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NEUROLOGICAL SURGEONS

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September 10, 2018

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

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

Dear Administrator Verma:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the above-referenced notice of proposed rulemaking.

EXECUTIVE SUMMARY

CODING AND REIMBURSEMENT ISSUES

Practice Expense (PE) Issues

- The AANS and CNS support the practice of using input from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) and expert stakeholders for the assignment of dominant specialty for PE service with a low volume in the Medicare population, as long as all relevant specialties have been consulted and agree.
- Regarding the CMS review of PE for clinical labor tasks, we agree with the RUC, the American College of Surgeons (ACS) and other stakeholders that CMS seems to fundamentally misunderstand the issue of standards for clinical labor activities. We urge the agency to review the RUC and ACS comments on this issue thoroughly.
- Neurosurgery agrees with concerns expressed by the ACS, RUC and others regarding the contract with StrategyGen to update supply and equipment pricing. We urge the agency to work with the RUC to allow more transparency of the updates proposed by StrategyGen. We support the ACS request for a delay in implementation, and at a minimum, to accept the RUC request to

continue to allow comments and changes during each year of the proposed four-year phase in.

Determination of Malpractice (MP) Liability RVUs

- The AANS and CNS urge CMS review thoroughly the MP liability issues included in our comments last year on the 2018 Medicare PFS, those raised in the ACS letter on the CY 2019 Medicare PFS and issues brought forth by the RUC Professional Liability Insurance (PLI) Workgroup in their March 30, 2018, letter to CMS.
- The AANS and CNS are disappointed that, despite our comments and those of the ACS, RUC and others last year stating that the crosswalk for non-physician providers significantly exceeds the actual premium costs of these non-physician providers, in the Addendum for the CY 2019 Malpractice Risk Factors and Premium Amounts by Specialty, CMS continues to crosswalk non-MD specialties to the lowest MD risk factor specialty, Allergy Immunology. As the percentage of non-MD providers billing Medicare for services increases, this distortion becomes increasingly problematic.
- Again, we commend the agency for accepting the RUC specialty designation “overrides” for very low volume services to prevent significant variation in year-to-year MP RUVs for reasons similar to those described above for PE.

Payment for Communication via Technology-Based Services

The AANS and CNS support expanding the use of telehealth for stroke patients and the CMS proposal to create a modifier for this purpose.

Non-Opioid Alternatives for Pain Treatment

We commend the agency for seeking comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage and have provided recommendations below.

Global Surgery Data Collection

The AANS and CNS agree that preliminary results of global surgical data collection are incomplete and cannot be used to change the value of existing codes. We support more education and outreach and oppose the use of a punitive enforcement mechanism to ensure the filing of claims using CPT code 99024.

CMS Valuation of Specific Codes

The AANS and CNS oppose the CMS plan to reduce the RUC-passed values for five neurostimulator programming codes, CPT codes 95970, 95X83, 95X84, 95X85 and 95X86.

Evaluation and Management Documentation Guideline Proposal

- The AANS and CNS are strong supporters of regulatory burden reduction and, as such, support the agency’s goal to simplify evaluation and management (E/M) documentation burden.
- The AANS and CNS do not support implementing the payment-related changes of the E/M office visit codes. We recommend that CMS take more time to consult with stakeholders, including the CPT/RUC Workgroup on E/M Coding, on this issue and delay any action at this time.

QUALITY ISSUES

Merit-Based Incentive Payment System (MIPS)

Administrative Simplification

- The AANS and CNS support changes to the MIPS program that will reduce complexity and allow physicians to spend less time on reporting and more time with patients. We urge CMS to move more quickly and aggressively toward a more simplified scoring methodology, including credit across performance categories.
- CMS should avoid making policy changes, such as increasing the performance threshold, changing the category weights and removing quality measures, based on irrelevant data and hypothetical assumptions from legacy programs (e.g., QRS, Value Modifier, and EHR Incentive Program). It also should not base these changes on incomplete MIPS data collected during the initial transition years of the program since this does not reflect the full extent of measure applicability and program engagement.

Low Volume Threshold

The AANS and CNS support the proposed modified thresholds, as well as the opt-in for clinicians who fall below these thresholds.

Hospital-Based Clinician Definition

We request that CMS modify its definition of hospital-based *group practice* so that it includes a group practice where at least 75 percent of the clinicians in the group meet the definition of hospital-based.

Sub-Group Participation Option

We urge CMS to continue to explore alternative mechanisms that would allow a portion of a group practice of any size to carve themselves out of the larger group and participate in MIPS as a more focused subgroup.

MIPS Category Weights

We oppose CMS' proposal to lower the weight of the Quality category and raise the weight of the Cost category. CMS should maintain a Cost category weight of 10 percent and consider shifting some of the weight from the Promoting Interoperability category to the Improvement Activity category.

Quality

- Overall, the quality category forces physicians to pick random measures that may or may not align with a clinical end goal. Instead, the MIPS program should be structured to allow physicians to focus on a targeted clinical or disease area or an action that contributes to higher value care, such as reporting to a clinical data registry.
- To reduce administrative burden, we strongly urge CMS to reduce the number of quality measures a physician must report under the Quality category.

- We support giving clinicians as much flexibility as possible to engage in and satisfy the requirements of this program meaningfully.
- We encourage CMS to identify an alternative to the current minimum reporting threshold/data completeness requirements, such as moving to a set minimum number of patients rather than a percentage of patients that meet the denominator. At the very least, CMS should reduce the threshold from 60 percent to 50 percent and not require reporting across all payers.
- We encourage CMS to promote outcome measures but reserve a role for process measures, which continue to serve an important purpose.
- We request that CMS provide maximum points for reporting on new measures or measures where there is no benchmark.
- We request that CMS abandon existing and proposed topped out measure removal and scoring cap policies at this time.
- We oppose the 12-month performance period in favor of a 90-day period.
- We support reporting and scoring performance across multiple data collection types.
- We request that CMS provide more flexibility by making the reporting of outcome and high priority measures optional.
- We oppose CMS' proposal to limit the availability of the claims-based reporting option to only clinicians in small practices.
- We request that CMS eliminate the All-Cause Hospital Readmission (ACR) Measure until it has been refined and deemed valid at the physician-level

Cost Category

- The AANS and CNS oppose CMS' proposal to increase the weight of this category.
- We have ongoing concerns about the relevance and appropriateness of the Medicare Spending Per Beneficiary and Total Per Capita Cost measures and continue to oppose their use in a program that applies accountability at the clinician level.
- We urge CMS not to use episode-based cost measures for accountability purposes until the public has had sufficient time to review feedback and understand the measures carefully.

Promoting Interoperability

- The AANS and CNS oppose mandating the use of 2015 Edition CEHRT.
- The AANS and CNS appreciate the more simplified proposed approach to scoring as a short-term solution but recommend that CMS consider additional reforms that provide even more flexibility in this category. As a short-term compromise, we also support CMS' alternative proposal, under which clinicians would be scored at the objective level.

- We support the Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement measures in concept, but request that they remain voluntary for 2019 and 2020.
- The AANS and CNS request that CMS maintain the Public Health and Clinical Data Exchange objective as an additional way for clinicians engaging in clinical data registries to satisfy the requirements of this category. We also request that this objective requirement include a mixture of methods for data capture or reporting, such as registries that rely on both automated and manual data entry.

Improvement Activities

- The AANS and CNS oppose this proposed extension of the timeframe for the Annual Call for Activities and recommend that CMS maintain the current schedule to ensure the timely inclusion of important and more relevant activities in the program.
- The AANS and CNS continue to urge CMS to adopt an Improvement Activity that recognizes Emergency Department (ED) Call Coverage by Surgical Subspecialties as a way of improving patient access to care.

Qualified Clinical Data Registries (QCDR)

- The AANS and CNS strongly support the proposal to require registries to have clinical expertise in medicine and quality measure development.
- We strongly oppose the proposal that QCDR measure owners be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure for purposes of MIPS, beginning with the 2019 performance year, because it undermines QCDR measure ownership and development. We urge CMS to allow QCDRs instead to enforce their ownership rights in the QCDR measures they develop and require third parties to enter into licensing agreements with measure owners before they can properly use QCDR measures.
- We oppose CMS' proposal to revise the QCDR self-nomination deadline from November 1 of the calendar year prior to the applicable performance period until September 1.
- We also oppose CMS' proposal to apply the Call for Quality Measures criteria to QCDR measures.

MIPS Scoring and Payment Methodology

The AANS and CNS oppose the agency's proposal to double the performance threshold in 2019 for multiple reasons, including: the ongoing complexity of the program; CMS' proposal to remove a substantial number of quality measures from the program; and insufficient historical MIPS data on which to set benchmarks and determine the feasibility of the current performance threshold.

Facility-Based Scoring

The AANS and CNS support facility-based scoring as a short-term solution to assist specialties, such as ours, with succeeding at MIPS and easing the burden of data collection. However, we do not view this as a long-term solution to more meaningful measurement for facility-based clinicians. We urge CMS to incentivize better the development and use of specialty-specific measures and participation mechanisms that encourage more direct engagement by facility-based clinicians without overburdening them.

Physician Compare

We have significant concerns about CMS' use of different methodologies when scoring clinicians for payment purposes vs. scoring them for public accountability and urge CMS to immediately move to one consistent set of policies between the two programs.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The AANS and CNS support deeming clinicians compliant with the AUC Program if they meet the requirements of the QPP.

