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August 30, 2019

SUBMITTED VIA ELECTRONIC MAILING

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

[Submitted online at: <https://www.regulations.gov/comment?D=CMS-2018-0133-0001>]

Re: CMS-1715-P Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professional; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancement to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professional; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancement to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations” published in the *Federal Register* on August 14, 2019.

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.

The CY 2020 Medicare Physician Fee Schedule (MPFS) proposed rule accelerates an alarming trend of progressive devaluation of surgical services over the past 20 years. Multiple factors have contributed to the current situation, including deflation of the Medicare conversion factor from \$36.68 in 1998 to the \$36.09 as proposed for CY 2020. 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. Otolaryngology-head and neck surgical physicians would benefit from the MPFS valuation in the short-term; however, we are concerned that further movement in this direction will create obstacles to surgeons' ability, particularly outside of the urban areas, to maintain technologically up-to-date practices that offer state-of-the-art care to their patients. Otolaryngology-head and neck surgery is already witnessing a failure to properly account for the transition to office-based procedures previously done only in hospital or ambulatory surgical center (ASC) settings.

The AAO-HNS remains significantly concerned that the conversion factor has stayed relatively constant since 1998. While costs are constantly increasing, the effective reimbursement rate for surgeons is slowly and consistently being eroded. We realize that the conversion factor is set statutorily, and that CMS does not have the authority to change the rate, but we want to ensure that all parties understand the pressure otolaryngologists are under because the conversion factor has not changed. **We are actively working with the House of Medicine to advocate in Congress for a legislative update to the conversion factor.**

We wish to provide detailed comments on several specific proposals contained in the extensive rule placed on display in the *Federal Register* on July 29. Our comments will address the following specific issues within the proposed rule: E/M codes and their value in the global surgery package, valuation of specific codes affecting the practice of otolaryngology, special endoscopy rules, market-based supply and equipment pricing, scope of practice, remote patient monitoring, bundled payments, Merit-based Incentive Payment System (MIPS), and changes to the Quality Payment Program (QPP).

I. Medicare Physician Fee Schedule

a. E/M Proposal

In recognition of the increasing amount of administrative burden that the present E/M system and EHRs created for the average practitioner, and in concert with other agency efforts to reduce regulatory burdens on providers, the CY 2019 MPFS proposed rule included a collapse of the E/M coding system with significant reductions in documentation requirements. Following stakeholder feedback provided through the official comment period, including that of the AAO-HNS, the 2019 MPFS final rule delineated significant changes to the E/M coding structure scheduled to take effect for CY 2021. Neither the proposed rule, nor the final rule, discussed revaluation of the new and established E/M office codes. The AAO-HNS strongly objected to the AMA-directed process that followed.

We continue to feel that the revaluation process was inappropriately conducted, with disproportionate representation of primary care specialties, and we firmly opposed the resultant recommendations for unprecedented increases in E/M services. The survey used by this group was poorly done and did not represent typical patients across the House of Medicine. The proposal that was voted on and passed at the RUC included the same valuation for all E/M services provided in the office - including those valued in global surgical packages. The failure to apply the proposed increases to E/M services provided in the global surgical package effectively creates two different conversion factors for E/M services in the Medicare fee schedule. This same situation existed previously, dating back to the 1990s, but was eliminated by the agency as a result of lowering the conversion factor for primary care due to persistent budget issues. If it is the intention of CMS to reinstitute split conversion factors, this revision should instead be applied to the entire global surgical package and not just the E/M portion of the global package. **We strongly oppose the revaluation of the E/M codes. However, if this proposal is finalized, it is imperative that the revaluation be applied to the entire office-based E/M service line including the E/M services included in the global surgical package.**

CMS proposes to adopt the RUC recommendations regarding values, times, and practice costs for standalone E/M visits effective January 1, 2021. This recommendation would keep the five current codes for existing patients, and, by deleting CPT code 99201, would keep four of the five new patient codes. CMS also proposes a new add-on code for extremely complex cases that take extra time not accounted for in the current code set. **The AAO-HNS feels that this proposed solution does not accomplish the original goal of simplifying the system and reducing burden appreciably, but rather was used as a vehicle to revalue E/M services, unevenly at that.** If CMS chooses to accept the RUC recommendation it should be an all-or-nothing decision. Failure to adopt the RUC recommendations, including the recommended adjustments to the 10- and 90-day global codes, would require CMS to implement the new values in a piecemeal fashion.

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 disrupting the relativity between codes across the Medicare physician fee schedule. E/M codes have been previously revalued three times and 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. Additionally, the CMS proposals would 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 the cost of surgical procedures by devaluing individual E/M codes is inconsistent with the intent and mandate of the legislation.

² 42 U.S. Code §1395w-4(c)(6).

b. Evaluation of Specific Codes

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 Academy via the RUC process. Those include the following:

Tissue Grafting Procedures (CPT Codes 15X00, 15X01, 15X02, 15X03, and 15X04)

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 2020 final rule.

Auditory Function Evaluation (CPT Codes 92626 and 92627)

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 2020 final rule.

Exploration of Artery (CPT Codes 35701, 35X01, and 35X01)

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 2020 final rule.

Computerized Dynamic Posturography (CPT Codes 92548 and 92XX0)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
92548	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report;	0.66	0.76
92XX0	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)	0.86	0.96

For the computerized dynamic posturography codes (92548 and 92XX0), CMS disagreed with the RUC recommended work RVUs for each code. **CMS has proposed to decrease the work RVU from 0.76 to 0.66 for code 92548 and 0.96 to 0.86 for code 92XX0.** CMS proposes that their alternate work RVUs

more closely align with the valuation of these codes than the RUC-recommended. However, the RUC-recommended work RVUs for these two codes are based on robust survey data. The Academy agrees with the AMA RUC comments and requests that CMS use valid survey data in establishing the work RVUs for both codes. The RUC thoroughly analyzed this family of codes by review of history, survey data, and magnitude estimation to other similar services. A detailed analysis of each code is outlined below.

92548

For CPT code 92548, CMS disagrees with the RUC-recommended work RVU of 0.76 and proposes a work RVU of 0.66 based on the intra-service time ratio. To get to this proposed work value, CMS divided the RUC-recommended intra-service time of 20 by the current intra-service time of 15 and multiplied the product by the current work RVU of 0.50 for a ratio of 0.66. This is a flawed methodology to value this service, one which the AAO-HNS strongly opposes. In addition, the agency has chosen code 93316 *Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only* (work RVU = 0.60, 20 minutes intra-service time, and 35 minutes of total time) as a crosswalk to support a proposed work RVU of 0.66 for code 92548. We are concerned that CMS may be misinterpreting the use of the term “crosswalk”. Historically, the use of the crosswalk methodology implies the crosswalk code has identical work RVUs as the service being valued. CMS’ choice of code 93316 (work RVU = 0.60) is not a crosswalk if the agency proposes a work RVU of 0.66, but rather solely serves as a reference service. The Academy strongly disagrees with CMS’ methodology to alternatively value CPT code 92548.

