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

Re: CMS -1751-P Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

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Dear Administrator Brooks-Lasure:

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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 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” published in the *Federal Register* on July 23, 2021.

The CY 2022 Medicare Physician Fee Schedule (MPFS) proposed rule continues an alarming trend of progressive devaluation of surgical services that has been advancing over the past 20 years. Multiple factors have contributed to the current situation, including deflation of the Medicare conversion factor from \$36.6873 in 1998 to the \$33.5848 as proposed for CY 2022, representing a cut of \$3.10 over this 24-year period. These factors include medical cost inflation, three significant increases in the value of E/M services since 2005, and 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. They reflect a reimbursement system that is politically motivated to alter healthcare payment system parameters away from surgical specialties.

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

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CMS projects that our specialty would derive an overall negative 1% update from the MPFS valuation in 2022. Importantly however, this calculation does not include the additional 3.75% cut scheduled for January 1, 2022 based on the expiration of the payment update included in the Consolidated Appropriations Act of 2021. Furthermore, this projection does not accurately depict the deep, unprecedented cuts to each procedure and surgical encounter performed by otolaryngologist-head and neck surgeons, as described in further detail in this letter. The continued degradation of reimbursement for procedures will create obstacles to surgeons' ability, particularly outside of urban areas, to maintain technologically up-to-date practices that offer state-of-the-art care to their patients. The field of otolaryngology-head and neck surgery is already witnessing a failure to properly account for the transition to office-based procedures previously performed only in hospital or ambulatory surgical center (ASC) settings.

We wish to provide detailed comments on several specific proposals contained in the proposed rule. Our comments will address the following issues within the rule: physician fee schedule policy changes including significant changes to the conversion factor, clinical labor pricing proposals including the inappropriate inclusion of audiologists in the clinical labor pool, E/M proposals, critical care services including the global surgical period and modifiers 24 & 25, valuation of otolaryngology services, telehealth and other services involving communications technology, scope of practice, appropriate use criteria; and quality payment program policy changes for the traditional MIPS program and MIPS Value Pathways (MVPs).

I. Medicare Physician Fee Schedule

a. Proposed 2022 Conversion Factor

As stated in our introductory comments, the AAO-HNS joins our colleagues across the House of Medicine in expressing our strong opposition to the proposed conversion factor of \$33.5848 for calendar year 2021. This decrease lowers the 2022 conversion factor below the 1998 conversion factor of \$36.6873, which would be approximately \$61.43 today after factoring in inflation. While costs are constantly increasing, inflation and the drop in the conversion factor have slowly and consistently eroded the effective reimbursement rate for physicians of all practice types and areas of practice.

The reduction of the conversion factor, combined with unprecedented cuts in reimbursement for supplies used by otolaryngologist-head and neck surgeons as part of the practice expense, could present access to care problems for Medicare beneficiaries in the office setting, which is often the most cost-effective. These cuts come at a time when our members are struggling with the negative financial impact of the COVID-19 pandemic in many ways.

b. Clinical Labor Pricing Proposals

In 2019, CMS began a four-year phase-in of an update to the supplies and equipment prices used for code-level direct practice expense (PE) calculations. CMS is proposing to update the clinical labor pricing

for CY 2022, in conjunction with the final year of this supply and equipment pricing update. This means that for CY 2022, changes are proposed for the pricing of all three components of PE RVUs: clinical labor (CL), supplies, and equipment. **As a result, we strongly urge the agency to delay implementation of the update until CY 2023, after the final transition year of the supply and equipment update, and phase-in any update over four years.** Furthermore, due to the disproportional impact that will fall on office-based services that utilize expensive supplies and equipment, the AAO-HNS once again advocates that CMS strive to reduce the problem with the practice expense for high-cost supplies by establishing Healthcare Common Procedure Coding System (HCPCS) Level II codes for supplies that exceed \$500.

1. Audiology codes

Our review of the CMS proposal to update clinical labor pricing, as detailed in Table 5 in the Notice of Proposed Rulemaking (NPRM), has exposed a significant problem related to revaluation of certain audiology codes. Effective October 1, 2008, Medicare established NPI numbers for audiologists, which enabled them to bill Medicare directly for their services. **As participating providers in the Medicare program, audiologists should not be included in the proposed clinical labor pricing update.** They are performing the procedures for which they are billing Medicare and should not be assigned any additional clinical labor time for their efforts. This oversight has created significant rank order anomalies within the audiology code family as included in the proposed rule.

The codes listed below were all valued prior to audiologists being able to bill with their own NPI number and therefore have received significant PE increases through the proposed rule which should not be permitted. Additionally, further investigation revealed a significant disparity in intraservice times between the majority of these codes that were last valued in 2002 compared to the more recently valued CPT 92557, which was surveyed and valued in 2009. This has resulted in increases in this set of codes ranging from 11% to 48% solely based on clinical labor time adjustment.

Table 1

CPT Code	Work RVUs	NF PE RVUs 2021	NF PE RVUs 2022	% change	Intraservice time (min)
92546		3.32	3.67	11	50
92546 TC		3.18	3.54	11	50
92551		0.34	0.38	12	19
92552		0.97	1.19	23	26
92553		1.19	1.47	24	31
92555		0.73	0.90	23	16
92556		1.16	1.45	25	26
92557	0.60				20
92562		1.37	1.55	13	41
92563		0.94	1.06	13	31
92565		0.51	0.69	35	13
92571		0.81	1.04	28	18
92572		1.09	1.50	38	33

92575		2.04	2.39	17	42
92576		1.11	1.39	28	24
92577		0.46	0.68	48	13
92582		2.23	2.81	26	49
92583		1.50	1.83	22	34

As result of the increases in the practice expense RVUs and inappropriate intraservice times, significant rank order anomalies now exist in this family. The most striking example of the rank order anomalies created by these proposed changes occurs in review of CPT codes 92552, 92553, 92556 and 92557. CPT 92557 (*Comprehensive audiometry threshold evaluation and speech recognition*), has component elements of 99253 (*Pure tone audiometry, air and bone*) and 99256 (*Speech audiometry threshold with speech recognition*). The total non-facility RVUs for 99257 are 1.08 while each of its components: 99253, valued at 1.49 non-facility RVUs; and 99256, valued at 1.45 RVUs; are now valued higher than the comprehensive code itself. The two component codes are valued at 2.94 RVUs as opposed to the comprehensive code at 1.08 RVUs. Even CPT 92552 (*Pure tone audiometry (threshold), air only*) is valued at 1.19 RVUs and is only one out of three elements contained in the comprehensive code 92557. Additionally, the intraservice times are considerably elevated compared to the most recently valued comprehensive code 92557. The total intraservice time for 92557 is twenty minutes while the intraservice time for 99252, 99253 and 99256 are twenty-six minutes, thirty-one minutes and twenty-six minutes respectively.

Should CMS opt to move forward with the clinical labor pricing update for 2022, the AAO-HNS requests audiologists be removed from the labor update pool, as audiologists have been billing Medicare with their own NPI number since 2008. If finalized for 2022, the agency should recalculate the proposed values for all of the codes in Table 1 above, other than 92557, without the increase based on the proposed updated clinical labor pricing for audiologists. The respective intraservice times also need to be revisited and adjusted to reflect the survey times included in 92557, the code in the family which was most recently reviewed.