DETAILED COMMENTS

Coding and Reimbursement Issues

Practice Expense RVUs

- **Low Volume Services.** CMS finalized a proposal in the CY 2018 PFS final rule to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For a procedure infrequently performed on the Medicare population, low volume status would subject its code to year-to-year fluctuation in the dominant specialty. This creates substantial year-to-year variability in PE RVUs. To address this issue, codes falling into this category are assigned to a dominant specialty based on medical review and input from expert stakeholders. We are pleased that CMS has agreed to work with the RUC to maintain and use the list for both PE and MP RVUs. The American Academy of Orthopaedic Surgeons (AAOS) has made us aware of their concerns regarding the omission of CPT code 22857 *Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar* from the proposed list published by CMS in the CY 2019 Medicare PFS. We support the inclusion of this code on the list and, at this time, support a specialty assignment of orthopaedic surgery. Both the Medicare and non-Medicare volume for this procedure is very low and slight changes in volume from year to year can cause significant disruption for those few surgeons and patients affected.
- **PE for Clinical Labor Tasks.** Regarding the CMS review of PE for clinical labor tasks, we agree with the RUC, ACS and other stakeholders that CMS seems to fundamentally misunderstand the issue of standards for clinical labor activities. We urge the agency to consider the RUC and ACS comments on this issue. The day before each full RUC meeting, the PE Subcommittee spends hours painstakingly reviewing each PE input for all code to be reviewed by the full RUC at the meeting. CMS staff is present at these meeting; however, in the CY 2019 Medicare PFS the agency seems to have confused issues of standards and RUC-developed minutes for clinical labor tasks.
- **StrategyGen Contract to Update Supply and Equipment Pricing.** In the Proposed Rule, CMS used its authority under the Protecting Access to Medicare Act of 2014 (PAMA) to initiate a market research contract with a consulting firm, StrategyGen, to update the direct practice expense inputs for supply and equipment pricing for CY 2019. Based on the report from StrategyGen, CMS is proposing updated pricing recommendations for 2,017 supply and equipment items currently used as direct practice expense (PE) inputs. CMS is proposing to update supply and equipment pricing over a 4-year phase-in. StrategyGen used a number of primary and secondary market research resources and methodologies to estimate and validate current prices for medical equipment and supplies. As CMS states in the Proposed Rule, there has not been a comprehensive review of supply and equipment prices since 2004-2005. There has been, however, a repricing of equipment and supplies on an item-by-item basis that was based on invoices submitted by specialty societies as

part of their practice expense recommendation to the RUC. The RUC PE Subcommittee does not evaluate pricing; rather the RUC collects the information and submits it to CMS as part of the RUC recommendation process. This process, although not comprehensive, represents a collaboration between physicians and CMS. We urge a delay of the implementation of the update based on the StrategyGen work due to concerns identified by the RUC and other stakeholders regarding approach, data, and methodology used to develop the CMS recommended price. If CMS does not delay the implementation, the agency should continue to accept comments and make revisions in each of the four years of implementation.

Malpractice (MP) RVUs

- **Calculating MP RVUs.** In the proposed rule for CY 2018, CMS outlined a plan to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCIs. Given the impact of the proposal and flaws in the data, AANS and CNS opposed the plan. We thank the agency for listening and not proceeding with the proposal. We urge the agency to thoroughly review comments from the ACS and the RUC regarding MP RVUs.
- **MP Data for Non-physician Providers.** We were disappointed to see that, in the Addendum for the CY 2019 Malpractice Risk Factors and Premium Amounts by Specialty, CMS continues to crosswalk non-MD specialties to the lowest MD risk factor specialty, Allergy Immunology. We agree with the RUC, the ACS and others that a risk factor linked to a physician specialty is too high for many of the non-physician health care professions. The RUC has provided additional details on this issue in its March 2018 letter to CMS. As the percentage of non-MD providers billing Medicare for services increases, this distortion becomes increasingly problematic.
- **MP Specialty Designation for Low Volume Services.** The AANS and CNS commend the agency for continuing to accept the RUC specialty designation “overrides” for very low volume services to prevent significant variation in year-to-year MP RVUs. The issue of valuing MP RVUs for low volume codes has long been a concern for neurosurgery, the specialty with some of the very highest professional liability insurance premiums. 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.

Payment for Communication via Technology-Based Services

The AANS and CNS support expanding the use of telehealth for stroke patients. We urge CMS to consider the comments of the American Heart Association and American Stroke Association regarding improving telehealth services for stroke patients covered by Medicare. The Balanced Budget Act of 2018 (BBA 2018) incorporated provisions of the Furthering Access to Stroke Telemedicine (FAST) Act, designed to increase rapid access to expert neurological care for stroke patients and eliminates the geographic restrictions on Medicare telehealth originating sites for telehealth services for the diagnosis, evaluation and treatment of symptoms of acute stroke. We support the agency’s efforts to implement the FAST Act provisions and improve assessment of stroke patients covered by Medicare to expedite their access to effective medical and surgical care, including to mechanical thrombectomy, when appropriate. Unfortunately, many stroke patients do not receive these lifesaving therapies in time, in part because many hospitals do not have access to a specialist qualified to determine that the patient is a candidate for medical or surgical intervention. The acute stroke telemedicine provision of BBA 2018 will facilitate more immediate access to expert neurological consultation to accurately diagnose stroke symptoms and direct these patients to a hospital prepared to provide the right care. We support the CMS proposal to require providers submitting claims for acute stroke telehealth services to attach a modifier to those claims, as this will aid in tracking of claims to help evaluate outcomes and cost-effectiveness of acute stroke telehealth services.

Non-Opioid Alternatives for Pain Treatment

We commend the agency for seeking comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage.

Care for patients in pain, including chronic pain that can be alleviated by neurosurgical procedures and acute post-operative pain from the procedures themselves, are a core part of the training and practice of neurosurgeons. The AANS and CNS have fully supported efforts to ensure the appropriate use of opioids to manage acute and chronic pain, while at the same time adopting measures to reduce the risk of opioid abuse.

Evidence-based, opioid-sparing surgical therapies can be an effective strategy to reduce opioid prescribing and abuse. For example, neurosurgical interventions such as neuromodulation (i.e., spinal cord stimulation, peripheral nerve stimulation, and brain stimulation) and neuroablative procedures (i.e., cordotomy and peripheral neurectomy) decrease pain-related disability and reduce opioid use. In particular, spinal cord stimulation provides chronic pain patients with increased treatment satisfaction with lower overall health care costs through fewer provider visits and less opioid medication.

Despite the high-quality clinical trial data supporting the use of these procedures, Medicare, Medicaid and other third-party payers often deny the use of these treatments for chronic pain patients. These restrictive policies only serve to encourage the use of opioids as physicians see few covered alternatives. Medicare, Medicaid and other insurers should allow coverage of these non-pharmacologic, opioid-sparing therapies for chronic pain when sufficient clinical evidence (including such resources as clinical trials, prospective data registries, and/or peer-reviewed clinical practice guidelines listing the therapy as a treatment option) exists. These noncoverage determinations are often based on the fact that studies for some of these treatments are relatively small compared to those for pharmaceuticals. It is important to understand that these treatments are not utilized in the same numbers as pharmaceuticals, and large studies may not be feasible.

Neurosurgeons are on the cutting edge of the development of non-opioid pain treatment using neurostimulation, and payment and coverage issues are significant barriers to progress on this front. The AANS and CNS, therefore, support the use of non-pharmacologic, opioid-sparing surgical therapies for the treatment of chronic pain when appropriate. We thank you for addressing this important issue and are eager to provide help and expertise as the agency moves to eliminate payment and coverage barriers to important innovative non-opioid treatments.

Global Surgery Data Collection Project

The Medicare Access and CHIP Reauthorization (MACRA) Act (Pub.L. 114-10, Section 523) requires the CMS to collect information on the number and level of medical visits furnished during the 10- and 90-day global surgery period from a “representative sample” of physicians and in 2019 use this information to improve/validate the accuracy of the valuation of surgical services. CMS began the implementation of this onerous data collection process on July 1, 2017, despite the fact that the agency has failed to (1) provide a detailed plan for data validation; (2) provide answers to a whole host of outstanding questions; and (3) adequately educate physicians subject to the data collection requirements. Therefore, we are not at all surprised that CMS has found that the data collected is not actionable.

The AANS and CNS have long believed that Section 523 of the Medicare Access and CHIP Reauthorization Act (MACRA) was inadvisable and unnecessary, as CMS already has in place a process for reviewing and adjusting the value of surgical services with input from the RUC. Nevertheless, we

understand that MACRA required the collection of data and CMS has collected data. We believe that the agency’s data collection project has met the requirements of the statute, even though the data collected are not useful or valid for making any changes in the global surgery services. As such, no further action on this project is warranted.

Valuation of Specific Codes

- **Neurostimulator Services.** The AANS and CNS oppose the CMS plan to reduce the RUC-passed values for the five neurostimulator programming codes listed below.

CPT Code	Descriptor	Current Work RVU	RUC-passed Work RVU	CMS Proposed Work RVU
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming	0.45	0.45	0.35
95X83	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	New	0.95	0.73
95X84	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	New	1.19	0.97

CPT Code	Descriptor	Current Work RVU	RUC-passed Work RVU	CMS Proposed Work RVU
95X85	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	New	1.25	0.91
95X86	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional	New	1.00	0.80

We urge CMS to support the RUC-passed values for this family of neurostimulator services, as they were thoroughly vetted by the RUC and approved unanimously. We echo the RUC rationale for each of the codes values below.

- **CPT Code 95970.** For CPT code 95970, the RUC recommended a work RVU of 0.45 and 3 minutes pre-service, 7 minutes intra-service and 5 minutes post-service time. CMS disagrees with the RUC’s recommendation because they do not believe that maintaining the work RVU, given a decrease of four minutes in total time, is appropriate. CMS is comparing accurate survey time to Harvard time, which holds no validity for comparison. Additionally, the survey’s pre-service time was reduced, which accounts for this service being reported with an E/M service. The previous Harvard time most likely did not take this into account. The RUC urges CMS to use accurate survey data for physician time and not to adjust the work RVU based on instituting inaccurate comparisons.

The RUC compared CPT code 95970 to the top key reference service CPT code 62368 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming (work RVU = 0.67 and 27 minutes total time). CMS notes that the reference CPT codes chosen by the survey respondents have much higher intra-service and total times than CPT code 95970 and also have higher work RVUs, making them poor comparisons. The survey respondents chose these reference services as a comparison, not recommending direct crosswalks. The respondents and the RUC agreed that CPT code 95970 requires less physician time and work and thus valued it lower than the reference codes. To clarify, the survey respondents choose a similar service from a list of 10-20 services and not all are going to match up with the exact same time. Additionally, the survey respondents do not see the physician times for any of the services in the reference list. Moreover, the respondents then indicate the time,

work, intensity and complexity differences and relativity between these services. The RUC examines the services based on clinical relativity of all measures compared to other services. CMS should not review one element, physician intra-service time, and compare it to invalid data or disregard the relativity between reference services.

CMS recommends that CPT code 95970 be directly crosswalked to CPT code 95930 Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report (work RVU = 0.35, 10 minutes intra-service time and 14 minutes total time). CPT code 95930 is reported when the physician reviews and interprets ophthalmological results of brain electrical activity measurements. CPT code 95970 requires more physician work and is more intense because the physician is performing the electronic analysis of the implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) and documenting the diagnostic analysis, including the battery state, current program settings, and impedances of electrodes, as well as any event logs from the programming equipment and patient device interrogation.