Historically, CMS has inconsistently selected a combination of inputs to apply, including: total physician time, intra-service physician time, “CMS/Other” physician times, Harvard study physician times, existing work RVUs, RUC-recommended work RVUs, work RVUs from CMS-selected crosswalks, work RVUs from a base code, etc. This selection process has the appearance of seeking an arbitrary value from the vast array of possible mathematical transformations rather than seeking a valid clinically relevant relationship that would preserve relativity.

The AAO-HNS is increasingly concerned that CMS is eschewing the bedrock principles of valuation within the RBRVS (namely, magnitude estimation, survey data, and clinical expertise) in favor of arbitrary mathematical formulas. Creative valuation methodologies that do not follow established protocols can only hasten the demise of a system already under significant scrutiny. We urge CMS to use valid survey data and supportive relative reference services when valuing codes. The RUC thoroughly discussed the physician work, time, intensity, and complexity required to perform CPT code 92548. The Academy urges CMS to utilize valid survey data and review the actual relativity for all elements (physician work, time, intensity, and complexity) when developing work values for services and not foster flawed methodologies.

The RUC recommendation for 92548 was based on the 25th percentile work RVU from robust survey results and favorable comparison to reference code 95992 *Canalith repositioning procedure(s) (eg, Epley maneuver, Semont maneuver), per day* (work RVU = 0.75, intra-service time of 20 minutes, total time of 30 minutes) and MPC code 93015 *Cardiovascular stress test using maximal or submaximal treadmill or*

bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report (work RVU = 0.75, intra-service time of 20 minutes, total time of 26 minutes). **The Academy urges CMS to accept a work RVU of 0.76 for CPT code 92548.**

92XX0

For CPT code 92XX0, CMS disagrees with the RUC-recommended work RVU of 0.96 and proposes a work RVU of 0.86 by applying the RUC-recommended incremental difference between codes 92548 and 92XX0, a difference of 0.20, to the agency's proposed value of 0.66 for CPT code 92548. The AAO-HNS asserts that the use of this methodology in valuing services is flawed. While CMS accepts the RUC work RVU increment between these codes, they disagree with the RUC-recommended work RVU for code 92XX0. The agency argues that it is appropriate to reduce the work RVU for code 92548 based on the value proposed by the RUC. Yet, the agency also agrees that it is appropriate to recalibrate the work RVU for code 92XX0 relative to the RUC's recommended difference in work between this code and code 92548. This valuation methodology is inaccurate and should not be applied to code 92XX0.

The Academy does not agree with the adjusted value for code 92XX0, which has been derived by an incremental difference. It is imperative that RUC survey data be used to correctly value this code. Using an incremental approach in lieu of survey data, strong crosswalks, and input from the RUC and physicians providing this service is unjustified. CMS does not provide any supporting rationale to their proposed work RVU other than the incremental difference between both codes and concluding their recommendation by listing two reference codes 95972 (work RVU = 0.80) and 38207 (work RVU = 0.89), stating that the agency's proposed value for code 92XX0 of 0.86 falls between these service's values.

The RUC recommendation for 92XX0 was based on the 25th percentile work RVU from robust survey results and favorable comparison to reference codes 95922 (*Testing of autonomic nervous system function; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and R-R interval changes during Valsalva maneuver and at least 5 minutes of passive tilt*) (work RVU = 0.96, intra-service time of 20 minutes, total time of 40 minutes) and 99448 (*Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician...*) (work RVU = 1.05, intra-service time of 25 minutes, total time of 35 minutes). **The Academy urges CMS to accept a work RVU of 0.96 for CPT code 92XX0.**

A. Somatic Nerve Injection (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	0.75	1.00
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve	0.94	0.94
64408	Injection, anesthetic agent; vagus nerve	0.75	0.90
64415	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, single	1.35	1.42
64416	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)	1.48	1.81
64417	Injection(s), anesthetic agent(s) and/or steroid; axillary nerve	1.27	1.27
64418	Injection(s), anesthetic agent(s) and/or steroid; suprascapular nerve	1.10	1.10
64420	Injection(s), anesthetic agent(s), and/or steroid; intercostal nerve, single level	1.08	1.18
64421	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, multiple, regional block, each additional level (List separately in addition to code for primary procedure)	0.50	0.60
64425	Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves	1.00	1.19
64430	Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve	1.00	1.15
64435	Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve	0.75	0.75
64445	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, single	1.00	1.18
64446	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)	1.36	1.54
64447	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, single	1.10	1.10
64448	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter replacement)	1.41	1.55

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
64449	injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)	1.27	1.55
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch	0.75	0.75

In May 2018, the CPT Editorial Panel approved the revision of descriptors and guidelines for codes 64400-64450 to clarify reporting (i.e. separate reporting of imaging guidance, number of units and converting 64421 to an add-on code.)

CMS has proposed to reject the RUC-recommended work RVUs for 12 of the 18 services in this family of services. The range in work value reduction for the rejected codes, from -5 percent to -25 percent, greatly collapses the variance in work values for this family of services, without providing any clinical rationale that the work is much more homogenous than what the RUC or the performing specialties have asserted. The physician work for this family of services varies based on the anatomic location of each nerve with specific inherent risks, whether the services are typically performed in the facility setting, the typical approach used by the dominant specialty to access the nerve that performs each service and whether the service involves continuous infusion by catheter. CMS' proposed values unfortunately do not sufficiently account for the specific attributes involved in performing each service.

The Academy only surveyed one code (64408) in this very large family, and therefore, we only offer comments regarding CPT 64408 below.

64408

For CPT Code 64408, CMS disagrees with the RUC-recommended work RVU of 0.90 and proposes a work RVU of 0.75 based on a direct work RVU crosswalk to the RUC's recommendation for another code in the same family, 64450. However, injection of the vagus nerve carries with it the risk of injury to the nerve controlling the larynx, as well as the proximate phrenic nerve which controls the diaphragm and the major vessels of the neck. This has the potential to lead to voice changes, dysphagia, aspiration, breathing difficulties, and laryngeal spasm. CPT code 64408 inherently carries significantly more risk and intensity than CPT code 64450. CPT code 64450 is a code that is for all other nerves/nerve branches that do not have a more specific code. The typical patient used for the survey for 64450 was a posterior tibial nerve injection and 78 percent of the survey respondents noted that vignette was similar to their typical patient. CMS would be creating a rank order anomaly by assigning 64408 the same value as 64450, as well as 64400.

The crosswalk or methodology used in the original valuation of this service is unknown and is not resource-based; therefore, it is invalid to compare the current time and work to the surveyed time and work. This code’s source of time is the Harvard study, implying that the time was merely extrapolated and not measured directly. CMS’ continued practice of referencing physician times and derived intensities created almost 30 years ago under the Harvard process as a method to critique RUC recommendations is not appropriate. The Harvard study employed much less rigor when determining physician time relative to the modern RUC/CMS process.

