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September 10, 2018

SUBMITTED VIA ELECTRONIC MAILING

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8013

[Submitted online at: <https://www.regulations.gov/document?D=CMS-2018-0076-0621>]

Re: CMS-1693-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program” published in the Federal Register on July 27, 2018. Our comments will address the following issues within the proposed rule: documentation requirements, E/M code collapse, application of MPPR to E/M services, balloon sinus surgery kits (SA106), practice expense, potentially misvalued services, valuation of specific codes, global surgery codes, telemedicine, and Quality Payment Program changes.

The AAO-HNS thanks CMS for its efforts to reduce administrative regulatory burdens for physicians by proposing to simplify documentation requirements for office and other outpatient Evaluation and Management (E/M) visits for new and established patients. We greatly appreciate the work being done through the Patients Over Paperwork Initiative to streamline regulations and reduce unnecessary burdens which providers face. We applaud your outreach to the provider community and are solidly behind your goal of reducing administrative burdens for physicians so they can devote more time to patient care.

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The proposals included in the 2019 NPRM demonstrate you listened to our members' concerns about the burdens caused by the documentation requirements associated with Evaluation and Management (E/M) services. We are grateful for your efforts to simplify these requirements and reduce their associated red tape. However, the Academy is concerned these policies, if finalized, may have unintended consequences that threaten Medicare beneficiaries ability to access care.

I. Documentation Requirements

The AAO-HNS applauds CMS for its willingness to consider significant structural changes in both its coding and payment systems to encourage a reduction in required documentation. CMS recognizes the detrimental effect administrative tasks can have on the overall wellness of physicians and other healthcare team members who perceive these tasks as non-essential to high-quality, successful patient care. Requiring only the documentation deemed essential to the accurate diagnosis and treatment of each individual patient would help restore a key component of the doctor-patient relationship, namely the face-to-face interaction.

CMS has proposed broad changes to reporting of E/M services including the associated documentation guidelines, same-day billing by practitioners of the same group and specialty, alteration of existing E/M code descriptions and valuation, removal of redundant E/M visit documentation, recognition of the resource cost for different types of E/M visits, and E/M resource overlap between stand-alone visits and procedural codes with global periods. We appreciate the substantial amount of work that CMS has done to study and amend this significant portion of the fee schedule. When taken as a whole, these proposals represent a complex series of changes that must fit together and work in concert to succeed. While the AAO-HNS thanks CMS for its efforts to account for the known effects these proposed changes would trigger, we have significant concerns, as set forth below, about the seemingly unintended consequences resultant from this broad-based proposal.

In general, while reduced documentation requirements are appreciated by the physician community, it is essential sufficient documentation remains in place to provide other members of a healthcare team the information necessary to care for the patient across all settings. The requirements must also suffice for medicolegal purposes. Further, as the evolution of data-driven quality metrics and improvement continues, a certain amount of documentation is necessary to help facilitate this transition which will ultimately result in better care for all. A primary example of these data needs is the Clinical Data Registry QCDR program. Finally, to the degree possible, documentation requirements across all payers should be the same. The burden of working within multiple systems for documentation would not only require EHR system enhancements, but also significantly add to the day-to-day stress for physicians.

More specifically, the Academy strongly supports the proposal to eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty. If finalized, this could provide a significant benefit to patients, particularly those who travel long distances. For example, a patient with head and neck cancer who also has chronic ear disease could be seen both by their cancer surgeon and an otologist to treat ear and hearing problems on the same trip. **The AAO-HNS also supports the elimination of the requirement for physicians to re-document information previously recorded in a patient's record, as well as the elimination of the requirement that teaching physicians must enter a separate note in the medical record.**

We do, however, have concerns with providing documentation based solely on the level of medical decision-making or face-to-face time. The AAO-HNS contends there is variable intensity in different portions of the E/M visit. Similar to surgical procedures where pre-and post-service services are valued at less intensity than in intra-operative service, these same stratifications should be recognized for counseling and coordination of care. **The AAO-HNS supports a revised system that integrates medical decision-making and time together as an acceptable form of documentation, as long as the record also includes adequate medical information for patient care.**

II. E/M Code Collapse

CMS proposes collapsing CPT codes 99202-99205 and 99212-99215 to develop a single payment rate for each of these codes that is roughly the equivalent of a Level 3.5 visit. On the surface, it sounds appealing for the provider community to only have to choose between two codes and document at a Level 2. However, the methodology used to structure and value these codes would not mirror the process used to value the rest of the fee schedule. The considerable scrutiny and methodology applied to describe and value physician work utilized by CPT and RUC, and subsequently approved by CMS, is not being followed in this circumstance. CMS seems to be acknowledging the lack of resource-based valuation by the inclusion of the add-on G codes. **While we would concur that five levels of E/M coding can be reduced, the AAO-HNS would recommend utilizing a process similar to the current CPT and RUC template where all stakeholders would have the opportunity to participate in a change of this magnitude, not just those chosen internally by the AMA.**

The AAO-HNS has concerns about the creation of new add-on G codes for primary care services (GPX1X), specialty care services (GCG0X), and prolonged services (GPRO1) to be utilized with the proposed collapsed E/M codes. Properly valued E/M codes should account for the resources used in providing them. For example, the services described by GPC1X should be built-in to the value of the E/M code with the additional recognition that many aspects of specialty care for chronic disease are similar to those provided by primary care, including counseling and coordination of care responsibilities. Similarly, GCG0X, which represents the proposed add-on code for visit complexity inherent to E/M associated with multiple specialty areas, should be built into and valued in the E/M service. One of the most concerning aspects of this proposed code would be the ability for any provider addressing disease processes within the named specialty areas to use this add-on whether or not they actually had the advanced expertise implied by the specialty designation. This could lead to a series of add-on codes to each patient visit that would inappropriately raise the overall cost of the service and, more importantly, the out-of-pocket cost for patients. Finally, the proposed prolonged services add-on (GPRO1) has been valued by taking 75 percent of a crossed-walked code 90785. The methodology used to select this cross-walk and the 8.75 minutes attributed is not clear, and similar to prior recommendations, we feel this calculation should be subject to the same scrutiny as the rest of the fee schedule. **For the above-stated reasons, the AAO-HNS believes the utilization of these type of add-on codes for the purpose of “equalization” should be addressed at the level of the primary service and would therefore oppose all three add-ons as proposed.**

An unintended consequence of the E/M code collapse proposal is a need to compensate for the effect of the proposal on indirect practice expense (PE) allocation for office visits. As part of establishing the

office visit single payment rates, CMS created a new Indirect Practice Cost Index (IPCI) solely for office visits and then transferred the indirect practice costs for office visits into the office visit IPCI and out of the IPCIs for all other specialties. As a result, many specialties, including otolaryngology, experienced very large IPCI changes with corresponding changes in payments to other services they provide. **Our specialty is subject to a -15 percent change in IPCI** and according to an analysis by AMA staff, 1100 CPT codes would experience a non-facility practice expense payment reduction that cannot be explained by any factor other than the IPCI change. These calculations do not mirror the resource use actually taking place in the physician office. Three specialties would experience a reduction of at least \$50 million in their indirect practice expense allowed charges for all services excluding office visits (Dermatology, Ophthalmology, and Otolaryngology). A redistribution of this magnitude not only creates enormous financial instability, it also ignores statutory requirements that payments under the physician fee schedule be resource-based. **The AAO-HNS believes that the development of an E/M Practice Expense/Hour and resulting IPCI distorts the relativity of the RBRVS and has massive unintended payment effects across the physician fee schedule.**