The AANS and CNS urge CMS to accept a work RVU of 0.45 for CPT code 95970.

- **CPT code 95X83.** For CPT code 95X83, the RUC recommended a work RVU of 0.95 and 3 minutes pre-service, 11 minutes intra-service and 10 minutes post-service time. CMS noted that this new code does not exactly replace the deleted CPT code 95974 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour (work RVU = 3.00 and 30 minutes pre-time, 60 minutes intraservice time and 20 minutes post-service time). The description of the work involved in furnishing CPT code 95X83 differs from that of the deleted CPT code in a few important ways, notably that the time parameter has been removed so that the CPT code no longer describes the first hour of programming. Also, the new CPT code refers to simple rather than complex programming; yet, CMS is still comparing the physician work and time of these two services. The physician work and times should be different, and CMS should not compare these two vastly different services.

CMS states that the top key reference service CPT code 95816 Electroencephalogram (EEG); including recording awake and drowsy (work RVU = 1.08, 15 minutes intra-service time and 26 minutes total time) is not an appropriate crosswalk. Again, the survey respondents are not recommending CPT code 95X83 be crosswalked to CPT code 95816 but notes that CPT code 95816 was chosen to assess the relativity and to establish a work RVU and physician time recommendation. Clearly, services performed by the same physician, intraservice time differences of 4 minutes, total time differences of 2 minutes, overall intensity and complexity measures indicated as 60 percent identical and 40 percent somewhat more for the key reference code, all support the RUC recommended work RVU of 0.95 and physician time relative to another similar service.

CMS recommends CPT code 95X83 be crosswalked to CPT code 76641 Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete (work RVU = 0.73 and 12 minutes of intra-service time and 22 minutes of total time). The RUC disagrees with crosswalking to another service of a different specialty when a valid survey was conducted, and accurate same specialty reference services were provided. CPT code 76641 is not a good crosswalk because although the physician time may be similar, CPT code 95X83

requires more physician work to interact with the patient and make programming adjustments to multiple parameters which result in real time changes in patient behavior; including but not limited to speech, breathing patterns, heart rate, and seizure activity. Side effects and risks of parameter adjustments are significant, and considerations must be weighed carefully, including identifying the correct parameter to manipulate. The identification of an adjustment of the correct parameter(s) requires considerable decision-making effort and concern for patient safety.

The AANS and CNS urge CMS to accept a work RVU of 0.95 for CPT code 95X83.

- **CPT Code 95X84.** For CPT code 95X84, CMS states that the RUC compared CPT code 95X84 with deleted CPT code 95975 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator / transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (work RVU = 1.70, ZZZ global period and 30 minutes total time). The RUC recommendation did not compare code 95X84 to deleted code 95975. The RUC recommended the survey 25th percentile work RVU of 1.19. The specialty societies reduced the pre-service time, which accounts for this service being reported with an E/M service. The RUC recommended 3 minutes pre-service, 17 minutes intra-service and 10 minutes post-service time. The specialty societies indicated, and the RUC agreed, that the 10 minutes required for the post-time include reviewing all the parameters, documenting final program measurements and any other relevant clinical information obtained during the programming session, reducing side effects and making treatment adjustments. The physician will also address patient and family questions about planned therapy and re-educate the patient and family on the use of the patient device. The RUC confirmed that the physician times appropriately mirror other similar services.

The RUC noted that the top two key reference services were disparate compared to this service. Therefore, as a better reference, the RUC compared CPT code 95X84 to MPC codes 99308 Subsequent nursing facility care, per day, for the evaluation and management of a patient (work RVU = 1.16, 15 minutes of intra-service time and 31 minutes total time), and 12013 Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22, 15 minutes of intra-service time and 27 minutes total time), which support the recommended work RVU as the survey code involves somewhat more intra-service and total time and a comparable amount of physician work. For additional support, the RUC referenced CPT codes 93975 Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study (work RVU = 1.16, 20 minutes of intra-service time and 30 minutes total time), and 67810 Incisional biopsy of eyelid skin including lid margin (work RVU = 1.18, 13 minutes of intra-service time and 27 minutes total time). Thus, the survey 25th percentile work RVU appropriately places CPT code 95X84 relative to the top key reference service and other similar services.

CMS is proposing to use a reverse building block in developing the work RVU for CPT code 95X84. The RUC has long stated that codes that are not developed using building block should not be manipulated with a reverse building block methodology. CMS is proposing a work RVU of 0.97 for CPT code 95X84 without the use of survey data or a direct crosswalk to another similar code. CMS is taking the difference in work RVUs from the RUC recommended values of 0.24. This inaccurately treats all components of the physician time as having identical intensity and is incorrect. The AANS and CNS recommend that CMS use valid survey data to develop work RVUs and not foster a flawed methodology in valuing this family of services.

The AANS and CNS recommend a work RVU of 1.19 for CPT code 95X84.

- **CPT code 95X85.** For CPT code 95X85, CMS states that the RUC's recommendation of 1.25 work RVUs is based on codes 12013 Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22, intra-service time of 15 minutes and 27 minutes total time) and 70470 Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections (work RVU = 1.27, 15 minutes of intra-service time and 25 minutes total time). The RUC actually based its recommendation on the survey 25th percentile work RVU of 1.25. Then to support the valid survey data the RUC referenced similar services from the Multi-Specialty Points of Comparison (MPC) list. The RUC recommended 3 minutes pre-service, 15 minutes intra-service and 10 minutes post-service time for CPT code 95X85, which corresponds in relativity for physician work and time to CPT codes 12013 and 70470.

CMS is comparing CPT code 95X85, which describes the first 15 minutes to the deleted CPT code 95978, which described the first hour. There is a coding nuance here — CPT code 95978 could still be reported for the first hour as long as it was over 31 minutes. Therefore, comparing the old coding structure to the new coding structure is not straightforward based on comparing the time in the descriptor and actual time to what will be reported now. The RUC examined this family of services and the RUC recommended values are work neutral, even when assuming code 95X85 may be reported once and code 95X86 reported multiple times.

CMS examines the use of a reverse building block in developing the work RVU for code 95X85. The RUC has long stated that codes that are not developed using building block should not be manipulated with a reverse building block methodology. CMS is proposing a work RVU of 0.91 for CPT code 95X85 by directly crosswalking CPT Code 95X85 to CPT code 93886 Transcranial Doppler study of the intracranial arteries; complete study (work RVU = 0.91, intra-service time of 17 minutes, and total time of 27 minutes). Although, CPT code 95X85 requires similar physician time as code 93886, code 95X85 is more intense and complex and requires more physician work because it entails programming adjustments to multiple parameters, which result in real time patient behavior. This includes monitoring for changes in the patient's speech, mobility, strength, voice, and ADLs, (as they can be assessed on an immediate basis). Side effects and risks of parameter adjustments are significant, and considerations must be weighed carefully to consider the benefits of clinical improvement with minimal negative side effects. The service includes observations based on adjustment made, a review of the results and further adjustments as needed.

The AANS and CNS urge CMS to accept a work RVU of 1.25 for CPT code 95X85.

- **CPT code 95X86.** For CPT code 95X86, CMS states that the RUC's recommendation of 1.00 work RVUs is based on is based on the key reference service CPT code 64645 Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure) (work RVU = 1.39 and 15 minutes of intra-service time). The RUC actually based its recommendation on the survey 25th percentile work RVU of 1.00. To support the valid survey data, the RUC indicated that the survey respondents chose CPT code 64645 as the key reference service for comparison for what they thought was the most similar services. The RUC noted that the survey respondents indicated the surveyed code is more intense and complex to perform but CPT code 64645 requires skill that is more technical. Therefore, CPT code 64645 appropriately requires slightly more work than CPT code 95X86. We believe CMS may be confusing the RUC's comparison to key reference services and MPC codes in support of the 25th percentile of the survey with a direct crosswalk. These comparison codes are used to support the appropriate relativity of services, preventing a rank order anomaly, and not a direct crosswalk code.

CMS is proposing a work RVU of 0.80 for CPT code 95X86, which is a random calculation using building block methodology and the incremental difference between CPT codes 95X85 and 95X86, followed by CMS choosing an RVU in between these calculations of 0.75 and 0.82. CMS then indicates that a work RVU of 0.80 is supported by crosswalking CPT code 95X86 to code 51797 Voiding pressure studies, intra-abdominal (i.e., rectal, gastric, intraperitoneal) (work RVU = 0.80 and 15 minutes intra-service/total time). The RUC recommends that CMS use valid survey data and review the actual relativity for all elements (physician work, time, intensity and complexity) when developing the work RVU for services and not place everything in a box by calculating increments and then pick a code to mirror the calculation. The RUC strongly discourages as the use of valuing a service by increment. The RUC recommends that CMS use valid survey data to develop work RVUs and not foster a flawed methodology in valuing this family of services. Additionally, CPT code 51797 is not a good crosswalk for CPT code 95X86. CPT code 95X86 require more physician work to perform programming adjustments to multiple parameters which result in real time patient behavior. This includes monitoring for changes in the patient's speech, mobility, strength, voice, and ADLs, (as they can be assessed on an immediate basis). Side effects and risks of parameter adjustments are significant, and considerations must be weighed carefully to consider the benefits of clinical improvement with minimal negative side effects. The service includes observations based on adjustment made, a review of the results and further adjustments as needed.

The AANS and CNS urge CMS to accept a work RVU of 1.00 for CPT code 95X86.

Evaluation and Management (E/M) Documentation

The AANS and CNS appreciate the agency's efforts on burden reduction for physicians. E/M documentation requirements may need to be updated. We urge CMS to provide ample time to allow all stakeholders to comment on the issue. Even before the adoption of electronic health records (EHRs), the AANS and CNS were concerned that E/M coding could devolve into a system of "bullet" counting that had little real reflection of the value of the service to the patient. Below are our initial comments on some of the key issues raised by CMS:

- **Timeline for E/M Changes.** CMS proposes to finalize both the documentation and payment policies by January 1, 2019. We do not support implementation with such a short timeline. The CPT Editorial Panel and the RUC created a workgroup, the CPT/RUC Workgroup on E/M, to develop a coding proposal to simplify the documentation burden related to the provision of E/M office visits. The Workgroup believes that any modifications to the office visit relative values must be resource-based. We encourage CMS to actively participate with the Workgroup. Any major changes to physician payment must be considered carefully and with the input of the physician community. We do not support the implementation of any coding or payment changes in 2019.
- **Use of Medical Decision Making to Document Code Level.** We support the use of MDM as a basis for selection of E/M code level. MDM takes into consideration the medical complexity of the patient. We believe MDM is a more valid representation of the intensity of physician effort in the evaluation of a patient; this measure better reflects the value of the service being provided to the beneficiary. We recommend that any changes in the E/M coding structure adopted by CMS prioritize MDM as a reflection of code level and value.
- **Use of Time as Basis for E/M Code Level.** We do not support the use of time as the sole factor in the selection of code level, other than the current CMS policy to permit the use of time for visits in which counseling constitutes more than 50 percent of the visit. Time alone does not reflect the

differences in intensity or complexity. Time in isolation is a poor reflection of physician effort and intensity and will not provide an adequate assessment of physician work.

