AdvaMed
Advanced Medical Technology Association

701 Pennsylvania Avenue, NW
Suite 800
Washington, D.C. 20004–2654
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

June 17, 2022

Via Electronic Mail
Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1771-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation

Dear Administrator Brooks-LaSure,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are pleased to offer comments on proposed changes to the FY 2023 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospitals proposed rule, published in the *Federal Register* on May 10, 2022 (CMS-1771-P). 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.

Our letter offers support for specific CMS proposals and also recommends modifications to ensure Medicare beneficiary access to high-quality medical technologies and procedures. Our comments cover the following categories:

- Proposed Changes to Medicare Severity (MS)-Diagnosis-Related Groups (DRGs) and Relative Weights
- Proposed Cap for Relative Weight Reductions
- New Technology Add-On Payment (NTAP) Program
- Hospital Market Basket Update
- CMS Quality Programs
- Condition of Participation Requirements for Hospitals and CAHs to Report Data Elements to Address Any Future Pandemics and Epidemics as Determined by the Secretary
- Continued Financial Relief for Providers and Beneficiaries

Proposed Changes to Medicare Severity (MS)-Diagnosis Related Groups (DRGs) and Relative Weights

Laser Interstitial Thermal Therapy (LITT)

In the FY 2022 IPPS final rule, CMS reassigned ICD-10-PCS codes describing laser interstitial thermal therapy (LITT) of the brain and brain stem from MS-DRGs 023, 024, 025, 026, 027 to MS-DRGs 040, 041, and 042. As AdvaMed has expressed in prior correspondence to CMS, we were greatly concerned that CMS adopted this change without having proposed it and without providing an opportunity for the public to comment. The reassignments raised concerns about procedural issues for AdvaMed member companies more broadly and beyond this particular technology.

While we were disappointed that CMS did not address this procedural error for FY 2022, we are pleased that CMS has proposed to assign new ICD-10 PCS codes for LITT of the brain, which will be effective October 1, 2023, to MS-DRGs 025 through 027, and we urge CMS to finalize the proposal.

We appreciate that CMS agrees that the LITT brain procedure is more appropriately aligned from both a cost and clinical homogeneity perspective with the procedures in MS-DRGs 025-027. We further commend CMS for recognizing the unique circumstances relating to these procedures and including discussion in the proposed rule of the pending code changes for LITT that were considered at the March meeting of the ICD-10-CM Coordination and Maintenance Committee, which would typically be included only in the final rule.

Surgical Ablation

In the FY 2022 IPPS final rule, CMS discussed a request to review the MS-DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation (Afib). For FY 2022, CMS finalized a revision of the surgical hierarchy of the surgical

for the MS-DRGs in MDC 05 (Diseases and Disorders of the Circulatory System) to sequence MS-DRGs 231-236 (Coronary Bypass) above MS-DRGs 228 and 229 (Other Cardiothoracic Procedures). Under this revision, when a procedure describing a coronary artery bypass graft (CABG) and a procedure describing an open surgical ablation are present, the GROUPER logic would assign the procedures to "Coronary Bypass with Cardiac Catheterization or Open Ablation with or without MCC" (MS-DRGs 233 and 234) to reflect this reassignment for FY 2022.

The proposed rule discusses a request to review once again the MS-DRG assignments of cases involving open concomitant surgical ablation procedures. AdvaMed supports this request and asks that CMS finalize our recommendations below.

Data analysis by Optum Insights of 2021 CMS MedPAR data for the FY 2023 Proposed Groupings shows that, similar to the analysis we presented in our comment letter for the FY 2022 IPPS Proposed Rule, average case costs for open concomitant surgical procedures, including those for mitral valve repair or replacement (MVR) and aortic valve repair or replacement (AVR), are consistently and significantly higher (as much as $7,000) when compared to the average costs within their respective MS-DRGs when the procedures are not concomitant with ablation. During concomitant surgery, sometimes 3-4 open heart procedures (e.g., AVR + MVR + Coronary Bypass + surgical ablation) are performed during the same hospital stay. We believe these higher-cost, resource-intensive ablation procedures argue for new MS-DRGs, or at a minimum regrouping to more appropriate MS-DRGs.

Optum's data analysis of 2021 MedPAR data also leads us to conclude additional time is not needed before CMS can move forward with reconsideration of MS-DRG assignments for cases reporting procedure code combinations describing open concomitant surgical ablations. The analysis by Optum demonstrates a similar underpayment for 3 consecutive years.

