AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY®

October 5, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8013

[Submitted online at: https://www.federalregister.gov]

Re: CMS -1734-P Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS)[1], I am pleased to submit the following comments on the "Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program

[1] The AAO-HNS is the nation's largest medical organization representing specialists who treat the ear, nose, throat, and related structure of the head and neck. The Academy represents approximately 10,000 otolaryngologist-head and neck surgeons practicing in the United States who diagnose and treat disorders of those areas.

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(MDPP) Expanded Model Emergency Policy" published in the *Federal Register* on August 17, 2020.

The CY 2021 Medicare Physician Fee Schedule (MPFS) proposed rule accelerates an alarming trend of progressive devaluation of surgical services that has been advancing over the past 20 years. Multiple factors have contributed to the current situation, including deflation of the Medicare conversion factor from $36.6873 in 1998 to the $32.2605 as proposed for CY 2021 representing a cut of $3.83 (nearly 11%) from CY 2020 to CY 2021. This reduction has failed to account for medical cost inflation, three significant increases in the value of E/M services since 2005, the lack of inclusion of proposed increases in the value of E/M services for those services provided as part of the global surgical package, and reflects a CPT/RUC system politically motivated to alter healthcare payment system parameters.

CMS projects that our specialty would derive an overall positive update from the MPFS valuation in 2021, based upon historical billing of evaluation and management services by otolaryngologists. However, this projection does not accurately depict the deep, unprecedented cuts to each procedure and surgical encounter performed by our specialty. The further degradation of valuation for procedure-based services will create obstacles to surgeons' ability, particularly outside of urban areas, to maintain technologically up-to-date practices that offer state-of-the-art care to their patients. The field of otolaryngology-head and neck surgery is already witnessing a failure to properly account for the transition to office-based procedures previously performed only in hospital or ambulatory surgical center (ASC) settings.

We wish to provide detailed comments on several specific proposals contained in the proposed rule. Our comments will address the following issues within the rule: significant changes to the conversion factor, E/M proposals, valuation of otolaryngology services, scope pricing proposals for CY 2021, technical corrections to direct PE input database and supporting files, telehealth and other services involving communications technology, care management services and remote physiologic monitoring services, scope of practice and related issues, updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act final rule and changes to the Quality Payment Program, including MIPS Value Pathway Development and the Merit-based Incentive Performance System.

I. Medicare Physician Fee Schedule

A. Proposed 2021 Conversion Factor

As stated in our introductory comments above, the AAO-HNS joins our colleagues across the House of Medicine in expressing our significant concerns about and strong opposition to the proposed conversion factor of $32.2605 for calendar year 2021. This decrease lowers the 2021 conversion factor below the 1994 conversion factor of $32.9050, which would be approximately $58.02 today in current dollars. While costs are constantly increasing, inflation and the drop in the conversion factor have slowly and consistently eroded the effective reimbursement rate for surgeons. This extraordinary cut to the conversion factor is triggered by a number of proposed increases to the values of many bundled services that are comparable to, or include, office/outpatient E/M visits.

The reduction of the conversion factor, paired with the failure to incorporate the revised office/outpatient E/M values in the global codes, will result in drastic cuts to procedures

performed by otolaryngologist-head and neck surgeons. These cuts come at a time when our members are struggling with the financial impact of the COVID-19 pandemic in many ways, including pay cuts from the suspension of elective surgery, salary reductions, furloughs, and layoffs.

B. E/M Proposals

In the proposed rule, CMS outlines the CY 2021 E/M changes that were finalized as part of the CY 2020 rulemaking process, including a policy to adopt new coding, prefatory language, and interpretive guidance framework provided by the AMA CPT Editorial Panel. These changes would keep the five current codes for existing patients, and, by deleting CPT code 99201, would maintain four of the five new patient codes. **The AAO-HNS reiterates its assertions, as communicated in multiple previous comment submissions, that this proposed solution does not accomplish the original goal of simplifying the system and reducing burden appreciably. Instead, we believe this process was used as a vehicle to revalue E/M services, unevenly at that.**

The current proposals would disrupt relativity in the fee schedule. Applying the RUC-recommended E/M values to stand-alone E/Ms, but not the E/M codes included in the surgical package, will result in a disruption of the relativity between codes across the Medicare physician fee schedule. E/M codes have been previously revalued three times, each time the payments for new and established payments were increased. CMS also increased the payments for the E/M portion of post-operative visits in the global period. For 2021, CMS proposes to pay physicians differently for the same work, thereby violating federal statute.[2] Accepting anything other than the entirety of the RUC recommendation would result in unequal payments for the same E/M services.

As part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress mandated that CMS collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. Attempts to accomplish this goal were derailed by the inherently flawed RAND survey. **Using this "back door" strategy to lower costs of surgical procedures by devaluing individual E/M codes is inconsistent with the intent and mandate of the legislation.**

Beginning in 2021, physicians may select the level of office visit (99201-99215) based on either medical decision making or total physician time on the date of encounter. In the CY 2020 PFS Final Rule, CMS finalized adoption of the RUC recommended survey median total times utilized in the valuation of office visits. However, CMS stated that they would continue to review the proposed times. In the proposed rule, CMS outlines a change to their initial proposal regarding total time. The agency is instead proposing to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

The pre, intra, and post services times do not add up to the RUC-recommended times, while the times that CMS proposes do equal the actual total time. CMS is proposing to use the actual total

[2] 42 U.S. Code §1395w-4(c)(6).

time rather than the RUC recommended times. **The AAO-HNS agrees with CMS and believes that the actual total time should be used to calculate reimbursement rather than the RUC-recommended times.**

1. Implementation of HCPCS Code GPC1X

CMS is soliciting comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how the agency might address those concerns and how CMS might refine the utilization assumptions for the code. In the 2020 PFS Final Rule, CMS stated that the revised E/M office visits and RUC-recommended values more accurately reflect the resources associated with a typical visit. CMS further stated that the typical visit described by the revised code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. CMS argued that there is still a need for an add-on code because the revised E/M office visits do not recognize that there are additional resource costs inherent in furnishing certain E/M office visits.

