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VIA ELECTRONIC TRANSMISSION

September 15, 2025

The Honorable Mehmet C. Oz, MD. MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1834-P
P.O. Box 8013
Baltimore, MD 21244-1850

Subject: CMS-1834-P, CY 2026 Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency.

Dear Administrator Oz:

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

EXECUTIVE SUMMARY

Outpatient Prospective Payment System Issues

- **Inpatient Only List**. We 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 2026. 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. We would support a more measured approach and note that even when a procedure comes off the IPO, inpatient admission should remain an option for patients who require that level of care.

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- **Facility Payment Reporting for Annular Closure Devices.** We support the CMS proposal to maintain HCPCS code C9757 with its current Ambulatory Payment Classification (APC) and status indicator for outpatient facility reporting in 2026 for annular closure devices. A new CPT add-on code will be used for physician payment. Still, given concerns about the CMS recognition of the additional resources in an add-on code, use of the C code for facility payment is reasonable.
- **APC Re-assignment for Neurostimulators.** We urge CMS to re-assign CPT code 61891 (Revision or Replacement of a Skull-Mounted Cranial Neurostimulator) from APC 5464 Level 4 to APC 5465 Level 5.

Ambulatory Surgery Center Issues

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

Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

- We support unbundling payment for non-opioid pain management under the OPPS and ASC payment systems. However, we remain concerned that CMS's interpretation of the NOPAIN Act is too narrow. We urge CMS to include all FDA-approved non-opioid therapies commonly used to treat pain. In addition, we encourage the agency to expand reimbursement for neurological devices such as pain pumps and spinal cord stimulators to treat pain. These innovative alternatives to opioids are a positive development in the response to the opioid epidemic.

DETAILED COMMENTS

OPPS Issues

Eliminating the IPO List

We believe the site of service should be determined by the operating surgeon in consultation with the patient, carefully considering the individual's clinical status. The unintended consequence of a rigid site of service policy is that the procedure is entirely agnostic to the patient's health status. A 66-year-old healthy tennis playing woman with a doting husband, adult children in the area on no medications with a BMI of 25 who has mild spondylosis at C5-6 with a radiculopathy looks no different to the IPO list than a 66-year old morbidly obese widow (BMI 35) with no social support who has profound myelopathy from severe stenosis at C5-6 with signal change abnormality and on Eliquis for atrial fibrillation. These two very different patients may require different settings for their care, and the surgeon's judgement and the patient's needs should be the determining factor. We are eager to work with the agency to determine what patient-specific considerations should be used to determine inpatient setting. The current process is too dismissive of unique patient needs.

However, we have heard from some of our members about retrospective denials of payment for inpatient admissions for elderly patients for whom that setting was medically necessary. Therefore, we oppose the wholesale elimination of the IPO list at this time. Without a clear CMS policy to

ensure that physician and patient choice are paramount and payment for inpatient care will be honored based on clinician judgment, rather than retroactive review, we support a more measured process for taking procedures off the IPO list. At a minimum, we request that CMS delay implementing the proposal to allow more time to assess the potential consequences and concerns. We support the CMS policy that any procedure that was previously on the IPO list and then removed is permanently exempted from review under the 2-midnight rule.

We urge you to review comments submitted by the American College of Surgeons, and we reiterate the remarks of our CY 2021 OPPS/ASC proposed rule letter submitted on October 5, 2020, below, as these issues continue to be of concern.

- **Proposed Policy Needs Additional Stakeholder Review.** Under the current policy for removing individual procedures from the IPO, CMS has a straightforward methodology for considering whether the outpatient setting is generally safe for the Medicare-eligible population. We believe that the 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. We 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.** We are concerned that a rush to eliminate the IPO list 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, the burden, cost, and delays in care. **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. 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 and involving appropriate stakeholders in developing site of service policy.

- **Best Practices Should be Developed.** Given that the inpatient setting is generally the most expensive treatment environment, we 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. As noted above, **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.**

Facility Payment Reporting for Annular Closure Device

We support the CMS proposal to maintain HCPCS code C9757 with its current Ambulatory Payment Classification (APC) and status indictor for outpatient facility reporting in 2026 for annular closure devices. Although the new CPT add-on code, effective January 2026, for the use of the annular closure device will be reported for physician work, we believe continued use of the C9757 code for facility payment is appropriate, given concerns about the lack of CMS recognition of the additional resources in an add-on service. Therefore, continued use of the C code for facility payment will allow CMS to gather more data on the costs involved with using the annular closure device in the hospital outpatient setting.

