AAHKS
AMERICAN ASSOCIATION OF
HIP AND KNEE SURGEONS

OFFICE: 847.698.1200 • FAX: 847.698.0704 • WEB: aahks.org
9400 W Higgins Road, Suite 230 • Rosemont, IL 60018-4976

January 1, 2024

<u>**VIA REGULATIONS.GOV FILING**</u>

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1786-FC
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Remedy CMS Violations of the Administrative Procedures Act Arising from Cuts in the 2024 OPPS and ASC Rates for Lower Extremity Joint Replacement that Were Not Included in the Proposed Rule

The American Association of Hip and Knee Surgeons (AAHKS) and American Association of Orthopaedic Surgeons (AAOS) appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule for calendar year 2024 (hereinafter referred to as "2024 OPPS Final Rule" or "Final Rule").

Our comments focus on CMS' decision to finalize changes to 2024 OPPS and ASC rates for musculoskeletal procedures that were not included in the Proposed Rule. In fact, CMS proposed an increase in rates for select procedures and then finalized a cut in rates without notice to stakeholders or the opportunity to comment on the cut.

I. Executive Summary of AAHKS' Comments to the OPPS Final Rule

CMS made material changes to payment policy for musculoskeletal services within the Final Rule that were (1) not included in the Proposed Rule and (2) were completely divergent from policies that were included in the Proposed Rule. Specifically, CMS transferred CPT 23472 from Ambulatory Payment Classification (APC) 5115 to APC 5116 without notice or comment. This has resulted in significant changes to Medicare payment rates for lower joint extremity replacement services that significantly impacts projected 2024 operating costs and budgets for ASCs and hospital outpatient departments.

This unilateral shift, made at the request of just one comment, violates the Administrative Procedures Act (APA), as interpreted by the D.C. Circuit Court and the Supreme Court, because it was not the logical outgrowth a Proposed Rule or a Final Rule. Not only did this APA violation deprive the public of their right provide their input on this material change, broadening CMS' understanding of impacts and trade-offs, it also harms the orthopaedic surgeons and providers who incorporated the APC 5115 payment rates from the Proposed Rule into their business operations and financial projections for 2024.

The APA requires CMS to remedy this situation by delaying the transition of CPT 23472 from APC 5115 to 5116 until public stakeholders like AAHKS have been given fair notice and an opportunity to comment. Alternatively, CMS could hold the providers who depend on APC 5115 harmless by finalizing the proposed APC 5115 payment rate for 2024, while still transitioning CPT 23472 from APC 5115 to 5116 in 2024. Finally, CMS should include in the 2025 Proposed Rule the addition of one or two new musculoskeletal APC levels to minimize the future impact of transfers of codes among APCs. The financial pressure on providers from ongoing swings in OPPS and ASC payment rates, particularly one-year cuts to OPPS and ASC rates of 3-4% without notice, undermine CMS' stated goal to move more procedures to lower cost sites of care.

II. CMS Failed to Provide Notice and Comment Before Transferring CPT 23472 from APC 5115 to APC 5116

In the 2024 OPPS & ASC Proposed Rule, CMS proposed increasing reimbursement for CPT 27130 (total hip arthroplasty or THA) and CPT 27447 (total knee arthroplasty or TKA) by 1.7% for hospital outpatient departments and by 1.5% for ASCs. CMS did not, in the Proposed Rule, discuss any changes to APC assignment for any musculoskeletal procedures.

CMS received a comment letter to the Proposed Rule from a joint implant manufacturer requesting that CMS transfer CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder) from APC 5115 to APC 5116 (Level 6 Musculoskeletal Procedures) for 2024, presumably to increase Medicare payment for procedures utilizing its implant. The requested transfer was expected to, and in reality did, increase the Medicare rate for OPPS and ASC procedures assigned to APC 5116, like total shoulder, and correspondingly decrease Medicare rates for procedures remaining in APC 5115, such as THA and TKA. It seems that CMS received only one comment letter out of 386,000 letters that suggested this change for 2024.

