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February 25, 2022

Carol Blackford
Director, Hospital and Ambulatory Policy Group

Jason Bennett
Director, Technology, Coding, and Pricing Group

David Rice
Acting Director, Division of Outpatient Care

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments in Advance of Calendar Year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Notice of Proposed Rulemaking (NPRM)

Dear Ms. Blackford, Mr. Bennett, and Mr. Rice,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are writing to urge the Centers for Medicare and Medicaid Services (CMS) to consider several important issues as the Agency begins to develop its CY 2023 OPPS/ASC proposed rule.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

In advance of the proposed rule, AdvaMed is submitting comments on the following:

- Comprehensive APCs for CY 2023 – Complexity Adjustments
- OPPS Payment for Devices
- OPPS APC Group Policies
- ASC Payment System Policies
- ASC Representation on the Advisory Panel on Hospital Outpatient Payment
- Incorporating Digital Health Technology into OPPS and ASC Payment Systems

Comprehensive APCs (C-APCs) for CY 2023 – Complexity Adjustments

CMS has developed a process for identifying and applying complexity adjustments to certain combinations of codes as a part of the comprehensive APC policy. AdvaMed supports the complexity adjustment as an important tool to help ensure adequate payment under the comprehensive APC methodology. We supported the changes made to the complexity adjustment criteria in the CY 2019 OPPS/ASC final rule but believe that important opportunities to refine the methodology remain.

AdvaMed recommends CMS: (1) expand its review of procedure combinations to include clusters of J1 and add-on codes, rather than only code pairs, to better reflect medical practice when multiple procedures are performed together; (2) continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the C-APCs; and (3) reevaluate the current policy restricting complexity adjustments to a single level APC reassignment for cases where the reported costs justify an additional level increase.

OPPS Payment for Devices

Proposing a One-Year Extension of Add-On Payments for Transitional Pass-Through (TPT)-Eligible Technologies During the Public Health Emergency (PHE)

In the CY 2022 OPPS/ASC Final Rule, CMS used its equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide a one-year (four-quarter) extension for TPT payments for device categories whose eligibility would be discontinued beginning CY 2022 because the technology would no longer be considered new.

We believe that the PHE has continued to have a major impact on hospitals' ability to use technologies awarded TPTs during a time when many elective procedures in across the country have been canceled and/or postponed over the last two years. The financial challenges hospitals faced in managing the daily demands associated with the PHE created a direct burden on resources and the utilization of technologies due to the unordinary treatment patterns for patients.

AdvaMed applauded CMS's decision to extend for one-year TPT payments that

otherwise would be discontinued beginning with CY 2022. Our companies with technologies approved for TPTs beginning CY 2020, during the peak of the pandemic, saw reduction in the number of procedures performed and have continued to observe low volume of procedures with TPTs during the resurgence of COVID-19 and we believe that the extension of transitional pass-through status for those device categories set to expire on December 31, 2022 is required to allow time to collect claims and cost data that align more closely with typical patterns of care. This extension would not apply to devices/technologies that had three years of pass-through status before the start of the pandemic.

AdvaMed also notes that with the PHE very likely to continue at least through the end of CY 2022, and many hospitals' admissions still impacted by the PHE, CMS will need to use its equitable adjustment authority to extend TPT payments beyond the one-year extension finalized in the CY 2022 OPPS/ASC Final Rule. We also believe that an extension of one additional year will have minimal impact on the Program from a budgetary perspective as Transitional Pass-Through is budget neutral. One additional year of TPT for these few technologies will facilitate appropriate claims data has been included to appropriately set APC rates.