- **Eliminating Duplicative E/M Documentation.** We support the CMS proposal for established patient codes to only require documentation of changes or pertinent items and not to require re-entering of previously captured information. In addition, we support the proposal not to require the physicians to re-enter information gathered by another staff member or recorded by the patient themselves.
- **Single Payment Rate for E/M Visit Levels 2 through 5.** We urge CMS not to implement the single payment rate. The single blended payment rate is not resource-based and has not been vetted through the RUC process. We are concerned about the impact on patient cost-sharing and on physicians who treat the most complex patients. Numerous potential unintended consequences might arise from this approach, not the least of which is a strong financial disincentive to provide care to the sickest, most complex beneficiaries.
- **Multiple Procedure Payment Reduction (MPPR).** We oppose the addition of E/M codes to the MPPR list for the least expensive procedure or visit that the same physician or physician in the same group practice furnishes in the same day. The MPPR was created to account for overlap of pre- and post-work for procedures and not for E/M services.
- **Add-on Codes to E/M to Account for Intensity and Complexity.** We are skeptical as to whether the add-on code for intensity would actually capture the additional work of higher-level codes and it certainly does not seem in keeping with the goal of simplification. In addition, we question whether the numerous references to “specialties,” rather than “services” violates the spirit, if not the letter of the law prohibiting specialty differentials under the RBRVS system. Restricting this add-on to a specific set of specialties is not logical and does not reflect the complexity of management of beneficiaries with multiple medical issues.
- **Prolonged Services Add-on Code.** We oppose the implementation of this code unless and until CMS can provide additional information on how the code would be reported with the E/M codes, other add-on codes and provide an accurate assessment of the likely impact on specialties. As with the other coding and payment provisions, we do not support the implementation of this change at this time.
- **Podiatric Visits.** We oppose the creation of E/M codes for a single specialty.
- **PE Calculation for Single Bundled E/M Payment.** CMS has proposed to create a single PE/HR values for E/M visits for the proposed single bundled rate for new and established patients. We oppose this plan, which would result in large shifts in the Indirect Practice Cost Index for many specialties.
- **Teaching Physician Documentation Requirements for E/M.** CMS proposes that presence of the teaching physician during procedures and E/M services may be demonstrated by notes in the medical record made by a physician, resident or nurse, except for renal dialysis services, psychiatric services, or services furnished in the hospital outpatient and certain other ambulatory settings. We support this provision.

QUALITY ISSUES

Merit-Based Incentive Payment System

Administrative Simplification

CMS is considering, for future years, to reduce further reporting burden by linking or otherwise bundling performance categories (e.g., creating sets of multi-category measures that would cut across different performance categories; allowing clinicians to report once for credit in all three categories). CMS also intends to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories. The public health priority sets would be built across performance categories and decrease the burden of having to report for separate performance categories as relevant measures and activities are bundled. CMS intends to develop the first few public health priority sets around opioids, blood pressure, diabetes and general health (healthy habits).

We greatly appreciate that the Administration is taking an incremental approach that focuses on ways to drive improvements in patient outcomes in the least burdensome manner possible and that appreciates current limitations related to system capabilities that are often outside of the clinician's direct control. However, the AANS and CNS continue to have overarching concerns about the complexity of this program; its failure to convert the disjointed and duplicative nature of legacy quality reporting programs into a more streamlined structure; and its overreliance on measuring for the sake of measuring, rather than promoting engagement that is more meaningful that truly improves patient care.

As CMS considers ways to reduce burden in future years further, we strongly urge it to focus on simplifying reporting requirements and scoring methodologies, as well as providing additional flexibility in regards to participation options and measure choices. We refer CMS to the AMA's proposal on "multi-category credit," which was developed with our input in an attempt to improve and simplify the MIPS scoring methodology by removing performance category silos and harmonizing the four performance categories to produce a more cohesive and holistic program. Overall, we believe that by allowing physicians to focus on activities that fit within their workflow and address their patient population needs, rather than focusing on segregated activities that fit into each individual performance category, the MIPS program could improve the quality of care and be more meaningful for physicians. For example, we believe that CMS could develop multi-category measures focused on targeted topics, such as Qualified Clinical Data Registries (QCDRs). Physicians participating in a QCDR could receive credit in all performance categories through a QCDR multi-category measure by reporting quality measures through a QCDR and using CEHRT, with no additional improvement activity or cost requirements given that QCDRs provide routine feedback on performance and areas of improvement that address the overall health of the physician's patient population, which reduces cost over time. We look forward to working with CMS to ensure these changes are adopted as soon as possible.

Currently, to be excluded from MIPS, clinicians and groups must meet one of the following two criteria:

- Have ≤ \$90K in Part B allowed charges for covered professional services; or
- Provide care to ≤ 200 Medicare beneficiaries

For 2019, CMS proposes to maintain these thresholds, but to add a third criterion:

- Provide ≤ 200 covered professional *services* under the Physician Fee Schedule (PFS)

CMS also proposes to allow clinicians to opt-in to the MIPS program if they meet or exceed one or two, but not all, of the low-volume threshold criterion.

The AANS and CNS support these thresholds as proposed since they offer ongoing protections to clinicians who are not yet ready to make the investment in MIPS. Although the third low-volume

threshold criterion is unlikely to exclude any additional physicians from the program (given that most physicians who provide fewer than 200 Medicare Part B services also treat fewer than 200 beneficiaries), we support this third criterion, as it will allow a greater number of physicians to opt-into to the MIPS program. There will be physicians who treat fewer than 200 beneficiaries, yet provide more than 200 covered professional services under the PFS, and will, therefore, be able to opt into the program under the proposed policy. **We also support providing low-volume clinicians with the opportunity to opt-in to MIPS if they believe they are ready to begin participating or want to begin engaging in the program before requirements ramp up in future years. In general, we urge CMS to maintain consistent thresholds and policies for at least three years to minimize confusion and to provide CMS with adequate time to evaluate the impact and appropriateness of setting the LVT at a certain level.**

Hospital-Based Clinician Definition

Although CMS does not propose any changes in this rule to its existing definition of “hospital-based” clinicians and groups, we reiterate our request for CMS to modify its definition of hospital-based *group practice* so that it includes a group practice where at least 75 percent of the clinicians in the group meet the definition of hospital-based. Currently, CMS requires that 100 percent of the clinicians in a group practice meet the definition of “hospital-based” for the group to be considered “hospital-based” and qualify for the automatic exemption from the Promoting Interoperability (PI) category. This 100 percent threshold is not only unnecessarily challenging to meet, but it is also inconsistent with the definition that CMS has finalized for “*facility-based group*” (discussed later in this letter). The group practice reporting option intends to ease the administrative burden of reporting on behalf of an entire group and to capture aspects of clinical practice that generally represent the group, as a whole. It is unreasonable to expect a group, where the majority of clinicians are hospital-based and do not have direct control over their EHRs, to parse out the small minority of clinicians who are not hospital-based for purposes of complying with the PI category’s reporting requirements.

Sub-Group Participation Option

CMS continues to hear from stakeholders requesting a mechanism that would allow a portion of a group to participate in MIPS as a separate sub-group and report on measures and activities that are more applicable to the sub-group. CMS notes there are several operational challenges with implementing a sub-group option, and because of potential gaming opportunities, CMS is not proposing any such policy in this rule. However, it will consider facilitating the use of a sub-group identifier in year four through future rulemaking, as necessary.

The AANS and CNS urge CMS to continue to explore alternative mechanisms that would allow a portion of a group practice of any size — such as members of a specific specialty practicing in a large multi-specialty practice — to carve themselves out of the larger group and participate in MIPS as a more focused subgroup. While in some cases the subgroup might focus on a particular specialty, in other situations, it might focus on a particular condition or type of care (e.g., spine care performed by a multi-disciplinary team of clinicians). Specialists and subspecialists in larger multi-specialty practices, facilities, and health systems continue to lack “skin in the game” since they have limited control over the selection of measures and reporting mechanisms that are best for their patient population. We strongly encourage CMS to give these clinicians the opportunity to engage more autonomously and more meaningfully in MIPS by recognizing engagement in MIPS at multiple levels that span beyond the billing Taxpayer Identification Number (TIN).

Contribution of Performance Categories to Overall MIPS Score

CMS proposes the following weights for 2019:

- Quality: 45% (down from 50%)
- Cost: 15% (up from 10%)
- Promoting Interoperability: 25% (no change)
- Improvement Activities: 15% (no change)

The AANS and CNS oppose CMS' proposal to lower the weight of the Quality category and raise the weight of the Cost category. The Bipartisan Budget Act of 2018 extended CMS' flexibility to weigh the Cost category at between 10% and 30% of the MIPS composite score for an additional three years. **We believe CMS should take full advantage of this opportunity and maintain the Cost category weight at 10%.** Clinicians have far more direct control over quality measures than they do over the current set of cost measures. Furthermore, the cost measures proposed for use in 2019 are either under refinement or under-tested, as we discuss in our Cost Category comments below.

We also urge CMS to consider raising the weight of the Improvement Activity category and lowering the weight of the Advancing Care Information category since the former recognizes a much broader array of quality actions that reflect a variety of practices whereas the latter continues to focus on inflexible metrics that target EHR functionality more than genuine improvements in quality.