In the Final Rule, CMS did in fact transfer CPT 23472 from APC 5115 to APC 5116. The justification for this change, as explained in the Final Rule, is because the geometric mean cost (GMC) of CPT 23472 exceeds the GMC of other CPT codes included in APC 5115, and because shoulder surgeries represented by CPT code 23472 are complex and are more clinically comparable to other procedures assigned to APC 5116. CMS did not give stakeholders the opportunity to comment on the clinically appropriate placement of CPT 23472 or on the impact of the timing of the change, or on the related decision to add CPT 23472 to the ASC Covered Procedures List. The final effect on providers is to increase 2024 rates for shoulder replacement and to decrease 2024 rates for THA and TKA by 3.8% in outpatient departments and by 2.7% in ASCs.

OPPS						
CPT	**2022**	**2023**	**2024 (proposed)**	**% change from 2023**	**2024 (actual)**	**% change from 2023**
27130	$12,593.29	$13,048.08	$13,269.40	**+1.7%**	$12,552.87	**-3.8%**
27447	$12,593.29	$13,048.08	$13,269.40	**+1.7%**	$12,552.87	**-3.8%**

ASC						
CPT	**2022**	**2023**	**2024 (proposed)**	**% change from 2023**	**2024 (actual)**	**% change from 2023**
27130	$9,027.63	$9,508.60	$9,646.38	**+1.5%**	$9,244.39	**-2.7%**
27447	$8,967.37	$9,322.62	$9,436.56	**+1.5%**	$9,054.68	**-2.8%**

III. CMS Lacks Authority Under the Administrative Procedures Act (APA) to Unilaterally Transfer a CPT 23472 from APC 5115 to 5116 Based on a Single Comment without First Providing a Full Opportunity for Notice and Comment on that Transfer

a. *CMS Can Finalize a Regulatory Provision Only if Such Provision is the Logical Outgrowth of a Previously Published Notice*

The APA requires federal agencies, including CMS to publish a Notice of Proposed Rulemaking that sets forth "either the terms or substance of the proposed rule[,] or a description of the subjects and issues involved" prior to formulating, amending, or repealing a rule.[1] This notice is critical "to 'ensure that agency regulations are tested via exposure to diverse public comment, . . . to ensure fairness to affected parties, and . . . to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.'"[2]

While a final rule need not be the mirror image of the proposed rule, CMS can only finalize provisions that are a "logical outgrowth" of a previously published notice of proposed rulemaking or interim final rule.[3] Under the standard articulated by the D.C. Circuit of Appeals and other courts, a final rule qualifies as a logical outgrowth "if interested parties `should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period."[4] The Supreme Court framed the issue slightly differently, stating that a logical outgrowth requires "fair notice" of the change and an opportunity to comment.[5]

b. *The Transfer CPT 23472 from 5115 to 5116 is Not the Logical Outgrowth of a Previously Published Notice*

CMS acknowledges that, in general, "APC reconfiguration may result in *significant changes in the payment rate* for the APC and, therefore, for the service being billed."[6] Yet, the 2024 OPPS & ASC Proposed Rule included no discussion to suggest that CPT 23472 could be

[1] 5 U.S.C. §§ 553(b), 551(5).
[2] *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin*., 626 F.3d 84, 95 (D.C. Cir. 2010).
[3] 42 U.S.C. § 1395hh(a)(4).
[4] *SX Transp., Inc. v. Surface Transp. Bd.*, 584 F. 3d 1076 , 1079-80 (D.C. Cir. 2009) (and citations therein).
[5] *Long Island Care at Home, Ltd. v. Coke*, 127 S.Ct. 2339, 2351 (2007).
[6] Medicare Claims Processing Manual, Ch. 4 § 10.2 (emphasis added).

transferred from APC 5115 to APC 5116 with a corresponding material reduction in payment for APC 5115 and therefore lower payment for TKA and THA in OPPS and ASC settings. As a result, the finalized 2024 reconfiguration of APC 5115 and its value cannot be the logical outgrowth of the proposed rule, because interested parties like AAHKS "would have had to divine [CMS's] unspoken thoughts" to anticipate that CPT 23472 would be transferred to APC 5116.[7] In fact, the CMS proposed rule increased the 2024 rate for APC 5115 by 1.7 percent relative to 2023, underscoring that this change "was surprisingly distant from the proposed rule."[8]

