AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

April 24, 2017

SUBMITTED VIA EMAIL

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8016

Re: CMS' Request for Information (RFI) on Episode-Based Cost Measure Development for the Quality Payment Program.

Dear Administrator Verma:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on CMS' Request for Information (RFI) on Episode-Based Cost Measure Development for the Quality Payment Program.

On December 23, 2016, CMS released the RFI, asking for input from stakeholders on care episode and patient conditions groups, referred to as "episode groups." The Academy shares CMS' desire to develop cost measures which provide clinicians with actionable information to reduce healthcare spending and promote the delivery of high-value care. However, the Academy believes the desire to develop these measures should not overshadow the necessity for providing clinicians with accurate, actionable information.

In 2019, as CMS notes in the RFI, the cost category is weighted at zero percent of the MIPS final score and the cost category will be weighted at 10 percent for the MIPS final score in 2020 and 30 percent in 2021. As we stated in our comments on the MIPS final rule, the Academy was pleased to see the reweighting of the cost category. In 2016, the Academy was asked to participate in a Clinical Committee to provide input on the development of episode-based resource use measures, led by Acumen. Through this process, the Academy provided direct input in the development of several measures, including Laryngectomy, Tracheal Repair, and Tracheostomy. The Academy is pleased CMS continues to engage stakeholders throughout the development of the episode-based cost measures to ensure our concerns regarding the methodology and implementation of these components is considered.

The following comments represent answers to questions within the RFI on episode groups that are a priority to the AAO-HNS and the patients we serve.

Episode group Selection

- **In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.**

As currently constructed, there are no applicable chronic episode groups directly available for Otolaryngologist – Head and Neck Surgeons to report. Depending on specific requirements CMS develops for the cost performance category, this could exclude Otolaryngologist – Head and Neck Surgeons from participating due to a lack of applicable measures. We fear in this case, Otolaryngologist – Head and Neck Surgeons would either be scored on episode groups that are not applicable to the specialty or will have an insufficient number of episode groups to ensure sound scoring methodology. The lack of applicable measures can disproportionally negatively impact our physicians and result in negative payment adjustment. We seek clarification from CMS on how it intends to score specialists such as Otolaryngologist – Head and Neck Surgeons that either have a dearth of episodes, or entire lack of applicable episode groups.

There are, however, several episode groups that Otolaryngologist – Head and Neck Surgeons may indirectly treat by addressing specific components of the treatment, including Asthma/ Chronic Obstructive Pulmonary Disease (COPD), Atrial Fibrillation, Rheumatoid Arthritis, and Lower Extremity Deep Vein Thrombosis (DVT) requiring anticoagulation. As currently constructed, it is not clear to Otolaryngologist – Head and Neck Surgeons that they may be scored on components of these and other episodes they may encounter. While the Academy understands further rulemaking and clarification from CMS on patient relationship categories and codes and other components of the cost performance category, the Academy encourage CMS to make it as clear as possible to clinicians to indicate they can participate in the episode groups. The Academy fears CMS will create an opaque system determining episode applicability that will only reinforce perceptions and distrust that processes like the Measure Applicability Validation (MAV) have created. It is essential that CMS develop a transpicuous process that reimburses clinicians and correctly attributes cost in an easy way to report.

Additionally, in reviewing the initial list of chronic condition episode groups, the Academy believes there are chronic conditions missing which would serve as excellent opportunities for the development of additional episode groups including, chronic rhinosinusitis, allergy, dysphagia, chronic pneumonia, the treatment of oral cancer, and obstructive sleep apnea. While these conditions affect patients of all ages and demographics and are treated by many Otolaryngologist – Head and Neck Surgeons, they specifically are conditions that are sources of large annual expenditures for Medicare, making them model conditions for future episode group development.

Finally, the Academy seeks clarification on whether CMS will measure inpatient care for episode-based cost measures, as was the case under the Value-based Modifier program. We believe the development of episode-based cost measures for chronic conditions that are treated in an outpatient setting are vital to allowing specialists such as Otolaryngologist – Head and Neck Surgeons to participate in the cost performance category. Otolaryngologist - Head and Neck Surgeons disproportionately treat patients in an outpatient setting where they typically manage the care of the patient as compared to the inpatient setting where Otolaryngologists typically act as consultants. The movement of patient care from the inpatient to

outpatient settings necessitates the development of chronic condition episode measures that are treated in the outpatient setting. As CMS works to develop episode-based cost measures for outpatient conditions, the Academy would be pleased to provide additional measure development recommendations in the future.