The RUC recommendation was based on the 25th percentile work RVU and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to CPT code 31575 *Laryngoscopy, flexible; diagnostic* (work RVU = 0.94, intra-service time of 5 minutes, total time of 24 minutes) and MPC code 36620 *Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous* (work RVU = 1.00, intra-service time of 7 minutes, total time of 17 minutes.) **The Academy urges CMS to accept a work RVU of 0.90 for CPT code 64408.**

Practice Expense

CMS is proposing refinements to the RUC-recommended direct PE inputs for the codes in this family. **The AAO-HNS agrees with these proposed refinements and recommends their inclusion in the final rule.**

B. Biopsy of Mouth Lesion (CPT Code 40808)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
40808	Biopsy, vestibule of mouth	1.01	1.05

The RUC identified CPT code 40808 via the screen for codes with a negative IWP/UT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. CPT code 40808 was subsequently surveyed and reviewed at the April 2018 RUC meeting.

40808

CMS disagrees with the RUC-recommended work RVU of 1.05 and proposes a work RVU of 1.01 based on the code’s current value. The agency’s rationale, that the RUC did not include compelling evidence is not well founded. If there was no compelling evidence to revalue the code, then the specialty should not have been required to expend the significant resources necessary to survey this or other codes that fall

within these arbitrary screens. As stated in the RUC recommendation, the RUC reviewed and accepted compelling evidence that the original valuation was based on flawed methodology when it was reviewed in 1995, resulting in a negative IWPUT. The value of the service was maintained without taking into consideration the times newly assigned to the service in 1995. That resulted in the physician time and work value having a distorted relationship. Contrary to the assertion made in the proposed rule, this compelling evidence makes a strong case that the work was formerly misvalued. If a work value was assigned by CMS in 1995 without the agency appropriately being informed by physician time data, then the work value assigned prior to the RUC's 2018 analysis used an inappropriate methodology.

The RUC recommendation is derived from an appropriate direct work value crosswalk from 40808 to MPC code 11440 *Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less* (work RVU = 1.05, pre-service time of 5 minutes, intra-service time of 10 minutes, post-service time of 5 minutes and one 99212 office visit). The RUC noted that both services have identical intra-service time, involve an identical amount of physician work and both involve a level 2 post-operative office visit. The RUC also supported the proposed value by referencing codes 11400 *Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.5 cm or less* (work RVU = 0.90, intra-time of 10 minutes, total time of 36 minutes) and 10160 *Puncture aspiration of abscess, hematoma, bulla, or cyst* (work RVU = 1.25, intra-time of 10 minutes and total time of 61 minutes) which appropriately bracket the RUC's proposal.

The IWPUT derived from the RUC recommendation is only 0.0194, which is sufficiently low for this relatively low intensity service. The IWPUT of CMS' alternate proposal, 0.0153, would be less than twice the intensity assigned to pre-service scrub/dress/wait time (0.0081) and less than the intensity assigned to positioning (0.024). The value is inappropriately low for the intra-service time required to perform this service or, for that matter, the majority of all services in the Medicare Physician Fee Schedule. **The Academy urges CMS to accept a work RVU of 1.05 for CPT code 40808.**

Practice Expense

CMS is proposing refinements to the RUC-recommended direct PE inputs for this code. **The AAO-HNS agrees with the proposed input changes to the equipment and staff time, but disagrees with the reduction in staff time to zero minutes given that the additional minute is required to order the specimen for pathology to review.**

C. X-Ray Exam – Sinuses (CPT Codes 70210 and 70220)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
70210	Radiologic examination, sinuses, paranasal, less than 3 views	0.17	0.20
70220	Radiologic examination, sinuses, paranasal, complete, minimum of 3 views	0.22	0.22

70210

CPT code 70210 was identified by the “CMS/Other Source – Medicare Utilization Over 30,000” screen, thus the current source of time for the code is CMS/Other. CMS disagrees with the RUC’s recommendation to increase the work RVU for CPT code 70210 from the current value of 0.17 to 0.20. The value recommended by the RUC is based on actual survey data, which is supported by the comparison with other axial x-ray codes, and their survey times. CMS’ reliance on a crosswalk methodology using CMS/Other is invalid and not resource based.

The AAO-HNS recognizes that there are many other radiology codes that have the same physician work and times as CPT code 70210. For example, 73610 *Radiologic examination, ankle; complete, minimum of 3 views* (work RVU = 0.17, 1 minute pre-service time, 3 minutes intra-service time, 1 minute post-service time) and 73630 *Radiologic examination, foot; complete, minimum of 3 views* (work RVU = 0.17, 1 minute pre-service time, 3 minutes intra-service time, 1 minute post-service time); however, these codes apply to the extremities unlike CPT code 70210 which is an axillary skeletal radiograph. Even though these codes represent similar times, the additional intensity to interpret 70210 justifies the additional .03 RVU as recommended by the RUC. The value of 0.20 RVU does represent the upper threshold among this cohort, and the increased complexity of interpretation justifies this position. Similarly, the two codes that CMS references, CPT code 73501 *Radiologic examination, hip, unilateral, with pelvis when performed; 1 view* (work RVU = 0.18, 1-minute pre-service time, 3 minutes intra-service time, 1-minute post-service time) and CPT code 73560 *Radiologic examination, knee; 1 or 2 views* (work RVU = 0.16, 1-minute pre-service time, 3 minutes intra-service time, 1-minute post-service time) are also studies of extremities.

CPT code 70210 is an x-ray procedure to evaluate anatomic abnormalities and the presence of inflammatory and neoplastic disease not only in the actual paranasal sinuses but also in surrounding areas delineated by these x-rays. The high concentration of related anatomic structures has historically resulted in interpretations that were considerably more complex than those listed above. **The Academy encourages CMS to independently review the surveyed time and work and not compare it to the invalidated CMS/Other source of the current time and work. The Academy also urges CMS to accept a work RVU of 0.20 for CPT code 70210.**

CT-Orbit-Ear-Fossa (CPT Codes 70480, 70481, and 70482)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material	1.13	1.28
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)	1.06	1.13
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections	1.27	1.27

70480

CPT code 70480 was identified by the “*CMS/Other Source – Medicare Utilization Over 30,000*” screen thus, the current source of time for the code is CMS/Other. CMS disagrees with the RUC-recommended work RVU of 1.28 for CPT code 70480, stating that since CPT code 70480 incurs a 12 percent reduction in the new total physician time (22 minutes), there should be a commensurate decrease in the work RVU to 1.13. The initial CMS/Other time does not capture accurate physician time or direct practice expense inputs from the current dominant specialties performing this service. CMS continuously applies this erroneous methodology that, if finalized, would create a rank order anomaly relative to other diagnostic imaging services.