CMS also clarified "HCPCS code GPC1X does not describe outlier visits, but visits associated with primary care or care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition(s), which we maintain is qualitatively different from the work accounted for in the revalued office/outpatient E/M visits."

The AAO-HNS wholeheartedly agrees with CMS that, for selected disease processes and patients, there are additional resources not accounted for in the standard E/M valuations as they currently exist. **We fully support the HCPCS add-on code GPC1X**. We do have some degree of concern that the description is somewhat vague, and our members might have difficulty in deciding the appropriate circumstances to utilize the add-on code GPC1X. If the code is finalized, we would suggest that CMS produce educational materials for participating providers helping to clarify appropriate usage of the code. The AAO-HNS would be willing to assist CMS in that endeavor in any way we can.

Finally, CMS stated that the add-on code is not intended to reflect any difference in payment based on specialty, but rather the recognition of different per-visit resource costs based on the kinds of care the physician, or other qualified health care professional, provides, regardless of their specialty.

GPC1X Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services **and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.** (Add-on code, list separately in addition to office/ outpatient evaluation and management visit, new or established)

a. Estimate of Utilization for GPC1X

For purposes of estimating the budget neutrality impacts, CMS assumed that the following specialties would report code GPC1X with 100% of their new or established patient E/M office visits: family medicine, general practice, internal medicine, pediatrics, geriatrics, nurse practitioner, physician assistant, endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonary disease.

The actual utilization of GPC1X carries significant influence on the overall projected costs for FY 2021 budget. The AAO-HNS feels that there is significant overestimation across the board for the utilization of this code. We believe that the 100% utilization figure reflects the assumption that every single visit for all patients, regardless of the E/M level, is not accurately valued. We disagree with that assumption based on the above definition "and/or with medical care services that are part of ongoing care related to a patient's single, serious or complex chronic condition." That definition is not meant to describe every office visit provided. We view this as a "special circumstances" add-on code. Using that logic, **we estimate that the utilization of this code for otolaryngology would be closer to 50% rather than the above listed 100%**. Properly utilized, we feel that this would apply to the other listed specialty and primary care services.

2. Revaluing Services That Are Analogous to Office/Outpatient E/M Visits

The AAO-HNS strongly opposes CMS's proposals concerning various analogous services with relationships to the outpatient E/M visits. As we stated in our comments on the CY 2020 PFS proposed rule, the differential treatment of the E/M services provided in the 10- and 90-day global surgical period is misguided and unacceptable. CMS takes great care to explain why the "Maternity Services" bundled E/M services deserve revaluation, while the global surgical E/M services do not. There is extensive discussion comparing the "building block" and "magnitude estimation" methodologies which are both used by the RUC and considered valid. CMS included the comment "In addition, unlike the global surgical codes, we have reason to believe the visits included in the maternity codes are actually furnished given the evidence-based standards and professional guidelines for obstetrical care." This comment is offensive and unsupportable by evidence. There is no proof that every physician follows a specialty-wide guideline with every patient. In stark contrast, every survey of surgical codes includes a survey of post-op E/M global services for both volume and level of service. We submit that this is more compelling evidence than the "feeling" that providers may adhere to a standard.

In 2015, section 523(a) of MACRA, Congress mandated that CMS collect data on the global surgical periods. CMS has failed to collect that data in an accurate fashion and should work with the surgical community and the AMA through the RUC process to collect valid information that will accurately reflect utilization of the services, not punish the surgical community for the failed RAND study. Nowhere in the last several PFS rulemaking cycles has there been a plan proposed to accomplish that mission.

The result is a meaningful disruption in fee schedule relativity which, if finalized, will create specialty differentials within the fee schedule among provider groups. Medicare statute prohibits CMS from paying physicians differently for the same work and states that the "Secretary may not vary … the number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."[3]

This also flies in the face of the recommendation of the RUC, approved by an overwhelming vote, to include the full incremental increase of work and physician time for office visits to be incorporated into the global periods for each CPT code with 10-day, 90-day and MMM (maternity). **CMS should follow the entire RUC recommendation in this area and not just the recommendation for maternity services. To spend $8.2 billion and not include the surgical global E/M visits is not only unfair, but it also continues a multi-year devaluation of surgical procedures, which will eventually decrease or end reasonable access to surgical care for patients.**

C. Valuation of Otolaryngology Services

Within the Notice of Proposed Rulemaking (NPRM), CMS proposes values for a variety of recently RUC-reviewed CPT codes, including several families of codes surveyed or commented on by the AAO-HNS via the RUC process. Those include the following:

1. Absorbable Nasal Implant Repair (CPT Code 30XX0)

We thank CMS for their proposal of RUC-recommended values for this family of CPT codes and support the agency's recommended values for the 2021 final rule.

2. Dilation of the Eustachian Tube (CPT Codes 697XX, 697X1)

We thank CMS for their proposal of RUC-recommended values for this family of CPT codes and support the agency's recommended values for the 2021 final rule.