APC Reassignment for Neurostimulator Procedures

CMS proposes to elevate CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) to APC 5465 (Level 5 Neurostimulator and Related Procedures) from Level 4. We support this proposal. However, we urge CMS to also re-assign CPT code 61891 (Revision or Replacement of a Skull-Mounted Cranial Neurostimulator) from APC 5464 Level 4 (Neurostimulator and Related Procedures) to the higher APC 5465 Level 5. As is stated by the code descriptor, the 61891 procedure encompasses both revisions that would not include a new implantable pulse generator (IPG) device and replacements that would include the IPG device, resulting in some diversity of resources for this code. We urge CMS to carefully review submitted cost data from facilities for this procedure, as we believe that replacement of the IPG is more frequent that revision and the level assignment should accurately reflect that fact.

<u>Ambulatory Surgical Center Issues</u>

CMS is proposing significant changes to the ASC Covered Procedures List (CPL), including expanding the CPL by adding 547 procedures to it, with 276 being new additions that meet revised criteria and 271 being codes previously on the Inpatient-Only (IPO) list. While there are some neurosurgical procedures on the list that may be safely performed in the ASC setting for the appropriately selected patients, we believe the revised criteria require additional review and consideration. As with the elimination of the IPO list, we urge CMS to delay the expansion of the CPL list and seek additional input from stakeholders.

Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment

CMS is proposing to provide temporary additional payment for specific non-opioid pain control devices and drugs in the hospital outpatient department (HOPD) and ASC settings. We support CMS's proposal to continue to pay separately for these products. We remain concerned that CMS is taking an inappropriately narrow approach to implement the NOPAIN Act, which risks limiting access to many safe and effective non-opioid therapies. We are concerned with CMS's assertion that in order to qualify for separate payment under the NOPAIN Act, products must have an explicit indication for use in the postsurgical setting. As an example, CMS allows separate payment for the use of an injectable version of a non-steroidal anti-inflammatory drug (NSAID) that has the postsurgical indication on its label, but not the tablet form of the same medication, which does not. CMS contends that these products do not qualify for separate payment because their label does not explicitly reference a postsurgical application. This approach violates the spirit and intent of the NOPAIN Act, which was to ensure patients could reasonably and easily access all FDA-approved, safe, and effective non-opioid treatment options that are indicated for moderate to severe pain and used in the post-surgical setting. We urge CMS to broaden its interpretation of the statute and to establish a transparent process for adding new qualifying products.

We have long supported adequate coverage and funding for neurological devices such as pain pumps and spinal cord stimulators that offer short and long-term non-opioid pain relief. Neurosurgeons evaluate and manage patients with various chronic pain conditions, such as postsurgical spinal pain syndrome, chronic regional pain syndrome, and others. Neurostimulation procedures, such as spinal cord stimulation (SCS), peripheral nerve stimulation, and deep brain stimulation, provide significant pain relief while allowing patients to reduce the use of opioid medications. These procedures often involve a trial period, allowing the physician and patient to evaluate the level of effectiveness before deciding on a permanent implant. Neurostimulation therapies are adjustable by the patient and physician to adapt the therapy as the patient's condition changes over time. We provide some additional specific comments on neurostimulation below. We are eager to continue to work with CMS to help promote innovative and safe non-opioid treatment.

With respect to potential future qualifying devices, we have often stated in our numerous comments regarding spinal cord stimulators that innovation and strong evidence for effectiveness have increasingly 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 health care utilization. We believe spinal cord stimulators should be considered qualifying devices for non-opioid pain treatment as the agency moves forward with innovation in the development of alternatives to opioids for pain. Again, as the agency continues to consider

appropriate reimbursement and increased availability of nonopioid pain treatment going forward, we are uniquely positioned to help, as we have a long history of innovation in chronic and acute pain care. 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.[1] 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. Expansion of the number and types of non-opioid products with separate payment under the OPPS and ASC systems will help bring these critical treatments to patients.

CONCLUSION

We appreciate the opportunity to provide feedback on the provisions of the FY 2026 OPPS/ASC proposed rule and look forward to working with CMS to find reasonable solutions to our policy concerns. If you have any questions regarding payment-related issues, please contact Catherine Jeakle Hill, Director of Regulatory Affairs at the AANS/CNS Washington Office, at chill@neurosurgery.org. Thank you.

Sincerely,

E. Sander Connolly, MD
President
American Association of Neurological Surgeons

Daniel J. Hoh, MD, MBA
President
Congress of Neurological Surgeons

[1] US Department of Health and Human Services, Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations (Final Report), May 9, 2019, https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf?language=es.