The Academy commented on this code via the RUC process and reiterates the RUC comments that carefully described the nuances of CPT code 70480 and how it should be viewed as a uniquely separate procedure from CPT codes 70481 and 70482. This family of CT codes does not have the normal step-up in times and work RVU related to the use of contrast as is the case for most other radiology code families due to differences in anatomy and typical diagnosis for the three codes. CMS agreed with the RUC-recommended times of 4 minutes pre-service time, 15 minutes intra-service time and 3 minutes post-service time for CPT code 70480.

CMS references CPT codes 72128 *Computed tomography, thoracic spine; without contrast material* (work RVU = 1.00 and 25 minutes total time) and 71250 *Computed tomography, thorax; without contrast material* (work RVU = 1.16 and 25 minutes total time), both of which have the same intra-service time (15 minutes) as CPT code 70480 but longer total times (25 minutes versus 22 minutes). CMS believes that CPT codes 72128 and 71250 more accurately reflect the relative work value of CPT code 70480. However, 70480 is a more anatomically complex study to read compared to 72128 and 71250. We feel that the RUC-selected reference codes are more reflective of the work required to perform 70480.

Additionally, a more accurate comparator would be 70460 *Computed tomography, head or brain, with contrast material(s)* which has an intra-service time of 12 minutes and a total time of 22, and an RVU of 1.13. 70480 has an intra-service time of 15 minutes, 25% more intra-service time than 70460 and the intensity of interpretation of this more complex area is greater. **The Academy urges CMS to accept a compromise work RVU of 1.19 for CPT code 70480.**

c. Potentially Misvalued Codes

Within the 2020 NPRM, CMS indicates that they received public nomination for revaluation of several potentially misvalued codes. Two of the nominated codes are utilized by the otolaryngology community. Specifically, CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*). CMS notes that these two CPT codes were recently reviewed within a family of 13 similar codes. For CPT code 10021, the RUC recommended a 32 percent reduction from its previous physician time and a 5 percent reduction in the work RVU.

The Academy appreciates CMS' acknowledgement of the recent review of this family of codes. Otolaryngology surveyed and then presented CPT 10021 at the October 2017 RUC meeting. We had a robust response of 158 members. **We believe that, given the time and resources recently put into the reevaluation of this service, it is unnecessary to re-survey them at this time and request that CMS reaffirm the existing value of 1.03 RVUs and times of 10 minutes pre, 15 minutes intra, and 8 minutes post for CPT 10021 within the 2020 MPFS.**

d. Special Rule Relating to Multiple Endoscopies

In the CY 2018 MPFS final rule (82 FR 53043), CMS indicated that they would continue to explore whether the broader family of nasal sinus endoscopy surgery services should be subject to the special rules for multiple endoscopic procedures instead of the standard multiple procedure payment reduction. The CY 2020 MPFS proposes to apply the special rule for multiple endoscopic procedures to nasal and sinus endoscopic procedures.

The Academy appreciates the opportunity to comment on this proposal. We have reviewed the references on the special rules (i.e. the 1992 MPFS final rule and Chapter 23 of the Medicare Claims Processing Manual) as well as the CPT Codes listed in Table 7: **Proposed Nasal Sinus Endoscopy Codes Subject to Special Rules for Multiple Endoscopic Procedures**. Our interpretation and understanding of the special rules lead us to believe that we are currently effectively operating under the provisions of this rule as well as the multiple procedure rule from a payment perspective. Currently, billing practices, in conjunction with the NCCI edits, dictate billing only for the operative nasal endoscopic code.

CPT Code 31231 is the diagnostic code within this group that would be considered the “base code” of the nasal endoscopic family. Our understanding is that a diagnostic endoscopy (31231) is included in the valuation of all surgical procedure codes (e.g. 31254, 31256, 31276, etc.). Therefore, CPT Code 31231 would not be billed on the same side that any nasal endoscopic surgical code(s) are performed. However,

CPT code 31231 could be billed for one side of the nose if it was the only procedure performed and there was no surgical intervention on that side. We understand that the multiple surgical procedures rules would also apply in these circumstances.

We are anxious to receive input from the agency to better understand if this interpretation is consistent with the CMS proposal. **If our interpretation is correct, we support the application of the special rules for endoscopy to the nasal endoscopy family.**

e. Market-Based Supply and Equipment Pricing Update

In 2019 rulemaking, CMS proposed and finalized the use of data from StrategyGen, an outside contractor, to assist them in conducting a market research study to update the MPFS direct PE inputs for supply and equipment pricing. CMS believes that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for specific items. The agency also continues to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2020, CMS received invoice submissions for approximately 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and equipment pricing update. These invoices were reviewed by StrategyGen and the submitted invoices were used, in many cases, to supplement the pricing originally proposed for the CY 2019 MPFS rulemaking cycle. The contractor reviewed the invoices, as well as prior data for the relevant supply/equipment codes, to ensure that the invoice pricing was representative of the supply/equipment item in question and aligned with past research. Based on this research, CMS proposes to update the prices of the following supply and equipment items relevant to otolaryngology- head and neck surgery:

Proposed CY 2020 Market-Based Supply and Equipment Pricing Updates Relevant to Otolaryngology

CMS CODE	Description	CMS 2019 Price	Prior CMS 2022 Price	Prior CMS 2020 Price	Updated CMS 2022 Price	Updated CMS 2020 Price
SA047	pack, EM visit	\$4.176	\$7.750	\$5.367	\$5.468	\$4.606
SA106	kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)	\$2,543.478	\$2,374.330	\$2,487.095	\$2,338.000	\$2,474.985

The Academy appreciates CMS’ consideration of the extensive information provided within our comments on the 2019 NPRM related to the pricing of SA106 kit, sinus surgery, balloon. As the agency is aware, this supply has been addressed through many years of rulemaking and we thank that CMS for gathering the most pertinent information and proposing a more accurate price for this supply for CY 2020. **As such, the Academy supports CMS’ recommended revaluation of SA106 for CY 2020. We are also supportive of the input price for SA047 as proposed for 2020.**

f. Scope of Practice

For CY 2020, CMS proposes to relax the supervision standards for physician assistants (PAs). Current law requires that PA services be provided under the general supervision of a physician. General supervision is the most lenient of the three supervision levels. The requirements are that PA services are furnished under a physician's overall direction and control, but the physician's direct presence is not required while the PA is providing services. The proposal included in the NPRM changes these requirements. The new requirement would require PAs to furnish services based on their state supervision requirements. If states do not have their own requirements, then the supervision requirement would be met with documentation in the medical record showing the PA's approach to working with physicians. The nexus of this proposal is that it would place PAs more in line with the requirements that nurse practitioners (NPs) and clinical nurse specialists (CNSs) operate under.

The AAO-HNS strongly opposes any changes to PA supervision requirements and requests that CMS continue requiring that PAs operate under the general supervision of a physician. The AAO-HNS maintains that, although PAs play a key role in the care provided to patients, the physician has ultimate responsibility for patient care. This responsibility is necessary to ensure that care is provided by the practitioners that have received the proper training and licensure.