Furthermore, stakeholders and the public were not put on notice of this change in the Final Rule simply because another party made the request to CMS in a comment letter to the Proposed Rule. In *Small Refiner Lead Phase-Down Task Force v. EPA*, for example, the D.C. Circuit rejected the government's argument that the government provided adequate notice because the plaintiff had a duty to monitor comments and that had the plaintiff done so, it would have seen a single comment and realized that it ought to respond.[9] The court explained that the notice obligation is the agency's obligation alone and does not shift; otherwise, the notice and comment process becomes a treasure hunt in which interested parties have to retain experienced attorneys to navigate.[10]

Similarly, the mere fact that a commenter has requested an alternative to the agency's Proposed Rule is insufficient to establish that stakeholders and the public were put on adequate notice. In *National Mining Ass'n v. MSHA*, the D.C. Circuit explained that "[e]ven if a party knows that a commenter has made some novel proposal to an agency during a rulemaking, the party cannot be expected to respond unless it has some reason to believe the agency will take the proposal seriously.[11] Actual notice, then, depends on awareness that the agency, despite its failure to alert the public, is considering adopting what the commenter has suggested.[12]

Further, CMS cannot rely on the fact that notice is given in a Final Rule with comment period, as opposed to a Proposed Rule, to satisfy its obligations to provide the public with an opportunity for notice and comment, as is the case here. In *Kooritzky v. Reich* the court ruled that this is not a logical outgrowth: "Something is not a logical outgrowth of nothing. The notice

---

[7] Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 407 F.3d 1250, 1259-60 (D.C.Cir. 2005).
[8] *Id.*
[9] Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 549 (D.C. Cir. 1983).
[10] *Id.* at 550-551; *see also Horsehead Resource Development Co. v. Browner,* 16 F.3d 1246, 1268 (D.C. Cir. 1994)("While we have noted that insightful comments may be reflective of notice and may be adduced as evidence of its adequacy, *see, e.g., Shell Oil,* 950 F.2d at 751, we have rejected bootstrap arguments predicating notice on public comments alone. Ultimately, notice is the agency's duty because "comments by members of the public would not in themselves constitute adequate notice. Under the standards of the APA, notice necessarily must come—if at all—from the Agency.")
[11] 116 F.3d 520, 531-32 (D.C. Cir. 1997).
[12] *Cf. Mid-Tex Elec. Coop., Inc. v. FERC,* 773 F.2d 327, 339 (D.C.Cir.1985) ("Petitioners had actual notice that FERC might adopt the alternative it ultimately chose."); *Sierra Club v. Costle,* 657 F.2d 298, 355 (D.C.Cir.1981) (parties had actual notice of "EPA's focus" on standard).

of proposed rulemaking contain[ed] nothing, not the merest hint, to suggest that the Department might tighten its existing practice of allowing substitution."[13]

IV. CMS Failed to Obtain Expert Input on All Elements Governing APC Assignment

For the purposes of assigning services within APCs, the Medicare statute requires that "services classified within each group are comparable clinically ***and*** with respect to the use of resources",[14] thus requiring consideration of ***both*** resource use and the clinical nature of the service. Yet, material discussion of this new policy in the Final Rule encompasses only resource use.

In the Final Rule, CMS states that

> "[t]he commenter also provided clinical information, stating that shoulder replacement and reverse shoulder replacement procedures represented by CPT code 23472 are very complex, involving three bones and limited access space due to the muscles, ligaments, and tendons surrounding the joint. These procedures are clinically comparable to other procedures assigned to APC 5116, such as total elbow arthroplasty (TEA) CPT code 24363. TEA and TSA procedures involve similar complexity and are typically performed by specialized, fellowship- or subspecialty-trained shoulder and elbow orthopaedic surgeons."[15]

However, in that comment letter, obtainable through www.regulations.gov, the commenting manufacturer only asserts

> "shoulder replacement and reverse shoulder replacement procedures represented by CPT 23472 are very complex, involving three bones and limited access space due to the muscles, ligaments, and tendons surrounding the joint. These procedures are clinically comparable to other procedures assigned to C-APC 5116, such as total elbow arthroplasty (TEA) CPT code 24363. TEA and TSA procedures involve similar complexity and are typically performed by specialized, fellowship- or subspecialty-trained shoulder and elbow orthopaedic surgeons."