Reassessing Interpretation of Device Category Criteria

In the CY 2022 OPPS/ASC final rule, CMS reviewed the Eluvia™ system against the TPT criteria. In determining the Eluvia™ system did not meet the first criterion for establishing a new device category (newness), § 419.66(c)(1), CMS relied on a previous determination that drug-eluting stents were described by an existing pass-through device category. While we understand the rationale underlying CMS' determination, we remain concerned about the precedent this sets for devices with an FDA breakthrough designation applying for TPT payment. The device category "Stent, non-coronary, temporary, with delivery system" was established in 2000 based on technologies available at the time. Under CMS' recent interpretation of § 419.66(c)(1), any new technologies that could be aligned to an existing category—however tenuously—would automatically fail this criterion, despite any improvements in technology and patient outcomes associated with the new technology. We believe this overly strict interpretation of the device category criterion may result in the inappropriate restrictions upon the use of the TPT payment pathway.

Additionally, in its decision, CMS stated that "…we do not believe it is appropriate for a discussion of substantial clinical improvement…to be the primary motivating determinant in a determination of whether a device meets the device category criterion in § 419.66(c)(1)." We strongly disagree with this position and believe the totality of the evidence should be considered when evaluating the device category criterion. In the case of Eluvia, it was compared to the standard of care technology in a randomized controlled study with positive results that CMS determined met the substantial clinical improvement criteria. It only stands to reason that if a new

technology compares itself to an existing technology and demonstrates that it provides a substantial clinical improvement in clinical outcomes as determined by the Agency, then by definition cannot fall within an existing device category.

For devices that have received FDA breakthrough designation, this implies that a device is a first of its kind in addressing the condition for which it was designed or offers significant advantage over other alternatives. Indeed, when CMS established an alternative pathway for breakthrough devices seeking New Technology Add-On Payment (NTAP) in the inpatient hospital setting, the Agency stated, "if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment." Not recognizing newness in the same way in the outpatient hospital setting is inconsistent and goes against the spirit of the change to accommodate these devices and recognize their novelty and impact on patient care and is contrary to the purpose of this designation by the FDA. We therefore request that CMS modify the TPT criteria for FDA breakthrough designated devices to indicate that an FDA designated breakthrough device is automatically considered to not be described by any of the existing (either currently active or expired) categories established for transitional pass-through payments and is therefore considered to meet the newness criteria for TPT.

Further, it is imperative that CMS address the inconsistencies in the criteria between NTAP and TPT. For technologies with Breakthrough designation, the Newness and Substantial Clinical Improvement criteria are automatically deemed to have been yet for NTAP. However, this is not the case for TPT given the device category criterion is still in place for these technologies. We believe that an unintended consequence of this criterion is that it creates a potentially perverse incentive for incremental payment to potentially occur in the hospital inpatient setting only. Both the NTAP and TPT programs are meant to minimize hospital financial disincentives to provide new technology while additional claims data is collected. By virtue of making it more difficult to secure TPT than NTAP for these technologies, we are concerned that CMS is inadvertently creating an incentive for Medicare beneficiaries to be treated in the hospital inpatient setting.

Revising TPT Payment Cost Test Thresholds

Currently, CMS requires that technologies meet three criteria in order to satisfy the cost test for TPT payment, including that the new device must exceed the cost of the device-related portion of the APC payment amount for the service by at least 25 percent, and that the difference between the cost of the device seeking pass-through and the device-related portion exceeds 10 percent of the total APC payment.

In many cases, a device that meets the newness and significant clinical improvement criteria for TPT payment may only replace a portion of the devices

included in the device-related portion of the procedure. In some cases, the novel device may not replace any of the devices included in the device-related portion. In these cases, the device-related threshold that a new device must meet may be inappropriately high since many of the devices it includes will still be utilized in the procedure.