3. Fine Needle Aspiration (CPT codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012)

CMS is not proposing any changes to the codes in the Fine Needle Aspiration family, as the reaffirmed CY 2021 RUC recommendations are identical to the CY 2019 RUC recommendations that already went through notice and comment rulemaking. CMS welcomes the submission of new information regarding these services that were not part of the previous CY 2019 review of the code family.

Regarding CMS's slight revisions to PE for several codes in this code family, the AAO-HNS respectfully disagrees with the proposed changes. Specifically, where CMS reduced equipment time for non-highly technical equipment, such as the exam

[3] 42 U.S. Code §1395w-4(c)(6).

table and mayo stand, the AAO-HNS believes the "default" formula should be used to calculate the equipment time. As such, the AAO-HNS has reviewed these formulas and confirmed that the RUC-recommended time is consistent with the "default" formula, and therefore, should be retained over the reduced time proposed by CMS.

D. Scope Pricing Proposals for CY 2021

CMS received invoices associated with the pricing of the scope video system (monitor, processor, digital capture, cart, printer, LED light) (ES031) equipment item as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. Based on the invoices, CMS proposes to update the price of the ES031 scope video system equipment to $70,673.38. They are not proposing to include an additional $1,000 to cover the expense of miscellaneous small equipment as the products listed on the component invoices indicated that the cost of cables was already included in this significantly higher equipment pricing. CMS requests additional comments from stakeholders regarding the pricing of the full ES031 scope equipment system as well as its components.

The AAO-HNS supports the proposal to update the pricing for ES031 based on the most recently submitted invoices. The AAO-HNS also supports the proposal to utilize a transition period for commonly used supplies and equipment as the reimbursement for those items is updated based on the most recent invoices. Based on this approach, the AAO-HNS agrees that the transition to the new ES031 price of $70,673.38 should be phased in and finalized in CY 2022.

E. Technical Corrections to Direct PE Input Database and Supporting Files

For CY 2021, CMS proposes to address the following inconsistency related to otolaryngology services: Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and clarified that CPT code 0466T (Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator) is always performed on an add-on basis and would never be used as a standalone code. Therefore, CMS proposes to update the global period for CPT code 0466T to add-on status (ZZZ) to more accurately reflect the way in which this service is performed.

The AAO-HNS supports this change and agrees that this technical correction is appropriate. Additionally, the AAO-HNS is proposing a new category I CPT code to replace CPT code 0466T, specifically for the hypoglossal nerve, and this proposal should help to accurately reflect the way that the service is performed.

F. Telehealth and Other Services Involving Communications Technology

1. Requests to Add Services to the Medicare Telehealth Services List for CY 2021

In March 2020, utilizing emergency rulemaking, CMS added a number of services to the Medicare telehealth services list on a Category 2 interim final basis for the duration of the COVID-19 Public Health Emergency (PHE). The Academy commends the agency for its

flexibility in adding these services to the Medicare telehealth services list during the PHE. (page 50096 of the NPRM published in the *Federal Register*).

CMS is proposing to add services, listed in Table 8 of the NPRM, permanently or on an interim basis after the PHE concludes, to the Medicare telehealth services list on a Category 1 basis. Among the services included in Table 8, **the AAO-HNS supports the addition of HCPCS codes 99XXX, 99334, 99335, 99337, and 99338 to the list of services which can be provided on a permanent basis to Medicare beneficiaries. However, we urge CMS to carefully monitor the impact that adding these services to the telehealth list will have on volume and utilization, as well as any quality implications that these additions may cause.**

Though the AAO-HNS strongly supports the proposed addition and valuation of GPC1X to the new E/M face-to-face visits, we oppose the addition of HCPCS code GPC1X to the permanent telehealth list, based on concerns regarding program integrity. Finally, we oppose the addition of HCPCS codes 96121 and 99483 as we do not believe a thorough cognitive evaluation and functional assessment can be conducted via telehealth. In this scenario, we do not believe that telehealth can replace a face-to-face visit with the patient and/or family or caregiver.

2. Proposed Temporary Addition on a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List

In Table 10 of the NRPM, CMS outlines proposed temporary additions to the Medicare telehealth services list on a Category 3 basis through the end of the year in which the PHE concludes. **The AAO-HNS supports the temporary addition of these services as described in Table 10.** Regarding Emergency Department visits performed via telehealth, we seek clarification from CMS on billing for services which begin as a telehealth encounter but then need to be transitioned to an in-person visit. In this scenario, the AAO-HNS is unclear if is it permissible to bill twice for same diagnosis code.

3. Services Added on an Interim Basis During the PHE for the COVID–19 Pandemic That CMS Is Not Proposing to Retain After the PHE Ends

Table 11 of the NPRM contains a list of telehealth services added on a temporary basis during the PHE that CMS is not proposing to retain after the PHE concludes. CMS requests public comment on whether any service added to the Medicare telehealth services list for the duration of the PHE should be added to the Medicare telehealth services list on a temporary (Category 3) basis. The AAO-HNS agrees that the majority of these HCPCS codes should not be granted Category 3 status. **However, we do support the addition of the speech therapy CPT codes listed in Table 11 (92521, 92522, 92523, 92524, 92507) to the temporary telehealth services list, when these services are furnished by a therapist and billed by a physician or practitioner who can furnish and bill for telehealth services provided that the "incident to" requirements are met.**

4. Continuation of Payment for Audio Only Visits

In March 2020, in response to the COVID-19 PHE, CMS established separate payment for audio-only telephone E/M services (CPT codes 99441, 99442, and 99443). We appreciate the agency's flexibility in temporarily adding these codes and acknowledge the potential benefits of telemedicine in the future. However, **the AAO-HNS does not support the continuation of payment for these codes beyond the PHE**. Our opposition to the proposal is outlined in our comments below.