Episode Group Definition

- **The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.**

The Academy thanks CMS for allowing our physician experts to review and provide comments via the process led by Acumen, on the composition of specific trigger events and codes last year. Specifically, the Academy provided comments on proposed Laryngectomy, Tracheal Repair, and Tracheostomy episode-based cost measures. While the Academy appreciates the ability to provide input on multiple episode-based cost measures, as previously mentioned, Otolaryngologist - Head and Neck Surgeons need additional applicable cost measures to ensure our physicians are fairly and appropriately scored by CMS. For our specialty and others, many applicable measures are in the outpatient setting for chronic conditions that represent a significant cost to Medicare. The previously identified episode-groups provide CMS the opportunity to work in the outpatient setting, which is especially important as CMS actively works to shift care to outpatient management. As this process moves forward, the Academy encourages CMS to apply episode-based measures to outpatient services.

Acute Inpatient Episode Groups

- **The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization.**

- **Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes comment on this approach.**

As previously mentioned, the Academy believes CMS should consider developing episode-based cost measures that will allow the greatest number of Otolaryngologists- Head and Neck Surgeons to accurately report on the cost performance category for MIPS. Similarly to the concerns stated in the episode group selection above, it is not clear to Otolaryngologist – Head and Neck Surgeons that they may be scored on components of these and other episodes they may encounter. Under the list of Acute Inpatient Medical Condition Episode Groups, there are several episode groups that Otolaryngologist – Head and Neck Surgeons may indirectly treat by addressing specific components of the treatment, including Acute Ischemic Stroke With Use of Thrombolytic Agent; Acute Myocardial Infarction, Discharge Alive; Acute Myocardial Infarction, Expired; Allergic Reactions; Cardiac Arrhythmia & Conduction Disorders; COPD; Endocrine Disorders; Esophagitis, Gastroenteritis & Miscellaneous

Digestive Disorders; Peripheral Vascular Disorders' Pulmonary Edema & Respiratory Failure; Pulmonary Embolism; Respiratory System With Ventilator Support < 96 Hours; Respiratory System With Ventilator Support > 96 Hours; and Simple Pneumonia & Pleurisy. The Academy once again calls on CMS to ensure correct episode attribution methodology and develop clear guidance for clinicians so they understand episode group applicability.

Specifically, the Academy believes CMS could consider the development of outpatient events that could be considered candidates for development as acute condition episode-based measures. Examples of acute condition episode-based measures include acute exacerbations and complications of chronic and acute rhinosinusitis; peritonsillar abscess; epistaxis; angioedema; dizziness (exacerbation); sudden hearing loss; aspiration pneumonia; and facial trauma including structural and soft tissue. The Academy believes these examples correspond to the acute inpatient episode group regardless of a presence of a chronic component. The development of additional such measures would greatly expand the number of episode-based cost measures available to the Academy's diverse and specialized members, and allow them to more accurately report under the cost performance category.

Chronic Condition Episode Groups

- **Should we develop a chronic condition episode specific to the management of patients, i.e., a patient condition group to better compare cost to treat like patients?**

The Academy appreciates CMS' acknowledgement of the challenges associated with the construction of episode-based cost measures for chronic conditions. The Academy is concerned about the aggregation of all conditions in the development of episode-based cost measures. It would seem impossible to ensure proper attribution of cost to individual clinicians with aggregated condition cost measures. The Academy believes physicians should only be scored for the care they are directly responsible for. Additionally, the Academy cautions CMS against the aggregation of conditions that are not directly related. By aggregating unrelated conditions, CMS risks ensuring the proper attribution and scoring of clinicians cost. Instead, CMS should pilot how cost attribution for existing individual measures works before increasing the aggregation of conditions.

Cost Measure Development

- **We comment on the use of the CMS-HCC Risk Adjustment Model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?**

The Academy is supportive of CMS' use of the CMS-HCC Risk Adjustment Model for severity adjusting chronic conditions. While the Academy is supportive of this risk adjustment model, we recommend CMS continue to update risk adjustment methodology based on data gathered and input from clinicians. Given issues with risk adjustment and attribution in legacy reporting programs such as the Value-based Payment Modifier (VM), the Academy recommends CMS pilot alternative risk adjustment methodology. CMS can use piloted data to make necessary modifications to ensure proper risk adjustment. Throughout any pilots or CMS-HCC Risk Adjustment models, it is pivotal that CMS

maintain regulatory flexibility for risk adjustment and allow for adjustments in coming years to ensure proper cost attribution.

- **CMS acknowledges that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. What would be the best way to incorporate Part D costs into the episode group development?**

The Academy appreciates CMS' acknowledgement that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. Without the incorporation of Part D costs into episode groups, CMS, patients and clinicians will not have a full understanding of the true costs of care for different episodes. This information could be beneficial in helping drive down the cost of care without sacrificing quality. The Academy encourages CMS to work to develop methodology to incorporate these costs into episode groups; however, when developing this methodology, we caution CMS to ensure clinicians are not unfairly punished for the cost of prescription drugs within episodes of care. It is incredibly important to ensure drug cost price transparency at the provider level. **CMS will not be successful incorporating Part D prescription drug costs into episode groups unless providers know the cost of drugs.** Prescription drug prices are factors outside of a clinician's control and CMS should not develop policies that may adversely influence patients' care by forcing clinicians to choose between a better cost score or decreased quality of care.

