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October 5, 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-1736-P Medicare Program: Calendar Year 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy; Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years; and Physician-owned Hospitals

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 above-referenced notice of proposed rulemaking.

EXECUTIVE SUMMARY

Outpatient Prospective Payment System Issues

- **Eliminating the Inpatient Only List.** The AANS and the CNS believe the site of service should be determined by the surgeon in consultation with the patient. We are concerned that the agency has not clearly indicated how it will protect access to the inpatient setting when necessary without overly burdensome requirements, such as preauthorization for inpatient admission. Therefore, we urge the agency not to implement its proposal to eliminate the Inpatient Only (IPO) list beginning in CY 2021. Inpatient admission should remain an option for patients who require that level of care. The IPO list should not be completely phased out until CMS has a plan to protect patients who need the inpatient setting.

- **Prior Authorization for Spine and Neurostimulator Procedures.** The AANS and the CNS strongly oppose the CMS proposal to require prior authorization for cervical fusion with disc removal (CPT codes 22551 and 22552) and implanted spinal neurostimulators (CPT codes 63650, 63685 and 63688). Any increases in utilization likely result from appropriate changing practice recommendations — such as providing non-opioid pain treatment for spinal disabilities. Additionally, the CMS process for prior authorization does not appear to facilitate rapid access to necessary care, but instead will create hurdles to avoid “unnecessary utilization.” While work is underway to develop appropriate use criteria and guidelines, any prior authorization requirements

that result in delayed care could result in patients' developing worsening neurological deficits (perhaps leading to more complex surgical procedures such as cervical decompression and fusion), increased narcotic use and avoidable patient suffering.

- **New C-APC 5465 (Level 5 Neurostimulator and Related Products)**. We note that CMS has created a new comprehensive APC (C-APC) for Neurostimulator and Related Products. The AANS and the CNS urge the agency to closely monitor payments in the new C-APC to ensure the payment reflects the costs of the elements in the bundle.

- **Physician-owned Hospitals.** The AANS and the CNS support the agency's recommendation to remove certain expansion limits for physician-owned "high Medicaid facilities."

- **Hospital Outpatient Quality Reporting Program.** In its Sept. 24, 2020, letter to CMS contractors, the AANS and the CNS requested that CMS consider concerns raised during the last two reviews by the National Quality Forum (NQF) when evaluating the revised measure, OP-8, titled "Lumbar Spine Imaging for Low Back Pain."

Ambulatory Surgery Center Issues

- **Expansion of the ASC List**. The AANS and the CNS urge CMS to carefully consider stakeholder comments on proposed new assessment models for selecting procedures for the ASC list.

DETAILED COMMENTS

OPPS Issues

Eliminating the IPO List

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. However, 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. Therefore, **we have concerns about a sudden and wide-sweeping elimination of the IPO list — unless CMS makes clear that physician and patient choice are paramount and payment for inpatient care will be honored based on clinician judgment, rather than retroactive review**. At a minimum, we request that CMS delay implementing the proposal to allow more time to assess the potential consequences and concerns that we describe below.

- **Proposed Policy Needs Additional Stakeholder Review.** Under the current policy for removing individual procedures from the IPO, CMS has a clear methodology to consider whether the outpatient setting is generally safe for the Medicare-aged population. We believe that decision is best made by the operating surgeon who understands the patient's unique needs, comorbidities and general health status. At the same time, we appreciate that the agency is also charged with assuring Medicare beneficiary safety. Nevertheless, we are concerned that an abrupt total elimination of the IPO list may lead to inappropriately burdensome barriers to obtaining inpatient admissions for patients who need that setting. The AANS and the CNS pledge to work with CMS and other health care stakeholders to develop demonstrable best practices to promote safe, effective and affordable surgical care in every setting.