CMS' proposal states that it would place PAs on the same footing as NPs and CNSs, but this would be a false comparison. The training that these practitioners receive is very different. The training model for PAs is based on physician supervision, which is very different from the training that NPs and CNSs receive. Their training is designed for increased independent work and, as a result, NPs and CNSs have more responsibilities than PAs.

The proposal would also defer to state law when it comes to the supervision of PAs. These state laws are not uniform, and PAs are actively seeking elimination of supervision requirements, despite a lack of alteration in training philosophy. Removing supervision requirements from PAs untrained to operate in that paradigm has potential negative consequences for the patient population. PAs, unlike physicians, are not trained to be a patient's primary caregivers. Additionally, the proposal states that if there is no state law, then the supervision requirement would be fulfilled by looking at the documentation in the medical record of the PA's approach to working with physicians in furnishing their services. This amorphous definition leaves the supervision requirements not up to a licensing or credentialing organization, but up to the individual practitioner to decide how much documentation is required. **CMS should require the same level of supervision nationwide and not lower the supervision requirement for PAs.**

g. Remote Patient Monitoring

The proposed rule would change CPT code 99457 to cover the initial 20 minutes of monitoring services, while a new CPT code 994X0 would be used as an add-on code for those patients who receive additional 20 minute-intervals of RPM per month. The proposed rule would also allow services to be delivered under general supervision rather than the currently required direct supervision. The physician supervising the auxiliary personnel need not be the same individual treating the patient more broadly. However, only

the supervising physician or other qualified health care professional may bill Medicare for the incident to services. **The Academy strongly supports the provisions in the proposed rule to expand remote patient monitoring (RPM).**

h. Bundled Payments

CMS is seeking comments on opportunities to institute principles associated with “bundled payments” into the PFS. Any system that supplements or replaces the existing PFS must be based on accurate data reflecting the true costs to provide the service or “basket of services”. It is also critical that agreement is reached on the full spectrum of services to be provided for the episode of care described in the bundle. Conceptually, this sounds relatively simple, however, in reality, it is a very complex process that is not easily accomplished.

The AAO-HNS has been in an episode-based project led by the American College of Surgeons and Brandeis University. For a significant number of commonly performed services, we feel that there is great potential for this model to be successful. If such a system is to be implemented, it must be with the understanding that adjustments will be needed on an early and regular basis until experience can dictate optimization of the valuation process.

The Academy believes that one area of potential applicability would be the current transition to more office-based procedural care for services which have typically been performed in the hospital or ASC settings. This type of structure would allow appropriate value for the services provided, while also accounting for the significant savings generated to the healthcare system through this transition. Major changes such as episode-based or bundled care should be validated through regional “pilot” programs prior to widespread adoption. Constructing a system that accurately reflects the elements included in the bundled service and true cost of those elements is quite difficult and labor-intensive. There is significant cost associated with this process and the reality is that very few can afford to undertake such a project without financial support. The Academy suggests this area warrants further investigation and would be willing participants in “piloting” new opportunities based on these principles.

II. QUALITY PAYMENT PROGRAM

a. Qualified Clinical Data Registries (QCDR)

CMS has included a considerable number of recommendations and modifications related to QCDR requirements. The unprecedented number of new requirements and change in measure requirements have the potential to effectively end the QCDR program and negatively affect the MIPS program going forward. Many specialties set up clinical data registries and QCDRs with multiple purposes in mind. These were created at great expense to the specialty societies and maintained at a significant unsubsidized cost. The proposed changes add significant expense and are yet another example of unfunded mandates. **Adoption of these proposals require QCDRs to perform services they are not designed to do and were not part of the original quality program.**

The most important potential benefit of these registries is not MIPS reporting, but the contribution to data driven scientific research that will define best care and lead advances in medicine. Requirements such as those proposed for 2020, along with the renewed discussion of intellectual property control, will have detrimental effects on the societal benefits these entities are already delivering, and will increasingly deliver in the future. The burdens added to QCDRs relative to Qualified Registries creates a markedly unlevel playing field that will produce consequences counter to the original intent of QCDR policies as initiated.

The Academy is concerned about the recent trend in attempting to expand responsibilities of QCDRs well beyond initially intended functions of these entities. In the CY 2020 proposed rule, CMS proposes that QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement in leading quality improvement initiatives. QCDRs were never intended as educational vehicles. Additionally, QCDRs are not equipped to monitor and validate the multiple different improvement activities taking place within the specialty across thousands of practices involving several thousands of clinicians nationwide. Aside from having to rely on additional vendors not contractually obligated to work with QCDRs, the cost to implement this mandate would be prohibitive. QCDRs should not be required to be the auditors for every CMS requirement.

b. Quality Data Submission Criteria

In the proposed rule, CMS seeks to increase the data completeness criteria to 70 percent for the 2022 MIPS payment year. The agency also proposes to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMS must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2020 MIPS performance period.

While the AAO-HNS would be able to transition to this requirement for those practices with electronic health records, this requirement will place a heavy burden on EPs in small and rural practices without EHRs who utilize the web-entry option of reporting through Reg-entSM, the AAO-HNS' clinical data registry. This represents approximately 15% of Reg-entSM participants. The additional time it would take to hand enter the increased volume of data would likely eliminate these EPs and practices from participation in the MIPS program since they do not have access to any other reporting mechanism (e.g. GPRO). The increase seems counter to CMS' overall strategy to reduce burden while improving quality. The inability to participate in MIPS, with associated 5-9% penalty, could cause some EPs to choose not to participate in the Medicare program.

c. Improvement Activities Performance Category

For the improvement activities performance category in 2020 performance year and future years, CMS is proposing to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent. The AAO-HNS disagrees with increasing the minimum

number of clinicians in a group or virtual group who are required to perform an improvement activity to 50%. This creates an undue burden on EPs, particularly specialists in multi-specialty practices or those not hospital-based, who may not be able to meet this new threshold for participation. Currently EPs reporting through QCDRs attest to their IA activities. To both increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity, and then to add the additional requirements that CMS is proposing for QCDRs to audit these activities, places an extra and unnecessary burden on both the EPs and the QCDRs

d. Performance Category Scores

In the NPRM, CMS is proposing to continue the scoring policies for measures that do not meet the case minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria; maintain the cap on measure bonus points for high-priority measures and end-to-end reporting; and continue the improvement scoring policy. In addition, the agency requests comment on future approaches to scoring the CAHPS for MIPS survey measure if new questions are added to the survey. As we have commented in past rulemaking cycles, the CAHPS for MIPS survey measure is not the best tool to measure the full scope of practice of our members. We would be interested in feedback from CMS as they look to modify this instrument. Specifically, if the agency would also consider adding the option of the surgical CAHPS for specialties, including Otolaryngology, whose EPs would find much more applicable to their patients and practice.