Quality Performance Category

- **Meaningful Measures Initiative.** We appreciate CMS' efforts to streamline regulations with the goal to reduce unnecessary cost and burden on physicians, as well as the initial efforts to identify the highest priority areas for quality measurement and improvement to improve patient outcomes through the Meaningful Measures initiative. We also recognize the need to move to more measures focused on outcomes; however, absent true reforms to the quality category, benchmark methodology and overall MIPS program we find the Meaningful Measure initiative short-sighted and not a true reduction of administrative burden. At a minimum, **if CMS would like to see an immediate reduction and return on "patients over paperwork" we strongly urge CMS to reduce the number of quality measures a physician must report.**

Under the current MIPS quality structure, CMS utilizes specialty measure sets and requires reporting on a minimum set number of measures (six), which still forces physicians to pick random individual measures and lumps a specialty together, regardless of sub-specialization. When you tie this to cost and episodes, it does not ensure that the specialty set matches up with the episode and can appropriately evaluate the potential for stinting on care to appear low cost. To move to a more unified MIPS program, specifically, a more meaningful quality category we recommend the following reforms:

- **Propose quality-reporting measurement through clinical continuums of care that tracks an episode and potentially spans across MIPS categories.** This allows for shaping measurement around improving or managing a disease or condition — similar to the concept of measure groups that CMS eliminated in 2017. Under the measure group option, the groups became problematic once CMS started incorporating unrelated measures into the individual measure groups outside of the original developer construction. The concept also allows measure stewards to focus on developing composites, which CMS has repeatedly highlighted through the years that it would like to move to when measuring quality.

- **Reduce the number of measures that must be reported** to allow physicians to truly select and report the most meaningful measures to their patients and practice.
- **Encourage CMS to identify an alternative to the current minimum reporting threshold/data completeness requirements** (see additional discussion below).
- **Reserve a role for process measures, which continue to serve an important purpose, especially when coupled with cost because it is often the breakdown in a process that contributes to poor outcomes and increased resource use.** Process measures, for which there is strong evidence that fulfillment of the measure intent, will improve patient outcomes or safety, and should be retained.
- Provide a maximum number of points for reporting on new measures or measures where there is no benchmark.
- **Abandon existing and proposed topped out measure removal and scoring cap policies at this time** (see additional discussion below).

The AANS and CNS support providing physicians with the flexibility to focus on activities that fit within their workflow and address their patient population needs — and providing them with credit for those activities that span across MIPS categories. We believe this will encourage increased participation and relevancy of MIPS and drive participation and continued improvement across categories. It would also facilitate the development of new measures and activities that address key gap areas such as patient-reported outcomes (PROs), leverage health information technology in a more meaningful way, and target key cost drivers such as through the use of clinical decision support and appropriate use criteria. Many QCDRs also operate through clinical continuums of care and, with the right incentives, specialty QCDRs could further move in this direction. Moving in this direction also would make the transition to APMs easier since many of the APM proposals are focused on episodes.

- **Performance Period.** CMS proposes to maintain a 12-month minimum performance period for the Quality Category.

The AANS and CNS continue to oppose the use of a 12-month performance period for the Quality category and strongly urge CMS to use instead a 90-day performance period, which would align with the Improvement Activities and Promoting Interoperability categories of MIPS. CMS notes numerous times throughout this rule that it would like to minimize the complexity of this program. One way to do that would be for CMS to adopt consistent policies across the MIPS performance categories and from year to year, as often possible.

The proposed 12-month performance fails to account for ongoing delays in the release of quality measure specifications and other technical guidance that is critical for participation. CMS typically does not release a final list of MIPS measure specifications until about a month before the start of the performance period. Traditionally, QCDR measures have not been finalized until a few months *into* the performance period. Once the final measures are released, it takes time for practices to choose the most relevant measures, to familiarize themselves with any new documentation requirements, and to update their billing/medical record systems and train staff and clinicians to capture such data.

CMS also has encountered serious delays in releasing details related to its MIPS data validation process. As of early September, clinicians still do not have any information about how they will be evaluated under CMS's Eligible Measure Applicability (EMA) process, which is critical for determining

which clinicians will be protected from penalties when less than six applicable measures are available.

CMS also must consider the timing of previous year MIPS feedback reports, which are released in July after the close of the reporting period (for example, 2018 MIPS Feedback reporting are released in July of 2019). Assuming CMS does not encounter delays in releasing feedback reports akin to its delay in releasing eligibility information, updating the website and that these reports are released in July, any necessary modifications will interrupt a calendar year reporting period. If the reporting period were reduced to a 90-day minimum with the option to submit additional data, clinicians would have greater flexibility to incorporate previous MIPS feedback into their 2019 performance and focus more of their attention on improving patient care as opposed to just reporting.

In light of these ongoing delays, we believe it is unrealistic to expect clinicians to be ready to report on January 1 and unfair to hold clinicians accountable for a calendar years' worth of quality data in 2019.

- **Reporting Across Multiple Data Collection Types.** For 2019, CMS proposes to score eligible clinicians and groups on quality measure data submitted across multiple collection types (e.g., via claims and registry). **The AANS and CNS support giving clinicians as much flexibility as possible to meaningfully engage in, and satisfy the requirements of, this program and thus, support this policy.** As CMS continues to scale back on the number of quality measures, it will be increasingly challenging for specialists to identify relevant measures. We support this proposal, especially if CMS is going to maintain the six-measure requirement, which is often challenging to meet.
- **Data Completeness.** CMS proposes to maintain the current data completeness threshold of 60 percent for the 2019 performance year. As such, clinicians using claims must report on at least 60 percent of Medicare Part B patients for the performance period, and those using QCDRs, qualified registries and EHRs must report on 60 percent of patients across all payers for the performance period. **The AANS and CNS continue to oppose this threshold and instead encourage CMS to identify an alternative to the current data completeness requirements.** For example, moving to a set minimum number of patients rather than a percentage of patients that meet the denominator could reduce administrative burden and simplify reporting. Currently, participants must estimate whether they have submitted at least 60 percent of their entire patient population, which is difficult to predict at the start of the reporting period. A practice does not necessarily know the exact number of patients and the point in time during a calendar year when they will treat patients. A more predictable threshold is particularly important in light of CMS' proposal to extend the quality performance period to 12 months.

If CMS is unable to adopt an alternative minimum number requirement this year, then we request that it at least lower the threshold to 50 percent for 2019. Reducing the threshold to 50 percent does not prevent a clinician from reporting submitting more data and still requires reporting on a majority of patients, which prevents cherry picking. It could also encourage clinicians to report on certain high priority measures, such patient-reported outcomes (PROs), which are often more administratively burdensome and costly, especially when considering the requirement to report on all-payer data when using a QCDR.

Finally, ideally, we would like to see CMS eliminate the all-payer data requirement and make it optional. The all-payer data requirement is extremely time-consuming due to the amount of data entry required. It also takes away time from patient care and ignores the fact that physicians are still contractually obligated to meet various other private payer quality initiatives using different data. We also note that CMS states that it wants to incentivize electronic reporting; however, the requirement

to report all-payer data does the opposite. Clinicians who report measures through the claims option are only required to report on Medicare Part B patients. CMS is placing the highest burden on physicians who choose to report via methods it should be incentivizing — EHR, qualified registry, or QCDR. Therefore, physicians may be deterred from adopting electronic reporting mechanisms.

As part of this policy, we also request that CMS provide more flexibility by making the reporting of outcome and high priority measures optional. Mandating that physicians report on an outcome measure, or high priority measure if an outcome measure is not available, may disadvantage certain specialties, as well as rural practices and practices that treat high-risk patients. There also are a number of methodological issues that must be addressed before requiring reporting on outcome measures, such as the development of better risk-adjustment models at the measure level (not just the program level), benchmark methodology and stratification by specialty.

- **Scaling Back on Claims Reporting.** Starting in 2019, CMS proposes to limit claims-based reporting of quality measures to clinicians in small practices (≤ 15 eligible clinicians). However, claims reporting for these practices would be available at both the individual and group-level. The AANS and CNS continue to encourage neurosurgeons to use more robust data collection mechanisms, such as QCDRs, but as the transition to this new program continues over the next few years, it is critical to maintain flexibility, including the availability of claims-based reporting, for those who still rely on it. As such, **we do not support limiting claims-based reporting to individual clinicians that are in practices of 15 or less. We urge CMS to revise its proposal to allow all individual clinicians, regardless of practice size to report through the claims collection type, as well as allow groups of ≤ 15 to report through claims.** Claims reporting remains the most popular reporting type so to restrict eligibility would further discourage meaningful and active participation in MIPS.
- **MIPS Clinical Quality Measures.** For 2019, CMS proposes to add three new measures, developed by Minnesota Community Measurement, to the Neurosurgical Specialty Set.
 - Average Change in Functional Status Following Lumbar Spine Fusion Surgery
 - Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery
 - Average Change in Leg Pain Following Lumbar Spine Fusion Surgery

Although we support the MN Community Measurement measures in concept, we are concerned that they require the use of specific tools to capture pain (i.e., Visual Analog Scale or VAS) and functional status (i.e., Oswestry Disability Index or ODI) despite the existence of equally useful scoring systems. We believe these measures should provide more flexibility to clinicians by instead focusing more generically on “improvement on a validated pain or disability patient-reported outcome tool.”

We also remind CMS of the ongoing need to employ a more transparent process when making decisions about which measures to include in a specialty set. The AANS and CNS were never consulted about the appropriateness of these measures and would have appreciated an earlier opportunity to provide feedback.

- **Topped Out Measures.** During last year’s rulemaking, CMS finalized a 4-year timeline to identify and potentially remove topped out measures. After a measure has been identified as topped out for three consecutive years through the benchmarks, CMS may propose to remove the measure through notice and comment rulemaking. CMS also previously finalized a 7-point cap to be applied to measures identified as topped out in the published benchmarks for two consecutive years. The final determination of which measure benchmarks are subject to the topped out cap in 2019 would not be available until the 2019 MIPS Quality Benchmarks’ file is released in late 2018.

In this rule, CMS proposes to change its existing policy so that once a MIPS measure has reached an extremely topped out status (e.g., a measure with an average mean performance within the 98th to 100th percentile range), it may propose to remove the measure in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle due to the extremely high and unvarying performance where meaningful distinctions in performance can no longer be made, after taking into account any other relevant factors. CMS also proposes to exclude QCDR measures from the topped out timeline previously finalized since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle. However, topped out QCDR measures might not be approved through the QCDR measure approval process.

