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NEUROLOGICAL SURGEONS

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September 5, 2016

Andy Slavitt, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: CMS-1654-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017

Dear Mr. Slavitt,

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), representing over 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the above-referenced Notice of Proposed Rulemaking (NPRM). The following comments focus primarily on the coding, payment and quality provisions included in the rule. We have submitted comments related to the global surgery proposal in a separate comment letter.

EXECUTIVE SUMMARY

Coding and Reimbursement Issues

Determination of Professional Liability Insurance (PLI) RVUs

- **Use of Geographic Practice Costs Indices (GPCI) Updated Data for Specialty-specific Risk Factors for PLI Relative Value Units (RVUs).** Neurosurgery has long advocated for the use of the most up-to-date data for PLI RVUs, and we continue to do so. As such, we recommend that CMS use the updated PLI premium data.
- **PLI Variation for Low Volume Services.** The AANS and CNS urge the agency to accept RUC specialty designation "overrides" for very low volume services to prevent significant variation in year-to-year PLI RVUs.

Validating RVUs of Potentially Misvalued Codes

- **Methodology for Reducing Work RVUs Using Formulaic Review of Time.** The AANS and CNS strongly disagree with CMS' suggestion for developing a formulaic RVU reduction method based on time, in which the agency insists on significantly lowering RUC-passed work RVUs when the time of a procedure has decreased. We urge the agency to heed our comments from previous years and the RUC's comments and to fully account for intensity, as well as time when valuing procedures. We do not support the use of the reverse building block methodology as the primary method for determination of work RVUs.

- **Valuation of Specific Codes--CY 2017 Proposed Codes**

- **Insertion of Spinal Stability Distractive Devices, CPT Codes 228X1 and 228X4.** The AANS and CNS disagree with the reduction of RUC-passed values for two new codes for Insertion of Spinal Stability Distractive Devices, CPT codes 228X1 and 228X4.
- **Insertion of Intervertebral Biomechanical Devices, CPT Codes 22X81, 22X82, and 22X83.** The AANS and CNS object to the reduction of the RUC-passed values for new codes to describe the work of CPT code 22851, which has been deleted. Also, we would point out that valuing 22X82 and 22X83 the same creates a rank order anomaly, as 22X83 is more work and more intense than 22X82.
- **Endoscopic Decompression of Spinal Cord.** The AANS and CNS disagree with the CMS proposed valuation for CPT code 630X1 and urge the agency to accept the RUC-recommended value.

- **Valuation of Specific Codes— CY 2016 Interim Valued Codes**

- **Implantation of Neuroelectrodes, CPT Codes 64553 and 64555.** The AANS and CNS disagree with the need for separate codes for temporary/testing and permanent placement for neuroelectrodes. As CMS has pointed out, CPT codes 64553 and 64555 will be considered by the CPT Panel in September.
- **Intracranial Endovascular Intervention Codes, CPT Codes 61645, 61650, and 61651.** The AANS and CNS are disheartened by the agency's continuing failure to correctly value the intracranial endovascular intervention codes — CPT codes 61645, 61650, and 61651. The explanation in the proposal rule regarding the refinement panel for these codes is not accurate, and we urge CMS to implement the RUC-passed values.

Quality Issues

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

- **Minimizing Burden.** The AANS and CNS strongly urge CMS to work closely with physicians to reduce the burden of this program and to ensure it is practical for everyday practice given the multiple other reporting mandates physicians will face in the coming years.
- **Clinical Priority Areas.** CMS should begin testing this program on a more limited set of clinical priority areas. It also should identify priority areas based on CPT codes, anatomical region, variation in treatment, and quality of the evidence, rather than simply utilization and volume.
- **Exceptions**
 - Exceptions from the program should be administratively easy for physicians to claim.
 - CMS' proposed hardship exception should be expanded to cover physicians who lack control over clinical decision support mechanism (CDSM) or electronic health record (EHR) decisions, as well as physicians who do not have access to low-cost integrated CDSMs.
- **Clinical Decision Support Mechanisms**
 - We urge CMS to continue to work with the Office of the National Coordinator (ONC) and other relevant stakeholders to ensure full interoperability of CDSMs with EHRs and with each other.

- The ordering physician should not have to report every instance where relevant appropriate use criteria (AUC) not available in the system since this could overwhelm physicians who regularly order diagnostic imaging.
- We appreciate that CMS would not require consultation or adherence to any specific AUC, so long as a qualified provider-led entity (PLE) develops it, but question how this will result in a clean analysis of outliers.
- We request that CMS push back the start date even further than January 2018 to ensure physicians have time to prepare for the program and its requirements.

Value-Based Payment Modifier and Physician Feedback

- The AANS and CNS appreciate that the agency is proposing to protect physicians from penalties in situations where unanticipated data issues arise, but we also strongly urge CMS to invest resources in preventing these errors from occurring in the first place.

Proposed Changes to the Medicare Shared Savings Program (MSSP)

- **Measures.** The AANS and CNS oppose CMS' proposal to add ACO-44 Use of Imaging Studies for Low Back Pain (NQF #0052) to the MSSP quality reporting requirements. This measure relies only on claims data, fails to incorporate critical caveats or "red flags" that might appropriately drive early imaging, and it fails to target the current gap in measures for overuse of imaging for low back pain in the older population.
- **ACO Participants Who Report PQRS Data Separately.** We support CMS' proposal to protect individual clinicians from penalties in situations where the ACO fails to satisfy reporting requirements, but ask the agency to consider also offering these clinicians a waiver should they not want to go through the effort of reporting again. CMS also should invest in broader strategies to prevent these situations from occurring in the first place.