e. Example of Adjustment Factors

In detailing the most recent payment adjustment factor based on MIPS reporting, CMS highlights an issue that threatens to undermine the incentive for participating in the MIPS program. After accounting for all the exemptions and GPRO participants, the current MIPS participation levels make it impossible to achieve the advertised positive adjustment. We hope CMS will review and rework incentives so that high performing clinicians receive a more meaningful incentive for participation in MIPS. MIPS reporting requires investments in technology, staffing, as well as adjustments to workflows to meet quality measure requirements throughout the year. It is disheartening for practices committed to quality care and performing at exceptional levels to receive adjustments less than two percent for reaching the highest levels of MIPS scoring.

f. Targeted Review and Data Validation and Auditing

An authorized third-party intermediary, such as a qualified registry, health IT vendor, or QCDR, that does not have access to their clients' performance feedback still would be able to request a targeted review on behalf of their clients. Third party intermediaries do not have access to the performance feedback of MIPS eligible clinicians and groups; therefore, CMS is proposing to share an URL link to the Targeted Review Request Form with these designated entities. We appreciate CMS working to provide third party intermediaries with performance feedback of MIPS eligible clinicians and groups. **In addition, the AAO-HNS encourages CMS to provide registry-level reports regarding final scores and incentives so that third party intermediaries can appropriately assess the registry's performance. This will enable**

their QCDRs to more adequately identify gaps in care and develop guidance to support QCDR participants.

g. Third Party Intermediaries

The Academy's introductory remarks alluded to the substantial expansion of expectation for third party intermediaries including QCDRs. We will address the most significant of these proposed changes below. CMS is proposing that QCDRs support the Quality, IA and PI categories for CY 2020. The AAO-HNS' Reg-entSM registry supports all three categories of MIPS (Quality, IA, PI) as currently defined. However, we caution CMS that if additional requirements are placed on QCDRs for supporting all three categories and if complexity continues to increase year over year, many QCDRs, including Reg-entSM, will need to reevaluate offering reporting through their clinical data registries and their attainment of QCDR status.

CMS asks for input on whether they should narrow or broaden the proposed exemptions for when QCDRs must support the PI category. We support the scope of the proposed exceptions as stated and do not advise narrowing or broadening the proposed exceptions for when QCDRs and qualified registries must support the Promoting Interoperability performance category.

CMS proposes that a condition for approval as a QCDR the third-party intermediary must agree to provide a transition plan to an alternative data submission mechanism or third-party intermediary prior to discontinuing services. **The AAO-HNS is in support of providing overall guidance and education to practices considering a transition from one MIPS reporting solution to another. However, it would be extremely burdensome for a registry to have to do individual transition plans given that the decision in this circumstance lies with the EPs and their practices to make such a transition.** Should a QCDR/QR no longer be able to provide MIPS reporting services to its participants, the AAO-HNS recommends that a CMS-approved transition advisory plan be developed. The AAO-HNS also encourages CMS to remain sensitive to and flexible in dealing with any extenuating circumstances outside the registry's direct control that could lead to or cause an interruption in MIPS reporting services.

The NPRM contains a proposal that, beginning with the 2023 MIPS payment year, QCDRs must provide services to clinicians and groups to improve the quality of care provided to patients by furnishing educational services in quality improvement and leading quality improvement initiatives. CMS further proposes to require QCDRs to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. As a medical specialty society, the mission of the AAO-HNS is to foster quality improvement in otolaryngic care. This mission is accomplished via its education and research programs, products and initiatives, which are available to all AAO-HNS members including participants in the Reg-entSM registry. This requirement creates an undue burden for specialty society QCDRs to duplicate a portfolio of initiatives that are already available to all otolaryngology head and neck surgeons. The role of the QCDR should be to identify gaps in care/areas for performance improvement. While the AAO-HNS provides overall education and guidance, it should be up to individual EPs and their practices to identify the best solution for the best method for resolving the issue and to tailor their own program based on their practice.

CMS encourages QCDRs to provide timely feedback on a more frequent basis than four times a year. The AAO-HNS works with its clinicians to secure data as early as possible and EPs currently have routine access to a quality dashboard which is updated at least monthly. However, it is not always possible to have data earlier in the reporting period as the registry and participating practices are both dependent upon the practice EHR hosting solution. If a practice has a cloud hosted EHR solution, then both the registry and the practice must wait on that vendor to push accurate and valid data. As new measures are added and/or measures specifications change, delays do occur that are outside the control of the registry and the EP.

Beginning with the 2023 MIPS payment year, CMS proposes to require QCDRs to provide performance feedback to their clinicians and groups at least 4 times a year, as well as provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. All clinicians participating in Reg-ent, the AAO-HNS QCDR, Reg-entSM, can currently compare themselves to other clinicians who have submitted data on any given measure within not only the registry, but their practice peers and to registry averages and CMS benchmarks. Each practice may also download reports containing the same information. This additional requirement sets in place another process layered onto an already existing self-directed technology focused solution that will increase the burden placed on QCDRs. We see any additional requirements as not leading to any earlier identification of quality issues and as an unnecessary exercise without proven benefit. **Therefore, the AAO-HNS does not recommend this requirement be implemented in any reporting year.**

CMS is seeking comment for future rulemaking on whether clinicians and groups can start submitting their data starting April 1, to ensure that the QCDR is providing feedback and the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline. **The AAO-HNS does not support requiring the submission of MIPS reporting data multiple times throughout the year.** Registries and their participating practices invest significant time and resources into both securing data from EHRs and then validating all measures data for accuracy. This is done to assure that the data submitted to CMS is valid, accurate and complete. The AAO-HNS is concerned that data quality would be undermined in the attempt to meet deadlines for reporting multiple times per year.

Flexibility is very important given the dependency of practices and registries upon EHRs, the need for appropriate time to analyze and validate data prior to presentation in registry dashboards and then validate that data with practices and their clinicians, and the dependency of the registry upon clinicians to actively engage with their data. The April 1st deadline is particularly burdensome for QCDRs that offer a web entry tool as these QCDRs depend upon the participants to meet timelines for data entry. The AAO-HNS encourages CMS to maintain flexibility surrounding the requirements for data submission throughout the year as there are many factors not under the direct control of the registry that impact the ability to have data by April 1st.

The AAO-HNS supports randomized pre-submission audits of quality performance measures, however, we strongly disagree with the proposal to require QCDRs to audit the Improvement Activities and Promoting Interoperability categories of MIPS. This creates an undue burden for

QCDRs. This will require QCDRs to monitor multiple different improvement activities taking place over various 90-day periods across thousands of practices and involving several thousand clinicians nationwide. Auditing Promoting Interoperability categories also adds to a QCDRs burden by effectively forcing QCDRs to depend upon EHR vendors to share the data reports used by clinicians to attest to the Promoting Interoperability categories. Currently, QCDR participants face roadblocks and additional costs in receiving this data. It would be much more difficult, if not impossible, for QCDRs to secure this data. Adding requirements for QCDRs to support all three categories of MIPS in addition to audit requirements for all three categories will make many QCDRs reevaluate the ability to provide these services to their members due to the resources required.

