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June 10, 2024

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1833-P
P.O. Box 8013 Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

Subject: CMS-1833-P Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals Policy Changes and Fiscal Year (FY) 2026 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Dr. Oz:

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 provisions of the above-referenced notice of proposed rulemaking.

MS-DRG CHANGES

Neurostimulator Implants

We appreciate CMS moving all intracranial neurostimulator implants (DBS and epilepsy) to a new MS-DRG group that better reflects the associated costs for these patients. As the agency's data show, the care of these patients often exceeds the average costs for cases in their existing MS-DRG assignments. CMS states that some of these cases will still incur costs that exceed the average costs of the MS-DRGs 021 and 022, which do not have a Major Complication and Comorbidity (MCC) designation. We request that CMS continue its effort to better align MS-DRG reimbursement and costs of care by ensuring that the reimbursement levels of these newly revised MS-DRGs adequately cover the costs of care for these complex patients who receive intracranial implants. The appropriateness of the FY 2026 reimbursement levels for these revised DRGs will need to be closely scrutinized. It should be strongly considered for analysis to determine possible further upward revisions in FY 2027, if the values set for FY 2026 are inadequate.

TRANSFORMING EPISODE ACCOUNTABILITY MODEL (TEAM)

The AANS and the CNS recognize that Medicare beneficiaries undergoing a surgical procedure either in the hospital or as an outpatient may experience fragmented care that can lead to

complications in recovery, avoidable hospitalizations, and other high costs. As such, we support efforts to improve care transitions and to incentivize care coordination and higher-value care across the inpatient and post-acute care settings. **However, the AANS and CNS continue to believe that TEAM is fundamentally flawed, as it is primarily focused on cost containment, despite being framed as a quality improvement initiative.**

Mandatory Participation

The AANS and the CNS strongly oppose compulsory participation in alternative payment and delivery models. CMS must maintain voluntary participation models that allow hospitals and surgeons to tailor bundled and other payment reforms to their specific patient populations, practice settings, administrative capabilities, and resources. While mandatory models can address participation challenges inherent to voluntary models, they also ignore real barriers that some providers face in terms of building the resources and infrastructure needed to succeed in these models. These include staff shortages, insufficient or otherwise non-representative patient volumes, and a lack of negotiating power within their community, all of which make it more difficult to provide higher-value, coordinated care. Despite years of attempts, a major lack of access to interoperable health information technology systems and robust data analytics remains. In this environment, what providers need most is more flexibility, better support and guidance, and stronger incentives — not a restrictive mandate that could drive participant hospitals to skimp on clinically necessary care and avoid higher-risk patients in order to meet price and quality targets. Mandatory models should not force hospitals and health systems that have already adopted their own innovative ways to provide high-value care to alter their care processes in ways that might reverse progress made in terms of patient outcomes and efficiencies.

Ultimately, if an alternative payment or delivery model is appropriately contemplated — with the active involvement of physicians in its design, implementation, and evaluation — then physicians will willingly participate, negating the need for mandatory participation.

Limited Role of the Physician

The AANS and the CNS are disappointed that CMS has not directly consulted physicians who are directly impacted by this model, including our spine surgeon members. **It is critical that CMS directly engage relevant practicing physicians in model development and implementation, including defining appropriate participation parameters, episode triggers, quality measures, and risk adjustments, as well as methods for assessing model success over time.** When CMS fails to engage front-line physicians, it raises questions about whether the agency is genuinely interested in higher-quality care or whether its sole goal is cost reduction. We ask CMS to maintain, as a guiding principle, that hospitals do not perform surgical procedures or determine if such procedures are clinically indicated; surgeons do.

We are equally concerned that CMS fails to provide physicians with any autonomy under TEAM and fails to recognize the leading role that physicians play in an episode. Surgical patients look to their surgeon, not the hospital, as the ultimate authority on their perioperative care. Yet under TEAM, only hospitals may be considered "participants," while it is at the hospital's discretion to engage with or form a financial arrangement with "TEAM collaborators," such as physicians. This differs from the BPCI-A, which allows physician group practices, as well as

hospitals, to take on leading roles through clearly defined partnership policies. We are concerned that the TEAM approach could result in perverse incentives that encourage hospitals to make care decisions that are not in the best interest of the patient — especially since this model includes elective and non-elective cases.