Based on these concerns, we believe there are two key opportunities for improvement in CMS' application of the TPT cost test criteria. First, in cases where a new device does not replace any existing devices used in a procedure, we recommend CMS deem the device to have automatically met the TPT cost test. Second, in cases where a new device replaces any portion, but not all, of the devices used in a procedure, we recommend CMS revise the cost test to assess the new device's cost using only the cost of the devices the new device replaces in the associated procedure. This revised cost test would address shortcomings of the current TPT methodology, under which a new device that is not intended to replace or does not replace the entirety of all devices used in a procedure could meet the requirements for substantial clinical improvement but fail on the cost criteria. This could be performed analyzing the device categories via C-codes in hospital outpatient claims to assign which categories are and are not replaced by the new technology.

AdvaMed recommends CMS: (1) revise the TPT methodology to eliminate the cost criteria for new devices that do not replace any other devices used in a procedure; and (2) revise the TPT methodology's cost criteria for devices that replace some, but not all, of the devices used in a procedure by assessing cost using only the cost of the devices the new device replaces in the procedure.

Addressing Pass-Through Payment Valuation in ASCs

As new, innovative devices enter the marketplace and receive TPT payment, it is imperative CMS ensure these devices are appropriately reimbursed in both the hospital outpatient and ASC settings. Currently, ASC payment for procedures using these devices is calculated by establishing the procedure payment rate, subtracting the applicable device offset percentage, and then adding the OPPS pass-through amount ("J7 payment") for the TPT device. However, there is currently no CMS-level guidance on how MACs should establish this J7 payment price for TPT devices. This lack of clear, consistent payment guidance has resulted in instances where the MAC payment for a procedure using a TPT device fails to appropriately account for the cost associated with the new device. We are concerned that, absent CMS intervention, inadequate reimbursement will disincentivize ASCs from using these devices and, in turn, limit Medicare beneficiaries' access to new, innovative technologies in the ASC setting. We therefore request CMS provide additional clarity on how MACs should establish payments for TPT devices in ASCs. Specifically, we recommend CMS clarify that MAC payment for TPT should be at least equal to the device cost, as reported by the ASC in box 19 or the electronic equivalent.

AdvaMed also requests CMS to require MACs to post clear instructions on how to format invoice pricing in box 19 or the electronic data field equivalent. This is consistent with CMS' guidance per MLN 12129,[1] where CMS clearly indicates that MACs must publish provider education and billing guidance for pass-through devices on their websites, which to our knowledge has not occurred for any MAC. While several MACs have posted instructions for this process on their website, only one lists HCPCS codes for devices both eligible for implant in an ASC and that have qualified for pass-through payment. None indicates this process applies to pass-through payments for implantable devices. MACs should be required to list applicable HCPCS codes during tolling windows and remove them upon tolling windows' closure, as well as confirm this process applies to claims that include pass-through devices. CMS should require these changes should be made to MAC websites before the next OPPS rule goes into effect on January 1, 2023.

AdvaMed requests CMS clarify how MACs should establish payment for TPT devices in the ASC setting to account for the additional costs of the new device.

OPPS Ambulatory Payment Classification (APC) Group Policies

Section 1833(t)(2)(B) of the Social Security Act requires that all services and items within an APC group be comparable clinically and with respect to resource use, a standard that applies to all procedures under the OPPS, including those being removed from the Inpatient Only (IPO list) and payable in the hospital outpatient setting for the first time. AdvaMed supports CMS' policy to halt elimination of the IPO List in its entirety in the CY 2022 OPPS/ASC final rule, and applauds CMS for listening to stakeholders' concerns about beneficiary safety and taking action to reverse the policy initially finalized for CY 2021. Nevertheless, addressing the misalignment between the IPPS and OPPS structures remains a critical aspect of ensuring that procedures removed from the IPO List when clinically appropriate, in accordance with the longstanding criteria codified beginning in CY 2022, are appropriately paid in the outpatient setting.