One final note on the proposed E/M collapse relates to Tables 21, 22, and 23. In an effort to achieve budget neutrality, the cost of the proposed changes to E/M payment would be offset, at least partially, by a proposal to reduce payment by 50 percent for the lower-valued CPT code when patients receive an E/M visit and procedure on the same day (see further analysis below). In Tables 21, 22, and 23 of the proposed rule, CMS provides estimates as to the net effect of these proposed changes on each specialty. However, based on data we received from otolaryngology practices representing roughly 10 percent of our membership, our calculations do not mirror the published projections by CMS. In fact, the differences are significant in certain cases. Therefore, the AAO-HNS is concerned that the lack of specificity regarding how these broad-based proposals will actually be implemented make validation of the impact tables by outside entities challenging. The AAO-HNS respectfully requests that any proposed changes be sufficiently transparent that their effects can be accurately calculated or replicated by multiple sources.

Overall, the E/M reform and documentation initiative proposed by CMS has great potential. The AAO-HNS would volunteer to participate, along with other stakeholders, in crafting a system that would be applicable to all payers that would simplify both the documentation and payment for E/M services. This would involve similar in-depth study methodology to value resources utilized relative to each other. The resulting benefit to patients and the provider community would help facilitate the ultimate transition to quality, value-based care.

III. Application of MPPR to E/M Services

Under the current PFS, E/M services are generally paid in one of two ways: as standalone visits using E/M visit codes, or as a part of global procedural codes. In both cases, RVUs are allocated to the services to account for the estimated relative resources involved in furnishing professional E/M services. In the case of procedural codes with global periods, the overall resource inputs reflect the costs of the E/M work considered to be typically furnished with the procedure. Therefore, the standalone E/M visit codes are not billable on the same day as the procedure codes, unless the billing professional specifically indicates that the visit is separately identifiable from the procedure.

In cases where a physician furnishes a separately identifiable E/M visit to a beneficiary on the same day as a procedure, payment for the procedure and the E/M visit is based on rates generally developed under the assumption that these services are typically furnished independently. In CY 2017 PFS rule, CMS noted that the current valuation for services with global periods may not accurately reflect much of the overlap in resource costs, and CMS has indicated particular concerns when a standalone E/M visit occurs on the same day as a 0-day global procedure.

In introducing its proposal for services currently reported with modifier 25, CMS references other existing policies under the PFS that reduce payments if multiple procedures are furnished on the same day to the same patient. Specifically, Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient by the same physician on the same day, largely based on the presence of duplicative service in PE and pre- and post-surgical physician work areas.

Based on the proposal delineated in the NPRM, supplementary information provided on the CMS website, and guidance from CMS staff shared through teleconference and in-person meetings, it is our understanding that CMS proposes to add the ten office visit CPT codes (99201-99215) to the list of codes with a surgical multiple procedure payment (MPPR) indicator of “2.” This effectively negates the current usage of the 25 modifier and would result in a 50 percent reduction in payment for the CPT code with the lowest total RVU value. This proposed policy change would have a widespread effect given there are currently over 5000 codes on this list.

The AAO-HNS contends this proposed alteration is distinctly different from the existing MPPR rules applied to the current definition of “multiple procedures.” We are concerned that the proposed reduction is based on inaccurate information related to overlapping time in the pre-and post-service categories. The RUC, along with its constituent national medical societies and other healthcare professionals, has established a table of “Pre-Service Time Packages” (included below) that has been accepted nationally, as well as by CMS through rulemaking. While there is no specific table or written guideline that applies to post-service times, a generally agreed-upon template includes “communication with the patient and/or their family” about the findings of the procedure and the post-operative care of the procedure performed.

Detailed Description of Pre-Service Time Packages (Minutes)							
		FACILITY				NON-FAC	
		1	2	3	4	5**	6
DETAILS							
A	History and Exam (Performance and review of appropriate Pre-Tests)	5	10	10	15	4	9
A	Prepare for Procedure (Check labs, plan, assess risks, review procedure)	2	2	2	4	1	1
A	Communicate with patient and/or family (Discuss procedure/ obtain consent)	3	3	5	5	2	3
A	Communicate with other professionals	0	0	5	5	0	2
A	Check/set-up room, supplies and equipment	1	1	5	5	0	1
A	Check/ prepare patient readiness (Gown, drape, prep, mark)	1	1	5	5	0	1
A	Prepare/ review/ confirm procedure	1	1	1	1	0	0
B	Perform/ supervise patient positioning	1	1	3	3	0	1
C	Administer local/topical anesthesia	1	1	0	0	1	5
C	Observe (wait anesthesia care)	0	0	10	15	0	0
C	Dress and scrub for procedure	5	5	5	5	0	0

**If the procedure does not require local anesthesia, 1 minute should be removed from pre-service time

1	Straightforward Patient/Straightforward Procedure (No anesthesia care)
2	Difficult Patient/Straightforward Procedure (No anesthesia care)
3	Straightforward Patient/Difficult Procedure
4	Difficult Patient/Difficult Procedure
5	Procedure with minimal anesthesia care (If no anesthesia care deduct 1 minute)
6	Procedure with local/topical anesthesia care requiring wait time for anesthesia to take effect

When valuing 0-day global procedures performed in the non-facility setting, the RUC has specifically worked to ensure there are no duplicative or overlapping times or resource costs embedded in procedure codes typically performed with an E/M service on the same day. The RUC's Relativity Assessment Workgroup applies its established screening mechanisms and reviews all procedures when same-day E/M services are typically reported to ensure the duplicate work has been accounted for. Additionally, AMA staff provides ongoing data analysis to specialties and the RUC in the development and review of both work RVUs' *indirect* practice expense costs in preparation for RUC review. Those analyses include information regarding the performance of an E/M on the same date of each procedure code.

To aid in our analysis of the proposed changes, the AAO-HNS has performed a detailed review of the most commonly-billed codes in our specialty that were also classified as having a "2" designation on the "surgical multiple procedure payment indicator table." We also reviewed one commonly-performed procedure in a similar family that is not designated as a "2." Specifically, we examined codes 30901 (Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method), 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)), 31575 (Laryngoscopy, flexible; diagnostic), 69210 (Removal impacted cerumen requiring instrumentation, unilateral) and 69220 (Debridement, mastoidectomy cavity, simple (e.g., routine cleaning)) which are all designated "2" under the "surgical multiple procedure payment indicator table" and 31579 (Laryngoscopy, flexible or rigid telescopic, with stroboscopy), which is designated "3." Below please find our analysis of each.

