing of CG-CAHPS survey data for surgeon specialists, such as otolaryngologist – head and neck surgeons, limits a patient's ability to effectively and judiciously select a providing surgeon because the information provided is derived from a source that does not appropriately evaluate patients' experience with surgeon specialists in the first place. ***To that end, we would be happy to work along-side CMS, and other surgical specialties who have been heavily involved, to discuss how best to operationalize the inclusion of the S-CAHPS survey for future quality reporting years. The Academy views the availability of this survey as key to surgical specialists' successful participation in CMS quality incentive programs, and welcomes the opportunity to discuss this further with CMS staff. As an additional alternative, should CMS determine that they are not able to incorporate the S-CAHPS survey for future PQRS use, we would recommend that CMS only report survey responses for the section "your care from this provider during your most recent visit" (questions 14-26 on the visit-specific survey), as we believe these questions are pertinent to overall quality of care and universally relevant, regardless of physician specialty.***

[1] https://www.facs.org/~/media/files/advocacy/sqa/2014sqa_publicreportingdocument.ashx

B. General Concerns with Posting Provider Specific Data

Similarly, while we appreciate the desire to provide patients with information on providers' quality program participation to aid them in selecting a physician, we remain concerned with CMS' decision to publish specific performance data for providers, such as all 2015 PQRS measures for individual eligible professionals. As CMS knows, many aspects of the quality incentive programs have yet to be finalized and currently require regular stakeholder feedback to address problems that have arisen as the programs unfold. And while CMS has acknowledged it will not publicly report a measure that is in its first year, we fear the one-year gap is insufficient to address these concerns. Because of such, ***we urge CMS to reconsider its decision to publish additional specific performance data (e.g. publicly reporting all 2015 PQRS measures for individual EPs collected through a Registry, EHR, or claims and accelerate the timeline for publishing; until the programs are more developed and greater opportunities for specialist participation have been afforded. To do so any earlier is an unfair burden on providers, and a disservice to patients, as it fails to ensure the information is provided adequately and appropriately reflects the provider's quality of care.***

It is also unclear how information on the specific quality measures will be used by patients who: 1) likely do not know what the program entails, and 2) do not understand the requirements for successful participation. Again, while we fully appreciate CMS' goal to provide information which helps patients find and make informed decisions, ***we urge CMS to be mindful about what information is necessary and meaningful to patients, and avoid inundating them with information derived from programs not yet fully developed. By only posting successful participation of providers for the quality programs at this point-in-***time, CMS limits the opportunity for patients to misinterpret or misconstrue the information provided while still advancing the intended goals of the program.

C. Concerns related to Accuracy of Data

Finally, concerns remain regarding the accuracy of the information posted, which only further inhibits patients' ability to make informed decisions based on this data. As we've noted in previous comments, review of several of our physician leader's information uncovered several errors in information, such as physicians being listed as affiliated with hospitals they have never worked in, or have languages listed which they do not speak. When our members attempted to correct their information listed on the website, they were asked for PECOS login information which many times is not immediately available, and were told that it would take up to 6 months for the information to be corrected. The inability to correct incorrect information in a timely manner not only unfairly punishes providers, but it also may have the unintended consequence of limiting patient choice. ***Therefore, while we believe CMS has made major strides in improving the usability of the Physician Compare website, we remain concerned about the accuracy of, and meaningfulness to patients related to, the information posted on the website and urge CMS not only to improve the accuracy of physician information, but also to streamline the process by which providers can correct their information.***

8. ELECTRONIC MEDICAL HEALTH RECORDS (EHR) MEANINGFUL USE (MU) INCENTIVE PROGRAM

The Academy appreciates the willingness of CMS to incorporate greater flexibility into the EHR MU Incentive Program by allowing providers that are unable to have CEHRT that is tested and certified to the most recent version of the electronic specifications for CQMs, the ability to not recertify their product and only report the most recent version of the electronic specifications for the CQMs. While we are pleased that CMS finalized this proposal, we remain concerned additional flexibility has not been proposed.