In many cases, procedures that have been removed from the IPO list have failed or, we anticipate, will fail to meet CMS's APC placement criteria of resource use and clinical similarity. If CMS's goal is for procedures to move from the inpatient to the outpatient setting when medically appropriate, these APC assignments will not cover the facility's cost to perform these procedures in the outpatient setting and will impede that goal. We offer several examples to illustrate this point:

- All total ankle replacement (TAR) procedures were reassigned specifically to MS-DRG 469 (even when no MCC was reported) beginning in FY 2018 due to the significant higher costs associated with this procedure compared to other procedures in MS-DRGs 469/470. Despite the procedure being assigned to the highest-paying and applicable MS-DRG, CMS assigned these same cases

[1] https://www.cms.gov/files/document/mm12129.pdf

to APC 5115, instead of 5116, when removing this procedure from the IPO List for CY 2021. This results in a significant difference in payment between the national average inpatient payment of $19,825 and the outpatient payment rate of $12,593. In addition, TAR violates the "two times rule" and should be placed from APC 5115 to APC 5116. The geometric mean cost for TAR is $22,591 and is over two times the lowest geometric mean cost procedure at $6,364.89 within APC 5115. A facility will lose almost $10,000 for every Medicare case when performed in the hospital outpatient setting.

- Similarly, total shoulder arthroplasty (TSA) (CPT code 23472) is assigned to MS-DRG 483 in the inpatient setting but was assigned to APC 5115 when removed from the IPO List for CY 2021. This also results in a significant difference in payment between the national average inpatient payment of $15,732 and the outpatient payment rate of $12,593. A preliminary cost analysis also demonstrated that the outpatient costs are more closely aligned with the median costs of procedures in APC 5116. In addition, TSA violates the "two times rule" and should be moved from APC 5115 to APC 5116. The TSA geometric mean procedure cost is $15,734, which is over two times the lowest geometric mean procedure cost of $6,364.89 within APC 5115. A facility will lose over $3,000 per Medicare case when performed in the hospital outpatient setting.
- CPT code 22633 represents a posterior approach 360-degree spinal fusion, which is a combination of a posterior interbody technique fusion (CPT code 22630; APC 5116) and a posterior/posterolateral technique fusion (CPT code 22612; APC 5115). Physicians must perform both components in order to have a posterior approach 360-degree spinal fusion. When CMS removed 22633 and 22630 from the IPO List this year, it assigned the CPT code 22630 to APC 5116 while the more comprehensive and costly 360-degree spinal fusion was assigned to APC 5115. We agree that APC 5116 is an appropriate assignment for CPT code 22630 given the resources involved in performing these procedures. However, we do not agree that CPT 22633, which is a more extensive procedure, of which CPT code 22630 is a component, should be assigned to a lower-level APC. As a result of the current assignments, hospitals are paid more to do only one component of the 360-degree spinal fusion (i.e., the posterior interbody technique fusion) than for completing the entire 360-degree fusion. This is despite the obvious increased costs of performing the 360-degree fusion due to additional instrumentation/hardware costs, operating room time, etc. We therefore request that CPT code 22633 be reassigned to APC 5116.
- We also note that the add-on code for additional levels of posterior lumbar interbody fusions, 22632, remains on the IPO only list, while packaged payment is allowed for additional levels of the other fusion codes (for example, 22552, 22858, 22614, and 22634). We request that CMS change the status indicator for CPT code 22632 from "C" to "N" in the proposed rule.

We further urge CMS to reevaluate the APC placement for technologies that have been uniquely, adversely affected by the continued use of CY 2019 data for OPPS ratesetting due to the ongoing PHE. For example:

- CPT code 55880 (previously HCPCS C9747) is a new CPT code approved for use effective January 1, 2021. This code, for ablation of prostate tissue using transrectal high intensity focused ultrasound, was assigned to APC 5375 (Level 5 Urology and Related Services). In its August 23rd meeting, the Advisory Panel on Hospital Outpatient Payment recommended CMS reassign CPT 55880 to APC 5376 (Level 6 Urology and Related Services). AdvaMed has concerns regarding the placement of this code into APC 5375 as we do not believe that payment for this grouping adequately reflects the resources used by hospitals in performing this procedure and may therefore create access issues for Medicare beneficiaries in need of this service. We therefore recommend CMS assign CPT code 55880 to APC 5376 (Level 6 Urology and Related Services) as this APC is more reflective of its resource requirements.