Open Payments Program

The AANS and CNS appreciate the opportunity to provide feedback on the Open Payment Program. We note that CMS has not specifically asked for comment on the onerous registration process, but we believe this is an area that remains a significant burden to physicians.

COMMENTS

CODING AND PAYMENT PROVISIONS

Professional Liability Insurance (PLI)

Use of GPCI Updated Data for Specialty-specific Risk Factors for PLI Relative Value Units (RVUs)

The AANS and CNS note CMS' question regarding updating specialty specific risk factors in CY 2018, before the CY 2020 Five Year Review of the PLI, based on new PLI premium data collected for the 3-year Geographic Practice Cost Indices (GPCIs). CMS states that the proposed CY 2017 GPCI reflects updated 2014 PLI premium data. However, CMS proposes not to use this data to update the current 2011 premium data employed in the creation of the PLI RVUs since it goes against their stated policy of only updating premium data every five years for PLI RVUs. The AANS and CNS have long agreed with the RUC in favoring a yearly collection schedule of premium data. However, since CMS has rejected that recommendation, the most recent available PLI premium data should be used. With these data readily available to CMS, there seems to be no logistical reason not to update the PLI RVUs accordingly.

PLI Variation for Low Volume Services

The AANS and CNS urge the agency to accept RUC specialty designation “overrides” for very low volume services to prevent significant variation in year-to-year PLI RVUs. The issue of valuing PLI RVUs for low volume codes has long been a concern for neurosurgery, the specialty with the highest PLI payments. Some codes are so rarely performed or have such low Medicare volume for a particular year that the dominant specialty may be incorrect and, therefore, may not accurately reflect the risk. We agree with the RUC that code-specific “overrides” are essential when the claims data are inconsistent with the specialty that would be reasonably expected to furnish the service. Some procedures may be very low volume for Medicare but have greater volume for Medicaid or other payers, further propagating errors.

Validating RVUs of Potentially Misvalued Codes

Methodology for Proposing Work RVU Reductions Using Formulaic Review of Time

We are keenly aware that CMS is required by law to develop a process for validating the RVUs under the MPFS, and we support this approach as it allows for greater accuracy and transparency. In the proposed rule, CMS is seeking comment on “...*whether, within the statutory confines, there are alternative suggestions as to how changes in time should be accounted for when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resources costs of time for codes describing the PFS services.*” We believe the question goes to the very heart of the RBRVS system, which considers both time and intensity in the valuation of a given physician procedure or interaction. Inherent to the vast number and variety of conditions physicians treat using different modalities and encounters, no 'magic bullet' formula will allow the agency to accurately reduce values in a direct proportion to a reduction in the time for a procedure. Often when time is reduced, the intensity of a procedure increases and the overall work remains the same. Perhaps more importantly, time alone does not create value, but rather it is a single cog in a complex wheel of valuation; and having formulaic adjustments driven by time alone will lead to grave inaccuracies.

For easy comparison: two watchmakers make watches at different rates. One makes two watches in a day; the other makes four. Each watch involves the same number of gears, sprockets, jewels, and escapements. One watchmaker is faster (facile) than the other: more focused, more experienced, more agile, and able to accomplish fastidious work more efficiently. At the end of one workday, the first watchmaker has two finished watches on the bench, while the other has four. If the watches are identical, why should the faster (better) watchmaker be paid half the price for each watch?

The current RUC process has evolved to be robust and thorough in its consideration of reduction in time for procedures it reviews. In some instances, time is reduced because of new technology or technique that reduces physician work. In other cases, time is reduced because physicians have gotten faster (better) at what they are doing to accomplish the service. New and revalued codes receive comprehensive and appropriate scrutiny for descriptions, times, intensities, logic and utilization. The establishment of a “time formula” or use of reverse building block methodology as the primary method for valuation would completely disregard the possibility that physicians actually get better at what they do in favor of the erroneous conclusion that physicians only find new ways to cut corners. Treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on *relative* valuation. The inherent professional work that physicians perform for patients does not lend itself to a stop-watch approach, nor can any formula only accounting for time accurately capture the nuances that contribute to the value that physicians provide to their patients. We are willing to work with the agency to ensure fair valuation for procedures that accounts for both time and intensity accurately, as is required statutorily for

the RBRVS fee schedule, and because we fundamentally believe this will continue to add value to the system, and lead to a more accurate MPFS.

2017 Proposed Codes

- **Insertion of Spinal Stability Distraction Devices**

CPT Code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
228X1	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	15.00	13.50	Disagree
228X2	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)	4.00	4.00	Agree
228X4	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level	7.39	7.03	Disagree
228X5	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)	2.34	2.34	Agree

We appreciate CMS’ acceptance of the RUC’s physician work recommendations for codes 228X2 and 228X5 and RUC’s direct practice expense and physician time recommendations for the entire family of services. However, we disagree with the agency’s decision to reduce the values for 228X1 and 228X4.

For 228X1, the RUC recommended a direct work RVU crosswalk to CPT code 29915 *Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion)*. CPT code 29915 has identical intra-service time, very similar total time (270 vs. 271 minutes), very similar intensity (IWPUT of 0.1083 vs. 0.1065) and a similar amount of time for postoperative visits (97 vs. 88 minutes). The RUC’s crosswalk code is a better match than the CMS crosswalk at virtually every point of comparison. CMS did not indicate why CPT code 29915 is not an appropriate crosswalk.