Furthermore, guidelines of the Society of Thoracic Surgeons and the Heart Rhythm Society recommend surgical ablation for Afib at the time of open-heart procedures (i.e., AVR, MVR). Our concern is that, due to this erroneous grouping logic, hospitals will choose to schedule a patient for two separate procedures despite data showing that mortality is significantly reduced in the subsequent years following concomitant treatment. We are therefore concerned that additional waiting time before revising these MS-DRG assignment may lead to access to care issues and in some cases patient harm.

A second concerning trend is patients undergoing hybrid surgical ablation for hard-to-treat, stand-alone Afib. This treatment employs a minimally invasive (percutaneous surgical ablation) approach combined with a catheter ablation for persistent and long standing persistent Afib. Many of these patients with severe Afib have failed prior treatments before this therapy. MS-DRG grouping for this

treatment currently falls under MS-DRG 228-229. Similar to open concomitant procedures discussed above, hybrid ablation lacks appropriate cost coherence for the resource intensive procedures. Optum analysis suggests a $4,000 underpayment for this therapy, which is the only FDA-approved solution currently.

AdvaMed therefore recommends CMS: (1) Assign valve repair/replacement with open surgical ablation procedures for Afib to new MS-DRG assignments or at a minimum regroup to higher more appropriate aligned resource intensity MS-DRGs (216-219); and (2) Maintain relative weights for MS-DRG 228-229 for a year to ensure payment stability. The reductions of approximately 30 percent over 6 years could jeopardize patient access to percutaneous endoscopic stand-alone hybrid surgical ablation for Afib. In the alternative, CMS could regroup all stand-alone percutaneous endoscopic surgical ablation from MS-DRG 229 to 228 to maintain clinical coherence.

Acute Respiratory Distress Syndrome (ARDS)

AdvaMed supports the proposal to reassign cases reporting diagnosis code J80 (ARDS) as the principal diagnosis from MS-DRG 204 (Respiratory Signs and Symptoms) to MS-DRG 189 (Pulmonary Edema and Respiratory Failure). As shown by the data presented in the proposed rule, the average length of stay and average cost of a case reporting ARDS is more appropriately aligned with MS-DRG 189.

Proposed Cap for Relative Weight Reductions

CMS is proposing a permanent 10% cap on the reduction to MS-DRG relative weights annually. The proposed 10% cap is budget neutral, meaning that total IPPS payments would be unchanged. CMS reasons that implementing this policy will provide greater predictability and stability in payment rates. AdvaMed supports CMS' proposal to adopt an annual, permanent 10% cap. However, given the disproportionate impact of the 10% cap on medical cases and the high degree of weight fluctuation in excess of 5% observed across surgical cases in the FY 2023 IPPS proposed rule, AdvaMed recommends CMS implement an alternative one-year 5% cap on the reduction to MS-DRG weights.

As the below analysis of this proposal demonstrates, most cases (91%) subject to the 10% cap are in medical DRGs. These medical DRG cases are concentrated in DRGs with a high proportion of Covid cases, with 52% of medical DRG cases subject to the 10% cap categorized as Covid cases compared to 12% of all medical DRG cases. Unlike most DRGs that experienced significant volume reductions from 2019 (18-24%), the medical DRGs subject to the 10% cap increased in volume by 34% from 2019 to 2022 due to the increase in Covid cases. The medical DRG cases subject to the 10% cap represent 1% of all medical cases while the surgical DRG cases subject to the 10% cap represent 0.3% of all surgical cases.

Table 1: All DRGs vs DRGs with 10% Weight Reduction Cap

DRG Type	All DRGs N	2021 Cases	% Covid	% Change in Volume from 2019 to 2021	Weighted Average Total Cost	% Implant + Supply Cost	DRGs with 10% Cap N	2021 Cases	% of All Cases	% Covid	% Change in Volume from 2019 to 2021	Weighted Average Total Cost	% Implant + Supply Cost
Overall	765	7,371,539	9%	-20%	$ 13,814	13%	27	61,968	0.8%	48%	27%	$ 10,008	9%
Medical	372	5,363,502	12%	-18%	$ 10,822	3%	11	56,256	1.0%	52%	34%	$ 7,994	3%
Surgical	393	2,008,037	2%	-24%	$ 24,225	28%	16	5,712	0.3%	2%	-13%	$ 39,488	26%

