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September 24, 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-1695-P Medicare Program: Calendar Year 2019 Hospital Outpatient
Prospective Payment and Ambulatory Surgical Center Payment Systems and
Quality Reporting Programs**

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

REIMBURSEMENT ISSUES

Outpatient Prospective Payment System Issues

- **Magnetic Resonance-guided Focused Ultrasound for Essential Tremor (MRgFUS).** The AANS and CNS urge CMS not to implement payment policy that would lower the reimbursement for this promising new technology.

Ambulatory Surgery Center Issues

- **Device Intensive Procedures.** The AANS and CNS support the CMS proposal to lower the device-intensive threshold to 30 percent.
- **Policy Proposals Regarding the ASC-Payable List.** The AANS and CNS note that CMS will be reviewing procedures added to the ASC list over the last three years. We urge CMS to study available data and consult appropriate stakeholders regarding the safety of performing surgery in the ASC setting. Ultimately, we believe the site of service should be determined by the operating surgeon in consultation with the patient.
- **Non-Opioid Alternatives for Pain Treatment.** The AANS and CNS commend CMS for efforts to promote the use of effective alternatives to opioid treatment for pain.

QUALITY ISSUES

Hospital Outpatient Quality Reporting Program

- **Removal of Topped Out Measures.** As expressed in our 2019 Medicare Physician Fee Schedule proposed rule comments, the AANS and CNS generally oppose the removal of measures based solely on topped out status.

Ambulatory Surgical Center Quality Reporting Program

- **CMS' Proposal to Remove Measures.** The AANS and CNS strongly urge CMS to maintain ASC-3 and ASC-4.

Hospital Inpatient Quality Reporting Program

- **Proposed Updates to the HCAHPS Survey Measure for the FY 2024 Payment Determination and Subsequent Years.** The AANS and CNS support the removal of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) pain questions given their tenuous link to higher quality care and ongoing concerns about the unintended consequences of tying payment to performance on these questions.

DETAILED COMMENTS

REIMBURSEMENT ISSUES

Outpatient Prospective Payment System Issues (OPPS) Issues

- **Magnetic Resonance-guided Focused Ultrasound for Essential Tremor.** The AANS and CNS urge CMS not to implement payment policy that would lower reimbursement for Magnetic Resonance-guided Focused Ultrasound (MRgFUS) for the treatment of essential tremor. We support fair and stable reimbursements for this promising new technology, which will allow neurosurgeons to offer this innovative therapy for essential tremor to appropriately selected patients. We are concerned that the proposed APC assignment for CPT code 0398T could significantly impede the development of this technology. MRgFUS is still in the early stages of adoption, and if the payment rate fails to adequately reflect hospital resources to furnish the service, as the proposed rate does, hospitals will be discouraged from adopting this breakthrough therapy, which ultimately means patient access will be jeopardized. We respectfully ask that CMS continue to assign CPT code 0398T to APC 1576 for 2019 instead of reassigning it to APC 1575, as proposed.

Ambulatory Surgical Center (ASC) Issues

- **Device Intensive Procedures.** We support facility payment that appropriately recognizes the cost of essential devices, as our specialty — which is highly dependent on medical technology — is one of rapid innovation. We share the common goal of enhancing efficiency in bringing lifesaving improvements to our patients and, therefore, we commend CMS for lowering the threshold for device intensive procedures from 40 percent to 30 percent.
- **Policy Proposals Regarding the ASC-Payable List.** The AANS and CNS note that CMS will be reviewing 38 procedures added to the ASC list over the last three years. We would like to see more details on how CMS plans to conduct this review and urge the agency to involve appropriate stakeholders, including through the CMS Advisory Panel on Hospital Outpatient Payments.

Sensational anecdotes, as have recently been reported in the lay press, do not promote balanced, impartial dialogue and should not be the basis for policy decisions. We are eager to work with the agency to intelligently and cooperatively promote high-quality surgical care in all health care settings, and we urge CMS to carefully consider objective data as the agency reviews site of service issues related to surgical procedures.

Over the last few years, we have supported the addition of several codes, particularly spine procedures, to the ASC list, which we believe research shows to be safe for *appropriately selected patients*. Determination of ASC appropriateness for individual procedures can and should be made on objective, evidence-based grounds. We believe the evidence of excellent and reproducible data strategies exists to facilitate determinations regarding ASC appropriateness. Similar strategies can and should be used to allow for transparency regarding the monitoring of safety and effectiveness in ASCs and inpatient environments. We refer the agency to an article in *Neurosurgery*¹ from March 2018, which provides a systematic review of clinical studies that report morbidity and outcomes data for cervical and lumbar surgeries performed in ASCs. The authors focus on anterior cervical discectomy and fusion (ACDF), posterior cervical foraminotomy, cervical arthroplasty, lumbar microdiscectomy, lumbar laminectomy and minimally invasive transforaminal interbody fusion (TLIF) and lateral lumbar interbody fusion, as these surgical spine procedures are becoming more commonly performed in ASC settings. A new analysis by eight neurosurgeons of the safety of ACDF specifically for Medicare patients in the ASC setting is expected to be published in *Neurosurgery*² soon and concludes that surgeons can safely perform ACDF procedures in the ASC setting when appropriate patient selection criteria and peri-operative management is used. The AANS and CNS are happy to share this paper with CMS when it is published.