The goal of incentivizing the meaningful use of electronic health records emphasizes greater efficiency in health care, decreased costs of providing medical care, and improving the clarity and legibility of medical information as it is shared between providers, regulators, and public health agencies. Unfortunately, many of these requirements are having the opposite effect. In fact, often times the requirements decrease the efficiency of healthcare visits. CMS has incorporated additional flexibility with this finalized policy, but additional flexibility beyond 2015 and recertification requirements are essential to obtaining the envisioned goals of the EHR MU program. ***CMS could achieve this increased flexibility in a number of ways, including: creation of alternative reporting options; alignment between the various quality initiatives; and more flexible reporting criteria.***

A. Timeline for Stage 2

The Academy applauds the role the EHR MU Incentive Program has played in advancing and promoting adoption of the health information technology (HIT) across the country, we remain troubled by the stringent timing requirements of program, especially in light of the lack of flexibility afforded to providers (as mentioned above). ***To that end, we previously requested an extension of Stage 2 for providers who need extra time to meet Stage 2 requirements and would like to reiterate this request.***

Many of our members have been under significant time pressures to meet the 2014 requirements, resulting in progression to Stage 2 being virtually impossible. The inability to successfully adopt, implement or upgrade to the 2014 Edition CEHRT further exacerbated such pressures, by affording providers even less time than originally anticipated to properly adjust workflow changes and receive additional training on the new software before progressing to Stage 2, and 2015 requirements. These significant burdens and lack of feasibility are especially prevalent for small and rural specialists who lack the resources of large practices, and who are likely not vendors' top priorities. ***A delay of Stage 2 for providers would further the goals of the EHR program, whereas a failure to extend may have the unintended effect of stifling innovation and increasing medical error. Allowing for sufficient time to ensure a safe and orderly transition through Stage 2 is critical to the long-term success of EHR MU Incentive Program and is of great importance to our specialists.***

B. Stage 3 Requirements

We also remain concerned that specialists, such as otolaryngologists – head and neck surgeons, will only continue to have difficulty meeting the increased thresholds in Stage 3. As previously stated, while we are supportive of the stated goals of HIT, and the vision of

Stage 3 which includes a "collaborative model of care with shared responsibility and accountability," we are concerned that Stage 3 includes higher objective thresholds with increased penalties. This will only increase pressure on small specialty practices that have encountered problems successfully meeting MU Stage 1 and/or 2 requirements. Stage 3 is scheduled to begin in 2017 and we believe that coupled with decreasing reimbursement and other potential penalties, these increased thresholds could continue to hinder not only HIT adoption, but also patient access to quality care.

Thus, the need for additional flexibility is particularly true in light of the lack of interoperability of EHR systems. Many of the program's requirements depend upon interoperability of EHR systems which has not yet been realized except within health systems sharing the same software. These limited networks decrease patient access to care, choice, and timely specialty availability, thwarting many of the overall objectives intended by the program. For example, a requirement of order tracking will provide an incentive to limit consultations to systems that share a similar EHR. Improved interoperability must precede some standards. ***As such, we reiterate our desire for CMS to carefully consider these potential roadblocks to successful implementation of the coming stages, as well as consider the aforementioned solutions.***

9. PHYSICIAN QUALITY REPORTING SYSTEM (PQRS)

A. Approval of New Measures Groups

The Academy is extremely grateful to CMS for finalizing the inclusion of the new Sinusitis and Acute Otitis Externa (AOE) measures groups. The Academy is confident that inclusion of these new measures groups will encourage greater PQRS participation within the otolaryngology community. We look forward to continued collaboration with CMS to develop additional measures groups that are broadly applicable to our highly subspecialized field of physicians.

Additionally, the Academy is pleased that CMS worked with stakeholders to identify a measure steward for the Sleep Apnea measures group, enabling the continuation of the measures group as a PQRS reporting option for AAO-HNS members in 2015.