Source: IPPS FY 2023 Proposed Rule Table 5, AOR/BOR Files, Proposed 2021 MedPAR File

Table 2 shows the characteristics of the DRGs that would be subject to the recommended alternate 5% weight reduction cap. All DRGs subject to the proposed 10% cap are included because their weight reduction is greater than 5%. The recommended 5% cap affects medical and surgical cases more evenly, with 46% of cases in medical DRGs and 54% of cases in surgical DRGs. Surgical cases subject to the alternative 5% cap have high implant and supply costs (45% compared to 28% of all surgical cases). This illustrates that DRGs with high device costs are more likely to experience weight reductions between -5% and -10% under the proposed rule, on top of the significant reduction in volume of procedures performed as a result of the ongoing COVID-19 PHE.

Table 2: DRGs with Alternative 5% Weight Reduction Cap

DRG Type	DRGs with 5% Cap N	2021 Cases	% of All Cases	% Covid	% Change in Volume from 2019 to 2021	Weighted Average Total Cost	% Implant + Supply Cost
Overall	91	348,375	4.7%	10%	-11%	$ 20,126	35%
Medical	38	160,074	3.0%	19%	-14%	$ 10,007	3%
Surgical	53	188,301	9.4%	1%	-8%	$ 31,272	45%

Source: IPPS FY 2023 Proposed Rule Table 5, AOR/BOR Files, Proposed 2021 MedPAR File

An analysis of the impact of an alternative 5% cap on budget neutrality found the cap policy weight adjustment factor for the 5% alternative is 0.998224, as compared to 0.99765 for the proposed 10% policy. This reduces the standardized amount from $6,795 to $6,786, which is a -0.14% change to the standardized amount. Payment rates for DRGs not subject to the 5% weight reduction cap would decline by -0.14%. Based on this analysis' FY 2023 Proposed IPPS replication, this would redistribute approximately $160 million from payments under the proposed weight reduction cap policy, which is 0.18% of total IPPS payments.

Given the positive impact of a 5% cap on surgical cases involving high implant and supply costs, and the minimal redistributive impact it would have in terms of budget neutrality, AdvaMed supports a one-time 5% cap to MS-DRG weight reductions in FY 2023, followed by a permanent 10% cap beginning in FY 2024. We believe this policy would align with CMS' stated intent to provide greater stability to hospitals' payments overall, while recognizing the uncertainty surrounding what hospital case mix and cost patterns will actually be in the year ahead, and how that compares to the FY 2021 claims data used to set the FY 2023 rates.

New Technology Add-On Payment (NTAP) Program

Extension of Add-On Payments for NTAP Eligible Technologies During the Public Health Emergency (PHE)

In the FY 2023 IPPS proposed rule, CMS summarizes the CDC hospitalization data that shows a peak of hospital admissions for patients with COVID-19 in January 2022 (that is associated with the Omicron variant of the virus). CMS also referenced a February 2022 CDC report that stated new COVID-19 variants will continue to emerge and even if a variant causes less severe disease in general, an increase in the overall number of cases could cause an increase in hospitalizations.[1] Unfortunately, as of May 16, 2022, CDC's forecast of new daily confirmed COVID-19 hospital admissions predicts that the number will likely increase with 1,300 to 11,000 new confirmed COVID-19 hospital admissions likely reported on June 10, 2022.[2] On May 19, 2022, the CDC reported that the current 7-day daily average for new hospitalizations for May 4-10, 2022 was 2,629, an increase of 17.5% from the prior 7-day average. The hospitalization rates among adult ages 65 and older have seen the sharpest increase in rates, from 6.5 per 100,000 populations on April 2 to 15.6 per 100,000 population on April 30, 2022. This increase is being associated with the Omicron BA.2 subvariants. These data suggest that COVID-19 remains problematic and will continue to depress utilization of non-COVID-19 services such as those that use NTAP-approved technologies.

CMS proposes to use FY 2021 MedPAR claims data for FY 2023 IPPS rate-setting with modifications to account for an anticipated lower level of Medicare hospitalizations for COVID-19 in FY 2023 as compared to FY 2021. We are concerned, however, given the persistence of the PHE and the decreased utilization of health care by seniors, that the PHE continued to have a major impact on hospitals' ability to use technologies awarded new technology add-on payments during FY 2021.