30901

CMS currently values this code based on a pre-service evaluation time of 6 minutes, a scrub, dress, and wait time of 5 minutes, intra-service time of 10 minutes, and a post-service time of 5 minutes. The AAO-HNS feels all of these times are justified based on the “Pre-Service Time Packages Table.” There is no time allocated for “History and Exam” in the 6 minutes of pre-service time which represents “Prepare for Procedure,” “Communicate with patient and/or family (Discuss procedure/obtain consent).” “Check/set-up room, supplies and equipment,” and “Check/prepare patient readiness (Gown, drape, prep, mark).” The 5 minutes currently allocated for post-service time includes observation to ensure successful control of the hemorrhage, discussion with the patient/family about the procedure, care of the operated area, and documenting the procedure. **This does not overlap with the post-service time allocated for the E/M visit, which would entail discussion of all abnormalities found, as well as a long-term strategy to deal with those problems.**

31231

This code is currently valued based on a pre-service evaluation time of 5 minutes, a pre-service positioning time of 1 minute, a scrub, dress, and wait time of 5 minutes, intra-service time of 7 minutes, and a post-service time of 3 minutes. The AAO-HNS asserts all of these times are justified based on the “Pre-Service Time Packages Table.” There is no time allocated for “History and Exam” in the 5 minutes of pre-service time which represents “Prepare for Procedure,” “Communicate with patient and/or family (Discuss procedure/obtain consent),” “Check/set-up room, supplies and equipment,” and “Check/prepare patient readiness (Gown, drape, prep, mark).” The currently allocated 3 minutes for post-service time represents discussion with the patient and/or family about the findings of the procedure, care of the nose post-operatively and documenting the procedure. **This does not overlap with the post-service portion of the E/M visit, which includes a full assessment of the patient’s condition and treatment recommendations.**

31575

This code is currently valued based on a pre-service evaluation time of 8 minutes, a pre-service positioning time of 1 minute, a scrub, dress, and wait time of 5 minutes, intra-service time of 5 minutes, and a post-service time of 5 minutes. The AAO-HNS contends all of these times are justified based on the “Pre-Service Time Packages Table.” There is no time allocated for “History and Exam” in the 8 minutes of pre-service time which represents “Prepare for Procedure,” “Communicate with patient and/or family (Discuss procedure/obtain consent),” “Communicate with other professionals,” “Check/set-up room, supplies and equipment,” and “Check/prepare patient readiness (Gown, drape, prep, mark).” The currently allocated 5 minutes for post-service time represents discussion with the patient and/or family about the findings of the procedure (including reviewing the video), care of the nose post-operatively, and documenting the procedure. **This does not overlap with the post-service portion of the E/M visit, which relates the findings of the procedure to the overall diagnosis and treatment planning for the disease process.**

69210

This code has undergone multiple reviews by the RUC and CMS. It was originally valued by the RUC as a unilateral code with the understanding that if the second ear was done the MPFS would apply with a 50 percent reduction. CMS rejected that and valued the code as either a unilateral or bilateral procedure. The current valuation includes a pre-service evaluation time of 3 minutes, a pre-service positioning time of 2 minutes, intra-service time of 10 minutes, and a post-service time of 2 minutes. There is no time allotted for any E/M service, and we feel that all of the pre-service time is consistent with the valuation stated in the “Pre-Service Time Packages Table.” The 2 minutes of post-service time is strictly allocated for communication with the patient/family and going over strategies to limit the problem in the future as well as documenting the procedure. **This does not overlap with the post-service time of the E/M visit, which relates to the problem triggering the initial visit including the diagnosis and management of the condition.**

69220

CMS has currently valued this code based on a pre-service evaluation time of 5 minutes, a pre-service positioning time of 1 minute, intra-service time of 10 minutes, and a post-service time of 2 minutes. The AAO-HNS asserts all of these times are justified based on the “Pre-Service Time Packages Table.” There is no time allocated for “History and Exam” in the 5 minutes of pre-service time which represents “Prepare for Procedure,” “Communicate with patient and/or family (Discuss procedure/obtain consent),” “Check/set-up room, supplies and equipment,” and “Check/prepare patient readiness (Gown, drape, prep, mark.)” The currently allocated 2 minutes for post-service time represents discussion with the patient and/or family about the findings of the procedure, care of the ear post-operatively, and documenting the procedure. **This does not overlap with the post-service portion of the E/M visit which goes over the entire assessment of the patient’s hearing and balance condition and treatment recommendations.**

31579

This code is currently valued based on a pre-service evaluation time of 8 minutes, a pre-service positioning time of 1 minute, a scrub, dress, and wait time of five minutes, intra-service time of 10 minutes, and a post-service time of 10 minutes. The Academy contends all of these times are justified based on the “Pre-Service Time Packages Table.” There is no time allocated for “History and Exam” in the 8 minutes of pre-service time which represents “Prepare for Procedure,” “Communicate with patient and/or family (Discuss procedure/obtain consent),” “Communicate with other professionals,” “Check/set-up room, supplies and equipment,” and “Check/prepare patient readiness (Gown, drape, prep, mark.)” The currently allocated 10 minutes for post-service time represents discussion with the patient and/or family about the findings of the procedure (including reviewing the video), care of the nose post-operatively, as well as the immediate care of the laryngopharynx related to the application of the topical anesthetic, and documenting the procedure. **This does not overlap with the post-service portion of the E/M visit which relates the findings of the procedure to the overall diagnosis and treatment planning for the vocal problem and related disease.**

Based on our analysis of these codes, the AAO-HNS strongly opposes the addition of E/M office visit codes (99201-99215) to the surgical multiple procedure payment indicator list. The medical

community and CMS have worked diligently to remove any overlap in the physician work and practice expense for procedures commonly performed during the same encounter as an office visit, as demonstrated by the individual code analysis listed above. If enacted, the proposal would result in an excessive, unjustified reduction in reimbursement. **The AAO-HNS respectfully requests that CMS not implement this portion of the proposed rule which would disproportionately impact our members who are appropriately using the 25-modifier to report services performed.**

IV. Balloon Sinus Surgery Kits (SA106)

The AAO-HNS recognizes the significant advances in the equipment and supplies used to perform balloon dilation of the sinuses and appreciates the opportunity to comment on the current status of the procedure. We agree accurate pricing and utilization frequency are essential to ensuring fair fee schedule valuation.

In the proposed rule, CMS requested stakeholder input on accurate pricing of a sinus surgery balloon (maxillary, frontal, or sphenoid) supply kit (SA106) that is used to perform CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa), 31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)), and 31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)). In addition, we would suggest the addition of CPT code 31298 (Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g. Balloon dilation)). This new code, introduced in the 2018 fee schedule, was not included when the original codes were first valued in 2011.

Pursuant to the opportunity to comment, the AAO-HNS has sought out and received input from multiple sources regarding the composition and pricing of currently utilized kits needed to perform the above-named procedures, as well as the actual number of sinus dilation procedures that typically can be performed per balloon. Our members, the facilities where they work, sub-specialty society leaders, and the device manufacturers all contributed valuable information leading to our comments and recommendations below.