B. Increase in Number of Measures Reported in Measure Groups

The Academy appreciates CMS' acceptance of the new measure groups for CY 2015 and understands the reasoning for the addition of the two additional measures to the Sinusitis and AOE measure groups. Despite this, we recognize it may take some time for our members to be able to make the transition to these groups because of the six measure requirement versus the previously required four for reporting on most measure groups.

C. Deletion of Measures for CY 2015 Reporting / Measure Maintenance

The Academy was disappointed to learn of the removal of the Perioperative measures group. The Academy believes the measures group provided a unique opportunity for AAO-HNS members new to PQRS reporting to establish a baseline for quality of care related to all surgical procedures. Moreover, the various subspecialties within otolaryngology do not have another such cross-cutting measures group on which to report.

We reiterate our concern regarding CMS' position that measures on which providers perform well do not "add value to the PQRS". To the contrary, the Academy continues to believe that high performance is an indication that providers in the surgical community are performing well, and providing high quality care to their patients during the preoperative period. As such, we believe surgeons should be rewarded for their high quality care and should be allowed to report on measures, even in cases where they are already performing at a high level. AAO-HNS continues to believe that removing measures due to providers' "high performance" assumes that the group of EPs is static and has reached sustainability; however, this is often not the case, as most groups of providers change over time, making these measures meaningful on an ongoing basis.

The Academy continues to urge CMS to consider a transition period in instances in future rulemaking when measures are proposed for removal from PQRS. A transition period would allow specialists with limited measures and measures groups time to evaluate additional or new measures they may need to utilize, given the removal of previously reported measures. We do not believe the period between the proposed rule and final rule is sufficient to allow practices to evaluate and modify their plans in terms of measures to report, and would prefer CMS operationalize a transition period/process in cases where they propose to remove individual measures or measures groups in future rulemaking.

D. New Cross-Cutting Measures Requirements for Claims and Qualified Registry Reporting

While the Academy supports the concept of increasing the number of measures that are applicable across medical specialties, AAO-HNS previously expressed concerns regarding the increased burden on physicians, given the proposed requirement to report two cross-cutting measures in conjunction with the already-expanded reporting requirement of nine measures across three National Quality Strategy domains. While we continue to be cognizant of the reporting burden placed on our members, the Academy applauds CMS' compromise of finalizing the reporting requirement of only one cross-cutting measure as part of the nine total required measures.

E. Suggestions for Including S-CAHPS Survey for Future GPRO Reporting

As the Academy both participated in the development of the S-CAHPS survey and tested it through our practice-based network, AAO-HNS continues to strongly support the inclusion of the S-CAHPS survey in CMS quality incentive programs. The Academy believes S-CAHPS would more accurately reflect the level of surgical care received by patients, when compared to the CG-CAHPS survey currently used in PQRS. The Academy understands CMS has been actively engaged in discussions with surgical specialties committed to the use of S-CAHPS for future reporting years, and the Academy is eager to engage in any future workgroups or town hall meetings to participate in this conversation. ***We continue to believe the inclusion of S-CAHPS would enhance the ability of otolaryngologists to meaningfully participate in quality incentive programs, and would more accurately reflect quality of care.***

F. Extension of Reporting Deadline for Qualified Registries

The Academy is pleased that CMS finalized its proposal to change the reporting deadline for qualified registries from the last Friday of February following the applicable reporting period, to March 31. We believe this will allow providers more time to successfully report their PQRS data and will result in an overall positive trend towards greater PQRS participation and an increase in successful reporting.

G. Changes in GPRO Registration Date

While the Academy understands CMS' rationale in finalizing an earlier deadline for GPRO registration, ***we continue to be concerned that practices may have difficulty transitioning to the earlier deadline. As expressed in previous comments, the Academy would have preferred a delay in the implementation of the earlier deadline until CY 2016, to allow practices to more fully prepare for this change.***

H. Provider Ability to Report Data More Frequently

While a change was not finalized for CY 2015, the Academy continues to support the concept of more frequent (quarterly or year-round) submissions for PQRS quality measure data submitted via the qualified registry, EHR, QCDR, and GPRO web interface reporting mechanisms.