CMS only recently accepted the use of telephone and other electronic means for conducting E/M visits. We believe it is premature to finalize telephone codes in the absence of considering how to revise other "virtual" services. For example, as CMS has noted in the NPRM, the term "telephone" may no longer be an adequate term as there are other means of conducting audio-only encounters besides a traditional telephone, such as a PC or tablet.

We are concerned that the elimination of the restrictions on reporting the codes, should the patient require an E/M visit within the next 24 hours or have had another E/M visit within the previous 7 days, will lead to possible overutilization and abuse. As such, we urge CMS to carefully consider the consequences of prematurely permanently adding these codes.

Due to the redundancy of the prefatory language, it is not clear that this proposal meets the CPT language and reporting rules that apply for Medicare billing in which "the descriptor structure, guidelines, and instructions are consistent with current for maintenance of the code set," particularly given the expected changes in the 2021 E/M guidelines. Finally, the need to add a significant amount of prefatory language that might either duplicate or contradict what is already described in the E/M section will not only fail to reduce administrative burden but may even increase it and cause confusion. If medical decision making is used as one means of selecting a level of care, this should be done as part of an overall assessment of the entire family of "virtual" E/M services. At a minimum, definitions and level of care requirements should refer to existing text in the E/M section to maintain consistency and clarity.

G. Care Management Services and Remote Physiologic Monitoring Services

1. Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

Remote physiologic monitoring is routinely used by otolaryngologists who perform sleep surgery reported using CPT codes 99453, 99454, 99457, and 99458 for sleep apnea remote monitoring. **The AAO-HNS believes that CMS should add these codes on a permanent basis and agrees that these codes should be for established (not new) patients. For sleep apnea remote monitoring, we suggest that a shorter duration of monitoring (10 days) rather than 16 or more days in a 30-day period proposed in the NPRM, would be appropriate.**

H. Scope of Practice and Related Issues

1. **Supervision of Residents in Teaching Setting through the Audio/Video Real-Time Communications Technology**

The AAO-HNS appreciates the decision to allow teaching physicians to use audio/video real-time communications technology to supervise residents during the pandemic. We also support the proposal to make the video real-time change permanent. **We do not support the use of audio only supervision. Our specialty requires visual examination for diagnosis, optimal patient care and teaching for many of our regularly treated diagnoses.** We feel that the audio only option is grossly inadequate and puts patients and residents at risk unnecessarily for certain diagnoses, including office-based otoscopy and endoscopy, as well as accurate interpretation of imaging studies. Specific policies should be developed, reviewed and implemented by each residency program in accordance with existing ACGME policy.

2. **Virtual Teaching Physician Presence during Medicare Telehealth Services**

The AAO-HNS supports allowing the virtual direction and supervision of teaching physicians during Medicare telehealth services and believes this change should be made permanent. We believe that teaching physicians should be compensated for services performed by residents, if the resident is under the physician's personal observation, direction, and supervision to include Medicare telehealth services. In order for these services to be performed safely, the respective training programs must adhere to ACGME standards.

3. **Supervision of Diagnostic Tests by Certain Non-Physician Practitioners**

The AAO-HNS categorically opposes allowing non-physician practitioners to supervise diagnostic tests on a permanent basis. The existing policy specifically states that "physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives may not function as supervisory physicians for the purpose of diagnostic tests." There has been no change in training levels related to the pandemic that would justify this change. This proposal stands in direct opposition to the training of physician assistants specifically. This practice is also expressly prohibited in certain states. Finally, the proposed permanent Medicare policy calls into question how non-physician practitioners can supervise diagnostic testing they are not able to perform. Emergency situations should not be used to create standards not justifiable under normal circumstances.

4. **Medical Record Documentation Requirements**

The AAO-HNS supports the CMS proposal to allow any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, and to review and verify notes in the medical record made by physicians, residents, nurses, students, or other members of the medical team.

I. Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule

For 2021, CMS proposes that physicians participating in Promoting Interoperability (PI) Programs, including the PI category of the QPP, must use technology certified under the Office of the National Coordinator for Health Information Technology (ONC) Certification Program according to the timelines established in the 21st Century Cures Act (Cures Act) Final Rule. CMS also proposes that after August 2, 2022, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

The AAO-HNS feels that this requirement has the potential to cause ECs to choose EHRs without complete evaluation review of new systems in order to meet this deadline. We suggest delaying this deadline to January 1, 2023 to allow for increased harmonization. There is a significant ongoing change, at least in our specialty of otolaryngology, with increased interoperability and less cost from a number of vendors in our field. This has resulted in more frequent change in systems, typically an upgrade, which will make data collection for quality easier and more available for QCDR and Clinical Data Registry participation, as well as easing documentation collection and reducing other stressors adversely affecting AAO-HNS members. It is certainly in the realm of possibility that the current Covid-19 pandemic may still be ongoing by mid-2021. The extra six months we request should not adversely affect CMS programs and does fall within the calendar year reporting mechanisms currently utilized.