We also note that the use of NTAP-approved technologies has been affected by the PHE even during periods when elective procedure volumes were more stable. For

[1] https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html. Accessed by February 25, 2022.
[2] https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html. Accessed May 19, 2022.

example, due to COVID burdens and staffing shortages, many hospitals canceled or significantly reduced meetings of their Value Analysis Committees (VACs), which are used by most hospitals to determine whether to use new technology. This has greatly limited adoption of new technology. Furthermore, companies' ability to train hospitals on use of new technologies has been severely limited. Thus, the PHE has negatively affected use of NTAP-approved technologies in ways that may not be apparent solely based on procedure volumes.

We offer this real-world example to illustrate these points. EXALT Model D, is a single-use duodenoscope used in endoscopic retrograde cholangiopancreatography (ERCP) procedures. ERCP procedures are not elective. However, hospitals can use reusable scopes instead of single-use scopes, which many have done because their VACs have not met and/or because they did not have staff or time for training. Thus, the procedure volumes of ERCP procedures haven't gone down, but adoption of single-use scopes (despite numerous FDA safety communications advising against use of reusable duodenoscopes) has been slow, and the higher costs of single-use scopes are not well reflected in claims.

For these reasons and similar to the concerns CMS discussed in the FY 2022 IPPS final rule,[3] we believe that the costs for a new technology for which the 3-year anniversary date of a product's entry onto the U.S. market occurs prior to the latter half of FY 2023 may not be fully reflected in the MedPAR data used to recalibrate the MS-DRG relative weights. Consistent with its policy for FY 2022, we recommend CMS use its authority under section 1886(d)(5)(I) of the Act to provide for a one-year extension of new technology add-on payments for FY 2023 for those technologies listed in table II.F-01 in the proposed rule. This policy would also be consistent with the Administration's framework for health equity for all patients needing NTAP-approved technologies, including for disadvantaged or underserved populations, the populations most impacted by COVID-19.

Proposal to Publicly Post NTAP Applications

Beginning with the FY 2024 application cycle, CMS proposes to post online the completed application forms and certain related materials it receives from NTAP applicants, as well as updated application information and additional clinical study information as it becomes available. CMS clarifies that with this proposal it would not post cost and volume information for either the traditional or alternative pathway applications as part of the materials that would be posted online. Nor would it post online any material that the applicant indicates is not releasable to the public because the applicant does not own the copyright or the applicant does not have the appropriate license to make the material available to the public.

AdvaMed supports this proposal because it would enhance transparency in the evaluation process for applications and facilitate input from other stakeholders and

[3] 86 FR 44976

would also streamline CMS's internal process for evaluating applications. We do, however, request that CMS make clear in the final rule, if it moves forward with its proposal, that it will retain a mechanism to enable applicants to submit proprietary or trade secret information that is not posted online, consistent with the Agency's current policy.

AdvaMed Recommendations for NTAP Process Improvements

A New NTAP Review Process

NTAP's analog for medical devices under the Hospital Outpatient Prospective Payment System (OPPS) is transitional pass-through payment (TPT) program. Unlike TPT, the NTAP statute is more prescriptive in requiring CMS to use the rulemaking process to approve a technology for NTAP. Under section 1886(d)(5)(K)(viii) of the Act, the Secretary must allow, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under Medicare Part A.

This provision of statute further requires the Secretary to make available a list of NTAP applicants, accept comments, recommendations, and data from the public on substantial clinical improvement, and provide for what we now know as the "New Technology Town Hall Meeting." CMS has traditionally used the IPPS proposed and final rule as the vehicle for approving NTAP applications. However, there is no requirement in statute that CMS use the annual IPPS proposed and final rules for this purpose.[4]

The lack of statutory prescription for OPPS TPT payments has allowed CMS to establish a quarterly process for evaluating TPT applications for pass-through payment. In recent years, CMS has also used the OPPS proposed and final rules to supplement the quarterly process to allow for transparency and give the public an opportunity to comment on CMS TPT decisions.

AdvaMed recognizes that CMS does not have the same flexibility for the NTAP process as it does for the TPT process. Nevertheless, AdvaMed does believe that CMS could provide more flexibility under the NTAP process than it does currently for NTAP applications that do not receive FDA approval by July 1 of a given year.