2. Additional Clinical Labor Update Recommendations

In the NPRM, CMS states that CL pricing was last updated in CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available. A review of the full discussion in the CY 2002 PFS final rule regarding the process of updating the CL rates shows that 12 (40%) of the 31 total staff types used “other sources” for pricing. Each of the examples of other sources represent data that are not readily available for public review to determine if the same process of collection is used. This adds a layer into the process that is not transparent, and we question if CMS compared the data from Salary Expert to the BLS data to ensure the wage data is appropriate to utilize as a basis for clinical labor pricing. **It is critical that this data accurately reflect changes in clinical labor resource inputs for the purpose of setting PE RVUs under the PFS.**

For CY 2022, 14 (44%) of the 32 single staff types are being updated using a BLS crosswalk because an exact match was not available. CMS is soliciting comments on the proposed updated CL pricing as well

as methods to identify the most accurate types of BLS categories that could be used as proxies to update pricing for CL types that lack direct BLS wage data. The agency is also interested in additional wage data that may be available. To maintain transparency, **CMS should publish the ‘other sources’ wage data details** and update specific clinical labor wage rates accordingly. **Updates to CL pricing should be held to the same transparency standard as updates to supplies and equipment pricing.**

In the clinical labor pricing update proposal, CMS utilizes the mean wage data to establish updated clinical labor rates, while the majority of the MPFS data inputs are based on the median. For example, in the process of developing RUC recommendations on work and practice expense, components including physician times, work RVUs, clinical staff times and clinical staff types all use median values. The BLS survey data also include wage rates for a variety of sites of service (e.g., hospitals, physician offices, farms) and wage data from a variety of industries. **We urge CMS to use the median wage data, instead of mean wage data, to more accurately reflect typical wage rates and to maintain consistency with the median statistic used for clinical staff time.**

The clinical staff time for codes is always based on the typical or median time when survey data are used. The most recent example of this is the clinical staff times assigned to activities for the office and other outpatient E/M visit codes updated for CY 2021; **median survey times were recommended by the RUC and approved by CMS.** Furthermore, using the mean across various sites of service is inconsistent because of the inherent variation in this data. We do not suggest that any specific industry category be used for pricing but wish to highlight that **the median rate will reflect the typical rate, and no additional code-level work would be required because the BLS tables all list the median statistic.** As such, we recommend that CMS use the BLS median wage rate to update CL pricing.

To account for employers’ cost of providing fringe benefits, such as sick leave, CMS proposes to use the same benefits multiplier of 1.366 that was utilized in CY 2002. We disagree with this proposal as this multiplier is not accurate according to *current* BLS data. Using the fringe benefits multiplier rate from 20 years ago (2002) is not consistent with CMS’ premise for updating the clinical labor pricing to “maintain relativity with the recent supply and equipment pricing updates”. BLS publishes benefits data routinely. The most recent [news release bulletin](#) for “Employer Costs for Employee Compensation” indicates that the private industry worker's median and mean benefit cost was 29.6%. We believe that the private industry workers rate is more appropriate as it eliminates overemphasis on non-healthcare wages, such as those for farmers and federal employees. **We recommend that CMS use the current fringe benefit multiplier of 1.296 (BLS)** in the calculation to update CL rates.

We agree that the MPFS clinical labor rates should be revised from the outdated 2002 rates. However, due to budget neutrality constraints, the CY 2022 scaling factor, used to account for this dramatic rise in one component of direct practice expense costs, is proposed to fall significantly to 0.44 from 0.59, an unprecedented decrease of 24%. As a result, the increase in the clinical labor rates results in a shift of RVUs that were previously directed to supplies and equipment. **Medicare will now reimburse 44 cents on the dollar instead of 59 cents on the dollar for supply and equipment costs, which is unsustainable.**

The reduced scalar adjustment has a significant negative impact on codes with high supply or equipment costs. Codes with a higher proportion of clinical labor in direct costs benefit from the high growth in the proposed labor rates. The growth in the labor costs for these codes are frequently offset by the reduction in direct costs that results from the lower direct scalar. However, codes with a high proportion of supply/equipment costs would experience large decreases, as there would be minimal positive offset from the labor portion. For example, **there are eighty-two codes with supply items greater than \$1,000 with the average percentage decrease in PE RVUs of 19%** (21% decrease in expected Medicare reimbursement).

To illustrate this point, Table 2 below shows a family of balloon sinus dilation codes, an office-based procedure performed by otolaryngologist-head and neck surgeons, that each will experience a decrease of >21% in non-facility payment rates under the proposed rule. Our analysis demonstrates that when these procedures are used to treat sinus disease in Medicare beneficiaries, almost **90% occur in the non-facility setting**.

Table 2: Percent Change in Non-Facility Payment from 2021 to 2022 Under MPFS

*Includes a 3.75% decrease in the conversion factor

CPT	Description	2021 Final Non-Facility Payment	2022 Proposed Non-Facility Payment	% Change in Non-Facility Payment (2021-2022)
31295	with dilation of maxillary sinus ostium (e.g. balloon dilation), trans nasal or via canine fossa	\$1,932	\$1,502	-22.2%
31296	with dilation of frontal sinus ostium (e.g. balloon dilation)	\$1,958	\$1,528	-21.9%
31297	with dilation of sphenoid sinus ostium (e.g. balloon dilation)	\$1,917	\$1,488	-22.4%
31298	with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)	\$3,113	\$2,444	-21.5%
69705	Nps, surgical, with dilation of eustachian tube; unilateral	\$3,113	\$2,444	-21.5%
69706	Nps, surgical, with dilation of eustachian tube; bilateral	\$3,206	\$2,534	-21.0%

We have significant concern that, **because of the high proportion of their direct costs associated with supplies, the codes in the table above pose a substantial risk of disrupting Medicare patients access to care or forcing them into the least cost efficient “facility” for care that could be safely delivered in the office at substantial overall cost savings.** This is particularly concerning in light of the -3.75% adjustment to the conversion factor for 2022 and the additional scheduled 6% reduction due to PAYGO and sequestration.

CMS requests input on whether the CL rate update should be phased-in over four years or fully implemented in CY 2022. The current clinical labor proposal requires further analysis and modifications prior to implementation. There is additional work to be done by both the agency and stakeholders to ensure accurate data is used and appropriate methodological steps are taken to update clinical labor pricing. It is important to note that CY 2022 will be the 4th and final transition year of the update to supply and equipment items, and it would be imprudent to introduce additional significant practice expense payment adjustments that are not based on complete, transparent data.

The AAO-HNS believes it would be **most equitable for the proposed CL rate update to be phased-in over four years**, and in addition, **we strongly urge the Agency to delay implementation of the update until CY 2023**, after the final transition year of the supply and equipment update. There is precedent for a phased transition for significant MPFS changes, across several calendar years. CMS utilized a 4-year transition for the market-based supply and equipment pricing update concluding in CY 2022. CMS also utilized a 4-year transition, starting in 2010, for the practice expense proposal. **CMS should use a 4-year transition to implement an updated clinical labor proposal, starting in CY 2023.** A four-year phase-in is more equitable to allow those specialties, like otolaryngology-head and neck surgery, that are disproportionately impacted to prepare and adjust to the major decrease in supply reimbursement.

c. E/M Proposals

Last year, CMS finalized its policy change to adopt changes to Evaluation and Management (E/M) codes, as approved by the AMA CPT Editorial Panel. In addition to significant reimbursement increases for E/M services, these changes preserved the previous five codes for existing patients and established four codes for new patients. **The AAO-HNS respectfully requests that the agency study the impact of these changes on physicians to ensure they accomplish CMS’ goal of reducing burden and documentation requirements while maintaining intended high standards of patient care.**

The AAO-HNS continues to strongly oppose the agency’s decision to not apply the RUC-recommended values to E/M codes included in the surgical package. Doing so results in a disruption of the relativity between codes across the Medicare physician fee schedule. As part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress mandated that CMS collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. Attempts to accomplish this goal were derailed by the inherently flawed RAND survey. **Using this “back door” strategy to lower costs of surgical procedures by devaluing individual E/M visits is inconsistent with the intent and mandate of MACRA.**

d. Split or Shared E/M Visits

In the NPRM, CMS is proposing to create a modifier to describe split (or shared) visits and proposing to require that the modifier be appended to claims for split (or shared) visits, whether the physician or NPP bills for the visit. Currently, CMS cannot identify through claims that a visit was performed as a split (or shared) visit, which means that the agency would know that a visit was performed as a split (or shared) visit only through medical record review.

The AAO-HNS opposes CMS' proposal to redefine split E/Ms. Changing the current billing requirements would result in non-physician providers (NPPs) expanding their scope of practice, as they do not have the same level of training or experience as physicians. CMS proposes to create a modifier for split E/M visits. **The AAO-HNS also opposes the creation of a modifier for split E/M visits.** Requiring a modifier adds a level of administrative burden that the new E/M coding structure and guidelines were designed to alleviate. It is important that physicians can focus on one consistent set of guidelines in reporting their services.