For 228X4, the RUC recommended a direct work RVU crosswalk to CPT code 29880 *Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/ shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed*. CMS simply just picked a different crosswalk code that is in the same code family as the RUC crosswalk. The RUC’s crosswalk is closer to the survey code in both intra-service time and physician intensity. Other than those differences, all other time components of 29880 and 29881 are identical. As both proposed crosswalk codes are in the same code family, their clinical comparison to the survey code is indistinguishable. The RUC’s crosswalk code is either identical or a better match than the CMS crosswalk at every point of comparison.

CMS' proposed work RVU recommendation is only 4.8 percent less than the RUC's recommendation and relies on a weaker crosswalk. Rejecting the RUC's proposed recommendation, in this case, is entirely unreasonable and devoid of a rationale that is consistent with the precepts of valuation that form the foundation of fair relative valuation.

The AANS and CNS urge CMS to publish a work RVU of 15.00 for CPT code 228X1 and a work RVU of 7.39 for 228X4 in the CY 2017 NPRM final rule. If the agency does not do this, we request refinement panel consideration of these services.

- Insertion of Intervertebral Biomechanical Devices**

CPT Code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
22X81	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges) when performed to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)	4.88	4.25	Disagree
22X82	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges) when performed to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect	5.50	5.50	Agree
22X83	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)	6.00	5.50	Disagree

The AANS and CNS disagree with CMS regarding valuation for two of the new proposed CPT codes 22X81, 22X82 and 22X83 for insertion of intervertebral biomechanical devices, which will be replacing CPT Code 22851 as of January 2017. We believe that the reduction for 22X81 and final assignment of 5.50 for both 22X82 and 22X83 reflects a fundamental misunderstanding of the work being performed. We want to clarify the nature of that work which, in our opinion, warrants the higher RVU recommended by the RUC.

For 22X81, we agree with the RUC recommendation for a direct work RVU crosswalk to CPT code 57267 *Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)* (work RVU = 4.88). CPT code 57267 has an identical amount of intra-service and total physician time relative to the survey code, whereas CMS' chosen crosswalk has physician times that are not identical. Following extensive deliberation, the RUC agreed that the survey code and 57267 involve an identical amount of physician work. The RUC's crosswalk code is a better match than the CMS crosswalk at virtually every point of comparison. CMS did not indicate why CPT code 57267 is not an appropriate crosswalk.

The work of 22X82 is fundamentally different from 22X83 because these codes serve different intents. When trauma, tumor, or infection destroys a vertebral segment, this segment must be reconstructed and durable bony fusion (arthrodesis) achieved from the segment above to the segment below the reconstructed segment. The work of 22X82 describes reconstruction of a vertebral body with a biomechanical spacer, to achieve an arthrodesis that will stabilize the unstable spinal segment and ultimately achieve bony healing and permanent, durable spine stability with little risk to subsequent shifts in the construct. The hardware provides immediate short-term stability, but it may weaken or fail over time; arthrodesis achieves the goal of one bone fusing to another through the 22X82 device and provides the long-term stability.

The work described by 22X83 is for placement of a biomechanical device with no intention of eventual bony arthrodesis. When tumor or infection causes neural compression, and the underlying pathology or its treatment creates spinal instability, the structural defect must be corrected, but bony fusion may not be possible or expected. In this setting, the biomechanical device must be fashioned and placed to provide durable spinal stability without the added security of arthrodesis. The additional precision required for creating a stand-alone construct that will be stable over time results in a quantifiable difference in the overall intensity of the work, even though there are similarities in the code descriptors and the description of work. This is why the RUC valued 22X83 higher than 22X82.

By way of example, 22X83 would be used in the circumstance where a patient with a metastatic thoracic lesion causing spinal cord compression undergoes a decompression. The patient will need immediate postoperative radiation, and arthrodesis is, therefore, exceedingly unlikely. In this case, the surgeon completes a transpedicular decompression and then reconstructs the anterior column with either the Steinman pin and methyl methacrylate or another biomechanical spacer. The increased intensity of work in that circumstance warrants a higher valuation, thus the recommended valuation of 6.0 that was put forward by the RUC.

For the reasons stated above, the AANS and CNS urge the agency to restore the RUC-passed values for 228X1 and 228X3 in the CY 2017 MPFS final rule. Should the agency not do that, we ask that 228X1 and 228X3 be referred to a refinement panel.

- **Endoscopic Decompression of Spinal Cord.** CMS has stated that it believes the recommendation for 630X1, *Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar* overestimates the overall work involved in performing these procedures. CMS proposed a direct work RVU crosswalk to CPT code 49507 *Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated* (work RVU= 9.09), noting its observation that both services have similar intensity and identical intraservice physician time.

We do not agree. Rather, we note that the recommended direct work RVU crosswalk to MPC code 47562 *Laparoscopy, surgical; cholecystectomy* (work RVU=10.47). CPT codes 630X1 and 47562 have similar physician time. However, the RUC agreed the intensity of 630X1 was greater, offsetting the 10-minute difference in intra-service time between the two codes. The difference in intensity between these procedures is based upon 630X1, which involves decompression around neural elements and the spinal cord, where the opportunity for complications and loss of function is high. The IWPUT of the RUC-recommended value is 0.085, an appropriate valuation when likened to other spinal decompression procedures. The RUC determined that these two codes were appropriate comparators.

The AANS and CNS urge CMS to accept the RUC-passed work RVU of 10.47 for CPT code 630X1 for inclusion in the CY 2017 MPFS final rule. If CMS does not make the change in the final rule, we request a refinement panel for consideration for these services.