First, we would like to address the pricing and composition of the kits themselves. The AAO-HNS recognizes that current pricing for this kit or its individual components was adopted through rulemaking in CY 2011. CMS is therefore soliciting comments as to whether the current pricing of the balloon sinus surgery kit is reflective of true cost. The AAO-HNS has reviewed invoices from multiple sources representing surgeons with varying utilization levels, as well as pricing from the manufacturers themselves. It is important to note that the components of the supply kits have changed from those listed in Table 5 (Balloon Sinus Surgery Kit (SA 106)). The current package compositions are reflected in the tables below:

Manufacturer 1

Supply Components – Kit # 1
Balloon catheter dilation device
Light fiber for transcutaneous confirmation
Extension Tubing for proper 12A inflation of the balloon
Inflation Syringe
Bending tool that allows manipulation of angle for treatment of the sinus

Supply Components – Kit # 2
Irrigation and suction device
Syringe for saline delivery
Bending tool for manipulation of angle treatment

Manufacturer 2

Supply Components – Kit # 1
Ultirra Balloon Catheter
Low Profile Handle
Luma Sinus Illumination System
Flex Frontal Sinus Guide Catheter
Flex Maxillary Sinus Guide Catheter
Flex Sphenoid Sinus Guide Cather
SEID Inflation Device
Light Guide Cable
ACMI Light Guide Cable Adapter

Supply Components – Kit # 2
SpinPlus Balloon Sinuplasty System
SEID Inflation Device
Light Guide Cable
ACMI Light Guide Cable Adapter

Supply Components – Kit # 3
Ultirra Balloon Catheter
Low Profile Handle
NavWire Navigation Guidewire
Flex Frontal Sinus Guide Catheter
Flex Maxillary Sinus Guide Catheter
Flex Sphenoid Sinus Guide Cather
SEID Inflation Device
Navigation System

Supply Components – Kit # 4
SpinPlus NAV Balloon Sinuplasty System
SEID Inflation Device
Navigation System

Manufacturer 3

Supply Components – Kit
Inflator Kit
Patient Tracker Non-Invasive
Instrument Tracker ENT 1PK
Balloon Seeker 70DG FRT
Balloon Seeker EM SPHN
Balloon Seeker EM MAXL

The above-listed supplies are utilized in combination in the contemporary performance of CPT codes 31295, 31296, 39217, and 31298. Two manufacturers currently offer a navigation option that requires a different kit composition than the kit used without navigation. Based on the information we received, the AAO-HNS would offer that the total cost of the balloon sinus surgery kit varies by sinus dilated, whether navigation is used, and by manufacturer. The average price for the “basic kit” which is capable of dilating the maxillary, frontal, or sphenoid sinus is \$2,204. The average cost of the kit used for navigation is \$2,850, not including the navigation device itself. These figures represent a price available to all surgeons performing these procedures, so it does not include discounts which may be available to select individuals or entities. Due to the confidential and proprietary nature of the information involved, specific invoices can be made available to CMS staff upon request to support this figure. We also believe the kit components should not be individually priced.

Second, the AAO-HNS would like to address the actual number of sinus dilation procedures that typically can be performed per balloon. Since there has been considerable debate over the proper methodology to accurately value the PE related to the number of balloons used per sinus, as part of this dialogue, the AAO-HNS believes it is important to summarize prior discussions dating back to 2011 on this issue. The AAO-HNS supported the AMA RUC’s past recommendation to establish separately billable HCPCS codes to report supplies actually used. However, CMS adopted the policy of allowing a value of 0.5 of a balloon kit per sinus dilated, noting that the sinus dilation codes are typically billed in units of two.

The AAO-HNS continues to assert that the quantity of supply items should reflect the actual units of the item utilized in the performance of an individual procedure. The variability inherent in the underlying anatomy, particularly the frontal sinus, makes it extremely difficult to reliably assign a fixed number of sinuses that can be dilated per balloon. We believe that with the additional option of navigation, which creates additional expense, it is more difficult to utilize a “generic” model and accuracy demands individual pricing based on utilization per case. **Therefore, the AAO-HNS would respectfully urge CMS to consider a shift away from the current methodology used that allows 0.5 sinus kits per sinus,**

and instead create a separate HCPCS code for the balloon sinus surgery kit that would be billable based on the number of balloons actually used per patient. This is the most accurate way to capture the actual costs.

Should CMS elect to preserve the current policy of assigning a fixed number of sinus dilations per kit, we recommend maintaining the current system that allows one kit for every two sinuses. We fully recognize the current system does allow potential payment for more resources than actually utilized in select individual circumstances. However, we have not been able to find compelling evidence that would indicate whether one, two, three, or four sinuses is the most appropriate number. In the absence of such data and a decision not to create new HCPCS code(s), the AAO-HNS supports maintaining the allowance of one kit for every two sinuses.

V. Practice Expense

A. Standardization of Clinical Labor Tasks

In reviewing the RUC-recommended direct PE inputs for CY 2019, CMS noted that the 3 minutes of clinical labor time traditionally assigned to the “Prepare room, equipment and supplies” (CA013) clinical labor activity were split into 2 minutes for the “Prepare room, equipment and supplies” activity and 1 minute for the “Confirm order, protocol exam” (CA014) activity. These RUC-reviewed codes do not currently have clinical labor time assigned for the “Confirm order, protocol exam” clinical labor task, and CMS does not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. As a result, CMS is proposing to maintain the 3 minutes of clinical labor time for the “Prepare room, equipment and supplies” activity and remove the clinical labor time for the “Confirm order, protocol exam” activity wherever it observed this pattern in the RUC-recommended direct PE inputs. CMS notes there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being used in the calculation of PE RVUs. **The AAO-HNS supports this proposal as put forth by CMS in the NPRM.**

B. Equipment Recommendations for Scope Systems

i. Scope Video System

The AAO-HNS appreciates CMS’ decision to accept further recommendations on this topic, and as such, we are reiterating our comments on the 2017 MPFS final rule.

In response to CMS’ comments that previously submitted invoices were too old, or that it received conflicting information on the pricing of certain pieces of scope equipment, the AAO-HNS engaged one of our industry partners to generate detailed pricing information on each of the scope system items. These items include: the five components of the video endoscopy system (printer, cart, monitor, processor, and digital capture); LED lights, rhinolaryngoscope, and a stroboscopy system. We believe the data previously submitted supports current pricing and, in many cases, demonstrates that present reimbursement rates are too low for many direct PE equipment items.

Based on the data gathered, we are concerned CMS' proposed pricing for both the video system (ES031) and the stroboscopy system (ES065) are less than the true cost of the equipment items, and therefore do not accurately reimburse physicians for their direct overhead costs. Further, CMS states it did not receive any data to indicate the new invoices were more typical than those utilized previously. We have supplied more recent invoices which should be taken into consideration in pricing, or re-pricing, these items.

Additionally, regarding CMS' proposal to create single scope equipment categories for all specialties, to include: 1) rigid scope; 2) semi-rigid scope; 3) non-video flexible scope; 4) non-channeled flexible video scope; and 5) channeled flexible video scope, we have significant concerns. While it conceptually makes sense to streamline these direct PE inputs for ease of review and pricing via rulemaking, this equipment is not always comparable across specialties who utilize it. For example, a rigid endoscope used by a gastroenterologist as compared to an otolaryngologist may vary in price significantly.

ii. Scope Accessories

The AAO-HNS supports the accessories included in the proposed list from CMS for scope video systems.

iii. Scope Proposals for CY 2019

The AAO-HNS appreciates CMS' decision to delay further changes to Scope Proposals within the MPFS until CY 2020 to allow integration of the RUC Scope Equipment Reorganization Workgroup. We are actively participating in that workgroup and feel its input will be very useful to CMS in revising policies in this regard.