Further, hospital administrators with no clinical experience could be empowered by this model to alter hospital operations to optimize their facility's short-term performance metrics at the expense of quality and cost after the measurement period. This increases the risk of cherry-picking, lemon-dropping, and other forms of favorable selection that risk-adjustment methodologies may not capture. In other situations, hospitals might cut necessary post-acute spending, which can impact patient outcomes and longer-term costs. Involving relevant clinicians who are directly accountable for the patient's care would minimize these risks.

We also believe that the current TEAM framework runs the risk of sidelining independent specialists— who ultimately are the main factor in the decision-making process for the patient to undergo the procedures being measured—and accelerating healthcare consolidation, which could drive up costs further, stifle innovation and local experimentation, and erode patient access to specialty care.

A 2024 analysis by the Congressional Budget Office found that ACOs led by independent physicians generated substantially larger Medicare savings than those led by hospitals.[1] The report noted that independent physician-led ACOs have clear financial incentives to reduce hospital care to lower spending, unlike hospital-led ACOs, which earn more revenue when patients are admitted. Hospitals also have less direct control over what services patients receive.

In light of these concerns and findings, we reiterate our request that CMS must adopt policies under TEAM that:

- **Require hospitals to integrate clinically relevant specialties into team leadership and governance roles to ensure the provision of appropriate care, and to ensure that savings result from improved efficiencies, rather than simply favorable selection or gaming at the expense of the patient.**

- **Require hospitals to pass on a proportional portion of the shared savings generated under this model to the surgeons responsible for treating patients that trigger the episodes. The distribution of such savings should not be left to the hospital's discretion. This better aligns with financial incentives.**

- **Ensure that physicians have adequate resources and flexibility under the model to deliver services that result in good outcomes for all types of patients and to ensure that physicians are not directly or indirectly at risk for outcomes or costs they cannot control.** Unfortunately, under some of the most widely implemented models to date, such as Shared Savings Program ACOs, physicians—particularly specialists—do not have a leading role. As a result, they have little control over decisions related to clinical appropriateness, patient selection, referrals, and performance measurement.

[1] https://www.cbo.gov/publication/60213

We also remind CMS that it is essential to provide physicians with autonomy and authority under TEAM to ensure that when BPCI-A ends this year, physician groups who have served as episode initiators will continue to have an opportunity to play a leading role in CMMI's next iteration of bundled payments.

Remapping Strategy for Spinal Fusion MS-DRGs

Last year, CMS finalized changes to MS-DRGs related to spinal fusion procedures, which aim better to reflect the resource intensity of different spinal fusion procedures, particularly distinguishing between single-level and multi-level fusions. CMS subsequently updated its definition of the Spinal Fusion episode category under TEAM to reflect these changes. The Spinal Fusion episode category is currently defined as any cervical, thoracic, or lumbar spinal fusion procedure paid through the IPPS under the following MS-DRGs or through the OPPS under the following HCPCS codes:

- 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical)
- 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device)
- 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC)
- 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC)
- 429 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC)
- 430 (Combined Anterior and Posterior Cervical Spinal Fusion without MCC)
- 447 (Multiple Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device)
- 448 (Multiple Level Spinal Fusion Except Cervical without MCC)
- 450 (Single Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device)
- 451 (Single Level Spinal Fusion Except Cervical without MCC)
- 471 (Cervical Spinal Fusion with MCC)
- 472 (Cervical Spinal Fusion with CC)
- 473 (Cervical Spinal Fusion without CC/MCC)
- 22551 (Anterior Cervical Spinal Fusion with Decompression Below C2)
- 22554 (Anterior Cervical Spinal Fusion without Decompression)
- 22612 (Posterior or Posterolateral Lumbar Spinal Fusion)
- 22630 (Posterior Lumbar Interbody Lumbar Spinal Fusion)
- 22633 (Combined Posterior or Posterolateral Lumbar and Posterior Lumbar Interbody Spinal Fusion

While these updates are a step in the right direction to help reduce the variance of procedures within each MS-DRG and will enable CMS to analyze the appropriateness of including both single and multi-level fusions in TEAM more effectively, we still believe there is room for improvement. Each of these MS-DRGs continues to represent a wide range of spinal fusion procedures, from simple to complex. **For example, multi-level fusions are heterogeneous in nature. TEAM target pricing, risk adjustments, and other analyses should not occur across blended categories of 2-7 level fusions, as the complexity of these procedures can vary substantially. Otherwise, high-complexity care will be undervalued, and hospitals will be incentivized to avoid complex patients with high acuity needs.**

We reiterate our request from last year for additional information regarding the potential impact of the newly adopted spinal fusion MS-DRG designations and an opportunity to study the changes further. Ideally, this would occur before the model begins.