Valuation of Specific Codes— CY 2016 Interim Valued Codes

- **Implantation of Neuroelectrodes, CPT Codes 64553 and 64555.** CMS has asked for comment on whether there is a need for separate codes for temporary/testing and permanent placement for neuroelectrodes. We do not support the creation of new separate codes at this time. As CMS has pointed out, CPT Codes 64553 and 64555 will be considered by the CPT Editorial Panel meeting September 2016. Although neurosurgeons do not constitute the majority of physicians utilizing these codes, these procedures are performed by a subset of neurosurgeons, and we will be presenting our views on this issue at the September CPT Editorial Panel meeting. Again, we believe current codes account for the work of both temporary/testing and permanent placement and creation of new codes is unwarranted.
- **Intracranial Endovascular Intervention Codes, CPT Codes 61645, 61650, and 61651.** In April of 2015, the RUC recommended values for 61645, 61650 and 61651 of 17.00, 12.00 and 5.50 respectively. CMS proposed values for CY 2016 of 15.00, 10.00 and 4.25 respectively with the rationale that these procedures would be performed in the outpatient setting. As a result, CMS recommended CPT 37231 as a direct crosswalk for 61645, 37221 as the crosswalk for 61650, and 37223 for 61651, resulting in the CY 2016 values. Medicare 2014 data demonstrated that 37231, was performed in the inpatient setting only 21.3 percent of the time. CPT codes 37221 and 37223 are performed in the outpatient setting 53.23 and 50 percent, respectively, and in the office setting 12.81 and 11 percent of the time, respectively. Additionally, based on the erroneous rationale that 61645, 61650 and 61651 are performed in the outpatient setting, CMS removed the 55 minutes associated with CPT code 99233 (level 3 subsequent hospital care, per day). The 30 minutes of intra-service time associated with 99233 was added to the immediate post service time. Although the post service time was now increased from 53 minutes to 83 minutes, this artificially and inappropriately reduced the total work time from 266 minutes to 241 minutes.

CPT code 61645 is always performed as a highly time sensitive emergent procedure for acute stroke patients with large vessel occlusions and will never be performed in the outpatient setting. CPT codes 61650 and 61651 are typically performed in the same setting as that subarachnoid hemorrhage and cerebral vasospasm patients with impending strokes, that is, in an intensive care unit. The survey results noted that these procedures were 100 percent performed in the inpatient setting. A multi-specialty letter outlined this erroneous rationale and requested refinement. The evidence that these patients are treated in the inpatient setting was clearly noted by the RUC, which, therefore, made no direct practice input recommendations.

On March 2, 2016, a refinement panel conference call was conducted by CMS with the AANS, CNS, Society of Interventional Radiology (SIR), American College of Radiology (ACR), Society of Vascular Surgeons (SVS) and American College of Cardiology (ACC). On the call, the societies outlined the erroneous rationale that mischaracterized the codes. However, CMS maintained the interim CY2016 values for CY 2017.

We are astonished by the casual dismissal of the careful analysis provided by the specialty societies for these codes, clearly outlining why the CMS recommended comparator codes were incorrect and thus resulted in the inappropriately reduced values. Evaluating the actual physician work performed in the inpatient setting is much more accurate than the applying a crosswalk to a CPT code that is performed predominantly in the outpatient setting. We strongly urge CMS to review data provided by the AANS, CNS, the RUC, and other specialty comments over the last two years. Also, we urge CMS to more accurately characterize the refinement panel call for these codes and publish the vote of the refinement panel. We trust that after thorough review and consideration of the flaws in the CMS analysis that used outpatient and office codes to value these intense inpatient procedures, the

agency will accept the RUC-recommended work values for 61645, 61650 and 61651 of 17.00, 12.00 and 5.50 respectively.

On the specific question from CMS regarding the inclusion of postoperative visits in a zero-day global, we believe, again, CMS is confusing outpatient and inpatient policy. We note that CMS has said that if global codes require postoperative visits, they are more appropriately assigned 10- or 90-day global periods. We disagree. CPT code 61645 appropriately includes a postoperative visit equal to the work time associated with postoperative visit CPT code 99233 (level 3 subsequent hospital care, per day).

Last year, CMS stated that the agency believed that for the typical patient, these services would be considered hospital outpatient services and that the 55 minutes of work time associated with CPT code 99233 (subsequent hospital care) should be removed, and instead 30 minutes of intraservice time from CPT code 99233 should be added to the immediate postservice time of the procedure. We objected then, and continue to object, as these codes are performed in the inpatient setting, not the outpatient setting. All of these patients require intensive neurologic and hemodynamic monitoring following the procedure to prevent and/or diagnose intracranial hemorrhage, a potentially devastating complication. Many of these procedures are also performed under general anesthesia. The intensity of the visit work is similar to an ICU visit. A request for an ICU visit was considered, and the request for a 99233 visit is more than justified. CMS has allowed inpatient hospital visits with zero-day global inpatient procedures in the past. Indeed, there are currently over 50 inpatient facility-only zero and ZZZ codes that have a postoperative visit — reviewed and accepted by CMS, including codes passed in the last few years. We believe this is appropriate.

Refinement Process

The AANS and CNS supported the change in the MPFS publication schedule for new and updated RVU values. We urge the agency to use this change in timing to restore the RUC-passed values for the codes described above for the CY 2017 MPFS final rule. Nevertheless, we continue to support a robust and fair refinement panel process to allow specialties to present their case to colleagues, CMS staff and medical officers, and carrier medical directors if the agency has not accepted the RUC-passed values in the final rule. As such, on August 23, 2016, we joined 87 other medical groups in sending a letter to CMS on this subject. The groups that signed the letter support restoration of the relative value refinement process and appeals process, as it existed before 2011. We hope you will review the history of the refinement process as stated in that letter and preserve a method for societies to present their case for valuation following the publication of the CY 2017 MPFS final rule in November 2016. As stated above, we are deeply disappointed by the agency's characterization of the refinement discussion for the intracranial endovascular intervention codes and the complete lack of transparency regarding the refinement panel vote. We believe CMS disregarded the facts surrounding the codes and this shakes our confidence in the agency's dedication to fairness in assessing the intensity of surgical procedures. The dismissive comments regarding the agency's error in characterizing the codes as typically performed in the outpatient setting, and the refusal to restore fair values despite comments, visits, and a refinement panel, is concerning.