Establishing Additional APCs

As stated in previous comments, AdvaMed remains concerned about large payment gaps between APCs and wide cost variance within individual APCs. The OPPS is currently comprised of 69 clinical comprehensive APCs (status indicators J1 and J2 codes) with payment rates ranging from $1,113 to $34,428. Looking forward, we encourage CMS to proactively identify and consider areas where additional levels within existing APCs or new families of clinical APCs could help better accommodate the variations in the clinical nature and resource use associated procedures performed in the hospital outpatient setting. These gaps also have far-reaching implications on the appropriateness of payment rates for procedures performed in ASCs, given the close linkage between OPPS payment rates and ASC payment rates.

For example, in recent years, CMS has at different times considered whether to establish a seventh musculoskeletal APC to reflect the broad array of orthopedic procedures performed in hospital outpatient settings. In the CY 2021 OPPS/ASC final rule, CMS discussed whether to add another musculoskeletal APC. While CMS opted to take no action, the agency noted that it would consider these comments for future rulemaking.

As CMS considers payment policy issues for the CY 2023 OPPS/ASC rulemaking cycle, AdvaMed urges CMS to consider such a change for CY 2023. The gap in geometric mean costs between APCs 5114 and 5115 is almost $6,000, which is too significant a gap in payment categories, especially given the payment impact on ASC payment rates between 5113 and 5114 is $3,505 and the payment gap between 5115 and 5116 is $3,139. An additional APC level within the family of Musculoskeletal APCs—for example, between APCs 5114 and 5115—would smooth out some of the substantial payment gaps and provide a more even distribution of

APCs that better align resource consumption with payment rates. We are conducting additional analyses to develop more specific recommendations regarding the procedures that could be potentially categorized into a seventh musculoskeletal APC to address the payment disparity across the existing musculoskeletal APCs.

Reevaluating Use of the Two Times Rule

In addition to recognizing the need for new clinical APCs, AdvaMed urges CMS not to consider the two times rule, as defined by section 1833(t)(2) of the Act, as the sole guiding principle in determining whether APC groupings meet the standard of cost coherence. The statute specifies that items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest mean cost for a service is more than two times greater than the lowest mean cost for a service within the APC. The implications of applying this standard to high-cost procedure groupings are very different from applying this standard to low-cost procedure groupings – i.e., placement of a $21,000 procedure in the same APC as a $40,000 procedure is vastly different in terms of cost coherence than placement of a $210 procedure in the same APC as a $400 procedure, even though both groupings technically meet the minimum standard set forth in the statute.

Rather than relying strictly on the two times rule, AdvaMed recommends CMS consider other standards for determining whether procedures should be appropriately grouped together in the same payment category from the standpoint of cost. For example, under the IPPS, CMS recognizes the need for more granularity within a set of MS-DRGs through the creation of CC and MCC subgroups when there is at least a 20 percent difference in average cost between subgroups amounting to at least $2,000. We believe that this standard for determining whether payment groupings result in appropriate and adequate payments is much more reasonable than the two times rule in the context of high-cost procedures payable through comprehensive APCs, which, similar to MS-DRGs, provide a single bundled payment to the hospital for an entire encounter.

ASC Payment System Policies

Improving Transparency in ASC Weight Scalar Adjustment

Each year when it updates the ASC payment system, CMS adjusts the relative payment weights used for the ASC payment system in order to ensure the changes from one year to the next in the relative payment weights do not cause total payments to rise or fall. To accomplish this, CMS compares total payments while holding constant the ASC conversion factor and the volume and mix of ASC cases, while comparing payments using the current year ASC relative weights and the prospective year ASC relative weights, derived from the prospective year OPPS relative weights. The ratio of total payments using the prospective weights to total payments using the current weights determines the adjustment factor applied to the prospective relative weights to ensure budget neutrality. This adjustment is

known as the secondary scaling factor because a similar budget neutrality adjustment has already been applied to the prospective OPPS relative weights.