All health care stakeholders must work to promote safe, effective and affordable surgical care. As ASC's are generally more cost-effective treatment environments, we should offer patients the option of receiving care in those settings, when safety and effectiveness can be assured. Of course, safety in one outpatient environment does not guarantee universal safety, and elements of care that are demonstrated to promote safe outpatient treatment need to be cataloged and disseminated. That stated, poor outcomes in a few select settings cannot and should not be interpreted as evidence that it is "unsafe" to perform the procedures in question in all other environments. Unsafe care is possible in any environment, inpatient or ambulatory. We support an expansion of the list of procedures approved in the ASC setting and ask the agency to consider expanding the allowable care time interval to 48 hours. ASCs can lead the way in providing evidence that select procedures can be safely and effectively performed in these lower cost, often more convenient settings.

Ultimately, the AANS and CNS believe the site of service should be determined by the operating surgeon in consultation with the patient, with careful consideration of the individual's clinical status. We have heard from some of our members that they have had retrospective denials of payment for inpatient admissions for elderly patients for whom that setting was clearly medically necessary. Our support for the inclusion of procedures on the ASC list in no way suggests that procedures should not be performed and paid for in the hospital for Medicare patients who need that level of care.

- **Non-Opioid Alternatives for Pain Treatment.** We commend the agency for seeking comment on appropriate facility reimbursement for non-opioid alternatives for pain treatment and management in the ASC, along with identifying barriers that may inhibit access to these non-opioid alternatives. Although we understand that the proposed policy change to unbundle and pay separately for the cost of non-opioid pain management in the ASC only involves one drug at this time, we appreciate the agency's request for additional comments regarding postoperative pain management. Coupled with a similar request in the CY 2019 Medicare Physician Fee Schedule proposed rule, we are

encouraged by the agency's follow up on recommendations of the President's Commission on Combating Drug Addiction and the Opioid Crisis and interest in more effective and safer non-opioid pain management. We agree with CMS that for the ASC setting, paying for non-opioid pain treatment separately is likely the more effective way to increase the use in that setting and we encourage to the agency to do so.

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 for Opioid-sparing Drugs.** To answer the specific question from CMS requesting evidence for opioid-sparing therapies for perioperative pain management strategies, we note several studies examining strategies to reduce perioperative opioid requirements. Below is a list of these articles and specific references are at the end of this letter. It is important to note that these studies do not address the question of long-term substance use disorder rates, but do support the use of non-opioid medications to reduce opioid requirements after surgery.
 - **Regional Blocks.** The American Society of Anesthesiologists Task Force Report on Acute Pain Management, *Practice Guidelines for Acute Pain Management in the Perioperative Setting*,³ recommends that when possible, surgeons should use multimodal therapy to control post-operative pain and reduce opioid requirements, including regional blockade techniques. They find that this technique is useful in peripheral nerve surgery, but the findings are less clear for cranial or spine surgery.
 - **Local Anesthetic Would Infiltration.** An article from 2008 in the *European Spine Journal*⁴ finds that injecting a local anesthetic into tissues prior to incision lowers perioperative opioid requirements and may shorten hospital stays. In addition, a 2008 article from *Spine*⁵ shows similar results for the use of paravertebral anesthetic infusion catheters and pumps.
 - **Acetaminophen and Nonsteroidal (NSAIDs).** A review of the literature by Cochrane⁶ shows that intraoperative dosing of an intravenous formulation of acetaminophen reduces postoperative opioid requirements. Similar results are shown for intraoperative dosing intravenous formulation of for NSAIDs.⁷
 - **Anticonvulsants.** A meta-analysis of seven clinical trials⁸ published in *Spine* looks at Gabapentin and Pregabalin in the management of postoperative pain after lumbar spinal surgery and found a corresponding reduction in postoperative opioid requirements.
 - **Ketamine.** A 2010 article in *Anesthesiology*⁹ found that the use of intraoperative ketamine reduces postoperative opioid requirements in spinal fusion patients on chronic opioid therapy.
- **Opioid Sparing Devices.** Evidence-based, opioid-sparing surgical therapies can be an effective strategy to reduce opioid prescribing and abuse. We are pleased that the agency also asked about device-related strategies that may be of help. 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.

- **Payment and Coverage Barriers to Use of Devices for Pain.** 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 support policies that encourage the use of non-pharmacologic, opioid-sparing surgical therapies for the treatment of chronic pain when appropriate, while maintaining access to opioid treatment when warranted. We thank you for addressing this important issue and are eager to provide help and expertise as the agency moves to eliminate barriers to important innovative non-opioid treatments.