Again, we hope the agency will consider the facts regarding the codes valued by the RUC and restore the RUC-passed values without the need for a refinement panel for these codes this year. However, we agree with the RUC and many medical specialty societies that having a transparent refinement panel in place consisting of carrier medical directors, clinical experts, and CMS staff to reconsider proposed values allows for consideration of appropriate changes and offers a full and fair hearing. We believe the result of the refinement panel votes should be published, as this reinforces CMS' accountability to its stakeholders who do not agree with the agency's decisions, as well as to Congress. We strongly urge

CMS to open the refinement panel review to all procedures and services that are under CMS review during the current rulemaking process.

QUALITY PROVISIONS

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Background

The Protecting Access to Medicare Act of 2014 (PAMA) directs CMS to create a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. To be paid by Medicare for these imaging services, *furnishing* professionals (e.g., radiologists) must report to CMS that the *ordering* professionals (e.g., neurosurgeons) consulted appropriate use criteria via a qualified clinical decision support mechanism (CDSM). This requirement applies to *all* advanced imaging services defined under the statute, including magnetic resonance, computed tomography, nuclear medicine and positron emission tomography (X-ray, fluoroscopy, and ultrasound are excluded). While this broader reporting requirement is mandated to begin in January 2017, the law also requires that, starting on Jan. 1, 2020, outlier ordering professionals — defined as those who have low adherence to AUC criteria when ordering imaging studies for *select priority conditions only* — will be required to obtain prior authorization from CMS.

CMS is taking an incremental approach to defining the parameters of this program. In this rule, the agency expands upon previously adopted policies by proposing the following:

- The definition of a CDSM that can be used under the program, and the qualifications and requirements that the CDSM must meet to be qualified for use under this program.
- The initial list of eight clinical priority areas that will be used to identify outliers who will be subject to prior authorization under the program starting in 2020.
- Proposed exceptions to the requirement to consult AUC and report data to CMS, including services related to an emergency medical condition, services paid under Medicare Part A, and professionals seeking a hardship exception under the Electronic Health Record (EHR) Incentive Program.
- Reiterates an earlier decision to push back the start date of the program by not requiring ordering professionals to consult AUC any earlier than Jan. 1, 2018, since qualified CDSMs are not expected to be available until mid-2017.

General Comments

In general, the AANS and CNS recognize that inappropriate use of imaging is a problem that affects the quality of care, patient safety and resource use. We support efforts to encourage more appropriate use of imaging and are committed to achieving that goal, in part, through our *Choosing Wisely*[®] recommendations and our support of other imaging-focused quality measures. However, we have serious concerns about the actual mechanics and workflow of the Imaging AUC Program, particularly because one physician's actions determine the payment of another. While we understand the goal is to encourage better coordination and communication between providers, the proposed rule says little about how this will play out in clinical settings, where an ordering physician might practice at a site where his/her technology is unable to communicate with that of a furnishing physician at another location. Given the critical and significant role of diagnostic imaging in our specialty, we are equally concerned about the burden this program could impose on ordering professionals, such as neurosurgeons, who rely heavily on imaging to make accurate diagnoses and to determine the most appropriate care plan for a patient. Although CMS proposes that CDSMs would have to include, at a minimum, AUC covering only the clinical priority areas, the statutory requirement that ordering professionals consult AUC for *every applicable imaging service defined under statute* means that the CDSM must still have a mechanism in

place to alert ordering professionals every time an imaging order is placed, but no applicable AUC exists in the system. It is our understanding that the ordering professional also would somehow have to communicate that information to the furnishing professional, regardless of whether an AUC was available. Given the frequency with which neurosurgeons place imaging orders, this could result in an inordinate number of pop-ups, alerts and clicks, which would be extremely disruptive to practice and contribute very little to higher quality patient care.

We strongly urge CMS to work closely with both ordering and furnishing professionals to determine how to implement this program in a manner that makes sense in everyday clinical practice. This program should not impose unnecessary and largely futile requirements on physicians or contribute further to alert fatigue, which is a very real and growing problem in medicine. CMS must also take into account the growing number of reporting requirements and administrative disruptions that physicians will face in the coming years as a result of the Merit-Based Incentive Payment System (MIPS) and other federal policies, such as CMS' proposed sweeping mandate to collect data about global surgery services.

Clinical Priority Areas

In determining which clinical priority areas would fall under the prior authorization requirement starting in 2020, CMS considered factors such as incidence and prevalence of disease, the volume and variability of utilization of imaging services, the strength of evidence for their use, and applicability of the clinical area to the Medicare population. The agency's proposed clinical priority areas include the following, which accounted for roughly 40 percent of part B advanced diagnostic imaging services paid for by Medicare in 2014:

- Low back pain
- Cervical or neck pain
- Suspected stroke
- Headache (non-traumatic and traumatic)
- Altered mental status
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Chest pain (including angina, suspected myocardial infarction and suspected pulmonary embolism)
- Abdominal pain (any location including flank pain)

In general, organized neurosurgery agrees with CMS' approach to limit the application of the outlier and prior authorization provisions to specific clinical priority areas. However, we strongly recommend that CMS begin testing this aspect of the program on a more limited number of clinical priority areas than the proposed eight. Again, there are many real-world challenges that CMS has not yet addressed, such as how it will identify outliers if multiple — perhaps even conflicting — AUCs exist for a particular clinical priority area or imaging order. CMS also has not explicitly addressed how it would handle situations where an ordering professional was unable to consult an AUC or communicate the consultation to the furnishing professional due to system challenges beyond his or her control. Would CMS automatically view these situations as a failure to adhere to the AUC and would those situations count towards CMS' calculation of outliers? And would payment penalties only impact furnishing professionals or could ordering professionals also be held financially responsible? These and other questions have not yet been addressed and must be carefully considered before full implementation of this aspect of the program.