Every year since 2008, the ASC scalar has reduced the ASC weights to achieve budget neutrality. In addition, the negative adjustment has grown over time from approximately a -6 percent factor to now over -14 percent. Between 2009 and 2021, the ASC scalar fell by 8.65 percentage points (from 0.9412 to 0.8547), while the OPPS scalar rose by 7.6 percentage points (from 1.3585 to 1.4341). Per CMS' rationale for the secondary ASC scalar, this would suggest year-to-year case-mix changes occurring in opposite directions between OPPS and ASCs. Alternatively, the declining ASC weight scalar may just be an artifact of the fact that the OPPS scalar increases.

This widening differential draws into question the validity of the ASC weight scalar. It may be the original purpose for the ASC weight scalar has become obsolete over time. If so, the ASC weight scalar will actually distort payments downward in ASCs and increasingly result in procedures being too costly for physicians to perform in ASCs relative to the Medicare payment. In addition, underpayments for procedures in ASCs will impinge the availability of innovative medical technology in these settings.

We encourage the Agency to undertake an analysis of what is causing the rising trend in the OPPS scalar, and whether those factors should or should not be offset in the ASC setting. It is likely there is a combination of factors leading to the rising OPPS scalar, perhaps including procedures that are removed from the inpatient-only list and being payable in the OPPS. However, these procedures are often subsequently added to the ASC covered procedures list as well, raising the questions of whether any subsequent adjustment to the ASC scalar would be appropriate.

As more procedures are performed in the ASC setting, it is important to understand whether the ASC weight scalar contributes to serve its purpose. AdvaMed therefore recommends CMS undertake an analysis of the factors driving the rising OPPS scalar and assess whether all of these factors should be offset by the ASC scalar.

Aligning ASC Payment System and OPPS Update Factors

The vast majority of procedures performed in the ASC setting are the same ones performed in the hospital outpatient setting and face similar input costs. However, CMS has historically updated the ASC payment rates annually using the Consumer Price Index for All Urban Consumers (CPI-U), while the hospital outpatient department payments using the hospital market basket. This inconsistency has contributed to a misalignment in the payment updates between the two systems. While the hospital market basket reflects the prices changes related to hospital services, the CPI-U reflects those of all consumer products, including those that are not related to healthcare. In 2019, CMS initiated a five-year trial period to align the

update factors and use the hospital market basket to update payments in ASCs to assess whether there would be a migration of the performance of procedures from the hospital setting to the ASC under this better-aligned payment policy. As the trial period will end in 2023, we think it reasonable for CMS to make permanent the alignment of update factors, helping to move to a more complete alignment of the ASC payment system and OPPS.

Providing Separate Payment for Add-On Services Under the ASC Payment System

Under the OPPS C-APC payment methodology, CMS recognizes that certain "secondary" services (secondary status "J1") or "add-on" services (status "N") performed with the associated "primary" service (primary status "J1") reflect a more complex version of the primary service if requisite frequency and cost threshold are met.[2] In this case, CMS determines that the code combination of these services merits a payment adjustment, called a complexity adjustment.

Under the ASC payment system, when secondary services that trigger complexity adjustments under OPPS are performed with the primary service, CMS does not provide a similar payment adjustment. Instead, CMS provides separate payment for both the primary service and the secondary service. However, when add-on services that trigger complexity adjustments under OPPS are performed with the primary service in the ASC setting, CMS does not provide separate payment for the add-on service or a payment adjustment to the primary service.

