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September 29, 2020

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-1734-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2021; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy**

Dear Administrator Verma:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the quality-focused provisions of the above-referenced notice of proposed rulemaking. Neurosurgery's comments on the payment-related aspects of the proposed rule are included in a separate letter.

## Quality Payment Program (QPP)

The AANS and the CNS refer CMS to comment letters submitted by the Alliance of Specialty Medicine (the Alliance) and the Physician Clinical Registry Coalition (PCRC). We are members of these two coalitions and support the Quality Payment Program (QPP) concerns and recommendations outlined in each of these comment letters. A summary of these concerns is provided below:

- **MIPS Value Pathways (MVPs)**
  - + The AANS and the CNS support CMS' proposal to delay the roll-out of MVPs;

  - Neurosurgery requests that finalized policies offer flexibility to test more innovative strategies to ensure a more cohesive and meaningful participation experience for specialists; and
  - Other priorities related to MVPs include: preserving clinician choice; adopting new participation mechanisms and scoring rules that support more meaningful engagement by specialists; avoiding the use of administrative-based population health measures; providing more flexibility in regards to Promoting Interoperability requirements; allowing for more innovative thinking with cost measures; and enhanced transparency and iterative feedback during the development stage.

- **Alternative Payment Model (APM) Performance Pathway (APP)**. CMS must ensure that any MIPS APM participant continues to benefit from zero percent weighting of the Cost performance category and full credit under the Improvement Activities (IA) performance category, regardless of which quality measures they report and whether they report under MIPS at the APM entity, TIN or individual level.

- **MIPS Performance Categories**
  - We strongly oppose CMS' proposal to shift additional weight from the Quality category to the Cost category due to concerns about disruptions in practice caused by the COVID-19 pandemic and ongoing concerns about the appropriateness and actionability of the current total cost measures;
  - For the Cost category, we also request that CMS make data on benchmarks and performance trends available to the public;
  - For the Quality category, we ask CMS to suspend the 7-point topped out measure scoring cap for 2021, and, in general, we continue to oppose policies that result in capped scoring or the complete elimination of topped out measures; and
  - For the Promoting Interoperability category, we continue to urge CMS to work with specialty societies to develop alternative pathways to comply with the Promoting Interoperability category that look beyond electronic health record (EHR) functionality and instead recognize diverse and innovative ways of sharing and otherwise making use of electronic health data to improve clinical outcomes (e.g., implementation of practice improvements based on clinical data registry data that incorporates EHR data).

- **MIPS Performance Threshold.** We oppose CMS' proposal to increase the overall MIPS performance threshold in 2021 from 45 points to 50 points. To whatever extent possible, we request that CMS maintain the status quo during this uncertain time.

- **COVID-19 MIPS Exceptions.** We urge CMS to continue to make the Extreme and Uncontrollable Circumstances exception application available to those clinicians who feel they cannot comply with MIPS during the 2021 performance year.

- **Qualified Clinical Data Registry (QCDR) Policies**
  - **Measure Testing Requirement**: We are concerned that validity testing beyond face validity is not feasible for most quality measures. We appreciate that CMS postponed these onerous measure testing requirements one year, but have concerns about CMS raising the bar in the future.
  - **Auditing Requirements**: We are concerned that routine and targeted auditing requirements by performance category, mechanism, and submitter type will place a significant burden on registry participants and the registry itself.

- **Updates to Certified Electronic Health Record (EHR) Technology due to the 21st Century Cures Act Final Rule.** While vendors may be able to develop, test, and make available to customers their upgraded products within a two-year period, we believe that clinician practices should be given more time to work with EHR vendors to install, customize, test and train providers on these new features and functions.

- **APM Incentive Payment.** CMS should adopt a streamlined approach to APM incentive payments that permits payment to individual QPs.

In addition to the feedback provided by these two coalitions, the AANS and the CNS would like to express concern about two other issues:

**QPP: MIPS Neurosurgical Specialty Measure Set**

The AANS and the CNS have multiple concerns with the specifications of MIPS measure *#459: Back Pain After Lumbar Discectomy/Laminotomy*. At its highest level, the measure is fundamentally flawed in that it uses an inappropriate patient-reported outcome to evaluate the procedure at hand. More specifically, the measure considers chronic low back pain to evaluate the effectiveness of lumbar discectomy/laminotomy even though these procedures are performed for leg pain and neurogenic claudication (pain, tingling, weakness/heaviness in legs) and not for low back pain. The measure also relies on a visual analog scale (VAS) score, whereas most centers actually use a numeric rating score (NRS). The NRS is also utilized most commonly in the current spine literature. These scores are also collected differently (e.g., the VAS is like a pain thermometer, making it challenging to assign numeric values for analysis).