We also have concerns about the approach used by CMS to identify these priority areas. For one, it relies on diagnosis codes to define priority conditions, which is problematic since diagnosis codes often are not known until the test is completed. We request that CMS instead explore a list of priority areas based on CPT codes and anatomical region. CMS also relies on volume and utilization as the only determinant of priority areas. Again, we believe this is problematic, and the AANS and CNS request that

CMS also consider variation in treatment and quality of the evidence in determining priority areas. We also remind CMS that ICD-10 will result in much more granular information about the indications for imaging. As such, this program, which is currently constructed based on ICD-9 data, might need to be re-thought once we have a foundation of ICD-10 data.

Exceptions Process

In this rule, CMS also formally proposes several exceptions to the AUC consulting and reporting requirements, as required by statute. These include:

- **Emergency Medical Condition.** CMS proposes that applicable imaging services ordered for an individual with an “emergency medical condition,” as defined under the Emergency Treatment and Labor Act (EMTALA), would be exempt from the requirements of this program. CMS notes that these conditions are not exclusive to the emergency department setting and could potentially arise in other settings. Furthermore, for this exception to apply, “the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or a woman’s unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part.” CMS notes as an example that if a patient, initially determined by the clinician to have an emergency medical condition before ordering an applicable imaging service, is later determined not to have had an emergency medical condition at that time, the relevant claims for appropriate imaging services would still qualify for the exception. Since neurosurgeons often treat trauma and other patients (e.g., stroke) with emergency medical conditions, we appreciate this exception, as well as the agency’s clarification of its applicability in situations where an emergency medical condition is suspected, but not yet confirmed. We request that CMS work with the AANS and CNS and other relevant stakeholders to determine how best to capture this exception via claims or another simple attestation process that does not further divert physician time away from patients.
- **Inpatient Services.** The statute creates an exception for applicable imaging services for an inpatient and for which payment is made under Medicare Part A. CMS proposes to codify this exception. The AANS and CNS support this exception.
- **Significant Hardships.** CMS proposes to allow ordering professionals who are granted certain significant hardship exceptions under the Medicare EHR Incentive Program also to receive a significant hardship exception for purposes of the AUC consultation requirement. These would include hardships for eligible professionals (EPs) located in an area without sufficient Internet access; EPs practicing for less than two years; and extreme and uncontrollable circumstances (e.g., a natural disaster or another unforeseeable barrier, or a vendor issue). While we support the agency’s effort to streamline these two programs and minimize the reporting burden, we are concerned by what appears to be a decision to propose a more limited set of hardship exceptions under the Imaging AUC Program than what is currently available under the EHR Incentive Program. For example, CMS is not proposing to include exceptions related to lack of sufficient patient interactions, EPs practicing at multiple locations, and those who lack control over the availability of CEHRT for more than 50 percent of patient encounters. This last one is of particular importance since physicians who lack control over CEHRT also typically lack control over CDSMs and other technologies needed to comply with the Imaging AUC Program. Adopting two similar, yet distinct sets of hardship exceptions, seems to contradict the intent of this policy and fails to protect physicians who do not have direct control over technology from being held accountable for the consultation and reporting requirements of this program. The AANS and CNS support the decision to include significant hardship exceptions, but we request that CMS further align the Imaging AUC Program with the hardships permitted under the EHR Incentive Program.

- We also request that CMS develop an automatic hardship exemption for any physician who does not have access to low-cost integrated CDSMs, given our concerns discussed below.

Qualified Clinical Decision Support Mechanism

This rule also proposes definitions, requirements and processes for CDSMs to be qualified under the AUC program. CDSMs are electronic portals through which clinicians would access AUC during the patient workup. Information regarding the clinical presentation of the patient would be incorporated into the CDSM from another HIT system or through data entry by the ordering professional. At a minimum, the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. The AANS and CNS appreciate that CMS is proposing that a CDSM may be a module within or available through CEHRT or a private sector mechanism independent from CEHRT since many physicians continue to face substantial barriers to CEHRT adoption. In fact, a major obstacle to seamless implementation of this program is an ongoing lack of interoperability, which prevents CDSMs from incorporating any standardized AUC and for sets of AUC to be easily interchangeable among various CDSMs. We urge CMS to continue to work with ONC and other relevant stakeholders to ensure full interoperability of CDSMs with EHRs and with each other.

In this section, CMS also proposes that, at a minimum, qualified CDSMs must include AUC spanning the entire clinical scope of the clinical priority areas, although they could include more if desirable. The AANS and CNS support policies that would allow physicians to select a CDSM that best meets their needs for compliance with this program. At the same time, we reiterate our concerns about the CDSM, and ultimately the ordering physician, having to flag every instance where no relevant AUC is available in the system since this could overwhelm physicians who regularly order diagnostic imaging.