Failure to account for the additional costs of performing these add-on services in the ASC setting is inconsistent with the payment policy under OPPS, where CMS applies a complexity adjustment to account for their additional cost. This further distorts the payment differential between the ASC and outpatient setting for resource- intensive procedures.

For example, clinical encounters involving primary procedures described by CPT code 22513 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic) and the associated add-on CPT code 22515 for each additional thoracic or lumbar vertebral body qualify for a complexity adjustment to APC 5115 (Level 5 Musculoskeletal Procedures) under OPPS, resulting in a payment rate of approximately $12,593 in CY 2022.

Under the ASC payment system, however, CPT code 22513 has a payment rate of only $2,998 (payment indicator "G2"), while payment for 22515 is packaged (payment indicator "N1") – resulting a payment disparity of nearly $10,000 between the hospital outpatient and ASC settings. As another example, performing the add-on physiology procedure fractional flow reserve and instantaneous wave-

[2] Frequency of 25 or more claims reporting the code combination (frequency threshold); and violation of the 2 times rule (cost threshold).

free ratio (FFR/iFR) described by CPT 93571 with the primary cardiac procedure described by CPT codes 93454-93456 and 93458-93461 qualifies for APC 5192 under OPPS resulting in a payment rate of approximately $5,061.89 in CY 2022. Under the ASC payment system, the primary procedure results in payment rate of only $1,437.45 (payment indicator "G2") while CPT 93571 is packaged (payment indicator "N1") – resulting in a payment disparity of over $3,600 between settings.

We are concerned this payment differential has the unintended consequence of disincentivizing performance of these resource-intensive procedures in the ASC setting, thereby limiting patient access to these services in their setting of choice and impacting physicians' exercise of clinical judgment in making site-of-service determinations. We therefore recommend that under the ASC payment system, CMS pay separately for covered add-on services that trigger a complexity adjustment under OPPS. To be eligible for separate payment in the ASC, we propose add-on services be required to meet three criteria: (1) the "add-on" service is identified with status indicator "N"; (2) the "add-on" service triggers a complexity adjustment under OPPS; and (3) the "add-on" service is included on the ASC Covered Procedures List.[3]

If all three criteria are met, CMS would provide separate payment for the add-on service in the ASC. We think providing separate payment for these procedures is the most straightforward approach given the operational limitations of the ASC pricer software and the challenges associated with reprogramming the software to perform the complex logic necessary to implement the C-APC methodology and complexity adjustments in the ASC. Moreover, separate payment for these add-on procedures would be consistent with the ASC payment policy for other procedures (secondary services) that trigger complexity adjustments under OPPS.

Adopting a set criteria to identify a limited number of "add-on" services that CMS has already determined reflect a more costly version of the primary service, and and merits an increase in payment under OPPS, ensures CMS payment policy is applied consistently across OPPS and ASC settings. This would also remove a payment disincentive for performing these services in the ASC, thereby making them a viable option for physicians and improve patient access to these services in the ASC.

Resolving ASC Copay Inequities

AdvaMed also asks the Agency to examine the feasibility of addressing a longstanding concern regarding the beneficiary co-payment for certain high-cost procedures when performed in the ASC C. There are several procedures that have a higher associated patient co-pay when performed in an ASC versus the hospital outpatient department, including procedures that include devices that have

[3] Under these criteria, 22 "add-on" services would currently quality for separate payment in the ASC setting. These codes are listed in Appendix A to this letter.

received TPT. In the hospital outpatient setting, any incremental TPT payment is not subject to the 20% patient coinsurance, while any TPT payment made in the ASC setting is subject to the 20% patient coinsurance. This poses a potential financial challenge to beneficiaries who, especially in light of ongoing concerns of contracting COVID-19, may be reticent to have a procedure performed in a hospital as opposed to an ASC.

Patients, in conjunction with their healthcare provider, should have the choice to select the facility where they believe they can safely have a procedure performed and that this should not be dictated by co-pay costs. This is especially important for Medicare patients that may be part of vulnerable and "high-risk for poor outcomes" populations.