10. VALUE BASED PAYMENT MODIFIER PROGRAM (VM)

A. Expansion of the VM to all Physicians, and groups of physicians by CY 2017

CMS finalized the proposal that beginning with CY 2017, the VM payment adjustment would be applied to physicians in groups of two or more EPs and to solo practitioners who do not participate in PQRS in the CY 2015 performance period. CMS revised their estimates from the proposed rule and estimate that the final policy will affect approximately 900,000 physicians, including 159,770 solo practitioners. The quality of care composite would be based on the quality data submitted under the PQRS at the group or individual level in accordance with PQRS policy. The cost composite would be based on the beneficiary attribution methodology and if a cost composite cannot be calculated for a group or solo practitioner, CMS proposes to classify the group or solo practitioner's cost composite as "average". For nonphysicians, CMS decided to postpone inclusion in VM by 2017, instead finalizing a policy that the VM will apply to nonphysician EPs in groups subject to the VM and to nonphysician EPs who are solo practitioners beginning in the CY 2018 VM adjustment period.

CMS also finalized a policy to hold harmless any downward adjustment for groups of two or more EPs and to solo practitioners who do participate in PQRS even if they do not meet reporting requirements for PQRS. For those groups of two or more EPs and solo practitioners who do not participate in PQRS, CMS finalized a payment adjustment of-2.0%. This would be in addition to the -2.0% penalty for not participating in PQRS. We believe that transitioning this program to all physicians by CY 2017 (reporting year of 2015), including solo practitioners, is extremely aggressive and may result in many providers being adversely affected by the PQRS and VM payment adjustment simply due to a lack of time to prepare and analyze quality resource use reports (QRURs) prior to the performance year.

While the Academy understands and supports CMS' goal of incentivizing higher quality care, we urge CMS to delay application of this program to solo practitioners and groups with 2-9 EPs in either Category (PQRS or non-PQRS reporters) until at least CY 2018 (reporting year of 2016), if not a later date, to allow for adequate preparation and adjustment to practice patterns such that practices can avoid penalties resulting from this program. Further, we strongly urge CMS to hold harmless solo practitioners and groups with 2-9 EPs during the first year of application, beginning in CY 2018 at the earliest.

B. Quality Resource Use Reports

Additionally, while we are pleased that QRURs will be provided to ALL PHYSICIANS this fall, we are concerned that the pending QRURs that will be released to providers will contain 2013 performance data which is not particularly meaningful given the scope of changes to the PQRS reporting requirements for CY 2014. Specifically, to avoid PQRS penalties based on the CY 2013 performance period, practices could report using the administrative claims option and report on only one quality measure. For CY 2014, that was modified to require reporting on up to 9 quality measures across 3 domains. Thus, the data contained in the 2013 QRUR reports will likely do little to inform practices and/or individual physicians how they will fare under the substantially heightened reporting requirements for 2014, and beyond. While we understand that CMS is limited in the information they can provide in these reports, and are appreciative of the steps taken thus far to enhance the usability of the QRUR reports, ***we would urge the Agency again, not to apply penalties to groups or providers (non-physicians) that have not had the chance to meaningfully evaluate their performance and/or to modify their practice patterns to avoid penalties under these programs.***

C. Payment Adjustment Amount under the VM

Additionally within the NPRM, CMS raises the payment risk under the VM from the previous +/- 2.0% to +/- 4% for CY 2017 (based on performance year of 2015). CMS states, however, that only groups of 10 or more EPs will be subject to upward, neutral, or downward adjustments. Groups of 2-9 will only incur upward or neutral adjustment, in essence, they will be held harmless from a penalty under the VM for CY 2017. Quality tiering will now become mandatory for all providers, despite smaller groups being held harmless from penalties. Groups and solo practitioners are eligible for an additional +1% if their average beneficiaries' risk score is in the top 25% of all beneficiary risk scores nationwide (i.e. if their patient population is "high risk").