Additionally, the measure relies on specific targets for pain that have no basis in the literature (i.e., "For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively"). These thresholds are problematic and assume improvement is possible when it may not be clinically achievable. While a VAS or Numeric Rating Score (NRS) less than 3.0 may be a reasonable target, a change of 5 points is a very aggressive target that would be challenging to achieve in a very high percentage of cases. The minimal clinically important difference (MCID) for NRS leg pain is 1.6, and substantial clinical benefit (SCB) is only 2.5.[1] A change of 5 points would only be achieved in a very small minority of cases. Finally, to date, CMS has been unable to benchmark this measure under MIPS due to low reporting rates, which is likely due, in part, to its lack of clinical relevance and validity of the measure results.

Neurosurgery recently shared these concerns with the Core Quality Measure Collaborative (CQMC), which has been considering measure #459 as part of its updated Orthopaedics Core Measure Set. We also shared our concerns with the measure developer, Minnesota Community Measurement, and we are in the process of trying to schedule a meeting with them to discuss how to capture the population of interest more accurately.

As we informed the CQMC, the AANS recently collaborated with the American Academy of Orthopaedic Surgeons (AAOS) to launch the American Spine Registry (ASR), a national quality improvement registry for spine care that collects procedural data, post-operative data, and patient-reported outcome

[1] *See* https://pubmed.ncbi.nlm.nih.gov/18762642/.

measurement (PROM) data. The ASR expands upon the prior Quality Outcomes Database (QOD) Spine Registry, previously the nation's largest spine registry, to offer a more far-reaching data collection platform that facilitates the participation of all North American spine surgeons. Since both neurosurgeons and orthopedic surgeons perform spine surgery, the development of a common data platform fuels the creation of a consistent, reliable quality information source for all major stakeholders, including physicians, patients, payors, regulatory groups, and industry. Data points and metrics supported by the ASR have been informed by clinical experts performing these procedures and are backed by the most current evidence-based literature. During our discussions with the CQMC and in other comments to CMS, we have highlighted the ASR as a resource for not only best practice, but also feasible metrics that can be implemented across programs nationwide.

**In light of our concerns and ongoing work to potentially update measure #459, the AANS and the CNS request that CMS reconsider its use under MIPS for the 2021 performance year.**

**Imaging Appropriate Use Criteria (AUC) Program**

Mandated by the Protecting Access to Medicare Act (PAMA) of 2014, CMS implemented the Appropriate Use Criteria (AUC) for advanced diagnostic imaging program in January 2020, but has not, to date, enforced the penalties for non-compliance due to ongoing operational challenges. Under this program, ordering professionals at outpatient sites must consult appropriate use criteria (AUC) for every advanced diagnostic imaging order using a federally approved clinical decision support mechanism (CDSM) before a radiologist can furnish a scan.

In early August, CMS announced that it would extend the "education and operations testing period" through CY 2021, meaning there would be no payment consequences associated with the AUC program during CY 2020 and CY 2021. While the AANS and the CNS appreciate CMS once again delaying the enforcement of penalties, **we continue to view the program as duplicative and unnecessary and support legislative and regulatory efforts to delay implementation of the mandatory AUC consultation.** Our concerns include:

- The AUC Program was enacted before MACRA and is now unnecessary or in need of re-thinking — particularly as CMS accelerates movement away from fee-for-service and towards bundled payment and other shared risk models;
- There are already multiple, significant demands being placed on claims forms due to the QPP and other initiatives;
- The law is financially advantageous to CDSM developers at the expense of clinicians who order advanced diagnostic imaging tests;
- Not all applicable AUC will be available for consultation by the ordering professional because CDSM vendors can "pick and choose" among qualified AUC; and
- The program may ultimately be costlier to administer than the potential for savings and lacks a patient outcomes or quality component.

CMS has admitted on multiple occasions that the program is plagued by operational issues and other limitations that it does not have solutions to, including the statutory requirement that CMS collect all necessary information via the claims form. CMS also has been very candid that Congress did not understand the complexity of this law when it handed it over to CMS. **We request that CMS continue to delay this program while working with Congress to re-evaluate the feasibility and utility of the program and how appropriate use of imaging can be addressed through the QPP or other value-based initiatives.**

The AANS and the CNS appreciate the opportunity to provide feedback on these quality-focused policies. If you have any questions or need additional information, please feel free to contact us.

Sincerely,

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