II. Quality Payment Program Updates for CY 2021

A. MIPS Value Pathway (MVP) Development

The AAO-HNS supports CMS in their transition to MVPs. This is likely the only pathway most specialty physicians, such as otolaryngologists, will ever be able to utilize to participate in the APM system as currently written. We continue to believe, as previously stated both in comments and in-person meetings with agency staff, that the only way this will be successful in the long run and be meaningful to patient care by improving outcomes, is by mirroring the patient evaluation and treatment paradigm used by physicians across all specialties. A system such as this would allow all components of the current MIPS system to be addressed within the structure of MVPs. One of the great advantages of this type system is the ability to include MVPs that cover the breadth of the specialty.

To have any chance of working, CMS will have to be flexible and consider creative methodologies for measure development within the MVP that can be validated through registry-based data i.e., “non-QCDR” measures. If CMS is willing to accept non-QCDR measures for utilization in the MVP, that would help accomplish the same goal to provide opportunities for the breadth of our membership. The typical NQF methodology will not allow the extent of coverage necessary to include many common disease processes. There are emerging strategies for measure development that we feel will be validated by registry-based data. These strategies will end up being a more accurate representation of all phases of care, including outcomes, than the traditional guideline-based measures. This would be consistent with the five guiding principles put forth by CMS on page 611 of the CY 2020 PFS proposed rule.

1. Timeline for MVP Implementation

The AAO-HNS supports CMS' proposal to delay the implementation of MVPs until the 2022 performance period.

2. Implementing Meaningful Measures in MVPs: Population Health Administrative Claims Measures

The AAO-HNS has concerns about the reliance of population health administrative claims measures as a major component of the MVP. Those data sets are not valuable in creating outcomes measures or measuring quality at different steps of the patient evaluation and treatment process. They have limited value in cost because of the attribution difficulties. While there may be utility for these types of measures, they should not be a predominant feature of the MVP.

3. MVP Principles, Process and Criteria

The AAO-HNS appreciates the fact that CMS is adopting principles by which to guide MVP construction and evaluation. We hope this signals that CMS is willing to accept a variety of proposals that meet these principles. It is clear this is not a "one-size-fits-all" process and needs to be individually crafted related to specialty areas, as well as subsets of providers within those specialties. **We agree with principles 1 and 4 as written and will comment on the remaining three below.**

Principle #2: We agree that ultimately the comparative data available in an MVP should assist patients and caregivers in shared decision-making about their care. We also agree that the use of subgroup reporting is valuable both for patient care and research purposes. We would envision subgroups in otolaryngology representing specialty areas, particularly with tertiary care clinical problems. Further definition of how these subgroups can be formed and what the specific requirements are for each grouping would be mandatory as organizations plan for their own MVP submissions.

We agree with the use of QCDR measures in an MPV, but not as the exclusive pool. We agree that the measures included in MVP should be tested for feasibility, reliability, and validity. New measures particularly should be given provisionary approval as the testing requirements are then completed by the specialty. CMS should work with the developers to identify any additional information they require on MVPs which have already been submitted and provide developers enough time to resubmit with these additional criteria. One of the most difficult and ill-defined areas currently revolves around cost. There are many strategies percolating that have the potential to be more accurate than the existing databases. CMS should try to partner with specialty societies, including the AAO-HNS, as they look to develop, validate, and implement meaningful cost measures across the spectrum of care. Specialty practices are very concerned about attribution of cost within episodes of care

Principle #3: We also agree that there is value in including the patient voice as is feasible but realize the great variability that this perspective brings into the equation. We currently use this strategy with development of our Clinical Practice Guidelines and

QCDR measures with good success. We would hope that there would be flexibility in these requirements to allow current operational strategies that have proven successful to be retained for the MVP program. **We do have concerns about the degree the patient voice would be involved in design, construction and implementation of an MVP compared to measure implementation and design.**

Principle #5: There are many types of digital measurements and data inputs available, with more being unveiled regularly. These have the potential to greatly enhance data placed into the EHR, particularly related to patient reported outcomes (PROMS) and remote patient monitoring. As these become more commonplace, it is essential that they be allowed as one of the many data sources that will be combined to provide the best "real world evidence". **We believe this category should include all potential validated data sources, not just administrative data. Otolaryngology currently has well over thirty validated PROMs that are used regularly and scientific studies and publications. We feel that these can be easily integrated into MVP proposals and should be allowed just as other data sources are.**

The AAO-HNS has had previous discussions with CMS about our concept of MVPs for otolaryngology. In February of 2020, we presented a "Clinical Pathways" (CP) concept that involves beginning to end evaluation of quality throughout the patient encounter, including diagnosis, treatment, and follow-up care. Many of these may be constructed using existing measures, but it becomes obvious that additional measures will be needed. **CMS seems to be moving toward a reduction in overall measures for the MIPS program, but this strategy will act as a de facto exclusion of our CP program that would cover the breadth of our specialty. For that reason, we hope that CMS allows flexibility in the number of measures used to evaluate these pathways, some of which would not be QCDR measures.** The development of CP as an MVP for our specialty also would require a reliable and consistent MAP process. We seek CMS guidance as to whether each CP would need to be its own MPV, or could a specialty wide MPV include multiple CPs?

Our greatest concern lies around the following sentence: "Since MVPs must be established through rulemaking, as described at § 414.1305, CMS will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the proposed rule." The development of multiple MVPs and/or CPs requires tremendous resources not only to design and implement, but also to maintain over time. Without some indication of success, the whole MVP program is subject to failure for several reasons. First, as organizations are planning for next year's reporting, the lack of approval until November in the year before implementation is simply not feasible. There is absolutely no way to communicate to Eligible Clinicians and their practices in time to get the required set up established in that timeframe. Additionally, very few organizations can commit and risk the resources necessary to create a high-quality MVP without probability of acceptance. The AAO-HNS urges CMS to work with the specialty society developers and offer guidance in an ongoing fashion to identify additional information required and suggestions on how the MVP program might be improved to the point of acceptance and provide a reasonable timeframe in order for this to occur.