QUALITY ISSUES

Hospital Outpatient Quality Reporting Program

- **Removal of Topped Out Measures.** As expressed in our 2019 Medicare Physician Fee Schedule proposed rule comments, the AANS and CNS generally oppose the removal of measures based solely on topped out status. We 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. In the aviation industry, 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 provider should be aiming for top performance.

If CMS decides to maintain topped out status as a criterion for removing a measure, then it should at least adopt a minimum timeframe (e.g., four years) during which it identifies a measure as topped out and monitors its topped out status over multiple years. CMS should then propose the measure for removal, through rulemaking, only if performance on the measure has remained consistently high and only after CMS has carefully considered any potential unintended consequences of removing the measure.

Ambulatory Surgical Center Quality Reporting Program

- **CMS' Proposal to Remove Measures.** CMS proposes to remove the following measures, beginning with the CY 2021 payment determination:
 - ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, which is a claims-based outcome measure being proposed for removal due to topped out status.
 - ASC-4: All-Cause Hospital Transfer/Admission, which is a claims-based outcome measure that evaluates the rate of ASC admissions requiring a hospital transfer or hospital admission

upon discharge from the ASC. This measure also is being proposed for removal due to topped out status.

The AANS and CNS oppose CMS' proposal to remove these two measures for multiple reasons. For one, we are generally opposed to the removal of measures based on topped out status alone, as expressed earlier.

In regards to ASC-3, although wrong site surgery is very infrequent, CMS has traditionally defined it as an egregious error. Given this stance, we are surprised that CMS would support the discontinuation of data collection and performance tracking of this measure. Dropping the measure may imply to providers that it is no longer considered important. Furthermore, ambulatory surgical centers tend to have more rapid patient turnovers than hospitals and may be more prone to these events. We strongly urge CMS to maintain this ASC-3 given the serious nature of these "never events."

In regards to ASC-4, the issues surrounding transfers to hospitals from ACSs, although infrequent, remain significant. A challenge regarding ACSs is that they can only function safely if there is a hospital available to care for complicated postoperative patients that present unanticipated problems. Even a low rate of events can indicate poor patient selection for ambulatory surgery. Poor outcomes from these situations can also point to an unclear and even competitive relationship between the ACS and the hospital, which can present a significant risk to patients. Because of these ongoing issues, we request that CMS maintain ASC-4 in the ASCQR.

Hospital Inpatient Quality (IQR) Reporting Program

- **Proposed Updates to the HCAHPS Survey Measure for the FY 2024 Payment Determination and Subsequent Years.** In 2016, decided to remove the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey pain management questions from the hospital payment scoring calculation, beginning with the FY 2018 program year, out of concern that clinicians were feeling pressure to overprescribe opioids because scores on those questions were tied to accountability. The following measures were removed:
 - During this hospital stay, did you need medicine for pain?
 - During this hospital stay, how often was your pain well controlled?
 - During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

Hospitals would continue to use the questions to survey patients about their in-patient pain management experience, but these questions would not affect the level of payment hospitals receive.

In 2017, CMS finalized a refinement to the HCAHPS Survey measures used in the Hospital IQR Program by incorporating new *Communication About Pain* questions for the FY 2020 payment determination (i.e., beginning with patients discharged in January 2018) and subsequent years. The following three survey questions are intended to address instead how providers *communicate* with patients about pain:

- During this hospital stay, did you have any pain?
- During this hospital stay, how often did hospital staff talk with you about how much pain you had?
- During this hospital stay, how often did hospital staff talk with you about how to treat your pain?

Additionally, CMS finalized that hospital performance data on those questions would be publicly reported on the Hospital Compare website beginning October 2020, using CY 2019 data. CMS also stated that they would provide performance results based on CY 2018 data on the *Communication About Pain* questions to hospitals in confidential preview reports.

Since CMS finalized these new questions, the agency has received feedback that — although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled — the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey. Also, in its final report, the President’s Commission on Combating Drug Addiction and the Opioid Crisis recommended removing the HCAHPS Pain Management questions to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.

Although CMS is not aware of any scientific studies that support an association between scores on the prior or current iterations of the *Communication About Pain* questions and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, CMS proposes to update the HCAHPS Survey by removing the *Communication About Pain* questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years.

The AANS and CNS support the removal of the HCAHPS pain questions given their tenuous link to higher quality care and ongoing concerns about the unintended consequences of tying payment to performance on these questions. As progress is made in regards to opioid policymaking, we hope to gain a better understanding of how to improve postoperative pain management. Sunsetting these questions will at least help to initiate the process of designing a potential replacement set of questions or else provide evidence that supports moving away from pain-specific questions.

CONCLUSION

The AANS and CNS appreciate the opportunity to provide feedback on these specific provisions on the 2019 Medicare Hospital OPPTS ASC proposed rule. If you have any additional questions or need additional information, please feel free to contact us.

Sincerely,



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