- **Patient Out-of-Pocket Costs May Surge.** We urge CMS to consider the impact that the sudden elimination of the IPO list will have on the accessibility and affordability of care for Medicare

beneficiaries. Under CMS rules, the copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible. However, a patient's total copayment for the cumulative cost of all outpatient services related to a single procedure may be equal to an amount greater than the inpatient hospital deductible. Therefore, patients treated in the outpatient setting may be subject to increased out-of-pocket costs that exceed the costs incurred had they been treated in the inpatient setting. **We urge the agency to review this issue and provide protections for beneficiaries to prevent an increase in out-of-pocket costs**.

- **Inpatient Admission Documentation and Audit Burdens will Increase.** The AANS and the CNS are concerned that a rush to eliminate the IPO may increase documentation and audit burden for physicians and hospitals. Therefore, we would like to see more specific program integrity and reporting guidelines to support provider education and compliance in selecting the care setting. Retrospective denials are inappropriate. We need more information about the agency's plan for utilization reviews of procedures performed in the hospital inpatient setting once there is no longer an IPO list. We are concerned that expanding such prior authorization requirements will increase, rather than decrease, burden, cost and care delays. **We also need to know the agency's plans for physician appeal rights if a payment denial is made for a procedure performed in the inpatient setting due to a perceived lack of site-of-service justification**.

- **Other Payors May Adopt an Ill-formed Policy.** It is a significant problem if other payors, including Medicare Advantage plans, use the lack of the IPO list to inappropriately force patients into the outpatient setting for cost-only reasons. In the proposed rule, CMS admits that stakeholders have informed the agency that removing a service from the IPO list creates expectations that the service must be furnished in the outpatient setting. As stated above, this is contrary to our belief that the site of service should be determined by the physician's clinical judgment and the needs of the patient. **We urge CMS to provide safeguards to ensure that payors do not use the elimination of the IPO list as an excuse for not paying for appropriate inpatient admissions.** Other payors often follow Medicare policy. Therefore, it is essential to consider all the potential consequences of removing the IPO list by providing more information about this proposed policy.

- **Best Practices should be Developed.** Given that the inpatient setting is generally the most expensive treatment environment, the AANS and the CNS agree that patients should be offered the option of receiving care in the outpatient and ambulatory surgery center settings — provided safety and effectiveness can be assured. However, 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. **We urge CMS to work closely with the physician community to help develop best practices. CMS must consider the impact on patients, physicians and hospitals before eliminating the IPO list.**

Prior Authorization for Spine and Neurostimulator Procedures

Last year, CMS established a process for requiring prior authorization for selected procedures under the OPPS system. This year, CMS proposes to expand the prior authorization process to include two new categories of services reimbursed under the OPPS — cervical fusion with disc removal (described by CPT codes 22551 and 22552) and implanted spinal neurostimulators (described by CPT codes 63650, 63685, and 63688). **The AANS and the CNS object to this expansion of prior authorization — particularly for the neurosurgical procedures selected in the proposed rule**. Firstly, last year's changes did not go into effect until July 1, 2020, so CMS has had no time to evaluate the impact of the requirements before consideration to expand the program. Furthermore, extending burdensome prior

authorization requirements will unnecessarily delay care to patients and increase administrative costs without benefitting the Medicare program. Despite the agency's "Patients Over Paperwork" initiative, CMS has done little to reduce burdensome prior authorization requirements, which have increased significantly over the last several years — delaying or preventing time-sensitive surgical care. Moreover, ongoing studies demonstrate that excessive and unnecessary prior authorization results in:

- Delays in medically necessary treatment;
- Patients abandoning treatment;
- Negative impacts on clinical outcomes; and
- Serious adverse events, such as death, disability or other life-threatening outcomes.[1]

Finally, prior authorization is particularly inappropriate during the COVID-19 crisis.

The AANS and the CNS offer the following comments on the specific technologies identified for prior authorization in the proposed rule.