In keeping with our comments outlined previously, the Academy is troubled by the proposal to double the payment risk under the VM within one calendar year. We believe the total risk, when combined with the payment penalties from PQRS and the EHR MU Incentive program; represents an extreme reduction in reimbursement that would be unsustainable by most physician practices if levied in one year (a potential total reduction of almost -10%). While we support the concept of aligning these quality programs, and the goals of improving quality of care and achieving cost efficiencies, we believe more time is needed for physicians and practices to prepare for the requirements of these programs.

Additionally, given our concerns outlined above, we do not believe it is reasonable to double the financial risk to practices without providing the data to them in advance to fully evaluate how their practice/TIN is operating as a whole under the VM cost and quality methodologies. Thus, we recommend that CMS delay any increase to the financial benefit or risk from the current +/-2%, until such a time that practices can fully evaluate their performance based on data for all providers, and modify it accordingly in order to avoid potential payment penalties under the VM.

D. Expanding the Informal Inquiry Process to allow for Corrections

For the CY 2015 payment adjustment period, to align with PQRS, CMS is proposing to expand the established informal inquiry process and establish an initial corrections process that would allow for some limited corrections. CMS notes there would be no administrative or judicial review of the determination resulting from this expanded informal inquiry process.

- CMS is finalizing a deadline of February 28, 2015 for a group to request correction of a perceived error made by CMS in the determination of the CY 2015 VM payment adjustment.
- For the CY 2015 payment adjustment period, CMS finalizes a policy to classify a TIN as "average" quality if they determine that they made an error in the calculation of the quality composite. CMS states that they do not anticipate it would be operationally feasible for them to fully evaluate errors with regard to quality measures for the CY 2015 payment adjustment period.
- CMS finalizes a policy to recompute a TIN's cost composite if they determine they made an error in the calculation.
- CMS finalizes a policy to adjust a TIN's quality tier if they make a correction to a TIN's quality and/or cost composites as a result of this initial corrections process.
- CMS finalizes a policy to continue the expanded informal inquiry process for the CY 2016 payment adjustment period (CY 2014 performance period). CMS anticipates having the necessary operational infrastructure to support this process and finalizes:
- A 60-day period that would start after the release of the QRURs for the applicable period for a group or solo practitioner to request correction of a perceived error in the VM for that payment adjustment period.
- Recompute a TIN's quality composite and/or cost composite when CMS determines an error was made in the calculation. If CMS lacks the operational infrastructure to allow this recomputation, CMS will continue the approach for the CY 2015 payment adjustment period.

The Academy appreciates and supports CMS' efforts to expand the informal inquiry/review process as it relates to the VM program. On the whole, we support the proposals as put forth by CMS, and we appreciate the Agency expanding the timeline for requesting a correction from 30 days in the proposed rule, to 60 days in the final rule. We appreciate CMS understanding that the 30 day window may be too brief to allow practices to carefully review their data and submit a request for a correction within that time frame. This is especially the case given that the clock starts ticking on the 30 day

window once the QRURs are released, so in cases where reports are lost or delayed due to delivery errors or problems that are not the fault of the practice and the practice is penalized by the short timeframe within which to request review. To avoid these issues, we appreciate CMS extending the timeframe to 60 days following the release of the QRURs so that no one is unintentionally disadvantaged by the timeframe to request review.

Conclusion

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide comment and recommendations regarding these important policies on behalf of our members. If you have any questions or require further information, please contact Jenna Kappel, MPH, MA, Director of Health Policy at jkappel@entnet.org or 703-535-3724. Thank you.

Sincerely,

James C. Denneny, III, MD, FACS
Executive Vice President and CEO