CMS also proposes that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified provider-led entity (PLE). The AANS and CNS support this proposal since it would ensure that a broader range of AUC are available to specialists and make the program more meaningful. This will also prevent a single producer of AUCs from dominating the market, which is important given the agency's loose interpretation of "provider-led entity."

Finally, the AANS and CNS also appreciate that CMS would not require consultation or adherence to any specific AUC, so long as it is developed by a qualified PLE. Instead, CMS only would require that the qualified CDSM clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a patient's particular clinical scenario. We very much support this flexibility and believe this policy helps to address concerns about the potential overlap — and even conflicts — between AUC produced by multiple entities. However, it is unclear how CMS would define and evaluate outliers (i.e., those who do not adhere to AUC) for purposes of the prior authorization requirement — set to begin in 2020 — if physicians are consulting different AUCs for the same clinical scenario. We request that CMS share with the public more details about how it intends to implement this policy.

Timeline

The AANS and CNS appreciate the agency's proposal to delay implementation of this program until at least 2018, since the first qualified CDSMs are not expected to be announced until June 30, 2017. Nevertheless, this would still leave physicians with only six months to research and select a qualified CDSM that is feasible for their practice and integrates with their EHR or medical record, as well as to learn new coding requirements to comply with the program. This rushed timeline also fails to account for all the new and time-consuming mandates facing physicians over the next year, including the Merit-Based Incentive Payment System (MIPS). If CMS is already using its authority to delay the program, it should push back the start date even further to ensure physicians have time to prepare for the program and its requirements.

We also reiterate our concern about the timeline for implementation of the outlier portion of the program. CMS should apply this requirement to a more limited number of clinical priority areas in the initial years of the mandate and gradually expand it to others after testing and as deemed necessary.

Value-Based Payment Modifier and Physician Feedback

CMS proposes formal policies regarding the calculation of the 2017 and 2018 value-based payment modifier (VM) in situations where unanticipated data issues arise either as a result of an informal review or widespread quality or cost data integrity problems. CMS notes it is unable to re-run the data in these situations and instead proposes to assign any physician with data issues an “average” quality composite score under the VM. If a physician earns an “average quality” score due to systematic quality issues or widespread claims data issues, and also earned a “high cost” composite score, CMS would re-classify their cost composite score to “average cost” in order to prevent the physician or from receiving a downward VM adjustment as a result of being classified as average quality and high cost.

While the AANS and CNS are concerned that this policy could limit potential upward payment adjustments to physicians who could have otherwise been classified as high quality if it were not for data issues beyond their control, we also understand that CMS is limited in its ability to re-calculate performance at that late of a date. Given the options available to CMS, we appreciate that the agency is proposing to protect these physicians from penalties. However, we strongly urge CMS to invest resources in preventing these errors from occurring in the first place, including test data submission windows and periodic feedback throughout the reporting so that vendors and physicians can identify and resolve data issues before it is too late to re-run the data.

Proposed Changes to the Medicare Shared Savings Program

Proposed Changes to Quality Measures Used to Assess ACO Performance

In this rule, to align the Medicare Shared Savings Program quality measure set with the measures recommended by the Core Quality Measures Collaborative and proposed for reporting through the CMS Web Interface under the MACRA proposed rule, CMS proposes to add measures, including the following:

ACO-44 Use of Imaging Studies for Low Back Pain (NQF #0052). This measure reports the percentage of patients (18-50 years of age) with a primary diagnosis of low back pain who did not have an imaging study (for example, MRI, CT scan) within 28 days of the diagnosis (a higher score indicates higher performance). Unlike most ACO measures, this would not be reported via the CMS Web Interface. Instead, it would be calculated using Medicare claims data without any additional provider reporting requirement. CMS proposes to add this measure to address a gap in measures related to resource utilization and align with the ACO measures recommended by the Core Quality Measures Collaborative core measure set.

While the AANS and CNS support the intent of this measure, we remind CMS of concerns we have registered in the past about this measure relying only on claims data and failing to incorporate critical caveats or “red flags” among low back pain patients that may appropriately drive early imaging. Although the measure includes exclusions for things such as cancer and IV drug abuse, it might be difficult to tell from claims data alone whether or not there is compliance with this measure. For example, a patient with a remote history of cancer may not have claims data denoting it; an IV drug abuser with new, severe low back pain may need imaging, but the drug use may not show up on claims-based reporting. Hence using claims-based reporting in isolation to judge compliance with this measure is inappropriate and likely will miss the exclusionary criteria that the NQF defined as vital to the appropriate use of the measure. Given these ongoing flaws, we do not support using this measure for pay-for-performance.

We remind CMS that the Measures Application Partnership (MAP) did not support this measure in the past because it only applies to ages 18-50 years and fails to target the current gap in measures for overuse of imaging for low back pain in the older population.

ACO Participants Who Report PQRS Data Separately

CMS proposes to allow physicians who bill under the Tax Identification Number (TIN) of an ACO participant to report separately for the 2018 PQRS payment adjustment when the ACO fails to report successfully on behalf of the physician. Also, CMS proposes relief for physicians who billed through the TIN of an ACO participant in an ACO that failed to report satisfactorily on behalf of physicians during the 2015 reporting period to avoid the 2017 payment adjustment. These physicians have the option to use a secondary reporting period — Jan. 1, 2016, through Dec. 31, 2016 — to report PQRS data to avoid the 2017 PQRS payment adjustment since the 2015 reporting period has already ended. Physicians could use 2016 data as a secondary reporting period for the 2017 payment adjustment, for the 2018 payment adjustment, or for both payment adjustments if the ACO failed to report PQRS measures satisfactorily for both years.