- **Cervical Fusion with Disc Removal (CPT codes 22551 and 22552). We object to the agency's proposal to require prior authorization for cervical fusion with disc removal — CPT codes 22551 and 22552.** This procedure can reduce pain and restore mobility for appropriately selected patients, allowing patients a significantly better quality of life. Requiring prior authorization will add additional burdens and delays without any benefits for patients for whom timely access can often be of the utmost importance. CMS Recovery Audit Contractor (RAC) policies often push these procedures into the outpatient setting, and yet when there is a resulting volume increase, the rate of growth is deemed inappropriate. Some of these changes are driven by CMS contractors, with admissions for cervical fusion with disc removal denied *a priori* by some Medicare contractors. This approach denies surgeons the opportunity to choose the best site of service for each patient.

  Demanding prior authorization for cervical fusion with disc removal (CPT codes 22551 and 22552) in an outpatient setting, rather than allowing surgeons the option to choose the appropriate site of service for each patient, is not constructive. A better approach would be to enable each surgeon to select the site of service the s/he believes is appropriate for the patient and study the outcomes. CMS should adopt this approach and then review several years of data to analyze volume growth and quality of care before implementing prior authorization requirements for these and other Medicare services. We understand this would require a change in CMS contractor policy. However, if the agency collected several years of data, it would obtain more useful information on cost and quality.

  One mechanism to support this data collection and review is for CMS to recognize and support participation in physician-led clinical registry programs. In our comments on the OPPS quality reporting program below, we provide details about one such effort — the American Spine Registry (ASR), a joint initiative by the AANS and the American Academy of Orthopaedic Surgeons (AAOS). Consistent with the ASR's operating procedures, we would be happy to share additional data from this excellent resource with CMS.

- **Implanted Spinal Neurostimulators. (CPT codes 63650, 63685, and 63688). The AANS and the CNS object to the agency's proposal to require prior authorization for Implanted Spinal Neurostimulators.** Increased innovation and strong evidence for effectiveness have increasingly

[1] *See* for example the following: 2019 AANS/CNS Prior Authorization Survey Results at https://tinyurl.com/yxfpj2ya; 2019 Regulatory Relief Coalition Prior Authorization Survey Results at https://tinyurl.com/yxl4dmwc; and 2019 American Medical Association Prior Authorization Physician Survey at https://tinyurl.com/y6excxx8.

made these procedures excellent choices for patients in pain. They offer effective, nonpharmacologic options for appropriately selected patients to treat chronic pain and have been shown to significantly improve pain control and decrease pain-related disability and opioid use.

Furthermore, effective pain control achieved through interventional care has also substantially reduced long-term healthcare utilization. Over the last several years, many high-quality studies have been published demonstrating the effectiveness of neuromodulation in treating chronic pain.

+ The SENZA Trial, published in 2015, reports the results of a large, prospective, randomized, controlled trial of high-frequency spinal cord stimulation (SCS) for the treatment of low back and leg pain. In this study, SCS delivered at both standard (60Hz), and high frequency (10Khz) levels produced significant reductions in chronic back and leg pain, with the high-frequency stimulation outperforming lower frequency stimulation. Concomitant reductions in disability scales were also seen.

+ A follow-up study, published in 2017, shows the durability of substantial treatment effects at two years post-implant.

+ The ACCURATE study, another randomized trial published in 2017, pitted the newer technical of dorsal root ganglion (DRG) stimulation against traditional SCS for the treatment of lower limb chronic regional pain syndrome (CRPS). Once again, both therapies significantly reduced patients' chronic pain.

+ The SunBURST study detailed successful results from a large clinical trial of SCS pulses delivered in short "bursts" rather than constant stimulation.

+ A recent observational study (Sharan, et al., 2018) demonstrated that chronic pain patients who undergo spinal cord stimulation (SCS) were able to stabilize their opioid requirements despite undergoing dose escalation at the time of implantation.

+ Finally, SCS allowed chronic pain patients on high dose opioid regimens to actually reduce their opioid intake after device implantation (Pilitsis, et al., 2018).