Last year, the AANS and CNS also expressed concerns about the timing of these MS-DRG updates. We noted that this change could lead to inaccurate performance calculations, as well as confusion during the first three performance years of TEAM, when hospitals would be billing the new spinal fusion MS-DRGs but would be assessed against baseline data built on certain MS-DRGs that are no longer billable. To address these immediate concerns and account for any future MS-DRG or HCPCS/APC changes, CMS proposes in this rule to apply a standard, three-step approach to account for MS-DRG and HCPCS/APC changes by remapping and adjusting relevant MS-DRG/HCPCS episode types during the baseline period to estimate performance year costs. In Table XI.A.06, CMS provides a limited example of how its proposed mapping logic would work for one of the deleted spinal fusion MS-DRGs (MS-DRG 453). **While we appreciate CMS's attempt to address this issue and provide an example of how its proposed logic would work, we are concerned that this remapping strategy lacks transparency and invites mispricing. As far as we can tell, CMS has not provided any details on how it would apply this logic to the four other deleted spinal fusion MS-DRGs (454, 455, 459, and 460), which will also show up in the baseline data and would need to be remapped. It is imperative that CMS provide the public with an opportunity to review and provide feedback on the proposed mapping logic as it would be applied to all impacted spinal fusion MS-DRGs before implementing this model. It is also imperative that CMS perform modeling to evaluate the impact of this proposed mapping strategy and share formal dry-run data results with the public prior to the start of the initial performance year.**

Inadequate Risk Adjustments

Last year, CMS finalized a risk adjustment methodology that relies on hospital-specific and beneficiary-specific risk adjustment factors, including the use of the "TEAM Hierarchical Condition Category (HCC) Count" variable. **While we appreciate CMS finalizing a more robust risk adjustment methodology than originally proposed, we do not believe that this methodology will sufficiently adjust target prices to reflect the complexity of patients**. For example, CMS's methodology continues to fail to account for a patient's functional and disability status, which is one of the strongest predictors of the need for and length of post-acute care. We encourage CMS to adopt a methodology that accounts for as many patient- and provider-level factors as possible that could impact surgical outcomes and post-acute care usage. Risk adjustment methodologies should be specific to each procedure category and episode, relying on standardized patient assessment data or other functional status data.

The AANS and CNS also have serious concerns about CMS's ongoing reliance on HCC coding for beneficiary-specific risk adjustments. As discussed in the study, *Is the Centers for Medicare and Medicaid Services Hierarchical Condition Category Risk Adjustment Model Satisfactory for Quantifying Risk After Spine Surgery?*,[2] HCC coding correlates more with billing behavior than true clinical risk. It rewards documentation and not acuity, which is extremely dangerous when payment is tied to expected spending and runs the risk of penalizing surgeons who take on the most complex cases. We remind CMS of the problems it encountered when applying HCC risk adjustments in Medicare Advantage—patients appeared to be sicker at hospitals that better captured a high count of HCCs, but caring for these patients was not necessarily more resource-intensive.

[2] Chan AK, Shahrestani S, Ballatori AM, et al. Is the centers for medicare and medicaid services hierarchical condition category risk adjustment model satisfactory for quantifying risk after spine surgery? Neurosurgery. 2022;91(1):123-131.

The AANS and CNS urge CMS to work with stakeholders to develop more accurate risk adjustment methodologies that are not influenced by billing codes and better reflect clinical risk. Until CMS can incorporate a superior methodology, it should incorporate the following elements, at a minimum:

- **Transparent calibration at the DRG or procedure level;**
- **Adjustments for socioeconomic status (SES) and dual eligibility to prevent penalizing hospitals caring for under-resourced populations;**
- **Explicit testing for surgical complexity in spine (number of levels, deformity, revision status) that is not captured in HCCs**

The AANS and the CNS also continue to have concerns that the current model does not adequately account for the distinction between elective and emergent surgeries. Patients who come to the emergency department for a workup of neurological symptoms may be found to have a spinal condition requiring a fusion or have known spine pathology with new, rapidly progressive, or concerning symptoms that require surgery on that same admission. Non-scheduled/non-elective surgeries might be earlier than initially planned on a scheduled basis, and the hospital and surgeon have little ability to control costs and outcomes ahead of time. **The AANS and the CNS strongly believe that CMS should exclude from TEAM spinal fusion MS-DRGs that are used for admissions with non-scheduled/non-elective surgeries, since the hospital has little ability to control costs and outcomes ahead of time. If CMS declines to exclude these cases, they should be sub-grouped or risk-adjusted at a minimum.**