B. Merit-based Incentive Performance System (MIPS)

1. **Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020**

We thank CMS for the modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020 and accommodations made to assist physicians during the PHE. The extension of the 2019 MIPS reporting deadline was extremely helpful. Many physicians were completing their reporting at the same time as making necessary practice accommodations to deal with the pandemic, such as the incorporation of telehealth visits, and needed the additional time to fulfill MIPS requirements. **Due to the wide variation across practice models and geographic areas experiencing the economic effects on practitioners, as well as the unknown duration of the current PHE, the AAO-HNS asks CMS to extend the hardship exception policies through 2021. This would allow a more orderly continued participation and resumption of participation in the MIPS program by those ECs most severely impacted by the pandemic.**

2. **MIPS Performance Threshold and Additional Performance Threshold**

The AAO-HNS appreciates CMS' recognition of the extreme stress practitioners have been under throughout the course of the pandemic. We are grateful for the agency's reexamination of the performance threshold for year 5 (2021 performance period/2023 MIPS payment year) due to the disruptions caused by the PHE. Given that the full ramifications of the pandemic are as yet unrealized and will vary widely depending on a variety of circumstances which the ECs participating in MIPS had no or minimal control over, **we ask CMS to further lower the proposed performance threshold from 50 to 45 points for the 2021 performance period/2023 MIPS payment year**.

3. **Quality Category**

a. Weight in the Final Score

The impact of the COVID-19 pandemic on all aspects of practice, particularly costs and disruption in the standard protocols for delivering service, has called into question the ability of most practices to handle additional administrative burdens including reviewing of cost data and making the appropriate adjustments to practice**. Given this new reality, and the fact that the cost measures are still undergoing refinement by CMS**, **the AAO-HNS requests that CMS maintain the weight of the quality category at 45% for the 2021 performance year.**

4. QCDR Measure Conditions

The AAO-HNS urges CMS not to remove what they consider to be "topped-out measures" prematurely. As we move into the MVP era, it will be critical to have some anchor measures with previously predictable scoring established prior to the pandemic. It is unclear how the ongoing COVID-19 disruption will affect scoring of these measures over a period of several years. The current CMS policy on topped-out measures ends up being punitive to providers who

have succeeded in identifying gaps and improving quality through this program. In a way it is telling them they are not providing quality healthcare despite their efforts to fully embrace these measures.

In addition, the AAO-HNS does not support the removal of QCDR measures lacking the case minimum and reporting volumes required for benchmarking after being in the program for two consecutive years. This eliminates the ability to develop and implement measures for less common disease processes which are needed for our vast array of subspecialty physicians. It takes at least two years or more to create and fine-tune practice workflow, checklists, coding and documentation changes within EHRs to support a new QCDR measure. Given the smaller number of providers in these subspecialties, it is much more difficult to attain the volume CMS requires. However, over time the volume will increase and the clinical benefit of reporting these measures will be realized.

5. Performance Period Benchmarks for 2021 MIPS Performance Period

The AAO-HNS supports the use of performance period benchmarks for the CY 2021 MIPS performance period rather than the baseline period historic data. CMS should also consider the possible distortion of this data over a three-year period depending on when the PHE ends and practices are able to return to more normal patterns. We have concerns over the advisability and accuracy of using data from the COVID-19 disruption to create benchmarks for future scoring. In addition, upon CMS' request, the AAO-HNS removed the telehealth exclusion language from several of our measures specifications. Therefore, the default to the use of 2018 data would be unreliable given the payment for these telehealth services in 2020 and beyond.

6. MIPS Benchmark Methodology Analysis and Recommendations for Improvement

The AAO-HNS recommends that CMS establish a consistent mechanism for reporting quality through MIPS and Physician Compare that utilize the same system. This would require an alteration of the current methodology and incorporate clinical knowledge and allow CMS to account for fluctuation in reported numbers that was not due to poor quality, but more statistically driven.

7. Data Completeness Criteria

The AAO-HNS was very concerned about the original proposal to move to 70% data completeness in last year's PFS/QPP proposed rule. At that time practice conditions were normal, and we still felt it would be very difficult for some of our practices to reach that goal. The onset of the pandemic has affected clinicians in a variety of ways and altered their financial and temporal abilities to accommodate this level of completeness. Additionally, office support staff have their hands full just trying to help get patients seen. **CMS has demonstrated the necessary flexibility in most areas to help the medical community navigate through the pandemic. We would urge them to apply that same flexibility to this standard until we are completely out from under the pandemic burden before raising the completeness criteria. We would ask CMS to lower the threshold to 50% for the COVID-19 affected years.**

8. QCDR Testing Timeline

We strongly believe in lengthening the time frame for submitting testing on reliability and validity for new measures. **We urge CMS to delay these requirements for both new and existing measures for two years.** This would ensure full data collection that may not be possible in the time frame listed in the proposed rule. It would also produce more annual consistency for the QCDR program. As outlined in our comments to the CY 2020 PFS/QPP proposed rule, our measures are developed with the appropriate rigor in that we have a comprehensive, physician-led process dedicated to otolaryngology specialty-specific measure development. Having to revert to utilizing a complex and resource-intensive measures testing process will only delay getting appropriate measures into the program and into specialty-specific MVPs.