There was no "clinical information" included in or attached to the letter from the manufacturer. If CMS otherwise separately received "clinical information", such as peer-reviewed studies or other data analysis, from the commenter, that information should be made public for review by medical organizations and specialty societies. Otherwise, it is surprising that CMS made a judgment in a Final Rule on the clinical comparability or services based solely on the

---

[13] 17 F.3d 1509, 1513-14 (D.C. Cir. 1994).
[14] SSA § 1833 (t)(2)(B) (emphasis added).
[15] 88 FR 81697 (Nov. 22, 2023).

FIRM:63390858v1

assertions of one manufacturer without seeking comment from medical organizations and specialty societies. The complexity of CPT 23472 as compared to that of CPTs 27130 and 27447 is a far more intricate question. A simple internet search of the question presents a variety of clinical opinions, ranging from 23472 being more complex, less complex, or no more complex than 27130 or 27447. Such initial evidence of variety is more than enough to warrant CMS issuing a request for information from specialty societies on the question of both clinical similarity and resource use for these services.

V. CMS Must Remedy its APA Violation by Maintaining CPT 23472 in APC 5115 in 2024, or Finalizing the Proposed APC 5115 Rate for 2024

CMS can fulfill its obligations under the APA by delaying the reduced OPPS and ASC payment rate stemming from APC 5115 until after stakeholders are given sufficient notice of this change in the 2025 OPPS/ASC Proposed Rule and are afforded the opportunity to comment.[16]

Specifically, AAHKS respectively requests CMS to either:

- Maintain CPT 23472 in APC 5115 until 2025; or
- Finalize for 2024 the value for APC 5115 as stated by CMS in the Proposed Rule, while still transferring CPT 23472 to APC 5116 in 2024.

This relief would allow the providers with practices built around the procedures within APC 5115, the opportunity to explain their unique perspective to CMS, while also affording them time to adjust their business practices and financials to accommodate a potential reduction in APC rates.

This entire episode perfectly illustrates the ongoing necessity for CMS to create one or two additional levels of musculoskeletal APCs under the OPPS and ASC payment systems. By increasing the number of musculoskeletal APCs from six to seven or eight, each APC will be more accurately valued to the services and procedures assigned to it. Fewer services will be assigned to each APC and the result will be less frequent need to transfer services between APCs and smaller increases or decreases in rates stemming from those transfers. All providers and stakeholders would be well served to face fewer and less drastic year-to-year shifts in payment rates.

As we have shared with CMS before, if CMS wishes to make lower extremity joint replacement available at lower-cost sites of care, particularly ASCs, then maintaining a system with frequent downward pressure on Medicare rates, along with unpredictable swings in payment rates, means that many ASCs will decline to perform the procedure for FFS patients. Surgical providers need Medicare rates that account for the greater level of preparation requisite to the successful performance of these procedures in an outpatient setting, such as discharge

[16] Where a regulatory provision is not a logical outgrowth, the provision must be treated as a proposed regulation and cannot take effect until there is further opportunity for public comment and a publication of the provision again as a final regulation. 42 U.S.C. § 1395hh(a)(4).

planning, care coordination, and acquiring durable medical equipment. Further, rates must be steady and predictable based on transparent factors and timeframes. CMS therefore should propose in the 2025 OPPS/ASC Proposed Rule to add one or two new musculoskeletal APC levels.

***

AAHKS and AAOS appreciate your consideration of our comments. If you have any questions, you can reach Joshua Kerr at jkerr@aahks.org.

Sincerely,

American Association of Hip and Knee Surgeons

American Association of Orthopaedic Surgeons

cc: Chiquita Brooks-LaSure, Administrator
Jonathan Blum, Principal Deputy Administrator & Chief Operating Officer
Meena Seshamani, Director, Center for Medicare
Liz Richter, Deputy Director, Center for Medicare
Ryan Howe, Director, Hospital and Ambulatory Policy Group, Center for Medicare

FIRM:63390858v1