It is illogical that practitioners in different practices would be allowed to bill for the same E/M and the creation of a modifier only creates additional levels of burdensome paperwork. Additionally, even if the agency expands split E/M visits, it would only apply in cases where the practitioners are in the same group. If the participating practitioners are all employed by the same group, there is no need for a modifier to further define services performed, as that is already required under current regulations.

e. Critical Care Services, Global Surgical Period, and Modifiers 24 & 25

For 2022, CMS proposes to bundle critical care visits with procedure codes that have a global surgical period. The agency's first rationale is that critical care visits are included in some 10- and 90-day global codes. CMS' second rationale is that the MACRA requirement to collect data on the number and level of postoperative visits provided within 10- and 90-day global periods is ongoing. CMS refers to previous concerns related to lack of sufficient data on the number and level of visits typically furnished during a global period, questions whether CMS will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and expresses concern about how global payment policies could affect services that are actually furnished. Even if adopted this proposal will not address or adequately document the majority of post-op visits which take place in the outpatient setting. **CMS should not finalize this policy as proposed.**

The AAO-HNS strongly opposes any proposal that would prevent surgeons from being able to appropriately use modifier 24 (*Unrelated E/M Service During Post-Operative Period*) or modifier 25 (*Significant Separately Identifiable E/M Service on the Same Day of a Procedure or Other Service*). Not only do CMS' rationales not support this policy, but this proposal will prevent surgeons who provide both operative and critical care services, including otolaryngologist head and neck surgeons, from being fairly reimbursed for time spent caring for their patients both in and out of the operating room. **CMS should instead maintain the current provision in the Medicare Claims Processing Manual that specifically allows modifiers 24 and 25 to be used to indicate that the critical care service can be billed and paid at full value when unrelated to the procedure.**

CMS states that “because critical care visits are included in some 10- and 90-day global packages, we are proposing to bundle critical care visits with procedure codes that have a global surgical period.”

Including critical care visits in some, but not all global codes, introduces problematic inconsistencies. Few global codes include critical care visits because few procedures require critical care services. This policy would presume that because *a few* 10- and 90-day global services typically require critical care services, then *all* 10- and 90-day global procedures require critical care services, which is not an accurate presumption. Whether or not 10- and 90-day global codes require postoperative critical care related to the operation is determined on a code-by-code basis as part of the AMA/RUC deliberations on valuation of codes. They are only included if the typical patient requires critical care services directly related to the procedure which are most appropriately and effectively handled by the operating surgeon on a consistent basis.

CMS’ second rationale, in reference to the MACRA data collection on number and level of post-operative visits, is that “because this work is ongoing, we are proposing to bundle critical care visits with procedure codes that have a global surgical period.” CMS also cites “lack of sufficient data on the number of visits typically furnished during the global periods” to support the ongoing MACRA data collection. This rationale does not support the proposal to bundle critical care services into visits with global codes and is a strong justification for *allowing* critical care services to be billed separately when the use of modifiers 24 and 25 are used as intended. **Considering the lack of sufficient data on the number and level of postoperative visits, as well as ongoing efforts to study these visits, it is premature to bundle all critical care into 10- and 90-day global surgical packages.**

This policy undervalues the care provided by surgeons to the sickest patients. **Specifically, this policy undervalues the ICU care required for some post-surgical patients and does not appropriately recognize the expertise of otolaryngologist head and neck surgeons caring for some of the most complex cases, such as head and neck cancer patients.** As described above, most surgical patients do not require ICU care, and ICU care is not included in the value of most 10- and 90- day global codes. Valuation of the codes at the RUC with expected ICU care took into account that additional consultations might be necessary and would be billed separately. However, some patients are either already critically ill at the time of surgery, or unpredictably become critically ill after surgery. In these cases, surgeons are best equipped to manage the critical care services related to the surgical procedure for these patients postoperatively even when additional services may be required. Surgeons are most familiar with their patients’ cases and their subsequent postoperative course. They are also most familiar with complex operations and the impact of comorbidities. Furthermore, surgeons have the best skillset to identify and manage surgery related postoperative issues. **The AAO-HNS expresses concern that this proposal does not accurately reflect the vital critical care services that are provided by surgeons and proper reimbursement for those services.**

In summary, we urge CMS not to finalize this policy as proposed, which will prevent surgeons from being properly and fairly reimbursed for providing critical care services to their patients. **Instead, CMS should continue to allow physicians to bill for critical care services within a global period using modifiers 24 and 25, when appropriate.**

f. Valuation of Otolaryngology Services

1. Transcutaneous Passive Implant-Temporal Bone (CPT codes 69714, 69717, 69X50, 69X51, 69X52, and 69X53)

CMS proposes the interim RUC-recommended work RVU for all six of the codes in this family. For the direct PE inputs, CMS proposes to refine the clinical labor time for the “Postoperative visits (total time)” (CA039) activity from the RUC-recommended 108 minutes to 99 minutes for CPT codes 69714 and 69717. 99 minutes is the clinical labor time associated with one Level 2 postoperative office visit and two Level 3 postoperative office visits; CMS notes they believe that the RUC inadvertently failed to update the clinical labor time associated with these postoperative office visits when CPT codes 69714 and 69717 were reviewed. They also propose to refine the equipment time for all equipment items other than the basic instrument pack (EQ137) from 108 minutes to 99 minutes to match this change in clinical labor time.

The Academy thanks CMS for their recommendation to accept both the interim RUC work RVUs for this family of codes and supports the proposed recommendation. We also agree with the recommended modifications to the practice expense inputs for this code and agree that those adjustments are appropriate, based on the refinements to number, and level, of post-operative visits for CPT 69714 and 69717, respectively. The Academy looks forward to working with the RUC to establish final values for these codes for consideration by CMS in the CY 2023 physician fee schedule.

2. Closed Treatment of Nasal Bone Fracture (CPT codes 21315 and 21320)

Within the NPRM, CMS agrees with the RUC’s recommendation to change CPT codes 21315 (*Closed treatment of nasal bone fracture; without stabilization*) and 21320 (*Closed treatment of nasal bone fracture; with stabilization*) to 000-day global period codes from 010-day global period codes to account for the degree of swelling within 10 days post-procedure, and because the patient can remove their own splint at home for CPT code 21320.

For CPT codes 21315 and 21320, however, CMS disagrees with the RUC-recommended work RVUs of 2.00 and 2.33, respectively, as they believe these values do not adequately reflect the surveyed reductions in physician time and the change to a 000-day global period from a 010-day global period for these CPT codes. Rather, they propose a work RVU of 0.96 for CPT code 21315 and 1.59 for CPT code 21320 based on the reverse building block methodology to remove the RVUs associated with the 010-day global period and the surveyed reductions in physician time. They feel the proposed work RVU of 0.96 for CPT code 21315 adequately accounts for the 50 percent decrease in intraservice and postservice time, a 31-minute decrease in total time. Further, CMS proposes a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary, and asserts that the proposed work RVU of 1.59 for CPT code 21320 adequately accounts for the 5-minute decrease in intraservice time, 3-minute decrease in total time, and 48 percent decrease in postservice time. Absent an explicitly stated rationale for an intensity increase for CPT codes 21315 and 21320, CMS proposes to adjust the work RVU to reflect significant decreases in surveyed physician time.

CMS also notes they do not believe the RUC adequately accounted for the loss of the E/M post-operative visits in their recommended work RVUs for CPT codes 21315 and 21320. They also state that the RUC's recommendations seem to dismiss the significant changes in surveyed physician time, without a persuasive explanation of a significant increase in IWP/UT that results from the RUC's recommended work RVUs for CPT codes 21315 and 21320. They believe the surveyed decreases in physician time in conjunction with the loss of the post-operative visits for CPT codes 21315 and 21320 merit decreases in the work RVUs from the current work RVUs.

CMS recognized within the NPRM that they have not previously used a modified total time approach to consider work RVU values when there is a change in the global period for a service in conjunction with significant surveyed changes to the pre-, intra-, and postservice times. Therefore, they seek comment on application of the modified total time ratio approach to value services that have a global period change and significant surveyed physician time changes. **The agency states they believe this methodology may account for the loss of post-operative visits and the surveyed changes in the pre-, intra-, and postservice times in this unique situation, given the potentially flawed methodology used to arrive at the current valuations for CPT codes 21315 and 21320 that are used in the total time ratios.**

The Academy has concerns that not only is CMS utilizing a brand-new methodology to revalue this family of codes, but that they are also entirely ignoring the data derived from the most recent RUC survey and subsequent review/valuation process. Specifically, while we agree that the change in global from a 010 to a 000 is appropriate, we do not believe simply removing the value of post-operative visits and exact percentages of RVUs that correlate to procedure time is a consistent or fair manner to modify the associated work RVUs. Rather, we encourage CMS to work with the RUC to outline a methodology that should be used when a code is adapted from having a global period to becoming a 000 global service.