9. Third Party Intermediaries

The AAO-HNS strongly believes that the progressive addition of auditing and validation requirements over the last several years has great potential to cause many specialty societies, including ours to discontinue their QCDR because of the cost and difficulty of operations. If there is a fundamental problem with the way these third-party intermediaries are performing, CMS needs to make this public, so the breadth and depth of the problem is apparent. If these requirements are necessary, there needs to be some cost-sharing program established. The MIPS and MVP programs are dependent on this type of data collection and analysis for their own existence. It does not make sense to run them out of business through overregulation.

In the CY 2021 proposed rule, CMS intends to modify Section 414.1400 of 42 CFR,
"Therefore we are proposing to amend the current 414.1400(a)(4) to propose a new paragraph at 414.1400(a)(4)(ii): The determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as a third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. We intend on utilizing all available information to make these approval determinations, including without limitation, information collected through compliance audits under our existing auditory authority as described in 414.1400(g). Third party intermediaries may be selected during the performance period to be audited for a given requirement. As a part of our outreach to a selected third party intermediary, we intend on providing additional direction with regards to the timeline and information needed for the audit. The results of the audit will be reviewed to inform future approval of a third party intermediary, and if remedial action is warranted, we will utilize our existing authority as described in 414.1400(f)."

We believe the above proposals are not conducive to a true partnership between CMS and specialty driven registries and amplifies the recent addition of unbearable burden to these vital components of the CMS quality program.

Additionally, *"CMS proposes to codify at 414.1400(b)(2)(iv) and (v) requirements beginning with the 2023 MIPS payment year as a condition of approval each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program. We believe it is important for QCDRs to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. We propose to codify at 414.1400(b)(2)(iv)(B) , the QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting interoperability performance categories."*

The AAO-HNS recognizes the importance of submitting accurate data to accomplish the quality goals of the MIPS reporting system. **While we support randomized pre-submission data validation audits of quality performance measures data to assure that the data submitted is accurate, true and complete, as well as the completion of targeted audits should errors be found, we disagree with the requirement that QCDRs validate and audit the IA and PI categories of MIPS as it creates an undue burden for QCDRs.** This will require QCDRs to monitor and validate targeted audits of multiple different improvement activities taking place over different 90-day periods across dozens of practices and involving several hundred clinicians participating in Reg-ent.

Although QCDRs and QRs encourage all clinicians to enter data often and in a timely manner, not all clinicians have incorporated this activity into their daily/weekly operations. In fact, a large percent of clinicians who are manually entering performance data do not complete this task until late in the fourth quarter of the year. However, the proposal requiring QCDRs and QRs to audit all three performance categories would require QCDRs and QRs to initiate audit activities early in the fourth quarter of the year to ensure timely completion prior to CMS submission. The timing of data submission by participants to QCDRs and QRs is, therefore, incompatible with CMS's proposed data validation requirements.

Moreover, the data submitted for the PI performance category is essentially an attestation. Physicians copy and paste the numerators and denominators for the measures from a report provided by their electronic health records ("EHR"). Although QCDRs and QRs can conduct a randomized audit requesting to examine the report from the EHR that lists the PI measure data, any errors discovered will be errors on the part of the practice or physician, not the QCDR or QR. **Accordingly, we urge CMS to clarify that it is the participants' responsibility to correct data errors prior to submitting the data to the QCDR or QR. Further, we are concerned that EHR vendor companies are charging practices to run these reports when a third-party entity (such as a QCDR or QR) requests them.**

It would also be unreasonable to require QCDRs and QRs to audit IAs. CMS has not provided QCDRs or QRs with appropriate guidance to complete such audits and has previously stated that the agency is responsible for validating data for IA. In order to provide flexibility and be responsive to the variability in our practices individual QI programs/projects, which are many times focused upon the disease conditions seen in their

specific patient populations, the Reg-ent registry offers over 50 IA activities to participants. The variation across the spectrum of the hundreds of participating practices allows for the ability to develop practice-specific QI in identified areas where improvement is needed. **It is imperative for CMS to be flexible and account for varying practice conditions and constraints that may present when completing an audit.** CMS has final authority for deeming what documentation supports a specific IA activity.

Auditing and validating Promoting Interoperability categories also increases burden by effectively forcing QCDRs to depend upon EMR vendors to share data reports used by clinicians to attest to the PI category. Registry participants have faced roadblocks in receiving this information from their vendors; it would be much more difficult for QCDRs to secure this data. **Requiring targeted audits for a non-statistically relevant error, and requiring QCDRs to conduct data validation audits on all three categories of MIPS, in addition to mandating targeted audits in the case of a single error, will lead many QCDRs to reevaluate the ability to provide MIPS reporting services through their registries to their members**. The additional requirement for QCDRs and QRs to conduct data validation testing for each submitter type for which they will submit data is unnecessary. Random audits and validation studies for the entirety of the program will include these groups. This will only add another significant cost and burden to QCDRs and QRs.

The AAO-HNS asks CMS not to require validation and auditing of IA and PI for third party intermediaries such as specialty sponsored QCDRs and QRs.

10. Health IT Vendors

CMS is soliciting comment on whether data validation requirements should be imposed on health IT vendors as part of the third party intermediary approval process and if so, how the data validation requirements for health IT vendors should differ, if at all, from those proposed for QCDRs and Qualified Registries. The AAO-HNS believes that all third-party intermediaries should be held to the same standard. In addition to providing data to CMS, many health IT vendors will be submitting data directly to QCDRs and QRs, particularly for the PI category.