CMS also makes proposals related to how the VM would apply to TINs participating in ACOs that do not satisfy quality reporting. Here, CMS would look at the PQRS data reported by clinicians apart from the ACO to determine whether the TIN(s) would be subject to automatic VM cuts or subject to performance-based adjustments under the VM. If the latter, CMS would automatically classify their quality composite for the 2017 VM as “average quality.” Since groups that participate in ACOs also automatically receive an average cost score, the clinicians affected by this policy would avoid a downward VM adjustment, but would not qualify for an upward adjustment since the ACO failed to report.

The AANS and CNS support the agency’s proposal to recognize physicians in ACOs for their individual commitment to quality improvement and to protect them from penalties in situations where the ACO fails to satisfy reporting requirements. Individual physicians are not in direct control of decisions or actions taken by the larger ACO and should not, therefore, be penalized. In fact, many clinicians do not even know they are part of an ACO and opt instead to report more directly relevant measures, such as those available through a QCDR. In addition to giving these clinicians another opportunity to report data, we recommend that CMS also consider offering clinicians who fall under this scenario a waiver should they not want to go through the effort of reporting again. We also again urge CMS to invest in strategies to prevent these situations from occurring in the first place, such as providing ACOs with more frequent feedback on their reporting compliance throughout the year.

OPEN PAYMENTS PROGRAM

The AANS and CNS appreciate the opportunity to share feedback on the Open Payments Data Reporting System for possible future rulemaking. We believe that appropriate interaction between physicians and industry is a critical component of advancing medical innovation, and we support proper transparency of these activities. However, information made public must be accurate and presented with proper context. Based on feedback from neurosurgeons since the beginning of the Open Payment program and a recent survey of our members, we offer the following.

Registration

Although CMS did not specifically ask for comments on the onerous two-step registration process for Open Payments, we continue to believe that registration is unnecessarily burdensome. Many neurosurgeons have told us that they started the process of registering but were not able to complete it due to interruptions. Because the data entered are not saved, physicians returning to the registration process at a later time, had to start over. Anything the agency can do to make registration easier will benefit the program and physicians.

Payment Categories

We urge the agency not to expand the scope of the program beyond the original 14 categories, but rather to use resources to make the program more user-friendly and to ensure that the data currently being collected is accurate and easy to understand. CMS has asked about reported research payments, and this is an area that requires more clarification. Neurosurgeons serving as Principal Investigators (PIs) have complained that research payments to their universities appear under their names, and they believe this is confusing and may give the erroneous impression that the physician, rather than the institution, is receiving the funds. A better context for these payments is needed. More clarification should be given for existing reporting but widening the scope of items covered is not useful or advisable.

Other Teaching Hospital Issues

With respect to teaching hospitals, some neurosurgeons have told us that resident physicians are inappropriately listed in the Open Payment System Database. Transfers of value to resident physicians are not subject to reporting under the Sunshine Act. Also, program directors have said that some industry interactions with residents have been inappropriately reported under the program directors' names. Greater clarification and accuracy is needed for existing reporting for physicians at teaching hospitals to make it entirely clear what compensation is an actual transfer of value to the physician versus payments to the research institution.

Educational Materials

The AANS and CNS have joined the AMA and other specialty societies in supporting S. 2978, the "Protect Continuing Physician Education and Patient Care Act," introduced by Sen. John Barrasso, MD. We strongly support an exemption from Open Payment reporting for the dissemination of peer and independent third-party reviewed services and products, including journal reprints and medical textbooks. When initially considering the Physician Payments Sunshine Act, Congress specifically intended to exclude such independent sources of clinical information so as to avoid chilling the dissemination of high quality and actionable clinical information that had undergone independent review. We also continue to support the exemption of independent continuing medical education (CME) from Open Payment reporting.

Pre-vetting and Notification to Physicians Regarding Reporting by Industry

Based on feedback we have received over the last few years and robust agreement by those who have responded to our poll, we strongly support a requirement for manufacturers to notify physicians when they report payments attributed to them to Open Payments. This should not be an undue burden on the manufacturers and could be incorporated into their routine process of reporting. If they have the information to report to CMS, they could notify the physician at the same time. Even better, is pre-vetting when the manufacturer notifies the physician and errors may be corrected before reporting.

Longer Window for Physicians to Review and Respond to Data

The majority of neurosurgeons responding to our survey indicated they would support a longer window to review their data, as the 45 days is a very short time in which to review and dispute data. Almost one-half of the respondents who checked their data said they found errors. Of those, about 20 percent were not able to resolve the dispute during the 45-day window.

Time and Cost Burden

Our survey results also indicate that the time and cost burden imposed by the Open Payment system is significant. Only about one-quarter of the neurosurgeons reporting said they were able to complete registration in the advertised 30 minutes or fewer. A little over one-third of respondents stated that they

spent 30 minutes to an hour, and another third reported they spent over one hour on the registration process. One-third indicated that they required office staff to assist them with the registration process. These findings highlight our concern that the time it takes for physicians to register is significant and costly, as is the time spent reviewing and attempting to correct data.

While the Open Payments Program is a laudable effort, it is of questionable value. According to our findings, not a single patient has asked our members about their open payment data; thus we don't think the program is particularly useful for patients. The AANS and CNS urge CMS to revamp the Open Payments Program to make it less burdensome and more meaningful to patients, physicians and other stakeholders. We look forward to providing additional feedback on any future proposed changes.

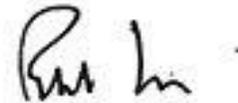
CONCLUSION

The AANS and CNS appreciate the opportunity to provide feedback on these specific provisions in the 2017 MPFS proposed rule. If you have any additional questions or need additional information, please feel free to contact us.

Sincerely,



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