Discount Factor

In response to concerns that episodes with higher procedure costs may reduce the magnitude of savings that can be achieved, CMS finalized a reduced discount factor to the benchmark price of 2 percent (versus 3 percent) for the Spinal Fusion episode category. The discount factor is intended to serve as Medicare's portion of reduced expenditures from the episode. While we appreciate CMS's attempt to address this issue, we remain concerned about the use of the discount factor, which arbitrarily assumes that all spending across all surgical procedure episodes included in this model should be the same percentage lower than it is today. Discount factors also fail to account for inflation and for the fact that successful value-based care delivery requires heavy investments in infrastructure and process re-design. It is inappropriate for CMS to take the first dollar of savings from the very entities that will require additional resources to invest in delivery reform and succeed under this model.

If CMS is genuinely concerned about overall value and not simply cost savings, it should reconsider the use of a discount factor — especially in the context of a mandatory model. If CMS insists on applying a discount factor, it should at least delay adoption so that it does not apply in the initial years of the program when participants need those resources the most. It is also critical that CMS make distinct determinations based on specific MS-DRGs to minimize risk selection and patient access issues. Additionally, we encourage CMS to explore linking the discount factor to variability in episode spending during the baseline. For example, an episode with minimal variability in baseline spending may have a lower discount percentage due to fewer opportunities for savings, compared to episodes with greater spending variability.

Quality Measures

While we appreciate that CMS is trying to minimize burden by focusing on quality measures that hospitals already report under other CMS quality programs, we continue to firmly believe that episode-based payment models must rely on episode-specific quality measures **to ensure accurate assessments of value and to guard against under- and inappropriate treatment.**

The current set of finalized and newly proposed measures are problematic for numerous reasons. **Most importantly, they provide little meaningful insight into the quality of care provided to spinal fusion patients since they are not procedure-specific**. CMS had the opportunity to propose more procedure-specific, patient-reported outcome-focused quality measures in this year's rule. Instead, it chose to propose the more generic Information Transfer Patient Reported Outcome-based Performance Measure (Information Transfer PRO-PM) to fill measure gaps related to outpatient procedures under TEAM, including outpatient fusions. Unfortunately, this measure does not provide meaningful accountability or relevance specific to spinal fusions procedures.

We are equally concerned about the lack of alignment between what CMS is measuring on the quality side versus what it is measuring on the cost side, which we believe will result in a flawed assessment of overall value. For example, the quality measures capture <u>all</u> hospital patients and not just those specific to the episode being analyzed under TEAM, which could dilute quality concerns related to specific episodes. This means that a TEAM participant could still receive a relatively high-quality performance score on the Hospital-Wide All-Cause Readmission measure, for example, despite having high readmission rates among its spinal fusion patients. In another example, the Hospital Harm – Postoperative Respiratory Failure measure excludes non-elective patients, while TEAM episodes include such cases. Other TEAM methodologies also suffer from misalignment. For example, when calculating Composite Quality Scores (CQS), CMS finalized last year to compare a participant's raw quality measure scores to the distribution of raw score percentiles among the national cohort of hospitals, which will consist of both TEAM participants and non-participants. It is inappropriate and inequitable to compare the performance of hospitals that have no choice but to participate in this model to hospitals that are free to function as they choose. Additionally, the CQS baseline period would be the calendar year 2025 (or 2026, depending on the measure) for the duration of TEAM, as opposed to a contemporaneous CQS baseline period or a rolling baseline period, which CMS contemplated but deemed too complex and challenging for participants to implement quality improvement efforts. At the same time, CMS has chosen to use three years of baseline episode spending, rebased and shifted up annually, to calculate benchmark prices so the quality and cost assessments are on different schedules. These misaligned policies will result in inaccurate assessments of value and lead to mistrust among TEAM participants.