CMS appears to be disregarding the compelling evidence that was accepted by the RUC in valuing these codes at the January meeting. Two compelling evidence arguments were accepted by the RUC to allow for an increase in value, despite a decrease in survey time and the change in global period. Those arguments are below.

1. Based on the 1991 Federal Register, these codes were assigned RVUs based on "Source 2" information. This is defined as "Physician work value[s] established by HCFA. It may have been a refinement of a Harvard value, or a gap fill for a code for which Harvard did not provide a value. These include codes reviewed by carrier medical directors." This assignment of values based on "Source 2" information means the code was never *surveyed by Harvard*. This may explain why CPT 21315 currently has a negative IWP/UT. We believe this speaks to compelling evidence and demonstrates a **flawed methodology was used in the previous valuation** as there is a discrepancy between this information and data provided by the AMA staff which indicates a Harvard phase 4 study was done for each code, resulting in 19 responses for 21315 and 103 for 21320. Given that it is unclear whether existing valuation is based on a Harvard survey or Source 2 data, we feel compelling evidence of "flawed methodology used in the previous valuation" is met.
2. Additionally, for both codes, there has been a **change in specialty** from oral maxillofacial surgeons to otolaryngology and plastic surgery. This is supported based on the database

information that indicates these codes were valued using input from oral maxillofacial surgeons, not otolaryngologists or plastic surgeons.

Given both the change in specialty, as well as the use of Source 2 data when originally valued by the HCFA, it is clear the original times were not based on an evaluation of the time, work, and intensity that is involved in these procedures when performed by the now dominant specialties, otolaryngology and plastic surgery. Additionally, a formal valuation of the services never occurred, and thus, we believe CMS would be remiss if they did not view the survey data received from this robust, two-specialty survey, as the most up to date, and accurate information available to correctly value the time and work involved in these procedures.

Further, while we agree that using the times from the survey is an accepted and valid component in valuation, by using **only** the survey result times compared to “current” value (which in this case is inherently problematic as noted above), CMS is also completely disregarding the remainder of the survey results from those who perform these procedures who were asked about relativity. In contrast, while the RUC recommended values fell at the survey’s 25th percentile, CMS’ proposed valuations fall in the less than 1st percentile of a survey with a high respondent number representing two different specialties for both codes. The RUC concurred with the use of these comparison codes and, as such, recommended them to CMS.

The result of CMS’ reliance on this flawed methodology are proposed values which will create significant abnormalities in the current fee schedule. The agency fails to account for the fundamental concept of **relative** value of services. Examples of how CMS’ proposed values would be problematic within the fee schedule are outlined below.

First, 21315 would have a negative IWPUT of -0.006 which already suggests an inappropriate valuation of work compared to time. 21320 would have an inappropriately low IWPUT of 0.025, below almost any other surgical procedure and even lower than an E&M visit despite the code’s inclusion of an intense intraservice time.

Second, when comparing the current proposed values to other similar codes in the RUC database, it becomes clear that CMS’ proposed values would not be able to be crosswalked to any other code within the fee schedule. Below are sample CPT codes currently in the code set which are potential comparator codes to establish relativity based on time and global period.

When evaluating the relativity within the code set for 21315, searching the RUC database for codes with 000-global, intra-time of 12-18 minutes, and total time of 60-75 minutes provides the following results:

Table 3

CPT	DESC	GLOBAL	WORK RVU	TIME SOURCE	PRE TIME	INTRA TIME	POST TIME	TOTAL TIME	IWPUT	RUC DATE	MPC	UTILIZATION
15040	HARVEST CULTURED SKIN GRAFT	0	2.00	RUC	35	15	10	60	0.0757	2005-04		362
36522	PHOTOPHERESIS	0	1.75	RUC	33	18	10	61	0.0437	2017-01		8,303
50387	CHANGE NEPHROURETERAL CATH	0	1.75	RUC	33	18	10	61	0.0517	2005-04		7,721
57410	PELVIC EXAMINATION	0	1.75	RUC	30	15	25	70	0.0345	1995-08		2,499
21315	Reduce Nasal fx w/o stab	0	0.96		43	15	10	68	-0.006			

At the CMS recommended value, 21315 cannot be considered **relative** to these other procedures with similar times. In a similar fashion, when evaluating the relativity within the codes set for 21320, searching the RUC database for 000-day global, intra-time of 20 minutes, and total time 70-80 minutes provides the following results:

Table 4

CPT	DESC	GLOBAL	WORK RVU	TIME SOURCE	PRE TIME	INTRA TIME	POST TIME	TOTAL TIME	IWPUT	RUC DATE	MPC	UTILIZATION
16035	INCISION OF BURN SCAB INITI	0	3.74	RUC	30	20	20	70	0.1310	2000-04		381
32551	INSERTION OF CHEST TUBE	0	3.04	RUC	33	20	20	73	0.0998	2012-04		33,044
93644	ELECTROPHYSIOLOGY EVALUATIO	0	3.04	RUC	29	20	25	74	0.0951	2014-04		56
30140	RESECT INFERIOR TURBINATE	0	3.00	RUC	43	20	15	78	0.0922	2016-10		49,954
69705	NPS SURG DILAT EUST TUBE UN	0	3.00	RUC	43	20	15	78	0.0922	2020-01		
30468	RPR NSL VLV COLLAPSE W/IMPL	0	2.80	RUC	38	20	15	73	0.0878	2020-01		
31240	NASAL/SINUS ENDOSCOPY SURG	0	2.61	RUC	38	20	15	73	0.0783	2017-01		6,458
57400	DILATION OF VAGINA	0	2.27	RUC	30	20	30	80	0.0463	1995-08		103
36512	APHERESIS RBC	0	2.00	RUC	40	20	15	75	0.0384	2017-01		2,896
21320	Reduce Nasal Fx w/ stab	0	1.59		43	20	12	75	0.0250			

At the CMS recommended value, 21320 cannot be considered **relative** to other procedures with similar times. It is important to note that this list includes three other similar nasal procedures with significantly higher wRVUs despite a similar intensity.

Third, we feel it is valuable to compare CMS proposed values for these two invasive procedures to the recently valued outpatient E&M codes. As part of this comparison, we highlight CMS' methodology included in the proposed rule related to the relative intensity of work provided in the pre-service evaluation time and post-service time. Specifically, CMS states the following in reference to overlapping work between an E&M and procedure:

Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU. Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes × 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU.

As a comparison for 21315, we offer 99202 (*Outpatient, New, Level 2*) as outlined in table 5 below.

Table 5

CPT	DESC	GLOBAL	WORK RVU	TIME SOURCE	PRE TIME	INTRA TIME	POST TIME	TOTAL TIME	IWPUT	RUC DATE	MPC	UTILIZATION
99202	Outpt New E&M – Level 2	xxx	0.93	RUC	2	15	3	20	0.0465	2019-04		2,490,658
21315	Reduce Nasal fx w/o stab	0	0.96		43	15	10	68	-0.0006			

These two codes have an identical intraservice time of 15 minutes. We assert that the surgical procedure, 21315, is more intense during the intratime. These two codes have a difference in total time of 48 minutes due to the pre- and post- work associated with procedures and accepted as valid times in the pre- and post- service packages used by both the RUC and CMS. Based on the CMS methodology noted above, the additional 48 minutes of pre- and post- time for 21315 compared to 99202 would be equivalent to an additional 1.08 wRVU (48min x 0.024 wRVU/min) to the wRVU for 99202. The addition of 1.08 wRVU to the current wRVU of 0.93 for 99202 would result in an wRVU of 2.01 which confirms the specialty and RUC recommended value for 21315 of 2.00 wRVU.

A similar comparison for codes 21320 and 99213 (Outpt Estab E&M – Level 3) is outlined below.