We disagree with the agency's assertion that the increase in the volume of spinal cord stimulation trials and device implantation procedures has been unnecessary. The baseline for counting the number of spinal cord stimulation procedures begins before 2010, more than a decade ago. As evidenced by listing several peer-reviewed studies above, the last decade has seen an unprecedented level of innovation in this field. New stimulation waveforms have been developed to give patients better pain control without perceptible paresthesia. New targets — such as the dorsal root ganglion and dorsal horn of the spinal cord — have been investigated and validated. Moreover, new devices allow patients to run multiple stimulation waveforms simultaneously, thus improving their chances for significant long term pain relief. The devices implanted today and how they function are nothing like the devices implanted at the time CMS selected as its baseline implant level.

Although we note that CPT code 63650, Implant Neuroelectrodes, experienced only a 1% increase in Medicare utilization from 2018 to 2019 and 63655 saw a decrease in Medicare utilization, we know the volume of these procedures have increased dramatically. Much of this is due to innovation and patient needs. However, some volume increases may be attributable to incorrect coding. Neurosurgery offers our expertise to ensure appropriate reporting for new devices. During the rapid innovation of neuromodulation, the AANS and the CNS continue to

work closely with the AMA CPT Editorial Panel to ensure correct coding for new devices and accurate coding advice.

Importantly, neurosurgeons have been diligently working for several years in concert with the AMA, CMS, U.S. Department of Health and Human Services (HHS), National Academy of Medicine and numerous other government organizations, private payors, and health care organizations to devise solutions to the opioid crisis and the epidemic of opioid-related morbidity and mortality. As stated above, neuromodulation procedures such as spinal cord stimulation are proven to reduce pain, pain-related disability and opioid use. These are non-pharmaceutical, reversible, adjustable and minimally invasive procedures that clearly play an increasing role in managing patients who may have many chronic pain diagnoses. Imposing prior authorization requirements will only delay and deny a larger number of Medicare patients from the benefits of these procedures, leaving them to continue with ineffective opioid therapies or, worse, to leave them without any good options for managing their chronic pain disability.

Evidence shows that neurostimulation procedures are more effective if they are employed earlier in the pain syndrome. Delaying utilization of these devices through unnecessary and burdensome prior authorization processes will likely result in patients not obtaining the optimal relief from the therapy as the treatment will be delayed as the pain syndrome progresses and becomes more refractory. As a result, patients will continue to have more pain-related disability and incur higher healthcare costs over time.

The HHS "Pain Management Best Practices Inter-Agency Task Force Report" emphasizes the importance of multidisciplinary chronic pain care and highlights barriers to accessing optimal pain care. The task force recognizes both the high level of evidence for neurostimulation and barriers "requiring patients and health care professionals to navigate burdensome and variable coverage policies may contribute to slow development, adoption, and implementation of timely and effective pain treatments and may force providers to treat patients in a less-than-optimal fashion. Consistently forcing providers to try a series of non-first-line treatments prior to authorizing treatment plans can be problematic, hindering appropriate patient care, creating tremendous inefficiency, and resulting in a loss of time and resources."

The AANS and the CNS urge CMS to adhere to the task force's recommendations and not require prior authorization for implanted spinal neurostimulators.

New C-APC 5461 (Level 1 Neurostimulator and Related Products)

The AANS and the CNS note that CMS proposes to continue the Comprehensive APC (C-APC) payment methodology implemented in CY 2015 and has created a level 5 C-APC for *Neurostimulator and Related Products* as part of that program. We urge the agency to closely monitor payments in the new C-APC relative to the actual costs of the procedures bundled together to ensure they are fairly compensated and available to appropriate patients in the ASC setting.

Physician-Owned Hospitals

The Affordable Care Act (ACA) severely restricts new physician-owned hospitals and limits the growth of existing facilities. As part of its Patients over Paperwork Initiative, CMS proposes removing certain expansion limits for "high Medicaid facilities." The AANS and the CNS have long supported physician-owned hospitals, which foster innovation and improved mechanisms to allow physicians to efficiently and effectively deliver care to their patients. We believe that the current statutory restrictions on physician-owned facilities prevent Medicare beneficiaries from having the full range of options to seek the care they need from the physician and provider of their choice. The AANS and the CNS opposed the provision of

the ACA that banned the construction of new facilities and placed significant restrictions on the ability of existing physician-owned hospitals to grow. In effect, this provision in the ACA removed an excellent model for expanding physician-led patient care. Since the passage of the ACA, organized neurosurgery has advocated for the repeal of these restrictions. To that end, the **AANS and the CNS support the provision to remove expansion limits for "high Medicaid facilities."**