We also appreciate the proposal to increase the price of the scope video system (ES031) from its current price of \$33,391 to a price of \$36,306. This reflects the addition of the LED light and miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories. We also appreciate the update to the name of the ES031 equipment item from "video system, endoscopy (processor, digital capture, monitor, printer, cart)" to "scope video system (monitor, processor, digital capture, cart, printer, LED light)" since the use of the ES031 scope video system is not limited to endoscopy procedures.

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

CMS proposes to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in 10 and 90 day global codes. **The AAO-HNS supports this effort as it serves to remedy any discrepancies/errors that may be in the fee schedule related to post-operative visits and the required multi-specialty packs needed to render those visits.**

D. Market-Based Supply and Equipment Pricing Update

The AAO-HNS appreciates CMS' desire to update supply and equipment pricing to ensure accuracy within the practice expense RVUs for services within the MPFS. We have concerns, however, that there

are some drastic changes in pricing for many supplies and pieces of equipment within the proposed spreadsheet from Strategygen. We understand that this is intended to be tempered by a four-year phase-in, however, we urge CMS to consider a cap on the overall reductions in excessive cases.

For new supply and equipment codes for which CMS establishes prices during the transition years (CYs 2019, 2020, and 2021) based on the public submission of invoices, CMS proposes to fully implement those prices with no transition since there are no current prices for these supply and equipment items. **The AAO-HNS supports this proposal as the pricing will be based on the most accurate information available at the time of valuation, derived from current and valid invoices from specialty societies or industry partners.**

E. Allergy and Immunology Codes

CMS requested comment regarding the supply and equipment pricing for CPT codes 95165 *Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)* and 95004 *Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests*. The AAO-HNS is extremely concerned about the drastic changes to pricing for these services commonly reported by our members.

For 2019, CMS proposes to reduce supply item SH007, *antigen, multi (pollen, mite, mold, cat)*, from \$6.70 to \$4.78 for 1 ml of antigen. **The proposed 29 percent decrease in the antigen costs does not reflect the current reality of the true costs for these supplies.** This decrease is particularly confounding given the RUC's recent review of the PE input for this code in 2016. SH007 represents the average cost of a variety of antigens and the typical amount to prepare is 10 doses. The proposed price of \$4.78 is too low to capture the full range of antigens and their costs. The current price of \$6.70 better reflects the full range of antigen costs, but this price should also be updated as costs have increased dramatically just within the last year. **We encourage CMS to accept invoices and other supporting materials from specialty societies, such as the AAO-HNS, to appropriately revise the pricing of the antigen, supply item SH007.**

Regarding CPT code 95004, it was recently reviewed by the RUC in October 2016. The direct practice expense costs for this code will only decrease by \$0.01 from \$3.03 in 2018 to \$3.02 in 2019, if the repricing proposal is implemented. This seems to be without a decrease to the antigen SJ092 *allergen, diagnostic, multi (eg, pollen, mold, environmental)* as this supply item is not listed on the recommended CMS price report, nor is SJ093 *allergy single-test device*. The AAO-HNS assumes that the current CMS price remains effective as those are the values listed in the direct PE input public use files.

Despite the minor direct PE cost decreases, CMS proposes to reduce the non-facility PE RVU for CPT 95004 from 0.13 to 0.10. For CPT code 95165, the PE RVU reduction is from 0.30 to 0.26. **This represents a decrease in overall non-facility payment of 10.7 percent and 19.9 percent, respectively. Such reductions could have a significant impact on patient access to immunotherapy for allergy care.**

There are a number of factors used in the PE RVU methodology including direct costs, as well as direct and indirect scaling adjustments, indirect costs, physician time, and work RVU. Utilizing this complex formula, it is difficult to single out one primary driver of a PE RVU change. However, the dramatic change in the PE RVU for many services, including 95004 and 95165, are certainly tied to the dramatic decrease in the Indirect Practice Cost Indices (IPCI). The Allergy/Immunology IPCI is 36 percent lower in 2019 (0.59153) as compared to 2018 (0.92911). As discussed in Section II, the larger than normal fluctuation in IPCI is linked to defining E/M as its own specialty in the specialty level IPCIs, impacting the indirect PE used in the formula to determine the PE RVU.

VI. Potentially Misvalued Services

Otolaryngology-Head and Neck Surgery did not have any codes impacted by the public nomination screen proposed for CY 2019. We have routinely reviewed the existing screens required by statute and feel these screens, along with the standing Relativity Assessment Workgroup's screens utilized through the RUC process, are sufficient to capture all potentially misvalued services with any meaningful volume.

VII. Valuation of Specific Codes

A. Physician Work

i. Fine Needle Aspiration (CPT codes 10021, 10X11, 10X12, 10X13)

CMS has proposed the RUC-recommended work RVUs for CPT codes 10X11 and 10X13. **The AAO-HNS agrees with this proposal and urges CMS to finalize the RUC-recommended physician work RVUs of 0.80 for 10X11 and 1.00 for 10X13.**

However, CMS rejected the RUC work recommendations for 10021 and 10X12. The rationale for both of CMS' proposed reduced values is based on the notion that the work RVU should be reduced with a reduction in time. This approach discounts the well-established physician work survey process and elevates the time components to the highest level of importance. This change in the methodological processes discounts the true physician work provided and does not take into account the intensity, complexity, and details of patient care.

The RUC noted that the current times in the RUC database were from 1995 and resulted in an inappropriately low IWP/PUT of 0.034. Therefore, the RUC agreed the drop in total time did not warrant a proportional change in work RVU as the previous times were not appropriate. The 10 minutes of pre-service time is appropriate to explain the procedure to the patient, including potential complications, obtain informed consent, position and prep the patient, and clean the biopsy site with disinfectant and inject local anesthesia and wait for it to take effect. The 8 minutes of post-service time is necessary to prepare a report of the procedure for the medical record. The slides and cell block solution are checked to insure proper sealing and transportability to pathology (either locally or via mail). The appropriate clinical history documents, labeling, and requisition forms are packaged in the sealed, transportable packaging and sent to the appropriate pathology agency. The patient is monitored for any evidence of hematoma, bleeding, drug

reaction, or other complication(s). The RUC reviewed the survey 25th percentile work RVU of 1.20 and agreed that this value appropriately accounts for the physician work involved.

The RUC's recommended work RVU and service period times are supported by the two most commonly chosen key reference services:

- 32554 (*Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance*), chosen by 27 percent of respondents, and
- 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.*), chosen by 8 percent of respondents.

The difference between the chosen key reference services and the surveyed code reflect the multiple specialties participating in the survey and the limitations of the reference service list. Specifically, there are few appropriate XXX global procedure codes to compare with this service. Even with the wide time and RVU ranges spanned by these comparisons, the relativity of the values is appropriately reflected. The surveyed code, 10021, has less intra-service time than both key reference codes, more pre-time than the E/M but less than the thoracentesis, less post-time than both procedures, and less total time than both procedures. These differences are appropriately reflected in the recommended WRVU. Accordingly, 10021 has a lower recommended WRVU.

In addition, the RUC's recommended RVU of 1.20 for 10021 is supported by two MPC codes with XXX global periods:

- 99283 (*Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.*), which has slightly more intra-service time and slightly shorter total time, and
- 74170 (*Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections*), which has a higher WRVU, slightly longer intra-service time, and less total time.