Table 6

CPT	DESC	GLOBAL	WORK RVU	TIME SOURCE	PRE TIME	INTRA TIME	POST TIME	TOTAL TIME	IWPUT	RUC DATE	MPC	UTILIZATION
99213	Outpt Estab E&M – Level 3	xxx	1.3	RUC	5	20	5	30	0.0433	2019-04		92,217,549
21320	Reduce Nasal Fx w/ stab	0	1.59		43	20	12	75	0.0250			

These two codes have the same intra time of 20 minutes. Again, we strongly assert the surgical procedure is more intense during this intratime. These two codes have a difference in total time of 45 minutes due to the pre- and post- work associated with procedures and accepted as valid times in the pre- and post- service packages used by the RUC and CMS. Based on the CMS methodology noted above, the additional 45 minutes of pre- and post- time for 21320 compared to 99213 would be equivalent to an additional 1.01 wRVU (45min x 0.024 wRVU/min) to the wRVU for 99213. The addition of 1.01 wRVU to the current wRVU of 1.30 for 99213 would result in an wRVU of 2.3,1 which confirms the specialty and RUC recommended value 2.33 wRVU for 21320.

While an exact building block methodology for pre- and post- service compared to a similar code would require an identical match of intraservice time and intraservice intensity, the above examples demonstrate how that CMS’ proposed wRVU values for 21315 and 21320 are not congruent with other values in the code set and the overall fee schedule’s relativity.

Based on these collective concerns, we strongly urge CMS to reconsider their proposed reductions in work RVUs for these codes and accept the January 2021 RUC recommended values of 2.00 and 2.33 for 21315 and 21320, respectively.

CMS proposes the RUC-recommended direct PE inputs without refinements and the surveyed physician times for CPT codes 21315 and 21320.

The Academy thanks CMS for their recommendation to accept the practice expense inputs for this code and we support that recommendation.

3. Hypoglossal Nerve Stimulator Services (CPT codes 645X1, 645X2, and 645X3)

New CPT code 645X1 replaces CPT Category III code 0466T which was previously reported with CPT code 64568.

CMS disagrees with the RUC recommendation that supports the survey median work RVU for CPT code 645X1. The agency suggests that an analysis of other 090-day global codes with similar time values indicates that this service is overvalued and instead proposes a work RVU of 14.00 based on an intraservice time ratio. The ratio uses the intraservice time (140 minutes) of the RUC recommendation and that of CPT code 64568 *Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator* (work RVU = 9.00, 90 minutes intraservice time and 275 minutes total time). **The Academy strongly disagrees with CMS calculating intraservice time ratios to account for changes in time.**

The Academy would like to remind CMS of both the agency's and the RUC's longstanding position that treating all components of physician time (pre-service, intraservice, post-service and post-operative visits) as having identical intensity is incorrect. Inconsistently applying it to only certain services creates and potentially amplifies inherent payment disparities in a payment system which is based on relative valuation. When physician times are updated in the PFS, the ratio of intraservice time to total time, the number and level of bundled post-operative visits, the length of preservice and length of immediate post-service time may all potentially change for the same service. Thus, changing components of physician time used to calculate work intensity per minute often change unequally when physician time changes. The Academy recommends that CMS always account for these nuanced variables.

CMS' proposal overrides the input of 89 otolaryngologists and the RUC by basing the work RVU of 645X1 on an intraservice time ratio using 64568. The RUC extensively discussed the difference between the work involved in 64568 and 645X1, and agreed that the work to place the hypoglossal nerve stimulator on the nerve is more intense than the work involved to place a stimulator on the vagus nerve. The physician work for hypoglossal nerve stimulator services is different than vagus nerve work. Identifying and placing a nerve stimulator on the trunk of the vagus nerve is different than identifying and placing a nerve stimulator on the distal and wispy branches of the hypoglossal nerve. The physician must find the specific branch that protrudes the tongue and implant it. Additionally, the physician is putting other cranial nerve branches at risk where they dissect to find the hypoglossal nerve. 645X1 includes placement of a distal inspiratory sensor through a different incision. Therefore, hypoglossal nerve services are more intense and have greater risk than the vagal nerve services.

CMS does not agree that the intensity of this procedure warrants higher values than codes with similar work times. The agency believes that the proposed value is more appropriate overall than the RUC recommendation when compared to the range of codes with similar work times. **The Academy, however, asserts that there is adequate evidence for increasing times and intensity for the additional work involved in the hypoglossal nerve stimulator family as described above.**

CMS believes that the proposed work RVUs, which represents the 25th percentile value in the survey, adequately represents the work of the service. The Academy strongly believes that the proposed value does not represent the intensity and complexity inherent in this service, as outlined above. Therefore, the Academy does not believe that the 25th percentile is an accurate reflection of the physician work involved in this service.

The Academy supports the RUC-recommended value of 16.00 wRVUs for CPT code 645X1. Table 7 (below) supports the RUC-recommended values by comparison to the following 6 CPT codes: 64911, 19303, 58544, 60500, 15733 and 49655. For example, CPT code 64911 (*Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve*) (work RVU = 14.00, 110 minutes intraservice time and 292 minutes total time) involves similar total time to 645X1 but 30 minutes more intraservice time, thus supporting a higher value. CPT 19303 (*Mastectomy, simple, complete*) (work RVU = 15.00, 90 minutes intraservice time and 283 minutes total time) involves similar total time and an additional 50 minutes of intraservice time when compared to 645X1, thus supporting the RUC-recommended value. CPT code 58544 (*Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)*) (work RVU = 15.60, 120 minutes intraservice time and 271 minutes total time) involves similar total time to 645X1 but 20 minutes more intraservice time, thus supporting the RUC-recommended value. CPT 60500 (*Parathyroidectomy or exploration of parathyroid(s)*) (work RVU = 15.60, 120 minutes intraservice time and 313 minutes total time) involves 20 fewer minutes of intraservice time when compared by 645X1 but additional total time, thus supporting the RUC-recommended value. CPT Code 15733 (*Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (ie, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae)*) (work RVU = 15.68, 120 minutes intraservice time and 305 minutes total time) involves additional total time but 20 minutes less of intraservice time when compared to 645X1, thus supporting the RUC-recommended value. CPT code 49655 (*Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated*) (work RVU= 16.84, 150 minutes intraservice time and 344 minutes total time) when compared with 645X1 has 10 minutes more of intraservice time and more total time, warranting the higher work value in comparison to code 645X1.

Table 7

<i>CPT Code</i>	<i>Work RVUs</i>	<i>Intraservice time</i>	<i>Total time</i>
64911	14.00	110 minutes	292 minutes
19303	15.00	90 minutes	283 minutes
58544	15.60	120 minutes	271 minutes
60500	15.60	120 minutes	313 minutes
15733	15.68	120 minutes	305 minutes
645X1	16.00	140 minutes	276 minutes
49655	16.84	150 minutes	344 minutes

These six codes, four of which are performed by our specialty, demonstrate that a value of 16 RVUs is appropriate. The Academy strongly recommends a work RVU of 16.00 based on the survey median and

comparator codes. We ask that CMS not use the intraservice time methodology which previously has not been considered valid to propose a work RVU for CPT code 645X1. **The Academy urges CMS to instead accept a work RVU of 16.00 for CPT code 645X1.**

645X2

New CPT code 645X2 replaces CPT Category III code 0467T which was reported with CPT code 64569. CMS disagrees with the RUC recommendation that supports the survey median work RVU for CPT code 645X2. Rather, the agency is proposing a work RVU of 14.50 based on the “recommended increment” of 0.50 RVUs above the proposed work RVU of 14.00 for CPT code 645X1. While the RUC takes changes in work and time carefully into account, time ratios and increments were not used nor recommended by the RUC in approving the value of 16.50 for CPT code 645X2.

Rather, the RUC utilized the robust survey data and supporting reference codes as listed below to determine the recommended value of 16.50, which represents the survey median and appropriately accounts for the physician work required to perform this service.

Table 8

CPT Code	Work RVU	Intraservice Time	Total Time
28171	16.41	120	365
645X2	16.50	140	276
49655	16.84	150	344
42415	17.16	150	333

The Academy supports the RUC-recommended value of 16.50 wRVUs for CPT code 645X2. Table 8 (above) supports the RUC-recommended values by comparison to the following 3 CPT codes: 28171, 49655, and 42415. For example, CPT code 28171 (*Radical resection of tumor; tarsal (except talus or calcaneus)*) (work RVU = 16.41, 120 minutes intraservice time and 365 minutes total time) involves 30 less intraservice time than 645X2 but less total time, thus supporting the RUC recommended value. CPT code 58544 (*Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)*) (work RVU = 15.60, 120 minutes intraservice time and 271 minutes total time) involves the same intraservice time as 645X2 and similar total time, thus supporting the RUC-recommended value. CPT code 42415 (*Excision of parotid tumor or parotid gland; lateral lobe, with dissection and preservation of facial nerve*) (work RVU = 17.16, 150 minutes intraservice time and 333 minutes total time) involves the same intraservice time as 645X2 and similar total time, thus supporting the RUC-recommended value. These three codes, one of which is performed by our specialty, demonstrate that a value of 16.5 RVUs is appropriate. As CMS has suggested, accepting a work RVU of 16.5 for 645X2 maintains relativity within the family.