The AANS and CNS are also concerned that the current measures finalized or proposed for TEAM are subject to gaming and unintended consequences. Rather than moving the needle on quality, measures such as 30-day readmissions often result in patients not getting the care they need as hospitals try to avoid a penalty. **We continue to believe that it is inappropriate to use measures and scoring methodologies that do not focus exclusively on the population of patients targeted by this model. Without more granular analyses and more episode-specific quality measures, CMS continues to give the impression that quality is simply not a priority under this model.**

Suppose CMS hopes to raise the bar on quality through this model. In that case, the agency must work with the specialties directly impacted by TEAM episodes to identify more focused quality measures, including patient-reported and other outcome measures collected by specialty society clinical data registries, that are relevant to each specific episode included under the model. These measures would be more relevant to each episode, rely on more accurate and informative clinical data versus claims data, provide participants with greater choice and flexibility, and result in much more actionable and meaningful feedback. These measures could also meet CMS' goal of reducing administrative burden since many providers already use these registries for quality reporting.

We believe it is possible for CMS to keep quality reporting simple but meaningful, while also resistant to gaming. Organized neurosurgery has developed registry-based measures that focus on important indicators of high-quality care, including functional improvement, pain reduction, and other patient-

reported outcomes that CMS could make use of rather than inventing new instruments with unclear links to surgical performance, such as the Information Transfer PRO-PM. We would argue that simple attestation of participation in a registry should be sufficient to meet quality metrics under TEAM, so long as the registry meets minimum standards and tracks outcomes. Such an approach would minimize gaming in value-based care models, like TEAM, by reducing incentives to manipulate data or care decisions, including cherry-picking, for financial gain. It would also help to **build reliable datasets** over time, which can later support fair and accurate performance comparisons across providers.

Finally, we continue to have issues with the way CMS factors quality into reconciliation payments under TEAM. Of concern is the fact that the quality component would result in little or no penalty if a hospital reduces costs by not providing appropriate services or even by providing inappropriate services. Under the current framework, there would be no penalty for a hospital that delivers low-quality care unless the hospital also reduces spending sufficiently to qualify for a reconciliation payment. Furthermore, if a hospital reduces spending enough to be eligible for a reconciliation payment, it could still receive at least 90% of that amount regardless of how poorly it scores on quality. **We strongly urge CMS to work with stakeholders to develop methodologies that place a greater emphasis on quality in relation to spending as it pertains to specific episodes.**

Episode Length

CMS maintains its policy that all episodes under this model would end 30 days after discharge from the anchor hospitalization or procedure. CMS believes that 30 days would cover time periods marked by significant post-acute care needs, potential complications of surgery, and short-term, intense management of chronic conditions that may be destabilized by the surgery. Although CJR and BPCI-A both utilize a 90-day post-discharge episode duration, CMS believes that an episode duration longer than 30 days poses a greater risk to the hospital due to variability caused by medical events outside the intended scope of the model.

The AANS and the CNS continue to strongly oppose the use of a universal 30-day episode length across TEAM episodes since each episode has unique patient populations and distinct patterns of post-operative care. For the spinal fusion episodes specifically, it is impossible to meaningfully analyze the quality of a spine fusion operation so soon after surgery, particularly if the aim of measuring quality is to determine if the operation achieved the surgeon's or patient's stated goals for undergoing the operation. As we stated last year, neurosurgeons often see their spine fusion patients at 30 days, three months, and six months (and often nine months) if all is going well. It is also quite common for surgeons to do a one-year follow-up. In fact, quality measures already used in CMS programs demonstrate, with clinical evidence, that a longer window is necessary. For example, measure #471: Functional Status After Lumbar Surgery, which is part of the Merit-Based Incentive Payment System (MIPS), evaluates functional status at one year (9 to 15 months) following surgery for fusion patients. When considered in the context of a 30-day episode window, the safety measures approved for TEAM represent more of a perioperative safety assessment rather than an accurate outcome measure, which is ultimately what the patient is most interested in. There is no doubt regarding the importance of safety metrics; however, given the wide variance in different spinal fusion procedures included in the bundle, the true efficacy of the procedures would not be realized until much later time frames. **The AANS and CNS urge CMS to consider a longer episode window for spinal fusions — ideally, 90 days**.

CONCLUSION

The AANS and the CNS appreciate the opportunity to provide feedback on provisions in the FY 2025 Medicare IPPS 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. For questions related to quality improvement and clinical affairs, please get in touch with Rachel Groman, Vice President of Clinical Affairs and Quality Improvement at Hart Health Strategies, at rgroman@hhs.com. Thank you.

Sincerely,

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American Association of Neurological Surgeons

Daniel J. Hoh, MD, MBA
President
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