In general, the AANS and CNS strongly oppose the removal of measures based on topped out status at this time. MIPS is still a relatively new program with low participation rates (e.g., less than 40% of clinicians are eligible to participate in 2018). With such a limited number of participants, it is virtually impossible to know with certainty whether performance is really at its peak or simply a reflection of the top performers in the country self-selecting measures they know they will do well on. Furthermore, quality reporting requirements and participation incentives have changed substantially over the past few years as clinicians shifted from PQRS to MIPS. It is unfair to make determinations about topped out status based on such inconsistent data and to rely on data from the PQRS, which had such low participation rates and under which less than five percent of eligible physicians reported on some measures. We also believe that the phased removal of topped out measures based on only one- or two-years of MIPS data is also problematic since 2017 and 2018 are transition years. Because of the pick-your-pace approach used in 2017, in particular, year one data is not a representative sample of how physicians are actually performing on quality measures, and neither is year two due to the continued phased transition on implementing the MIPS program, including changes to the low-volume threshold definition. At least in the early years of the program, CMS must maintain a consistent measure inventory and continue to incentivize the reporting of all existing measures so that performance data reflects a broader and more diverse sample of physicians and is a more consistent and accurate indicator of topped out status. Furthermore, **MIPS benchmarks should be developed and based on MIPS reporting, not a program that sunset in 2016.**

We also remind CMS of the risks involved with removing a measure that contributes to greater patient safety. Once a topped out measure is removed from the program, there is no way to monitor whether high performance is being maintained over time. As our surgical colleagues at the ACS have pointed out, pilots are still required to conduct a pre-flight checklist prior to every flight departure despite performance on this metric being topped out according to CMS' definition. CMS must recognize that there are measures for which every physician should be aiming for top performance.

If CMS decides to finalize a topped out policy, then it should, at a minimum, maintain the four-year timeline for the removal of topped out measures that it finalized last year, but delay implementation of this policy so that it is not based on transition year data. The topped out analysis should examine the breadth and depth of reporting based on the number of physicians who successfully report on a measure and the length of time a measure is reported on within a given performance year since physician performance can vary by practice setting, patient population, geography, years in practice, volume of cases of a particular condition, or how long the physician has been reporting. CMS also should consult with measure stewards and specialties to determine whether there is a measure in development that could replace the topped out measure. If a measure is almost ready for implementation but needs a little more time, then it should be kept in the MIPS program until it can be replaced.

We also oppose CMS' policy of capping the points that may be earned on topped out measures at this time. Physicians should be eligible to earn maximum achievement points for

reporting such measures until a measure is removed. Capping achievement points adds to the complexity of scoring and disregards the fact that there are multiple factors that go into the decisions for reporting on specific measures, such as a limited number of available measures by specialty or reporting mechanism, especially if the topped out measure is an outcome or high-priority measure. Capping points also discourages clinicians from reporting on these measures, which contributes to the ongoing lack of data on which to make accurate determinations regarding topped out performance. The cap also ignores that CMS is making classifications on measures based on extremely faulty data with low reporting rates. For instance, five of the measures from the neurosurgery specialty set are at risk of being subject to the seven-point cap in 2019 and/or nearing highly topped out status. The remainder of the measures in the set have no benchmark.



Additionally, we urge CMS to notify measure owners and MIPS eligible clinicians as early as possible that measures are topped out so that they have sufficient time to develop alternative measures and reporting strategies.

It is critical that CMS apply these policies to both MIPS measures and QCDR measures to ensure there is sufficient data on which to make these determinations and to give measure developers and clinician participants time to prepare for the potential removal of measures and development of new ones. Applying this policy to QCDR measures will also ensure consistency across the program and minimize complexity. Maintaining measures in the program for a minimum number of years will also limit situations where CMS does not have sufficient historical data on a measure to set a benchmark or otherwise evaluate performance. This is especially critical in regards to QCDR measures, most of which are relatively new and often subject to scoring caps due to the lack of a benchmark.

- **All Cause Readmission Measure.** The AANS and CNS also request that CMS eliminate the **All-Cause Hospital Readmission (ACR) Measure until it has been refined and deemed valid at the physician-level.** The ACR measure lacks transparent evaluation on whether it is appropriate to use at the physician-level and the continued lack of adjustment for social risk factors in the risk-adjustment model continues to be a concern. There is also emerging evidence that the Hospital Readmission program and the associated measures, such as ACR, may be leading to negative unintended patient consequences and no longer be capturing the appropriate patient population due to the structure and timeframe of the measures. Until appropriate evaluation and potential refinements to the measure can be made, physicians should not be held accountable for the ACR measure, and the measure should be removed from the program.

Cost Performance Category

- **Cost Measures.** CMS proposes to retain the Total Per Capita Costs measure and the Medicare Spending Per Beneficiary (MSPB) measure for this category. Most clinicians still lack a clear understanding of these measures and question whether the measures capture costs over which they have direct control. In fact, many clinicians were disappointed to see that the 2017 MIPS Feedback Reports only included general performance scores related to these cost measures. Clinicians were not provided with any drill-down data to allow them to understand more fully why they were being attributed certain patients and why they were being scored a certain way. We also have concerns that the MSPB measure is currently being refined by a Technical Expert Panel (TEP). The fact that CMS convened such a TEP demonstrates that there are ongoing issues with the measure that need to be fixed before it can be used for accurate clinician-level cost evaluations. **As such, the AANS and CNS continue to have concerns about the relevance and appropriateness of these measures and continue to oppose their use in a program that applies accountability at the clinician level.**

In regards to the eight Episode-Based Cost measures being proposed, we believe these measures are a step in the right direction and appreciate the transparent and inclusive process under which they were developed. However, the field-testing period was unreasonably brief, which led to confusion and prevented clinicians and professional societies from providing meaningful feedback. Furthermore, these measures have received only conditional support from the Measures Application Partnership (MAP) and have not yet been submitted to the National Quality Forum (NQF) for endorsement. **As such, the AANS and CNS do not believe that the episode-based cost measures should be used for purposes of scoring the MIPS Cost Category until clinicians are first given the opportunity to review additional confidential feedback under a more reasonable timeline carefully.**

- **Cost Category Weight.** As noted earlier, **the AANS and CNS also oppose CMS' proposal to increase the weight of this category due to the ongoing refinements being made to the MSPB measure, as well as ongoing confusion and an inadequate opportunity to comment on meaningfully and understand the episode-based measures.**

Promoting Interoperability Category

- **Mandating 2015 CEHRT.** Whereas clinicians may currently use either 2014 or 2015 Edition Certified EHR Technology (CEHRT) (or a combination of both) to satisfy the requirements of this category, for 2019, CMS proposes to require clinicians to move to 2015 Edition CEHRT. The AANS and CNS appreciate that many clinicians have already transitioned to 2015 CEHRT and that the 2015 Edition offers enhanced functionalities that better promote interoperability. However, **we oppose mandating the use of the 2015 Edition since there are still many clinicians who continue to face financial or other logistical barriers that prevent them from easily upgrading.**

We also remind CMS that many of the improved features of 2015 Edition CEHRT are off limits to surgical specialists. CMS points out that one of the major improvements of the 2015 Edition CEHRT is the Application Programming Interface (API) functionality. However, there are few, if any, well-developed apps in the marketplace that are relevant to surgical care and that would allow surgeons and their patients to leverage these API functionalities. As a result, there is less of an incentive for surgical specialists to invest in upgrades at this time.

Since MIPS is still a relatively new program, we urge CMS to continue to offer flexibility for clinicians who find it infeasible to upgrade their systems in time for the 2019 MIPS performance period. **If CMS insists on adopting the 2015 Edition mandate, at the very least, it should clarify that lack of available 2015 CEHRT in 2019 is a valid reason to claim an “extreme and uncontrollable circumstances” exception under the hardship application’s “Vendor Issues” option.**

- **Scoring Methodology.** CMS also proposes to reduce the number of measures and to simplify the overall scoring methodology of the PI Category. CMS would eliminate the base, performance, and bonus scoring structure and instead use a single performance-based methodology, rather than the previous threshold approach. **The AANS and CNS appreciate and support this more simplified approach as a short-term solution to the problems that currently plague this category. However, we strongly recommend that CMS consider additional reforms that provide even more flexibility in this category, which we discuss below.** The proposed scoring methodology still relies on an all-or-nothing approach since a clinician must report on every single measure to receive a score in this category. Instead, clinicians should be able to pick and choose which mix of measures is most relevant to their practice. Not all of the measures work for all practices, as demonstrated by the continued number of necessary exclusions. **As a short-term compromise, we support CMS’ alternative proposal, under which clinicians would be scored at the objective level — that is, scored based on reporting one measure from each objective and receiving bonus points for any additional reported measures.** So, for example, a physician could report on the “send” measure in the Health Information Exchange (HIE) objective, but not have to report on “receive & incorporate” in order to receive credit for that objective.

Similarly, clinicians should only have to earn 50 points to receive full credit in the PI category, which would translate into 25 points toward the final MIPS composite score. This policy aligns with the number of points that hospitals need to earn to be considered a “meaningful user” and avoid a penalty under the Hospital EHR Incentive Program, as finalized through the recent 2019 Inpatient Prospective Payment System (IPPS) final rule. Clinician practices often have fewer resources (both monetary and human) than hospitals do and should not be held to a higher standard. We note that elsewhere in our comments, we also recommend that CMS adopt a lower overall MIPS Performance Threshold than the proposed 30 points. If CMS were to adopt a lower MIPS Performance Threshold (e.g., 25 points), along with a 50-point minimum to receive full credit in the PI Category, clinicians fully satisfying the PI category could avoid a penalty, which aligns with policies adopted for the Hospital EHR Program.

For the 2020 performance year and subsequent years, we request that CMS only require physicians to attest to meeting the program’s measures — i.e., physicians should only be required to report “yes” or “no” on whether they had at least one patient in the numerator of each measure. Each “yes” would be worth whatever that measure’s potential points are (e.g., under the current proposal, a “yes” attestation to e-prescribing would be worth 10 points). In addition to reducing the reporting burden on physicians, a yes/no attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report, and could help prioritize both existing and future gaps in health IT functionality. It also capitalizes on changes made in the Bipartisan Budget Act of 2018, which removed the requirement that HHS increase the stringency of EHR measurement over

time; Congress has clearly recognized that measuring EHR usage for measurement's sake does not promote interoperability.