CMS states that “the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity.” **Throughout CMS’ proposals on the valuation of specific codes for 2022, the Academy remains concerned about the use of flawed methodologies to arrive at valuations such as time ratios and incremental adjustments.** In many scenarios, CMS selects an arbitrary combination of inputs to apply, including total physician time, intraservice 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 calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity.

The Academy strongly recommends a work RVU of 16.50 based on the survey median. The Academy disagrees with CMS utilizing incremental differences for valuing services and entreats the Agency to rely on robust survey results and magnitude estimation to maintain relativity. **The Academy urges CMS to accept a work RVU of 16.50 for CPT code 645X2.**

645X3

New CPT code 645X3 replaces CPT Category III code 0468T which was reported with CPT code 64570. CMS disagrees with the RUC recommendation that supports the survey median work RVU for CPT code 645X3. However, the agency agrees that “the relative difference in work between CPT codes 645X1 and 645X3 is equivalent to the recommended increment of -2.0 RVUs.” CMS is proposing a work RVU of 12.00 based on the “recommended increment” of 2.00 RVUs below the proposed work RVU for CPT code 645X1. While the RUC takes changes in work and time carefully into account, time ratios and increments were not used nor recommended in arriving at the value of 14.00 for CPT code 645X3. Rather, the RUC utilized the robust survey data and numerous supporting reference codes, all with identical intraservice times, to determine the recommended value of 14.00. The value is appropriately bracketed by CPT codes 31591, 21395, and 58674.

Table 9

<i>CPT Code</i>	<i>Work RVUs</i>	<i>Intraservice time</i>	<i>Total time</i>
31591	13.56	120 minutes	275 minutes
645X3	14.00	120 minutes	275 minutes
21395	14.70	120 minutes	347 minutes
58674	14.08	120 minutes	266 minutes

The Academy supports the RUC-recommended value of 14.00 wRVUs for CPT code 645X3. Table 9 (above) supports the RUC-recommended values by comparison to the following 3 CPT codes: 28171, 49655, and 42415. For example, CPT code 31591 (*Laryngoplasty, medialization, unilateral*) (work RVU = 13.56, 120 minutes intraservice time and 275 minutes total time) involves the same intraservice and total time as 645X3, thus supporting the RUC recommended value. CPT code 21395 (*Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)*) (work

RVU = 14.70, 120 minutes intraservice time and 347 minutes total time) involves the same intraservice time as 645X3 and more total time, thus supporting the RUC-recommended value. CPT code 58674 (*Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency*) (work RVU = 14.08, 120 minutes intraservice time and 260 minutes total time) involves the same intraservice time as 645X3 and similar but less total time, thus supporting the RUC-recommended value. These three codes, two of which are performed by our specialty, demonstrate that a value of 14 RVUs is appropriate. Furthermore, accepting the RUC-recommended RVU assignment validates CMS' proposal to maintain relativity across the family.

While CMS mentions that the proposed work RVU is also the survey 25th percentile, the Academy considers the survey median more appropriate for code 645X3 because of the intensity and complexity that is inherent in this service. It is further supported by the aforementioned codes with identical intraservice times, demonstrating consistency within the fee schedule. Thus, the 25th percentile is not an accurate reflection of the physician work involved in this service.

CMS restates its belief that “the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity.” The Academy continues to be concerned about the Agency's use of flawed methodologies to arrive at valuations such as time ratios and incremental adjustments. In many scenarios, CMS selects an arbitrary combination of inputs to apply, including total physician time, intraservice 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 calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity.

The Academy strongly recommends a work RVU of 14.00 based on the survey median. CMS is not using a valid method to propose a work RVU for CPT code 645X3 by proposing a value based on an intraservice time ratio and interval difference. **The Academy urges CMS to accept a work RVU of 14.00 for CPT code 645X3.**

CMS proposes the RUC-recommended direct PE inputs without refinements for CPT codes 645X1, 645X2 and 645X3.

The Academy thanks CMS for their recommendation to accept the practice expense inputs for this code and we support that recommendation.

4. Drug Induced Sleep Endoscopy (CPT codes 42XXX)

CMS proposes the RUC-recommended work RVU of 1.90 for CPT code 42XXX as well as the RUC-recommended direct PE inputs for this code.

The Academy thanks CMS for their recommendation to accept both the RUC work RVU and practice expense inputs for this code and we support their proposed recommendation.

g. Telehealth

Throughout the current PHE, AAO-HNS members have benefited from CMS' telehealth flexibilities to the benefit of the practitioners and their patients. **The AAO-HNS strongly supports the continuation of reasonable telehealth policy for the duration of the public health emergency.**

1. Audio Video Requirements

CMS proposes to require all telehealth appointments, with the exception of mental health services, utilize audio and video capabilities. The AAO-HNS generally opposes audio only telehealth visits. Recognizing that being able to see a patient's face and facial movements is beneficial for mental health practitioners, the AAO-HNS understands the carve out for these types of services. **The AAO-HNS supports CMS' proposal to require video for telehealth appointments with CMS' proposed exception for mental health services.**

2. Virtual Supervision

CMS proposes to continue allowing virtual supervision during calendar year 2022. These provisions were put in place due to the PHE and resulted in fewer people being in confined spaces lessening the chances of spreading diseases and protecting vulnerable physicians and patients from additional unnecessary contact. Additionally, CMS proposes to require audio and video capabilities in order to allow an attending physician to supervise their residents. **The AAO-HNS strongly supports virtual supervision with audio visual requirements.**

CMS also proposes that residents, when billing for total time under an E/M code, can only bill for the time when they are being virtually supervised. The AAO-HNS has concerns about this proposal and while supervision may be needed for the actual exam, there may be other portions of the encounter where supervision is not necessary. Non-physician providers can provide some care without virtual (or in person) supervision, and therefore physicians, who have years of additional training, should at least have the same privileges as the non-physician providers.

3. Virtual Check-in

In calendar year (CY) 2021, in response to the PHE, CMS finalized virtual check ins (HCPCS code G2252) on a temporary basis. In the CY 2022 proposed rule, CMS proposes to make virtual check ins permanent. **The AAO-HNS supports making virtual check-ins permanent.** Physicians have been using this provision to reduce the amount of time that a patient spends in their office, and the reductions in burdens have demonstrable value beyond the current pandemic.

4. Category 3 Codes

Category 3 telehealth codes were added to the CMS telehealth list on a temporary basis during the current PHE. CMS proposes to remove these codes not before the end of calendar year 2023 even if the PHE

ends before December 31, 2023. This extension allows CMS, and Medicare providers, time to determine if these codes should be added to either category 1 or 2. Otolaryngologists have benefited from the creation of category 3 as it has allowed physicians to safely provide quality care to their patients during the ongoing PHE. While there are concerns about whether these codes can be done virtually or should be added to the permanent telehealth lists, the **AAO-HNS supports keeping these codes on the temporary category 3 list to ensure enough time for the PHE to end and to determine whether it is feasible for these codes to remain telehealth eligible.**

5. Patient Visits

CMS proposes adjustments to the requirement for in-person visits that must currently be conducted by the provider delivering telehealth services in the six months preceding a telehealth visit. The adjustment to current policy would allow another physician in the same specialty (and subspecialty) who must also be part of the same practice to conduct this in-person visit if the original physician is unavailable. **The AAO-HNS supports allowing different physicians in the same practice to see patients in person if the original physician is unavailable.**

CMS is also seeking comment on whether to shorten or lengthen or maintain the allowable time period if it is determined that this would neither present a prohibitively burdensome travel requirement for the patient nor be detrimental to the quality of care. **The AAO-HNS supports a policy that allows the physician and patient to determine how often they must meet in person in order to receive the highest quality care.**

h. Scope of Practice

In the NPRM, CMS is implementing the provision in the Consolidated Appropriations Act, 2021 that allows physician assistants (PAs) to bill the Medicare program, receive direct reimbursement for their services, reassign their rights to payment for their services, and incorporate as a group comprised solely of practitioners in their specialty and bill Medicare. While PAs play a critical role in caring for Medicare beneficiaries, physicians are the only practitioners qualified to lead the health care team. Every state in the country requires PAs to practice with some level of physician oversight. **It is imperative, therefore, that any changes to the billing authority of PAs be carried out within the parameters of these state laws and transitively ensure that such billing authority does not introduce negative impacts on quality of care for Medicare beneficiaries.**

The AAO-HNS believes that PAs should be authorized to provide patient care services only if the PA is functioning under the direct supervision of a physician or group of physicians. There is a large difference in rigor and standardization between medical school and residency and PA programs. PAs are integral members of the care team, but the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise their patients' care.