Under current regulations, if an applicant's product does not receive FDA approval by July 1, there is no opportunity for that product to receive NTAP until the subsequent fiscal year. Thus, if a product that would otherwise meet the requirements for NTAP does not receive FDA approval until shortly after July 1

[4] While section 1886(K)(i) of the Act specifically required that Secretary use the IPPS proposed and final rule published no later than April 1 and August 1 respectively of each fiscal year to "establish a mechanism to recognize the costs of new medical services and technologies," that provision of statute applies to the original NTAP regulation and not the evaluation of each NTAP application CMS receives annually.

(e.g., at any time in July or August), the product will be ineligible for NTAP payments until October of the following year and another NTAP application is required.

AdvaMed believes the July 1 deadline can be extended until September 1 to allow CMS to make a final determination on NTAP applications where FDA approval is not received until after July 1 but sometime in July or August up until September 1. While CMS would not use the IPPS final rule published by August 1 to make an NTAP determination on the applicant's new technology, it could supplement the IPPS final rule with an additional final rule or notice published sometime prior to the October 1 beginning of the fiscal year. CMS would respond to comments and make a final determination on the NTAP application in this supplemental final rule or notice. Alternatively, CMS could make a provisional recommendation in the final rule, approval pending an FDA clearance/approval by August 31.

There is precedent for CMS supplementing final rules with additional information. CMS used the IPPS proposed rule published on May 4, 2001 (66 FR 22646) to propose the original NTAP regulations. While CMS finalized the IPPS rule on August 1, 2001 (66 FR 39828), it did not publish the original NTAP final rule until September 7, 2001 (66 FR 46902).[5] Similarly for FY 2007, CMS published the original IPPS final rule on August 18, 2006 (although the actual rule was place on public display on August 1, 2006) but published a 159-page supplemental notice with IPPS rates, wage indices, reclassification determinations and occupational mix adjustments on October 11, 2006. This supplemental notice was a consequence of adverse litigation against CMS that required a new occupational mix data collection that could not be completed timely to be included in the IPPS final rule released for public display on August 1, 2006. In addition to these examples, CMS annually publishes an IPPS rule correction notice after the final rule (sometimes after the October 1 start of the fiscal year that it makes retroactive to October 1).

Given the above examples, we do not believe there are statutory impediments to CMS adopting AdvaMed's request to allow up to September 1 of each year for FDA approvals of new technologies in order to begin making NTAP payments on October 1 of the immediate subsequent fiscal year. While CMS may believe a 60-day delay in the effective date is necessary under the Congressional Review Act, AdvaMed believes the likelihood of a supplemental IPPS final rule only for the few NTAP applications likely to be FDA approved in July or August is unlikely to reach the $100 million threshold for the rule to be classified as a major rule requiring the 60-day delay in the effective date.

[5] Arguably, this publication schedule was not consistent with the section 1886(d)(5)(K) of the Act requirement to use the IPPS proposed rule required annually by April 1 and the IPPS final rule required annually by August 1 as the vehicle to establish the mechanism to recognize the costs of new technology. However, there was no harm from any procedural defects as CMS was incapable of receiving and acting on NTAP applications until the following year in 2002.

AdvaMed further believes that there would be good cause for waiving the 30-day delay in the effective date under the Administrative Procedures Act in order to allow NTAP approvals to be effective by October 1. Under current policy, the alternative to missing the July 1 deadline is an administrative burden on the NTAP applicant to submit the application a 2nd time the following year. There is further administrative burden on CMS to review the NTAP application for a 2nd time. Meanwhile, patients will have lost access for a whole year to innovative new technology that may later have been found to provide a substantial clinical improvement. There is also a lost year of payment data for receiving Medicare claims for the technology—data could have been received to better incorporate the technology's cost into the IPPS MS-DRGs.

Another option CMS could potentially consider would be to use the OPPS final rule as the vehicle to finalize any supplemental NTAP applications receiving FDA approval after July 1 up until September 1. In this circumstance, CMS could avoid having to administratively clear a 2nd freestanding final rule and would instead use the OPPS final rule as a vehicle for obtaining administrative clearance simultaneously of the NTAP supplemental final rule. The NTAP supplemental final rule could be separate and apart from the OPPS final rule but obtain administrative clearance at the same time. This option would provide CMS with more time to address public comments on substantial clinical improvement as well as not having to duplicate an administrative clearance process for a freestanding final rule. However, the good cause waiver would have to allow for retroactive application of the NTAP decision to October or, alternatively, have prospective effect on the IPPS necessitating a quarterly IPPS change to start NTAP payments.