- **Objectives/Measures.** CMS also proposes to add two new opioid-focused measures to the PI Category, which would be voluntary in 2019 and required in 2020: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. While we fully appreciate the intent of these two measures, we believe there are too many ongoing challenges related to e-prescribing of Schedule II opioid prescriptions and the ability of EHRs to query easily a PDMP. State laws still vary widely, as does user experience with PDMPs across the country. **If CMS adopts these measures, we recommend that they both remain voluntary for 2019 and 2020.**

In this section of the rule, CMS also notes its intent to propose in the future to remove the Public Health and Clinical Data Exchange objective and measures from the PI Category no later than CY 2022. The agency seeks public comment on this decision and other policy levers to encourage reporting to public health and clinical data registries. **While this objective has been challenging for many clinicians to comply with due to ongoing data exchange barriers erected by EHR vendors, we believe it is critical for the PI category to continue to recognize and reward clinicians who opt to use clinical data registries to advance care information. Measures in this objective should continue to be offered as an option for clinicians who feel they can comply with them, or alternatively, as a way to earn bonus points in this performance category.**

At the same time, we request that CMS define “specialized registry” for purposes of the Public Health and Clinical Data Exchange Objective. Similar to the development of commercial QCDRs, many EHR vendors are establishing “specialized registries” in order to help their customers fulfill this PI objective. These “specialized registries” have no public health benefit and are not created to address a legitimate public health need but rather are created as a way to enable their customers to receive additional MIPS credit. To ensure the specialized registries are advancing the goals of the Public Health and Clinical Data Exchange objective, we recommend that CMS apply meaningful criteria to specialized registries to ensure they are not created for a commercial purpose and that they are aimed toward achieving a public health objective.

We also request that CMS expand the Public Health and Clinical Data Exchange objective requirement to include a mixture of methods for data capture or reporting. Currently, for clinical registry reporting to be recognized under this performance category, it must be based on end-to-end electronic reporting. Registries continue to face challenges in regards to seamless exchange of data with EHRs. It is an incorrect assumption that chart-abstracted or hand-keyed data has any less value than end-to-end electronically captured and reported data. Many registries still rely on both automated and manual data entry. Furthermore, most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection.

- **Fundamentally Reforming the Promote Interoperability Category Beyond 2019.** As noted earlier, **the AANS and CNS strongly urge CMS to consider more fundamental reforms to this performance category over the long term that provides clinicians with even more flexibility to demonstrate interoperability and data exchange in a variety of innovative ways. Ideally, we would like CMS to establish an alternative pathway that recognizes physicians utilizing certified EHR technology to participate in a clinical data registry (regardless of whether or not the EHR has a direct interface with the clinical registry) as satisfactorily achieving full credit for the PI category.** To realize the full power of data and the potential of information exchange, this category needs to be less prescriptive and to allow clinicians to creatively incorporate a variety of technology, including registries, into their unique clinical workflows in a manner that best responds to

their patient's needs. This would not only further incentivize EHR adoption and participation in clinical data registries but also recognize the value of registries in facilitating a culture of performance improvement that benefits patient care and patient outcomes.

We believe that CMS has the statutory authority to modify the PI requirements in this manner since the statute defining "meaningful use" specifies that the meaningful use of CEHRT includes the electronic exchange of health information to improve the quality of health care, and reporting on quality measures. Both of these can be achieved by using CEHRT to participate in a registry. The third requirement is that Meaningful Use "shall include the use of electronic prescribing as *determined to be appropriate by the Secretary*," which we interpret to mean that CMS has the authority to waive application of e-prescribing requirements as appropriate. For other measures that CMS deems important or necessary, such as the security risk assessment measure, we believe that these measures still could be fulfilled through an attestation to a QCDR. Finally, MACRA also provides CMS with substantial discretion to modify meaningful use requirements for incorporation into the PI component of MIPS to ensure that the application of meaningful use requirements is "consistent with the provisions of" MIPS.

- **Reweighting Policies. The AANS and CNS believe that CMS should more evenly distribute the performance category weights when clinicians are eligible for a PI exception.** Specifically, we suggest that CMS distribute PI's 25 percent weight to the Improvement Activities category for a total of 40 percent in IA, 50 percent in quality, and 10 percent in cost in 2019.

Improvement Activities Category

- **Annual Call for Improvement Activities Timeline.** For 2019, CMS proposes an extension to the current Annual Call for Activities timeframe. If adopted, this would extend the submission timeframe/due date, allowing an additional four months for activity submission, but also increase the time from submission of an Improvement Activity to possible implementation from one year to two years. **The AANS and CNS oppose this proposed extension of the timeframe for the Annual Call for Activities and recommend that CMS maintain the current schedule to ensure the timely inclusion of important and more relevant activities in the program.**
- **Reweighting Policies. The AANS and CNS strongly recommend that CMS more evenly and fairly distribute the PI performance category weight across the other MIPS components if and when it is reweighted. More specifically, we recommend reweighting the PI component entirely to the IA component such that IA is would be worth 40 percent in 2019.** This would avoid creating an undue emphasis on only one category, help to create a more unified program, demonstrate the value of the IA category while still prioritizing quality.
- **Potential New Activities. The AANS and CNS continue to urge CMS to adopt an Improvement Activity that recognizes Emergency Department (ED) Call Coverage by Surgical Subspecialties as a way of improving patient access to care.** When surgical subspecialists provide emergency call coverage it leads to improvements in patient access to care, decreases the need for patient transfers and wait times for ED patients, and is a valuable contribution to population health. However, the lack of emergency access to physician specialists can be a serious problem that impairs timely patient care and adversely affect clinical outcomes. Studies have found difficulties in obtaining specialty on-call coverage a pervasive issue for EDs at the national and local level. For example:
 - For a majority of Level I trauma centers, more than half of incoming patient transfers are due to the lack of on-call specialist coverage at the referring hospital.

- Over half of all hospital sentinel events involving death or permanent disability due to delays in treatment occur in EDs, with 21% of ED patient deaths or permanent injuries directly attributed to delays in treatment due to specialist shortages.
- An audit of transfers to a tertiary care facility in Chicago found that the average time to transfer was over 5 hours. Two-thirds of transfers occurred from facilities without available neurosurgical coverage.
- 60% of neurosurgeons believe that there are problems with neurosurgical emergency coverage nationwide.

The AANS and CNS have submitted this request multiple times through CMS' formal "Call for Improvement Activities" process. However, CMS continues to argue that "being on call is part of an agreement with the hospital and thus is also part of their usual practice" and that this Improvement Activity would not result in a significant increase in specialists taking call. We question the basis on which CMS has come to that conclusion. To clarify, not all hospitals require medical staff to be on call — it is a point of negotiation and represents extended care on the part of the specialist. Other factors that contribute to gaps in on-call specialist coverage include:

- The nation's surgical workforce shortage and growing/aging patient population.
- Financial/legal disincentives that make specialists reluctant to provide on-call coverage. For example, specialists often have difficulty getting paid for emergency and trauma care due to the high numbers of under- or uninsured patients using EDs. Procedures in this setting also hold high legal liability due to the lack of an established relationship between the physician/patient, leading to higher insurance premiums for specialists electing to take call.

Providing recognition of the value of call coverage within the MIPS program will incentivize physicians to engage with their local facilities and to provide emergency coverage, when feasible, leading to greater patient access to higher quality care.

Qualified Clinical Data Registries (QCDR)

- **Proposed Update to the Definition of a QCDR.** CMS proposes to modify the definition of a QCDR to require that an approved QCDR have clinical expertise in medicine and quality measure development beginning with the 2022 MIPS payment year. Under this proposal, entities may also meet this definition through a signed, written agreement with an external organization with expertise in medicine and quality measure development.

The AANS and CNS strongly support this proposal to require registries to have clinical expertise in medicine and quality measure development. We agree with CMS that entities without expertise in medicine and quality measure development do not satisfy the intent of QCDRs. In the past, we have raised concerns about EHR vendors and other commercial entities qualifying as QCDRs without the participation of clinician-led professional organizations focused on quality improvement. These vendor-led registries do not have quality improvement or population health management as their primary purpose and do not have the clinical expertise or in-depth understanding about quality measurement. Instead, they are created only for commercial purposes. For-profit companies, such as EHR vendors, do not appear to have any population health impact, as measured by published articles in the scientific peer-reviewed literature and practice guidelines for clinicians. As a result, we agree with CMS that approval of commercial QCDRs does not fulfill CMS' intent for the broad population health and public health use of QCDRs. We refer CMS to additional comments submitted by the Physician Clinical Registry Coalition (PCRC) and supported by the AANS and CNS, which discuss in more detail how commercial QCDRs without quality measurement expertise threaten the integrity of quality measure performance data, and may inappropriately affect the CMS benchmarks used to calculate MIPS Quality scores.

- **QCDRs Seeking Permission from Another QCDR To Use an Existing, Approved QCDR Measure.** CMS proposes that, as a condition of a QCDR measure's approval for purposes of MIPS, QCDR measure owners be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS, beginning with the 2019 MIPS performance year. Our understanding is that, should this proposal be adopted, once a QCDR measure is approved for reporting in MIPS, it would be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.

The AANS and CNS strongly oppose this proposal because it undermines QCDR measure ownership and development. The ability of QCDRs to license measures incentivizes organizations to invest in developing new and improved measures, and is crucial to ensure users respect the intellectual property rights of measure developers. The AANS and CNS have invested heavily in the development of valid measures, including significant effort and time from physicians and society staff, and additional time to test, maintain and implement the measures. Testing new measures can also be costly. Without the ability to license measures and collect royalties to offset the cost of developing measures, QCDR measure owners have no way to control the appropriate use of their measures and cannot responsibly invest in measure development.

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

The agency's proposal is also inconsistent with CMS's decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner. Last year, the AANS and CNS supported CMS's proposal that QCDR vendors must seek permission from the owner of a QCDR measure before using that measure during the performance period, and that such permission should be obtained at the time of self-nomination. Through comments submitted by the PCRC, we also recommended that CMS record the ownership of all approved measures to protect the intellectual property rights of the owner and ensure that the measures are used appropriately. In the CY 2018 final rule, CMS finalized these proposals and clarified that the borrowing QCDR must use the exact measure specification provided by the QCDR measure owner. CMS is now backtracking on this prior rule to protect the intellectual property rights of measure owners — as discussed above, this action would threaten quality measure development.

CMS' proposal also is inconsistent with the way the Medicare program has treated the AMA's CPT code set. The AMA owns and collects royalties on the use of its CPT code set. From an intellectual property perspective, there is really no distinction between the AMA's ownership of the CPT and QCDRs' ownership of their measures. Both require substantial time and resources to develop and should qualify as original work equally subject to copyright and other intellectual property protections.