The vast majority of state regulations reflect the necessity for oversight of PAs and the importance of physician-led care. In 48 states, a PA's scope of practice is determined with the supervising or collaborating physician at the practice site. Moreover, in 34 states PAs are supervised by physicians and

in 16 other states PAs are subject to other forms of collaborative or alternative agreements. **Thus, as the billing abilities of PAs change it is important to ensure that this change does not impact patient care or current scope of practice requirements.**

i. Appropriate Use Criteria

Under Section 218(b) of the Protecting Access to Medicare Act (PAMA), Congress required that CMS establish an Appropriate Use Criteria (AUC) Program to promote appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries. The AUC program requires ordering physicians to consult appropriate use criteria using a clinical decision support mechanism prior to ordering advanced imaging services for Medicare beneficiaries and furnishing physicians to report this information on the claim. Currently, CMS is scheduled to begin denying claims that do not report AUC information on January 1, 2022. CMS proposes to delay enforcement of the AUC program by at least one year until the later of January 1, 2023, or the January 1 that follows the end of the public health emergency.

The AAO-HNS strongly urges CMS to finalize its proposal to delay the penalty phase of the AUC program until the later of January 1, 2023, or the January 1 following the end of the PHE. The proposed delay recognizes the significant disruptions caused by the COVID-19 pandemic and will allow more time for the education and operations testing period, which is critical given CMS' finding that only 9-10% of 2020 diagnostic imaging claims would have met the AUC reporting requirements to be paid if enforcement had been in effect. **The AAO-HNS appreciates CMS' recognition that the COVID-19 PHE has adversely impacted physicians' ability to prepare for AUC implementation.** Due to the surging fourth wave of COVID-19 cases and hospitalizations and the ongoing demands of meeting patient care needs, physicians are still not in a position to devote the necessary resources to ensure a successful implementation of the AUC program.

While there may be differing ideas about how to foster the use of AUC by clinicians, there is widespread agreement the program should not and cannot be implemented as originally envisioned by Congress. Although the requirements for consultation and reporting of AUC were enacted in 2014, many physician members of the AAO-HNS remain unaware of the underlying program requirements. The AUC Program implementation is occurring at the same time providers are struggling to assign adequate resources for information technology infrastructure and Quality Payment Program participation. The AUC Program has no metrics of quality or patient outcomes. Our concerns are underscored by CMS' claims analysis finding that only 9-10% of claims would have been paid in 2020 had AUC been in effect. In other words, 90-91% of Medicare claims for advanced diagnostic images would have been rejected and unpaid in 2020 if AUC was in effect that year. The impact on providers and patients alike would have been hugely burdensome. **CMS should not move ahead with the AUC penalty phase until the vast majority of applicable claims would meet the requirements to be paid.**

Finally, the AAO-HNS continues to have foundational concerns about the burden of AUC and how best to implement the program, including the proper, standardized procedures for transmitting information from the ordering to the rendering provider, efficient reporting of the required data on claims, and

understanding aspects of the program requirements and exceptions. We urge CMS to take substantial steps to alleviate the burden of AUC and improve its relevance to physicians and Medicare. **The AAO-HNS encourages the agency to discuss potential legislative fixes with Congress or limiting reporting to the priority areas.** The AUC Program sets up a complex exchange of information between clinicians that is not yet supported by interoperable electronic health record systems and relies on claims. **CMS should also allow compliance via means other than claims, such as qualified clinical data registries.**

II. Quality Payment Program

a. Merit-based Incentive Performance System (MIPS)

1. QCDR Measure Rejection Criteria

CMS proposes to add two rejection criterion for QCDR measures: A QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period and if a QCDR measure owner is not approved or is not in good standing, any QCDR measure associated with that QCDR will not be approved. **The AAO-HNS supports both rejection criteria.**

CMS notes that the “inactive QCDR measure owner has the option to transfer ownership of the QCDR measure to an active QCDR or agree upon terms set forth with the active QCDR allowing co-ownership of the QCDR measure.”² CMS is seeking feedback on what should be done in circumstances when an active QCDR wishes to use an inactive QCDR’s measure. The AAO-HNS supports continuation of the current policy under which an active QCDR that wishes to use an inactive QCDR’s measure can approach the inactive QCDR and the two QCDRs can negotiate an agreement regarding the transfer of ownership if the active QCDR has the appropriate experience and expertise in QCDR measure development.

2. Sunsetting Traditional MIPS

CMS is seeking feedback on the timeline to sunset traditional MIPS and to make MVP reporting mandatory. The AAO-HNS believes that CMS should maintain traditional MIPS until it is demonstrated that the MVP program is successful and have at least ten MVPs approved and in operation.

3. Data Completeness

The AAO-HNS was very concerned about the original proposal to move to 70% data completeness in the 2020 PFS/QPP proposed rule. At that time practice conditions were not yet disrupted by the COVID-19 public health crisis, and we still felt it would be very difficult for some of our practices to reach that goal. The onset of the pandemic has affected clinicians in a variety of ways and altered their financial and temporal abilities to accommodate this level of completeness. Additionally, office support staff have also been overtaxed in simply trying to facilitate patient care during the PHE. CMS has demonstrated the necessary flexibility in most areas to help the medical community navigate through the pandemic. **We**

would urge the agency to apply this same flexibility to the completeness standard, waiting until burdens from the pandemic are alleviated before raising the completeness criteria. We are therefore requesting CMS to maintain data completeness at 70% in the 2023 performance period.

4. MIPS Performance Threshold and Additional Performance Threshold

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

5. QCDR Testing Timeline and Face Validity Testing

We continue to have concerns about the proposed requirement that any QCDR measure accepted for the MVP program must be fully tested prior to acceptance, as this greatly reduces the opportunity to widely represent our specialty area. As stated in our earlier MVP comments, there are emerging strategies for measure development that we feel can be validated by registry-based data which will end up being a more accurate representation of all phases of care, including outcomes, than the traditional guideline-based measures. If CMS is willing to accept these "non-QCDR" measures for utilization in the MVP, that would help accomplish the same goal to provide opportunities for the breadth of our Academy's membership.

In addition, and as outlined in previous comments, our quality measures are developed with the appropriate rigor in that we have a comprehensive, physician-led process dedicated to otolaryngology specialty-specific measure development. Having to revert to utilizing a complex and resource-intensive measures testing process will only delay getting appropriate measures into the program and into specialty-specific MVPs.

The AAO-HNS supports CMS in its proposal to allow new measures to be "face valid" beginning with the 2024 MIPS payment year. We believe that face validity testing should be expanded to two years, which would result in the new measure to be fully tested in its third year of life in the MIPS or MVP program.

6. APM Performance Pathway

We are seeking further clarification on CMS' comments that they are proposing that QCDRs, beginning in the 2023 performance period/2025 MIPS payment year, must support APPs. We would oppose the requirement to support the APP as QCDRs are not currently required to provide this support and many operational changes would be required to do so.

As outlined in our 2021 Proposed rule comment letter, the AAO-HNS strongly believes that the progressive addition of requirements of QCDRs over the last several years has great potential to cause many specialty societies, including ours to discontinue their QCDR because of the cost and difficulty of operations.

7. Bonus Points

The AAO-HNS is supportive of CMS’s proposal to assign five bonus points for the Clinical Data Registry Reporting measure, the Public Health Registry Reporting measure, or the Syndromic Surveillance Reporting measure. However, we are concerned about the proposal to eliminate the bonus points for high priority measures as these points can incentivize participants to utilize QCDR measures over non-specialty specific QPP measures and drive improvement across the specialty.