In order for the proper valuation and rank order throughout the physician fee schedule, the AAO-HNS urges CMS to accept the RUC's recommended physician work value of 1.20 for 10021.

For CPT code 10X12, CMS proposes to base the value off of its proposed value of 10021. Again, the AAO-HNS urges CMS to discard its use of time ratios to value physician services and use the integrity of the RUC and its physician survey processes. The RUC noted that the current times in the RUC database for 10022 were from 1995 and resulted in an inappropriately low IWPUT of 0.034. Therefore, the RUC agreed the drop in total time did not warrant a proportional change in work RVU as the previous times were not appropriate.

Our recommended work RVU and service period times fall between the two most commonly chosen key reference services (KRS):

- 32555 (*Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance*), chosen by 45 percent of respondents, and
- 76536 (*Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation*), chosen by 9 percent of respondents.

The difference between the chosen key reference services and the surveyed code 10X12 reflect the multiple specialties participating in the survey and the limitations of the reference service list. Specifically, there are few appropriate XXX global procedure codes to compare with this newly-bundled service. Additionally, since the imaging guidance was bundled into these new codes, it was unavailable as a comparison for the survey respondents.

Even with the wide time and RVU ranges spanned by these comparisons, the relativity of the values is appropriately reflected. The surveyed code, 10X12, has twice the intra-service time of 76536, more pre- and post-time, and is an invasive procedure as opposed to a diagnostic imaging study. These differences are appropriately reflected in the recommended WRVU. While 10X12 has the same intra-service time as 32555, it has much less pre- and post-service time, as well as being a relatively safer invasive procedure. Accordingly, 10X12 has a lower recommended WRVU.

The surveyed code (10X12) is bracketed by two non-radiology MPC codes with XXX global periods:

- 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.*), which has identical intra-service time and slightly shorter total time, and
- 93351 (*Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional*), which has a higher WRVU, identical intra-service time, and slightly less total time.

The surveyed code (10X12) has 10 more minutes of pre- and post-service time than 99203, which itself accounts for the WRVU difference of 0.21 WRVUs. As well, 10X12 has the same intra-service time as 93351, as well as more pre-service time, but a lower WRVU recommendation. We believe 10X12 is appropriately positioned in the RBRVS at the recommended value given these comparisons.

In order for the proper valuation and rank order throughout the physician fee schedule, the AAO-HNS urges CMS to accept the RUC's recommended physician work value of 1.63 for 10X12.

ii. **Removal of Impacted Cerumen (HCPCS code G0268)**

CMS proposes the RUC-approved value of .61 WRVU for this code. The AAO-HNS supports this recommendation and encourages CMS to finalize this value for CPT G0268 for the 2019 MPFS.

B. PE Direct Input Refinements

Regarding CMS' specific recommendations to amend direct PE inputs for the code families discussed above, please see the attached spreadsheet (Attachment A) which addresses specific changes proposed by CMS. These comments are consistent with those submitted by the AMA and the RUC related to proposed changes for these codes.

VIII. Global Surgery Codes

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) included a provision requiring CMS to implement a process to collect data on the number and level of postoperative visits related to 10- and 90-day global codes. In response, CMS finalized a claims-based data collection process intended to determine the typical number of post-operative visits for certain commonly performed surgical services. In the proposed rule, CMS provided several reporting statistics from states where reporting was required. Of practitioners that met the criteria, only 45 percent participated by reporting CPT code 99024. Among 10-day global services, only 4 percent had one or more matched visits reported. Among 90-day global services, 67 percent had one or more visits reported. The logistics of matching up procedures to visits proved difficult, so the Agency excluded many instances of 99024 as part of its analyses. CMS observed “one potential explanation for these findings is that many practitioners are not consistently reporting postoperative visits using CPT code 99024.”

CMS is seeking comment on whether or not it may be reasonable to assume that many visits included in the valuation of 10-day global services are not being furnished, given this early snapshot of the global surgery data collection initiative. In response, we do not believe this early review of the dataset can reasonably be used to forecast any trends, given the limited and likely intermittent participation. As only 45 percent of eligible physicians and other healthcare professionals participated and with several large specialties having participation rates of less than 5 percent, it is evident that lack of participation is not simply *one potential explanation* but the dominant factor driving this early snapshot of the dataset. These preliminary results are not yet actionable as they are incomplete and are more likely to lead one to false conclusions than to provide any illumination.

The AAO-HNS, the American College of Surgeons, and other surgical specialty societies worked to inform our members of the global codes data collection reporting requirements leading up to July 1, 2017, and thereafter. However, despite our collective best efforts, it is highly unlikely that all clinicians who are required to report are doing so for every post-operative visit for every procedure. We believe CMS has met the MACRA requirements to collect data on the number of post-operative visits. CMS has indicated that it will soon be surveying three additional codes for data related to the level of visits—we believe this will satisfy the data collection portion of the law. MACRA also requires CMS “improve the accuracy” of global codes based on the data collected or other available data. The AAO-

HNS does not believe the data collected thus far can be used to improve the accuracy of the existing codes, and we urge CMS not to proceed with revaluing global codes at this time.

IX. Telemedicine

A. Brief Communication Technology/Virtual Check-In (HCPCS Code GVCII)

The AAO-HNS supports the concept of creating and paying for a physician's brief non-face-to-face check-in with the patient via communication technology to determine if the patient's condition necessitates an office visit. We believe the utilization of a service such as this has the potential to maximize patient benefit, as well as time management and cost for the health system in general. To a large degree, this service has been taking place for years using services described in code 99441 (*Telephone E/M service by a physician or other qualified healthcare professional who may report E/M services provided to establish patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*).

The expansion to additional technologies such as live video, "store and forward" communication, as well as the use of email and social media has, and will continue to, expand opportunity and value for the Medicare population. The AAO-HNS envisions this new service, GVCII, involving more than one medium during the same service, such as a teleconference that included "store and forward" communication that in combination would allow the physician to make the determination as to whether an office visit was necessary. It is imperative, however, that whichever combination of technology communication employed should include actual oral communication. Documentation for this type of visit should include the chief complaint, a brief history of the problem, and an assessment and plan. CMS has asked for comments related to the appropriate timing of including GVCII as a bundled service when an E/M service results. As stated by CMS, a concern would be bypassing the rule by scheduling a visit just past the existing parameter. Another scenario that needs to be addressed involves the circumstance where a patient may contact their physician regarding a problem that is evolving. One could foresee circumstances where multiple communications over a several-day period might occur and eventually lead to an E/M visit due to progression of the disease process. The physician may have participated in several encounters that would qualify as a GVCII service, but due to the proposed 24-hour rule, may not be able to bill for those services if an E/M visit resulted. In trying to determine the amount of time between a GVCII service and the trigger for activating a bundled service with the E/M visit, the AAO-HNS would suggest a 72-hour window which would account for most weekend and holiday scenarios. We would also encourage CMS to propose a policy clarifying how the above-mentioned scenario with multiple GVCII services would be handled.

B. Remote Evaluation of Pre-Recorded Patient Information (HCPCS Code GRAS1)

The AAO-HNS supports the creation and valuation of HCPCS Code GRAS1 as described in the proposed rule relating to remote evaluation of pre-recorded patient information. We believe this service should not include any oral evaluation of the patient and be strictly based on review of the "store and forward" technology submitted by the patient. We also believe application should not be limited to established

patients, but should also include potential new patients. In addition, the AAO-HNS agrees with the proposed time parameters recommended that would trigger bundling with the ensuing E/M visit.