The AANS and CNS urge CMS to allow instead QCDRs to enforce their ownership rights in the QCDR measures they develop, and require third parties to enter into licensing agreements

with measure owners before they can properly use QCDR measures. Through the PCRC, we would be happy to work with CMS to create safeguards to protect the proper implementation of these measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

- **Self-Nomination Process.** CMS proposes to revise the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. This change would negatively affect the life cycle of QCDRs and the maintenance process for QCDR measures. QCDRs dedicate a significant portion of their time during each performance period to reporting for the previous year's MIPS program and validating the data and submitting the Data Validation Execution Report by May 31 of a calendar year. Often, it is not until May or June that QCDRs can review performance on measures and convene groups of expert clinicians to discuss updates to existing measures or develop new measures. By moving the self-nomination period deadline to September 1, CMS would provide QCDRs with a limited time frame to update existing measures and develop new measures. As a result, **the AANS and CNS oppose these changes to the self-nomination period for QCDRs. If CMS does adopt these proposed changes to the self-nomination period, it is essential that the agency change its expectations for providing data for measures accordingly, as it is not feasible to have data to support a measure so early in the calendar year.**
- **Topped Out QCDR Measures.** We refer CMS to our earlier comments on topped out measures. **The AANS and CNS urge CMS to treat topped out QCDR measures consistently with topped out MIPS measures.**
- **QCDR Benchmarks.** CMS has received feedback from QCDRs that MIPS-eligible clinicians are hesitant to report QCDR measures without established benchmarks because they are assigned only three measure achievement points. To encourage reporting of QCDR measures, CMS seeks comment on an approach to develop QCDR measure benchmarks based on historical measure data. This proposal may require QCDRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS.

The AANS and CNS appreciate CMS' effort to encourage reporting of QCDR measures but remind CMS not to be overly restrictive in its definition of "form and manner" to ensure alternative sources of data can be used. For example, QCDRs may be able to provide more robust benchmark data using data collected across its registry participants, including participants that are not reporting the measure to CMS for purposes of MIPS. This data could and should be used to establish CMS benchmarks that would enable QCDR measures to be scored.

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

We remind CMS that many of the criteria used under the Call for Quality Measures Process are problematic. For example, one criterion CMS proposes is prioritizing outcome measures over process measures. Outcome measures are valuable to the clinical process, patients and caregivers. However, often for specialties such as ours, meaningful outcomes in a calendar year may be difficult to measure when the disease status is degenerative, results in increased co-morbidities, is terminal with limited treatment options, or rare. As such, CMS should continue to recognize the important role

of process measures in certain clinical scenarios until they can feasibly be converted to meaningful outcome measures.

The AANS and CNS oppose CMS' proposal to apply the Call for Quality Measures criteria to QCDR measures. The Call for Measures process is cumbersome, does not recognize the unique nature of QCDRs, and should remain distinct from the QCDR measure approval process. The creation of more stringent standards for QCDR measures would place an additional burden on QCDRs and run counter to CMS's intention to encourage the use of QCDRs and other clinical outcomes registries.

MIPS Scoring and Payment Methodology

The Bipartisan Budget Act of 2018, gives CMS flexibility in establishing the MIPS performance threshold for three additional years (through program year five) to ensure a gradual and incremental transition to the sixth year of the program, when the performance threshold must be based on the mean or median of final scores from a prior period. Using this authority, CMS proposes to increase the MIPS Performance Threshold from 15 points to 30 points and to increase the exceptional performance threshold from 70 points to 80 points for 2019.

The AANS and CNS oppose CMS' proposal to double the performance threshold in 2019 for multiple reasons, including: this being too steep of an increase considering the ongoing complexity of the program; CMS' proposal to remove a substantial number of quality measures from the program; and insufficient historical MIPS data on which to set benchmarks and determine the feasibility of the current performance threshold. We urge CMS to more gradually increase the performance threshold as clinicians continue to adjust to this new and confusing program and until there is more robust data on which to make determinations about appropriate performance thresholds.

Facility-Based Scoring

In the CY 2018 QPP final rule, CMS established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. Facility-based scoring allows for "facility-based" clinicians or groups to have their MIPS Quality and Cost performance category scores based on the performance of the hospitals at which they work. A "facility-based clinician" is defined as a MIPS eligible clinician who furnishes 75 percent or more of their covered professional services in inpatient hospital (Place of Service code 21), on-campus outpatient hospital (POS 22), or an emergency room (POS 23), based on claims for a period prior to the performance period. As proposed in this rule, the clinician also would be required to have at least a single service billed with POS code used for inpatient hospital or emergency room. A "facility-based group" would be one in which 75 percent or more of eligible clinicians billing under the group's TIN are eligible for facility-based measurement as individuals.

The MIPS Quality and Cost performance category scores for facility-based clinicians would be based on how well the clinician's hospital performs in comparison to other hospitals in the Hospital Value-Based Purchasing (VBP) Program. Facility-based clinicians would be attributed to the hospital where they provide services to the most Medicare patients. CMS proposes to apply automatically facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined Quality and Cost score.

The AANS and CNS support facility-based scoring as a short-term solution to assist specialties, such as ours, with succeeding at MIPS and easing the burden of data collection. However, we do not view this as a long-term solution to more meaningful measurement for facility-based

clinicians, especially as CMS hospital programs are moving away from clinically specific measures and towards more general measures (e.g., all-cause mortality, all-cause readmissions, etc.) that might not reflect a specialist's care. We urge CMS to incentivize better the development and use of specialty-specific measures and participation mechanisms that encourage more direct engagement by facility-based clinicians without over-burdening them.

Physician Compare

In the CY 2018 QPP final rule, CMS finalized a policy to report on Physician Compare publicly, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years. CMS clarifies that although all information submitted under MIPS is technically available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database. These data must first meet CMS' public reporting standards.

The AANS and CNS reiterate our strong concerns about CMS' use of different methodologies when scoring clinicians for payment purposes vs. scoring them for public accountability. For example, MIPS involves awarding points to physicians based on where they fall in decile-based categories calculated from historical quality measure data (when available), which translates into payment adjustments. This methodology differs from Physician Compare's star rating method, which relies on the Achievable Benchmarks of Care (ABC) methodology to place physicians into one of five categories (each with a corresponding "star rating") for purposes of helping patients compare physicians to make more informed decisions about where they seek care. This is not only confusing but results in inconsistent performance assessments depending on the purpose of the program. **Furthermore, we strongly oppose the use of the ABC methodology for QCDR data, specifically, since it differs from our own QCDR's methodology for rating performance, which could further confuse and mislead patients.**

The AANS and CNS urge CMS to immediately align and move to one consistent data calculation policy between the two programs on the following issues:

- **Only incorporate data used to calculate a physician's quality measure score.** Under MIPS, a physician may report measures through multiple submission mechanisms or report more than the required number of measures. For purposes of avoiding a penalty, CMS only considers the most successful method and measures. However, under Physician Compare, as long as a physician successfully satisfies MIPS quality reporting requirements, *all* data, regardless of whether the data was used to calculate the physician's score, is publicly posted and included in the downloadable database.
- **Individual vs. Group Reporting.** Under MIPS, CMS calculates separate benchmarks and scores based on each reporting mechanism (claims, EHR, registry, QCDR and web-interface) and combines individual and GPRO data to calculate the benchmark and score. However, under Physician Compare, CMS calculates and displays separate scores for measures reported as an individual and measures reported as a group.
- **Create Separate Benchmarks for Each Reporting Mechanism.** CMS is mixing various reporting mechanisms when developing the benchmarks for Physician Compare, which CMS does not do when setting MIPS benchmarks. Therefore, CMS should create separate benchmarks for each reporting method instead of aggregating data from all reporting mechanisms.

- **Move to the same number of achievable points across programs.** Physician Compare places physicians into one of five categories to calculate star ratings, while the MIPS methodology uses nine categories (and point system) to score physicians on quality measure reporting to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive.
- **Retain only the “successful” performance indicator for PI.** CMS should limit the PI performance category indicator to that of only “successful.”

We also recommend the following additional policy changes related to Physician Compare:

- **Expand the Preview Period.** We strongly urge CMS to extend the preview period from 30-days to at least 90 days to allow physicians reasonable time to review and correct their data. To expect physicians to access, review, and contest their Physician Compare data in 30-days ignores the demands of patient care and competing priorities physicians face on a daily basis. In addition, data under appeal should not be publicly reported.
- **Allow Physicians Three Years to Report on Measures Prior to Public Reporting.** CMS has proposed not to report publicly first-year quality measure for the first two years a measure is in use. The AANS and CNS support this expanded policy but remind CMS that it takes multiple years for new measures to accrue data that can be used for accountability purposes. Thus, we continue to urge CMS to expand this exclusion to measures that have been in use for less than three years to provide adequate time for CMS to evaluate trends over time and provide physicians with an adequate period to address data collection issues.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 (PAMA) established the AUC reporting program, which has yet to be fully implemented. However, this program was authorized prior to the passage of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which intentionally consolidated the legacy physician quality reporting programs into the Quality Payment Program (QPP). We remind CMS that AUC consultation is inherent within the QPP’s dual tracks: MIPS and alternative payment models (APMs), both of which hold clinicians accountable for quality and patient outcomes, as well as for resource use. For instance, there are a number of existing measures for appropriate use of imaging in the Quality category of the QPP. In addition, CMS has added consultation of AUC as an Improvement Activity within MIPS — essentially folding key aspects of this program into MIPS.

While the AANS and CNS support decision support and evidence-based AUC, we also believe that the Medicare AUC Program for Advanced Diagnostic Imaging, if allowed to take effect, will become yet another duplicative and burdensome regulation. Requiring health care professionals to participate in a stand-alone AUC reporting program, in addition to the complex requirements of the QPP, is burdensome, duplicative and costly. Additionally, there is an ongoing lack of appropriate measures, which will prevent the program from having any meaningful impact.

The AANS and CNS support deeming clinicians compliant with the AUC Program if they meet the requirements of the QPP, including both the MIPS and APM tracks. We recognize that CMS is limited in its authority to deviate from existing statute. However, organized neurosurgery, along with a broader coalition of specialty societies, are working with Congress to seek modification to the law to afford clinicians maximum flexibility in the use of AUC in the least administratively burdensome manner possible while meeting the intent of PAMA to ensure appropriate imaging through enhanced education of ordering professionals and support for clinicians in achieving high-value performance in MIPS or APMs.

We thus recommend that CMS also seek legislative authority to exempt physicians participating in the QPP from the AUC requirements.

CONCLUSION

The AANS and CNS appreciate the opportunity to provide feedback on these specific provisions in the 2018 MPFS proposed rule. If you have any additional questions or need additional information, please feel free to contact us.

Sincerely,



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