CMS proposes to provide five bonus points to new measures without a benchmark for two years. We are supportive of this proposal and ask that CMS consider extending this to existing QCDR measures that are also currently without benchmarks. It is difficult to drive utilization of these measures by participants because of current CMS scoring policies. Without a process for obtaining benchmark data there is a continued risk to lose high impact, specialty-specific quality measures from the program due to no or low utilization due to existing scoring policies.

b. MIPS Value Pathways (“MVPs”)

We continue to believe, as previously stated both in comments and meetings with agency staff, that the only way MVPs will be successful in the long run and meaningful to patient care through improved outcomes, is by mirroring the patient evaluation and treatment paradigm used by physicians across all specialties. MVPs would allow all components of the current MIPS system to be addressed within the structure of MVPs. One of the great advantages of this type of system is the ability to include MVPs that cover the breadth of the specialty.

The Academy appreciates CMS’ decision to include QCDR measures in MVPs, and the agency’s commitment to working collaboratively with stakeholders like the AAO-HNS to develop MVPs that are clinically relevant and meaningful to specialties and subspecialties and their patients. CMS will have to be flexible and consider creative methodologies for measure development within the MVP that can be validated through registry-based data as well, i.e., “non-QCDR” measures. If CMS is willing to accept both QCDR and non-QCDR measures for utilization in the MVP, that would help accomplish the same goal of providing reporting opportunities for the breadth of our membership.

The typical NQF methodology will not allow the extent of coverage necessary to include many common disease processes. There are emerging strategies for measure development that we feel will be validated by registry-based data. These strategies will end up being a more accurate representation of all phases of care, including outcomes, than the traditional guideline-based measures. This would be consistent with the five guiding principles as outlined by CMS in the NPRM.

1. Timeline for MVP Implementation

The AAO-HNS supports CMS' proposal to delay the implementation of MVPs until the 2023 performance period and to keep MVP reporting remain voluntary through at least the 2029 MIPS payment year. Until there are a significant cohort of approved MVPs for clinicians to report, traditional MIPS should remain in effect. One of the strongest arguments for moving to MVPs is that they provide meaningful information to clinicians and their patient with measures that form a clinically aligned, cohesive reporting mechanism and include cost measures that have clinical association with the quality measures in the MPV. Until this occurs, traditional MIPS should be an available alternative to MIPS participants.

2. Subgroup Reporting

In the proposed rule, CMS states that single specialty groups would be able to report on the same set of relevant and applicable measures for all clinicians within the group and would be able to ascertain results that may lead to improvements in the patient care provided. The agency therefore does not anticipate the need to require single specialty groups to form subgroups in order to report an MVP. **AAO-HNS believes that there may be exceptions when all parts of a single specialty MVP may not be of equal applicability to all subspecialties within a specialty. For these reasons, clinicians should be able to report the sections of an MVP that are relevant to their practice.** We also feel that clinicians practicing in a multispecialty situation should have the option of reporting through their given specialty's MPV or the multispecialty group they participate in.

We remain concerned about the requirement that QCDRs support subgroup reporting beginning with the 2023 performance year. We urge CMS to delay this proposal and allow QCDRs adequate time to implement reporting processes. This is of particular importance given the requirement that registries would need to track the subgroup identifiers and support the data submission process by identifying through a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI. This will require QCDRS to incorporate complex technical changes, leading to increased vendor costs and requiring enough lead time to make and test the required changes prior to implementation. In addition, CMS proposes that the agency will issue a new identifier when a provider transitions to a new practice. Given the frequency of these types of practice transitions, there could be numerous changes that QCDRs would have to track on an annual basis as these identifiers are reissued.

3. Supporting MVPs

CMS proposes that MVPs applicable to registry participants are offered through QCDRs beginning with the 2023 performance year. While not requiring that QCDRs support all MVPs, CMS is proposing that QCDRs "should identify and support MVPs that are relevant to the clinicians and group they support". If a specialty QCDR was not involved with the development of a particular MVP or is not in agreement with the care pathway demonstrated through the MVP, there would be good reason to not want to allow reporting of such MVP through a specialty QCDR. We request further clarification of this proposed requirement and urge CMS to delay this proposal until there is a better explanation of how it would be operationalized by QCDRs.

The AAO-HNS has had several discussions with CMS about our three MVP concepts (for Chronic Rhinosinusitis, Early Oral Cavity Cancer and Hearing Loss). These are constructed using existing measures. With the removal of 19 MIPS quality measures, CMS is moving toward a reduction in overall measures for the MIPS program in 2022, but this strategy will act as a de facto exclusion of our clinical pathways to cover the breadth of our specialty. While we are encouraged to see that CMS has allowed flexibility in the type and number of measures they will require to evaluate an MVP, including non-QCQR measures, we caution CMS to reconsider removal of so many measures. **The AAO-HNS urges CMS not to remove what they consider to be “topped-out measures” prematurely.**

As we move into the new era of MVPs, it will be critical to have some anchor measures with previously predictable scoring established prior to the pandemic. It is unclear how the ongoing COVID-19 disruption will affect scoring of these measures over a period of several years. The current CMS policy on topped-out measures ends up being punitive to providers who have succeeded in identifying gaps and improving quality through this program. It seems to send the message that they are not providing quality healthcare despite their efforts to fully embrace these measures.

Not only will this reduction in relevant measures effect MVP development, but it can also lead to difficulty for many clinicians to report six benchmarked measures. Especially after experiencing the strains from the PHE during the past eighteen months, clinicians and their practices need to experience program stability. A delay in this proposal would also allow QCQRs to test and offer new measures either for use in MVP development or for traditional MIPS reporting.

One of the most difficult and ill-defined areas of the current proposal revolves around cost. There are many strategies percolating that have the potential to be more accurate than the existing databases. CMS should look to partner with specialty societies, including the AAO-HNS, as they try to develop, validate, and implement meaningful cost measures across the spectrum of care. Specialty practices are very concerned about appropriate attribution of cost within episodes of care.

As expressed in previous comments and in meetings with CMS, the AAO-HNS has concerns about the reliance of population health administrative claims measures as a major component of the MVP. The two available population health administrative claims measures available are not relevant or usable by most otolaryngologists, particularly in the non-academic setting. Those data sets are not valuable in creating outcomes measures or measuring quality at different steps of the patient evaluation and treatment process. They have limited value in cost because of the attribution difficulties. While there may be utility for these types of measures, they should not be a predominant feature of the MVP. We appreciate CMS responding to concerns that the proposed population health administrative claims measures are not necessarily applicable to all and proposing that an MVP Participant be scored on 1 population health measure, the measure with the higher score.

4. MVP Registration Process

When establishing the deadline to register an MVP Participant (April 1 thru November 30 of the applicable performance period), we urge the agency to consider QCQR deadlines. We also request that CMS offer MVP Participants the opportunity to change their registration after the deadline if the

Participant wishes to move from the selected MVP back to traditional MIPS before submission for the 2023 and 2024 performance year. Such flexibility may be necessary where, for instance, a practice discovers that its electronic health record (EHR) vendor does not support collection and sharing of data points for measures within the MVP.”)

5. Notification of Approved MVPs

We remain concerned that CMS will not communicate to stakeholders whether an MVP candidate has been approved, rejected, or is being considered for a future year, prior to the publication of the proposed rule. The development of MVPs requires tremendous resources not only to design and implement, but also to maintain over time. Without some indication of success, the whole MVP program is subject to failure for several reasons. First, as organizations are planning for next year’s reporting, the lack of approval until November in the year before implementation is simply not feasible. There is no way to communicate to eligible clinicians and their practices in time to get the required set up established in that timeframe. Additionally, very few organizations can commit and risk the resources necessary to create a high-quality MVP without probability of acceptance. **The AAO-HNS urges CMS to work with specialty society developers and offer guidance in an ongoing fashion to identify additional information requirements. Collaboration and suggestions on how the MVP candidate proposals might be improved to the point of acceptance and a reasonable timeframe for adoption are also necessary.**

III. Conclusion

The American Academy of Otolaryngology-Head and Neck Surgery appreciates the opportunity to provide comment and recommendations regarding these important policies on behalf of our members. We look forward to working with CMS as it continues its efforts to improve patient access to quality care and reduce regulatory burdens for providers. If you have any questions or require further information, please contact healthpolicy@entnet.org.

Respectfully submitted,



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