Cost Measure Development

- **CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.**

It is vital for CMS to develop alignment between quality of care and cost measures to ensure patients are protected, ensuring clinicians deliver high value care at the most appropriate cost. As clinicians are scored for cost in future years, CMS must link the quality and cost of care to avoid under and over-utilization of services. Protections must be put into place through the incorporation of quality metrics to ensure clinicians do not simply cut the cost of care at the expense of the quality of care a patient receives. CMS should link cost to known standards of care. Disease severity or staging information can be built into the treatment quality measurement to ensure the continued alignment of quality of care. Currently, appropriate use criteria and clinical practice guidelines are tools CMS can use to further align quality of care with cost measures. As the healthcare system continues to move towards outcomes measures with the development of additional and future quality measurement tools, the Academy believes CMS should continue to emphasize the alignment of cost with quality of care.

- ***CMS seeks input on the degree of responsibility of attributed services in episode-based cost measures.***

The Academy supports the concept of proportional shared accountability and believe that more work needs to be done to stratify risk and share accountability across provider, patient, and system groups in episode-based cost measures. As CMS promotes team based care, it is critical for CMS to ensure

clinicians are score only on the cost they are directly responsible for. Additionally, the Academy believes patient compliance should be considered as an additional element to consider in developing cost measures, as patient non-compliance to a recommended treatment plan could lead to increased costs and decreased outcomes. CMS should consider the development of positive incentives to encourage patients to follow prescribed treatment plans.

Procedural Episode Groups

- **We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development.**

The Academy appreciates the inclusion of two procedural episode groups applicable to Otolaryngologist – Head and Neck Surgeons, Laryngectomy and Thyroidectomy Partial or Complete. The Academy believes these are appropriate episode groups for inclusion. As CMS considers expanding procedural episode groups in the future, the Academy reiterates comments that CMS should consider the shift to outpatient care settings. Chronic rhinosinusitis, additional cancer surgeries, cochlear implantation, positional vertigo, glottic insufficiency, and treatment of eustachian tube dysfunction are all procedural episodes linked to the management of a condition and are treated in an outpatient setting. We believe these examples provide the ability to add episodes to ensure the greatest number of clinicians can report

Cost Measure Development

- **Cost measures are being considered for development from episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups.**

As CMS considers the development of cost measures from episode groups, it is important for CMS to ensure clinicians are only be scored for the care they are directly responsible. Proper attribution for the cost of care will help clinicians buy into cost measurement methodology. It is equally as important to ensure there is sufficient risk adjustment in place to protect clinicians that treat patients with multiple comorbidities compared to those that treat relatively healthy patients. Adverse selection of patients driven by cost considerations would have a detrimental impact on the health of Medicare beneficiaries. Parallel to this, CMS must incorporate safeguards through quality measurement consideration to ensure protections against under or over-utilization of care.

CMS also should consider the number of times a procedure is performed annually when converting to an episode group. Many procedures Otolaryngologist – Head and Neck Surgeons perform that have high cost have relatively low utilization. Due to this low utilization, it is possible these procedures will never be able to be converted to episode groups. The Academy seeks clarification from CMS on the minimum utilization threshold for conversion to episode groups.

- **The draft list does not currently include specifications for episode sub-groups (a subgroup is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an**

episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential sub-groups.

As previously mentioned, due to low utilization, we do not feel we are currently candidates for episode sub-groups now. As CMS considers sub-groups, the Academy cautions CMS to ensure accurate data is still obtainable with enough cases and patients, coupled with appropriate risk adjustment protections. The Academy also believes the list of clinical subcommittees CMS is currently soliciting volunteers for is appropriate. The Academy is interested in following developments from these subcommittees in the coming months and looks forward to working with CMS in the future on possible sub-groups.

- **CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians).**

As previously mentioned, CMS must ensure that there are sufficient protections in place to ensure the quality of patient care does not suffer due to under or over-utilization of care. Furthermore, CMS should safeguard cost protections without stifling clinical innovations. CMS should incorporate quality metrics that safeguard levels of patient care to protect from drops in quality in the name of cost savings. Additionally, CMS must develop appropriate risk adjustment mechanisms that protect patients from adverse selection by clinicians trying to maximize their cost and quality scores. CMS must adjust for patients with multiple comorbidities to ensure these patients receive the appropriate care they deserve without decreased reimbursement for the clinician charged with treating them.

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. We are committed to working collaboratively with CMS and others as regulations in future years are prepared and the agency continues to work to implement these MACRA reforms. As CMS works to develop the cost performance category and continue to implement MACRA reforms, it is important for CMS to retain institutional flexibility to adjust and correct program requirements based on input from clinicians and data collected in the early years of the program. If you have any questions or require further information, please contact Joseph Cody, Senior Manager, Health Policy at jcody@entnet.org or 703-535-3729. Thank you.

Sincerely,

James C Denneny III

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