The AAO-HNS suggests that CMS modify the public health and clinical data exchange objective so that there are two categories – clinical data registries and public health registries – and require EPs meet one or the other, or else have two exemptions. Now, most providers can claim 2 or more exclusions even when there is a clinical data registry available for them to report which does not incentivize EPs to participate in clinical data registries. CMS should clarify that registries created by EHR vendors do not count as clinical data registries. These registries do not promote interoperability, as the data stays within one vendor’s system, and these vendor “registries” are not helping to advance quality improvement or public health.

h. QCDR Measure Conditions

CMS proposes a QCDR measure that does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance years may not continue to be approved in the future. Beginning with the 2020 performance period, CMS places greater preference on QCDR measures that meet case minimum and reporting. **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 2 consecutive years. This would eliminate 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 get the volume CMS requires, but over time the volume will increase and the clinical benefit of reporting these measures will be realized. Specialty clinicians are engaged with their QCDR measures and invest significant effort and resources to support specialty measures. Removal of measures that address a specialist’s or sub-specialist’s scope of practice would undermine the AAO-HNS’s ability to improve patient care and would reduce meaningful engagement by clinicians in MIPS reporting.

i. QCDR Measures Testing

Beginning with the 2021 performance period, CMS proposes all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR

measure at the time of self-nomination. We note that the testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type. Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization.

The Academy agrees that QCDR quality measures should be developed with the appropriate rigor. In that regard, we have a comprehensive, physician-led process dedicated to development of otolaryngology specialty-specific measures. In addition, we have an advisory group of seven clinical advisory committees representing the specialties of otolaryngology-head and neck surgery who assist in the prioritization of important clinical topics within the specialty which will benefit from quality measurement. The majority of our measures are developed from our clinical practice guidelines with supporting evidence. We are currently in the process of publishing our process for measure development including testing in our specialty's journal, *Otolaryngology-Head and Neck Surgery*. Our measures go through appropriate testing with our clinical data registry Reg-entSM. As outlined in other sections of our comments, having to revert to utilizing a complex and expensive measures testing process will only delay getting appropriate measures into the program for use by our otolaryngologists.

With regard to CMS intent to move toward elimination of process measures and support of outcome-based measures only, the Academy agrees that outcome measures are valuable to the clinical process and to patients and caregivers. However, we urge CMS to consider that it is often not feasible to measure rare surgical outcome events during the course of one year in a way that is statistically appropriate or reliable. Some outcome measures that evaluate rare incidences require measurement over the course of multiple years to yield sufficient statistical power. Given the recommended one-year time-frame of the program, it can be inappropriate to use outcome measures for less common events. We propose that CMS interject flexibility to their proposed time frames for measures dealing with less common medical problems.

j. QCDR Measure Requirements

Beginning with the 2021 performance period and for future years, CMS proposes that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) cost measure (b)Improvement Activity; or (c) CMS developed MVPs. Under the pathway framework for example, a surgery specific QCDR should be able to correlate their surgery related QCDR measure to an MVP, such as the Major Surgery pathway. **The AAO-HNS disagrees with requirements to link QCDR measures to cost measures in the 2021 performance period and encourages CMS to defer this requirement until clear definitions and examples of each category (Cost, IA and MVP) have been proposed, commented on, and finalized. Doing so would ensure that ambiguities and overlap are avoided and decision making into which category a measure should be linked is readily apparent.**

k. Enhanced Performance Feedback Requirement

CMS proposes two changes to more expressly emphasize CMS enforcement authority. First, the agency proposes to clarify that remedial action and termination are triggered if it is determined that a third party intermediary submits a false certification. Second, the agency proposes to clarify in this proposed rule that CMS authority to bring remedial actions or terminate a third-party intermediary for submitting data that is inaccurate, unusable or otherwise compromise extends beyond the specific examples set forth in § 414.1400(f)(3). These revisions would affirm existing CMS authority to pursue remedial actions or termination if it is determined that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, submits a false certification under paragraph (a)(5), or has submitted data that are inaccurate, incomplete, unusable, or otherwise compromised. CMS anticipates that these proposed revisions will emphasize to third party intermediaries the sanctions they may face from the agency if they submit improper data to CMS. Finally, the proposed rule asserts that third party intermediaries may face liability under the federal False Claims Act if they submit or cause to submission of false MIPS data

As a QCDR/QR in good standing, the AAOHNS understands the importance of the accuracy of QCDR/QR submissions and providing a platform that instructs EPs and their practices how to accurately report and continually monitor performance through registry policy. We also have processes in place to maintain high quality in data submissions. **However, we caution CMS in their approach to enforcement authority that even with all safeguards in place, if a provider falsifies or inaccurately reports data, QCDRs/QRs cannot be held responsible and should not face termination.** This does not follow the CMS philosophy that when and if an issue is found, it is identified, and education is then provided through to issue resolution. The AAO-HNS agrees that intentional misreporting by a third party intermediary should result in CMS pursuing remedial action or termination.

I. QCDR Self-Nomination Applications

CMS presents its time and cost estimates for the QCDR self-nomination process. We appreciate CMS' concern for the costs of participation in the QCDR portion of the MIPS program. The agency's realization that, for all practical purposes, the MIPS program cannot succeed on a broad basis without the "donated time and expense" dedicated to this process by specialty societies through their quality programs and QCDR operations, is critical in the development of new processes and rules required to participate in the MIPS program.

The Academy takes issue with the estimated times and actual cost contained in the proposed rule. The "true costs" associated with a QCDR application, whether using the simplified or full application, must reflect more than the actual time to input the data required. This narrow view fails to account for the significant time and expense put forth by the QCDR nominator to create and maintain the registry and quality measures described in the application. Quality improvement is a complex endeavor. The proposed services are created through data review and clinician consensus regarding any previously identified gaps in care. Clinicians must then be recruited to develop quality improvement initiatives, staff hired to support and develop content and services identified by these clinicians, and finally, necessary technology secured to support the quality improvement services.

While it may take a few minutes to summarize, it can take up to one full year to create one quality improvement initiative. Additionally, each year data validation requirements change, which requires modification to existing plans previously approved. Each year, even when using the simplified process, an entirely new data validation plan and audit steps must be created, validated, submitted, reviewed and approved. These are in addition to basic operating requirements. After accounting for the above-mentioned costs, the “true cost” comes in many fold greater than recognized in the proposed rule.

m. IP considerations- QCDR Measure Requirements

The Academy has considerable concern that the issue of Intellectual Property (IP) continues to appear in CMS proposed rulemaking discussions. The CY 2020, CMS proposes that all MIPS quality measures that are not available to all eligible clinicians be removed for that reason alone. At this time this would not apply to QCDR-based measures, only MIPS measures. **The Academy is adamantly opposed to this proposal and reasserts the position that the IP rights afforded to QCDR measures equally applied to MIPS measures.** We feel that such a policy would undermine measure ownership and development and violate the intellectual property rights of measure owners. The ability of an organization to license measures incentivizes organizations like the AAO-HNS to invest in developing new and improved measures. Testing and stewarding measures is extremely resource intensive, requiring significant time and effort from physicians and staff members to develop these measures and additional time to test, maintain and implement the measures. Without the ability to license measures and collect reasonable royalties to offset the cost of developing measures, measure owners would have no way to control the appropriate use of their measures and cannot responsibly invest in future measure development.