X. Quality Payment Program

A. Measure Licensing Requirements

CMS proposes that, as a condition of a qualified clinical data registry (QCDR) measure's approval for purposes of MIPS, QCDR measure owners will be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification), beginning with the 2021 MIPS payment year. Our understanding is that, if finalized, once a QCDR measure is approved for reporting in MIPS, it would be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.

The AAO-HNS strongly opposes this proposal, as we believe it undermines QCDR measure ownership and development and violates the intellectual property rights of QCDR measure owners. We also believe this proposal is an arbitrary and capricious reversal of the policy that CMS adopted just last year to protect the intellectual property rights of QCDR measure owners in violation of the Administrative Procedure Act and the U.S. Constitution. The ability of QCDRs to license measures (and charge reasonable licensee fees or royalties) incentivizes organizations like the AAO-HNS to invest in developing new and improved measures. Testing and stewarding measures is extremely resource intensive—a single measure takes a minimum of one year to develop requiring significant effort and time from physicians and society staff, and additional time to test, maintain, and implement. Without the ability to license measures and collect reasonable royalties to offset the cost of developing measures, QCDR measure owners would have no way to control the appropriate use of their measures and cannot responsibly invest in measure development.

QCDR measures clearly constitute works of authorship that are subject to copyright protection. CMS has already acknowledged this fact in its decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner.¹ Even the proposed rule recognizes that CMS must have a license from QCDRs to sublicense those measures to other QCDRs. The problem is the proposal requires QCDRs to give CMS a mandatory, exclusive, and unfettered right to sublicense their QCDR measures for MIPS purposes as a condition of measure approval. This radical reversal of CMS' existing policy violates both judicial and agency precedent.

If third parties can routinely use these measures and, in the case of commercial QCDRs, profit off of the societies' time and expense, medical societies may no longer be able to dedicate resources to developing QCDR measures. Without the contribution of medical societies, the measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance. In fact, many societies do assert copyright protection over the QCDR and QPP measures they develop. The goal is not to limit physicians' ability to report on the measures, but rather to protect the integrity of the measures by limiting

¹ CY 2018 QPP Final Rule, 82 Fed. Reg. 53,568, 58,813-14 (Nov. 16, 2017).

inappropriate use and preventing commercial entities from profiting off of the societies' intellectual property.

We urge CMS to instead allow QCDRs to enforce their ownership rights in the QCDR measures they develop, and require third parties to enter into licensing agreements with measure owners before they can properly use QCDR measures. QCDRs must also be able to charge a reasonable fee, based on the cost of development, for licenses to use their measures. **We welcome the opportunity to join with other members of the Physician Clinical Registry Coalition to work with CMS to create safeguards to protect the proper implementation of these measures and ensure that QCDRs can enforce their intellectual property rights in the measures they develop, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.**

In the interim, we strongly object to CMS' decision to require QCDRs, in their self-nomination applications, to attest to their willingness to license their QCDR measures to CMS *while this rulemaking is pending*. Such a requirement, puts QCDRs in the position of having to agree to what we believe to be an unlawful policy reversal and an unjustified taking of their intellectual property before the agency has finalized its proposal. It also exposes the irrationality of proposing to make the new policy effective for the 2021 MIPS payment year, which essentially requires the unlawful policy to be implemented in 2019. At a minimum, QCDRs should only be required to make the licensure attestation if and when the proposed rule is finalized. However, it would make much more sense for CMS to delay the effective date of the proposal at least one year to allow a fuller discussion of the concerns we have expressed about the new policy and to give QCDRs a meaningful opportunity to decide whether they want to participate in a program that forces them to give up effective control over their QCDR measures.

B. Definition of a QCDR

The proposed rule would modify the definition of a QCDR to require that an approved QCDR have clinical expertise in medicine and quality measure development beginning with the 2022 MIPS payment year. Under this proposal, entities may also meet this definition through a signed, written agreement with an external organization with expertise in medicine and quality measure development. The AAO-HNS supports this modification to the definition of QCDRs. We agree with CMS that entities without expertise in medicine and experience in quality measure development do not satisfy the intent of QCDRs. As a result, **we encourage CMS to adopt this modification to the definition as soon as possible, ideally beginning with the 2021 MIPS payment year.**

In comments on past rulemaking, the AAO-HNS previously raised our concerns about EHR vendors and other commercial entities qualifying as QCDRs without the participation of clinician-led professional organizations focused on quality improvement. For-profit companies, such as EHR vendors, do not appear to have any population health impact, as measured by published articles in the scientific peer-reviewed literature and practice guidelines for clinicians. As a result, we agree with CMS that approval of commercial QCDRs does not fulfill CMS' intent for the broad population health and public health use of QCDRs.

The AAO-HNS urges CMS to further refine the definition of a clinician-led clinical data registry to mirror the following statutory language included in the 21st Century Cures Act: “The definition requires leadership by a tax-exempt physician society...devoted to the care of a population defined by a particular disease, condition, exposure or therapy.” The AAO-HNS strongly encourages CMS to consider adopting this or similar language to ensure QCDRs are focused on quality improvement and not commercial interests.

C. MIPS Self-Nomination Period

CMS proposes to revise the self-nomination period which currently runs from September 1 until November 1 of the year prior to the applicable performance period to July 1 until September 1 of the calendar year prior to the applicable performance period. The AAO-HNS appreciates CMS’ efforts to align the self-nomination period with the finalized regulations for the following year. However, by moving the self-nomination period, it will be difficult to update existing measures, develop new measures, and provide CMS with data for the QCDR measures application in this timeframe.

The AAO-HNS opposes this change as proposed by CMS because it would negatively impact the life cycle of QCDRs and the maintenance process for QCDR measures. QCDRs dedicate a significant portion of their time during each performance period to reporting for the previous year’s MIPS program and validating the data and submitting the Data Validation Execution Report by May 31 of a calendar year. Often, it is not until May or June that QCDRs can review performance on measures and convene groups of expert clinicians to discuss updates to existing measures or develop new measures. By moving the self-nomination period deadline to September 1, CMS would provide QCDRs with a limited time frame to update existing measures and develop new measures.

While some clinical registries might support this change to the self-nomination period for QCDRs if CMS would adopt a multi-year approval cycle for QCDRs, the AAO-HNS opposes the changes as proposed in the context of the current approval cycle. If CMS does adopt these proposed changes to the self-nomination period, it is essential that the agency change its expectations for providing data for measures accordingly, as it is not feasible to have data to support a measure so early in the calendar year.

D. Topped Out QCDR Measures

In the CY 2018 QPP Final Rule, CMS finalized a four-year timeline to identify topped out measures, after which CMS may seek to remove such measures through rulemaking. Since QCDR measures (as opposed to MIPS measures) are not approved or removed from MIPS through rulemaking, CMS proposes to exclude QCDR measures from the 4-year timeline for topped out measures. Under the proposal, once a QCDR measure reaches topped-out status through the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period. The AAO-HNS urges CMS not to move forward with this proposal.