Hospital Outpatient Quality Reporting Program

Although CMS is not proposing to make any changes to the Hospital Outpatient Quality Reporting Program (HOQRP) measures in this proposed rule, the AANS and CNS recently submitted comments to CMS contractors regarding the re-specified version of measure OP-8, titled "Lumbar Spine Imaging for Low Back Pain." CMS adopted OP-8, a facility-level measure, for use under the Hospital OQR in the CY 2010 OPPS Final Rule. The measure was previously endorsed by the National Quality Forum (NQF), but lost its endorsement in 2017 based on its failure to meet the Scientific Acceptability criterion. In fall 2018, CMS approved the re-specification of OP-8 for several reasons:

- Documentation of imaging overuse persists;
- The clinical concept is a primary target of several Choosing Wisely® recommendations; and
- The existing measure demonstrates substantial performance variation across participating facilities.

In its Sept. 24, 2020 letter to CMS contractors, the AANS and the CNS requested that CMS consider the concerns raised during the last two reviews by the NQF when evaluating this revised measure. Specifically, the NQF committee questioned whether the list of exclusions was sufficient and expressed concerns that administrative claims data would not capture all of the antecedent conservative therapies received by a patient. These issues must be adequately addressed before CMS implements this revised measure. **If claims data do not provide valid information on a facility's performance, then the measure should not be finalized, and CMS should work with stakeholders to evaluate alternative data sources.**

The AANS and the CNS also provided the following more specific input:

- **We agree with the measure developer that advanced age is a red flag for potentially treatable pathology and that elderly patients (greater than 64 years[2]) with no previously diagnosed underlying etiology should be excluded from the measure based on their age alone.**
- **We urge CMS to add CT myelography, in addition to CT, to the measure specifications.**
- **We recommend that the measure exclude individuals with chronic steroid use and osteoporosis. The measure exclusions also should account for the fact that there are circumstances where advanced imaging — particularly dynamic films, CT and CT myelography — is extremely valuable and should not be excluded from the surgical workup. For example, these modalities may be useful for problem-solving when MRI is either non-diagnostic or contraindicated.**

Our organizations also remind CMS that the AANS is collaborating with the AAOS in sponsoring the ASR,[3] a national quality improvement registry for spine care that collects procedural data, postoperative data, and patient-reported outcome measurement (PROM) data. The ASR expands on the formative AANS Quality Outcomes Database (QOD) Spine Registry — previously the nation's largest spine registry — to

[2] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898572/.
[3] For more information about the ASR, visit https://www.americanspineregistry.org/.

offer a more far-reaching data collection platform that facilitates the participation of all North American spine surgeons. 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. **We encourage CMS to consider the ASR as a resource for best practices and feasible metrics that can be implemented across federal programs nationwide.**

ASC Issues

Although CMS has not proposed procedures typically performed by neurosurgeons for CY 2021 under its current system of determining the ACS list codes, we note that the agency has asked for feedback on two possible new methodologies for selecting ASC procedures. As stated above, we emphasize the importance of patient selection in determining the site of service for any individual Medicare beneficiary. Just as inpatient admission should always remain an option for patients who require that level of care, the ASC should be permitted for patients for whom that setting is optimal. CMS should allow high-quality surgical care in all appropriate settings. **Therefore, we urge the agency to delay changes in the ACS list methodology for CY 2021 as it carefully considers objective data related to site of service**.

CONCLUSION

The AANS and the CNS appreciate the opportunity to provide feedback on these specific provisions on the 2021 Medicare Hospital OPPS ASC proposed rule. In the meantime, if you have any questions or need additional information, please contact us.

Sincerely,

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