11. Data Validation

In the proposed rule, the agency includes a number of additional proposals for verifying and validating submissions. For example, CMS proposes a requirement that QCDRs and QRs provide clinical documentation to validate that the action or outcome measured actually occurred or was performed. In otolaryngology, as we have learned from trying to obtain similar documentation for clinical research studies, this type of information often exists in records that are not specifically tied to the patient's EMR data. Additionally, most QCDRs and QRs do not receive PHI from their participants; rather, the participants submit PHI to vendors engaged by the registry and vendors subsequently submit de-identified data to the QCDR or QR for MIPS reporting. The AAO-HNS does not have the resources to search for and report this data. Most specialty driven registries do not hold the PHI because of the legal risk of a data breach.

CMS proposes a sampling methodology that requires QCDRs and QRs to use a sample size of at least 3% of the TINs/NPIs for each data validation audit that includes at least

25% of the patients of each TI N/NPI in the sample. The AAO-HNS supports this methodology for the Quality performance category only. However, this proposal would be extremely burdensome to incorporate for IA and PI categories for individual practices as well as QCDRs and QRs with limited resources. CMS also requires that if a data validation audit identifies one or more deficiencies or data errors, the QCDR must conduct a targeted audit into the impact in root cause of each such deficiency or data error for the MIPS payment year.

Finally, CMS proposes that, in a form and manner and by a deadline specified by the agency, a qualified Registry must report:

- **the results of each targeted audit, including the overall deficiency or data error rate,**
- **the types of deficiencies or data errors discovered,**
- **the percentage of clinicians impacted by each deficiency or data error; and**
- **how and when each error type was corrected.**

The AAO-HNS absolutely opposes this proposal as written. This is another example of layering on additional administrative burdens that have little or no benefit to the overall program. These burdens are becoming so costly in terms of time and resources that there will be no time left to create new measures and new ideas for MPV or other improvements into the CMS quality program. This is counterintuitive to the overall goals of the program as espoused by the agency.

12. Measure Testing

The AAO-HNS firmly believes that the ability to measure quality and outcomes, outside of a limited number of selected common disease processes, lies in the ability to create innovative models such as our "Clinical Pathways" model. Programs such as these, as well as those that incorporate outcomes and cost measures, will require considerably more measures than can be created in the next twenty years using the NQF existing formula. This will be resource and time intensive and, as mentioned in the MVP section, will require flexibility, including the willingness to accept measures with face validity subject to validation and testing after acceptance into the program.

The requirements put forth in this year's proposed rule virtually eliminates any opportunity for producing new measures, since the majority of the time will need to be spent on testing and preserving existing QCDR measures. That strategy will not only eliminate progress, but also likely eliminate the program down the line. CMS states their desire to move to subsets of measures and activities, where clinicians may have a more focused selection of items to report on. We are in complete agreement that this is the correct pathway. However, we believe this would require enough "focused selection" opportunities so all otolaryngologists can participate. **The CMS decision to require all QCDR measures to be fully developed and tested beginning with the CY 2023 payment year, with complete testing results at the clinician level, will become the greatest roadblock to achieving the agency's overarching goal of relevant, quality measurement that actually improves overall results.**

13. Face Validity

The AAO-HNS supports CMS in its proposal to allow new measures to be "face valid" beginning with the 2024 MIPS payment year. As mentioned earlier, we believe that face validity testing should be expanded to two years, which would result in the new measure to be fully tested in its third year of life in the MIPS or MVP program. **We continue to have concerns about the proposed requirement that any QCDR measure accepted for the MPV program must be fully tested prior to acceptance, as this greatly reduces the opportunity to widely represent our specialty area.** As stated in our earlier MVP comments, there are emerging strategies for measure development that we feel can be validated by registry-based data which will end up being a more accurate representation of all phases of care, including outcomes, than the traditional guideline-based measures. If CMS is willing to accept these "non-QCDR" measures for utilization in the MVP, that would help accomplish the same goal to provide opportunities for the breadth of our Academy's membership.

14. Removal of Measures

QPP 333: Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) This measure is stewarded by the AAO-HNS it is considered topped out by CMS. **We request that CMS consider extending the life of this measure with an updated denominator that adds telehealth as an eligible encounter.** We think it would be valuable to see how the telehealth practice of medicine compares to traditional means of care delivery in our specialty. We would be able to compare this over several years with the known rate for the measure. We also feel this would be an excellent measure to include in one of our first "Clinical Pathways" MPV submissions.

15. Changes to the OTO specialty set

QPP-93: Acute Otitis Externa: Systemic Antibiotic Therapy-Avoidance of Inappropriate Use
QPP-331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
QPP 332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate
QPP 464: Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

The AAO-HNS supports the CMS proposals to add telehealth as eligible encounters to the above four measures by adjusting the denominator. In addition, we note that on table D.105 Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use, there is an error in the Substantive Change: "Updated denominator: Added telehealth exclusion to patient encounter." The Substantive Change should instead read "Updated Denominator: Telehealth exclusion to patient encounter **is removed**" as telehealth encounters are applicable to this measure and these patients should not be excluded in the denominator.

III. 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 look forward to working with CMS as it continues its efforts to reduce regulatory burdens for providers and improve patient access to quality care. If you have any questions or require further information, please contact healthpolicy@entnet.org.

Respectfully submitted,

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