The AAO-HNS supports greater consistency between the standards for reviewing and determining topped-out QCDR measures and MIPS measures. CMS’ proposal is inconsistent with the agency’s other efforts to align the process for QCDR and other MIPS quality measures and is a barrier to the success of QCDRs, as

it places a stricter set of criteria on QCDR measures. Furthermore, time should be provided before measure elimination to ensure the benchmark is valid based on a sufficient number of clinicians reporting the measure and for the QCDR to make updates and adjustments based on performance data collected. This would take no less than two years. The AAO-HNS recognizes that in order to demonstrate quality improvement for a payment program, there must be a reasonable gap in care to measure. However, **we would urge CMS to ensure that the policies for topped-out measures are consistent between QCDR and MIPS quality measures.**

Additionally, it is imperative that specialists have enough meaningful measures for MIPS reporting. **The AAO-HNS is disappointed by the choice to remove the Adult Sinusitis CT scan measure, given that CMS did not follow its established process of utilizing a four-year, step down period for removing topped out measures.** The AAO-HNS requests that CMS follow this process so that measure stewards are able to plan accordingly for other measure development before an existing measure is retired.

E. QCDR Benchmarks and MIPS Scoring

In order to encourage reporting of QCDR measures, CMS seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data. This proposal may require QCDRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. The AAO-HNS supports CMS' efforts to encourage reporting of QCDR measures; however, we also urge CMS to delay adoption of this proposal pending additional information and discussion with QCDRs.

Similarly, the AAO-HNS has concerns about the proposed tiering methodology for measures, as we believe it is premature to implement these changes. We are concerned that CMS is requiring increased complexity of measures reported by eligible clinicians, while at the same time reducing the quality component of the overall MIPS score. The AAO-HNS believes additional data and stability are needed before making changes to the measures methodology. We also request that the data driving the decisions be shared with stakeholders.

It is imperative that CMS give QCDRs the ability to provide data to create benchmarks of QCDR measures, while also providing opportunities for interested and capable QCDRs to develop benchmarks themselves. QCDRs may also be able to provide benchmark data using data collected across its registry participants, including participants that are not reporting the measure to CMS for purposes of MIPS. This data could be used to establish CMS benchmarks that would enable QCDR measures to be scored. That said, many QCDRs may run into operational issues in supplying data in the form and manner CMS would require, especially in terms of only submitting data that includes MIPS eligible clinicians. In addition, when establishing historical benchmarks, it is only appropriate to use measure data from a previous year if the measure specification is the same as the year for which the benchmark is being established. If CMS establishes benchmarks for QCDR measures, they must be done prior to the submission window in order to give practices a sense of how they are performing compared to their peers. **The AAO-HNS, along with our colleagues in the Physician Clinical Registry Coalition (PCRC), would like to further discuss with CMS how QCDR benchmarks should be developed.**

F. Measure Development

CMS proposes to consolidate its previously finalized standards and criteria used for selecting and approving QCDR measures. Specifically, CMS proposes to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year.

Many of the criteria used under the Call for Quality Measures Process are problematic. For example, one criterion CMS proposes is prioritizing outcome measures over process measures. The AAO-HNS agrees that outcome measures are valuable to the clinical process and to patients and caregivers. However, 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 have sufficient statistical power. Given the one-year time-frame of the program, it can be inappropriate to use outcome measures for rare events. **We urge CMS to withdraw this proposal and ensure the QCDR measure approval process remains separate from the standards used for the Call for Quality Measures process.**

G. Promoting Interoperability

The AAO-HNS thanks CMS for continuing to work with the Office of the National Coordinator for Health IT regarding implementation of the interoperability provisions included in the 21st Century Cures Act. Interoperability is a significant issue for QCDRs trying to gain access to data from EHR vendors. We strongly urge CMS to continue its efforts in this critical area.

CMS proposes to remove in future rulemaking the Public Health and Clinical Data Exchange objective from the Promoting Interoperability performance category no later than CY 2022 and seeks public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the objective is removed.

The AAO-HNS joined the PCRC in submitting comments on the FY 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) NPRM regarding CMS' proposal to remove the Public Health and Clinical Data Exchange objective and measures from the Promoting Interoperability Program no later than CY 2022. **We encourage CMS to retain the Public Health and Clinical Data Exchange Objectives**, and concerns raised in our comments on the FY 2019 IPPS proposed rule are equally applicable here. Further, the AAO-HNS continues to encourage CMS to provide full credit under the Promoting Interoperability category to eligible clinicians and groups using an EHR to participate in a QCDR.

H. Facility-based Reporting by Specialists

CMS proposes to give facility-based clinicians and groups the option to be scored under the MIPS Quality and Cost categories based on their facility's Hospital Value-Based Purchasing (VBP) Program score. This proposal recognizes the challenges that facility-based clinicians currently face with MIPS reporting, but CMS ultimately fails to address the core need to accurately evaluate specialists' quality and value and to incentivize specialists to more fully engage in MIPS.

The challenges that facility-based clinicians face are often due to the limited MIPS reporting options that fail to incentivize the reporting of specialty-specific measures. While CMS' proposal provides an alternative reporting option, it still does not allow specialists to demonstrate their unique value. This is especially true as the Hospital VBP Program moves away from episode-specific measures and toward the use of broader, hospital-wide measures. In addition, while the group reporting option is intended to ease reporting burden, individual specialists within multi-specialty group practices often have little to no control over their groups' measure selections, reporting mechanisms, and overall participation decisions and thus, no way to demonstrate the value of their own care.

I. MIPS Web Interface Measures

Given the limited number of MIPS Web Interface measures, CMS seeks feedback on building upon the Web Interface submission type by expanding the core set of measures available to include other specialty specific measures (such as surgery). The AAO-HNS has concerns regarding such an expansion. In addition to not having a quality improvement component, by incorporating the specialty specific measures, the Web Interface will compete against specialty QCDRs. Societies, like the AAO-HNS, have invested heavily in our registries and encourage our members to utilize them not only for reporting purposes, but for overall quality definition and improvement.

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,



James C. Denny, III, MD
Executive Vice President and CEO

ATTACHMENT A

HCPCS code	Specialty Society Surveyed	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
10021	ACR, SIR	Fna bx w/o img gdn 1st les	EF015	mayo stand	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00	Agree	
10021	ACR, SIR	Fna bx w/o img gdn 1st les	EF023	table, exam	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01	Agree	
10X12	ACR, SIR	Fna bx w/us gdn 1st les	EF015	mayo stand	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00		
10X12	ACR, SIR	Fna bx w/us gdn 1st les	EF023	table, exam	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01		
10X12	ACR, SIR	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, p	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.26		
10X14	ACR, SIR	Fna bx w/fluor gdn 1st les	ED050	Technologist PA	NF		49	47	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.04		
10X14	ACR, SIR	Fna bx w/fluor gdn 1st les	EF015	mayo stand	NF		44	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00		
10X14	ACR, SIR	Fna bx w/fluor gdn 1st les	EL014	room, radiograph	NF		44	34	E2: Refined equipment time to conform to established policies for highly technical equipment	-16.87		
10X16	ACR, SIR	Fna bx w/ct gdn 1st les	EF015	mayo stand	NF		52	50	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00		
G0268		Removal of impacted wax md	L037D	RN/LPN/MTA	NF	Clean surgical instrument package	3	0	G1: See preamble text	-1.11	Agree	