If third parties can routinely use these measures and, in the case of commercial entities, profit from the society’s time and expense, medical societies may no longer be able to dedicate resources to developing these measures. The goal is not to limit physicians’ ability to report on the measures, but rather to protect the integrity of the measures by limiting inappropriate use in preventing commercial entities from profiting from the society’s intellectual property. We urge CMS to acknowledge and enforce the ownership rights of society owned measures.

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The Academy has worked collaboratively with other specialty societies on both the development of measures as well as in licensing each other’s measures for QCDR use. Developing, testing and stewarding measures is extremely resource intensive, requiring significant time and effort from physicians and staff

members to develop these measures and additional time to maintain and implement the measures. QCDRs should not be required to license their measures to third parties including commercial entities who can routinely use these measures, and profit from the society's time and expense and this may lead to medical societies no longer being able to dedicate resources to developing these measures. The goal is not to limit physicians' ability to report on the measures, but rather to protect the integrity of the measures by limiting inappropriate use in preventing commercial entities from profiting from the society's intellectual property. **We urge CMS to acknowledge and enforce the ownership rights of society owned measures.**

o. MIPS Value Pathway (MVP)

CMS proposes to apply a new MIPS Value Pathway (MVP) framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. The AAO-HNS appreciates that CMS is looking at a new and improved framework for MIPS and plans to engage with clinician professional organizations and front-line clinicians to develop the MVPs, however we caution CMS to provide enough of a timeframe for development including for feedback and piloting prior to making such a drastic change in the program. Specialty societies who have invested major resources in providing education and platforms for reporting in order to assist our members in meeting the requirements of the current MIPS program cannot expect our members to be able to adjust and transition to a completely revamped program by 2021. At a time when CMS is trying to reduce burdens on EPs, we caution CMS to thoroughly think through the timeline for incorporating an entirely redesigned program.

Although there currently is not enough detail provided in the Proposed Rule to adequately respond to all aspects of the MVPs program, we have identified several major concerns. First, is what role would QCDRs play in such a program? Although many societies, including AAO-HNS, have developed clinical data registries for multiple quality improvement endeavors, one of the major functions is to provide the ability for our members to successfully participate in MIPS. This has taken a significant investment and therefore it is important that QCDRs are incorporated in any new model being considered by CMS if they expect meaningful participation by specialty physicians. Secondly, our specialty consists of many subspecialties. There is not one clinical condition that is treated across even fifty percent of our physicians. Therefore, we caution CMS in its deployment of a hybrid approach where "clinicians would be measured on unified set of measures and activities around a clinical condition or specialty, layered on top of a base of population health measures, which would be included in virtually all of the MVPs".

Multiple MVPs will need to be developed in order to be representative of the full practice of otolaryngology-head and neck surgery. This will require cost measures and improvement plans, in addition to quality measures, that are specific to these subspecialty areas if we are interpreting the pathways correctly. Again, it will take time for these to be fully developed. While we agree that flexibility can lead to complexity, given the vast differences in the care provided and patients treated across the house of medicine, any program will still require flexibility to be successful. Finding the correct balance will take time and input from all parties. Finally, CMS has begun to develop specialty-specific episode-

based cost measures, but to date the vast majority of specialties are still using the default measures of Total Per Capita Cost and Medicare Spending Per Beneficiary. Since the MVP vision is to have cost measures link to specialty-specific quality measures and improvement activities, the development of episode-based cost measures specific to specialty/disease condition will need to accelerate to meet the needs of all participants in the program.

That being said, **the AAO-HNS supports the concept of transition to a system where there is alignment of all quality elements. If accomplished, this realization would be a great step forward to the final goal of a coordinated program that is easily understood by providers and appreciably improves patient care.** Most users of the current system would not categorize the current process as making any significant difference in promoting quality care. To reach that final goal, a process that follows normal workflows and day to day clinical decision-making thought processes is essential to gain maximum provider acceptance. Repackaging procedural measures that are only peripherally involved in the patient care process does not accomplish that goal. CMS must be willing to re-examine the entire measure development process to truly reach this goal. There is no way that the traditional NQF process will produce the type, breadth and volume of measures necessary to create a process that truly measures outcomes that patients and providers care about. We are in complete agreement that the current process has no chance of achieving that result.

The AAO-HNS is in the process of developing a “clinical pathway” based measure development process based on key decision points in clinical care episodes for several common disease processes in our field. This development is time-consuming and costly, but if we can establish a validated template the process is scalable. We would hope that CMS will be flexible and look at some of these models that we feel meet patient and system needs. We would also hope that finalized rules and requirements would include the opportunity to “pilot” some of these projects. Incumbent on these opportunities would be the understanding that we need to move forward from the current antiquated NQF strategy and allow novel measure development strategies based on actual clinical data from the registries.

p. Otolaryngology Measure Set

CMS requests comment on the proposed Otolaryngology specialty measure set as revised in the MPFS. The AAO-HNS has the following comments after review of the latest revisions to the Otolaryngology measure set. We agree with the removal of QPP 110 Preventive Care and Screening: Influenza Immunization and QPP 111 Pneumococcal Vaccination Status for Older Adults. However, we are opposed to the removal of one of the few specialty-specific measures, QPP 91, Acute Otitis Externa (AOE): Topical Therapy. This is an important measure to the specialty, is evidenced-based, and is applicable to the practice of many Otolaryngologists and other specialties who may treat these patients. **We strongly oppose its removal from the measure set We agree with the addition of the new Adult Immunization Status measure which replaces QPP 110 and 111.**

q. **Physician Compare**

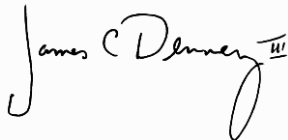
In past comments submitted to CMS, the Academy stated its support for the goal of Physician Compare to help consumers make informed health care decisions; however, we shared concerns that consumers who misunderstand what is represented in the quality score and improperly interpret data will be unable to use Physician Compare information in a meaningful way to make informed decisions. **The Academy remains concerned that consumers will be unable to understand and interpret the data CMS proposes publishing on Physician Compare, including “aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible; and (2) an indicator on the profile page or in the downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible”.**

The Academy continues to believe that the publicly reported data on Physician Compare should be derived from sources which adequately and appropriately demonstrate the quality of care provided and are presented in a manner easily understood by patients. **In addition, the Academy urges CMS to develop language clearly explaining that failing to meet a MIPS reporting criteria does not necessarily constitute poor quality of care so patients can appropriately make decisions regarding their choice of clinician.**

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 improve patient access to quality care. If you have any questions or require further information, please contact healthpolicy@entnet.org.

Respectfully submitted,



James C. Denny, III
Executive Vice President and CEO