AdvaMed recommends CMS work with Congress to limit the maximum co-pay amounts for ASC procedures to match the maximum co-pay paid by beneficiaries to have these same procedures performed in the hospital outpatient department. For example, as noted on the CMS "Procedure Price lookup tool" Medicare pays $11,886 for a total knee arthroplasty in the hospital outpatient department and $8,063 when performed in the ambulatory surgical center yet, the patient co-payment is $267 more in the ASC setting.[4]

ASC Representation on the Advisory Panel on Hospital Outpatient Payment

The Advisory Panel on Hospital Outpatient Payment (HOP Panel) advises the Secretary and CMS Administrator on the clinical integrity of the APC groups and their associated weights, and supervision of hospital outpatient therapeutic services. The Panel consists of a chair and up to 15 members. CMS requires that nominees to the Panel must meet certain criteria, including each panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS, and that they must have technical expertise to enable them to participate fully in the Panel's work. ASC employees do not qualify under these criteria to participate on the HOP Panel.

As ASCs continue to play a significant role in the healthcare delivery system and the impact of the OPPS/ASC payment rules on ASC's operations, it is important to allow representation of ASCs in the Advisory Panel. AdvaMed therefore requests CMS revise the HOP Panel criteria and explicitly allow employees from ASCs to join the Panel, regardless of whether they are employed by full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS.

Incorporating Digital Health Technology into OPPS and ASC Payment Systems

Digital health technology is reshaping healthcare systems around the world. An increase in virtual doctor visits and telemedicine, remote patient monitoring

[4] https://www.medicare.gov/procedure-price-lookup/cost/27447

(including the use of consumer apps), and digital surgery using robotics, computer-assisted imaging, and artificial intelligence are all affecting reimbursement policy decisions related to digital health technology. Robotic-assisted surgeries (RAS), computer-assisted navigation (CAN), and artificial intelligence (AI) are all terms familiar to providers working in today's fully equipped operating room. While the human surgeon is and will continue to be the essential component of the operating room, these technological advancements are helping to enhance the surgeon's skills to provide better outcomes for patients. AI is also driving important improvements in the ability of physicians to diagnose and treat diseases outside of the operating room. As these technologies develop, they are beginning to merge, and we are beginning to see products that combine RAS, CAN, and AI together.

We believe there are two specific opportunities for CMS to enable quicker access to innovative digital technologies in the outpatient setting. The first is relative to the qualifying criteria for medical devices to be considered for transitional pass-through payments. The current criteria specifically require a device must —

- Be an integral part of the service furnished;
- Be used for one patient only;
- Come in contact with human tissue; and
- Be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.

Furthermore, the device cannot be any of the following:

- Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or
- A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than radiological site marker).

As RAS, CAN, and AI technologies are increasingly introduced for more and more procedures and frequently include components that do not come into contact with patients or represent a capital expenditure, these criteria are inappropriately exclusionary for these technologies. In particular, because capital costs are included in establishing the APC payment rate, the same rationale applies equally when calculating the operating costs for pass-through payments.

A second opportunity is for CMS to consider that the use of RAS, CAN, and AI may represent new and significantly different procedures eligible for consideration under the New Technology APC policy. As these technologies evolve, they are changing procedures in important ways that improve efficiency and clinical outcomes. But their introduction is frequently hindered by payment policies that require hospitals to absorb their costs without any payment adjustment until claims data become available two or three years later. We strongly urge CMS to consider recognizing such technologies through the creation of procedural HCPCS codes and assignment

to New Technology APCs to help encourage faster introduction and development of these important innovations.

We appreciate this opportunity to share our recommendations for your consideration in preparation for the CY 2023 OPPS/ASC proposed rule. If you have any questions, please contact Kirsten Tullia (ktullia@advamed.org).

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy Department