Conditional Approval for NTAP Alternative Pathway Applications

Under the alternative pathway for NTAP, an FDA-approved breakthrough technology is considered new and not substantially similar to an existing technology and does not need to demonstrate a substantial clinical improvement over existing technology. Applications for new technology add-on payments must have FDA market authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. AdvaMed has supported CMS's conditional NTAP approval alternative pathway for add-on payments for certain antimicrobial products that do not receive FDA approval by July 1. These products receive conditional approval for NTAP pending FDA approval to market the product if FDA occurs after the July 1 deadline.

AdvaMed believes this conditional approval pathway should be extended to all other breakthrough technologies that fill critical needs for the Medicare beneficiaries, beyond antimicrobial products. These other innovative breakthrough technologies should not have to wait almost a full year to re-apply for NTAP because they fail to obtain FDA approval by the current July 1 deadline. This year-long delay impacts beneficiary access to breakthrough technologies that the FDA has determined meet

a unique and critical need for patient care and creates additional burden associated with the submission of another NTAP alternative pathway application.

Increasing the Payment Level for Approved NTAPs

AdvaMed appreciates CMS's decision to increase the add-on payments for approved NTAPs to 65 percent of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology. However, we believe that the add-on payment level for approved NTAPs should be increased to 80 percent. An analysis by Avalere Health LLC found that despite receiving $40.5 million in NTAP payments between FY 2006 and FY 2013, hospitals also received $23.2 million in outlier payments on these same cases. The fact that so many NTAP cases also qualify for outlier payments highlights how inadequate the NTAP payment is to achieve the program's objectives and for this reason, we believe that 80 percent of the difference is the more appropriate level for add-on payments. We believe that this higher level would mitigate these losses, further encourage adoption of new technologies, and continue to provide incentives for hospitals to act as prudent purchasers.

Hospital Market Basket Update

For FY 2023, CMS proposes a market basket update of 3.1%, less a productivity adjustment of 0.4 percentage points, plus a documentation and coding adjustment of 0.5 percentage points, resulting in an update of 3.2%. This update, as well as the FY 2022 payment update of 2.7%, are simply inadequate for reflecting the impact of current inflationary trends have on costs that hospitals are incurring now and are expected to continue to incur through FY 2023. Because the market basket is a time-lagged estimate using historical data to forecast into the future, it is not a good predictor of future costs when the inflation rate is at a 40-year high. Because this high rate of inflation is not projected to abate in the near term, and inflationary pressures are also likely to continue to work their way into wage expectations, it is critical to account for these challenges when considering hospital and health system financial stability in FY 2023 and beyond.

We ask that CMS take into account some portion of current inflationary trends by: (1) implementing a retrospective adjustment for FY 2023 to account for the difference between the market basket update that was implemented for FY 2022 and what the market basket is currently projected to be for FY 2022; and (2) eliminate the productivity cut for FY 2023.

CMS Quality Programs

Hospital Value-Based Purchasing (VBP) Program

CMS is proposing to adopt a special scoring rule for the Hospital VBP Program for FY 2023 wherein funds withheld from hospitals for that fiscal year (as required by statute) would be returned to hospitals as value-based incentive payments in

amounts that match their withholds, yielding a new Hospital VBP Program percentage payment adjustment of zero. AdvaMed supports this proposal.

Hospital Acquired Condition (HAC) Reduction Program

CMS is proposing to suppress all six HAC Reduction Program measures for the FY 2023 program year and not calculate measure scores, Total HAC Scores, or assign payment penalties for this program year. AdvaMed supports this proposal.

Hospital Inpatient Quality Reporting (IQR) Program

Proposed Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e)

AdvaMed supports CMS' proposed Hospital IQR Program measure "Hospital-Harm – Opioid-Related Adverse Events" for FY 2024. There are multiple current published reports of inpatient opioid-related adverse events that compromise patient safety, many of which CMS cited in its overview of the measure. There are also routinely available cost-effective and convenient patient monitoring technologies through which signals of adverse events can be detected and acted upon to reduce potentially avoidable adverse events. This measure has undergone extensive testing and validation. Therefore, incorporation of this measure into the Hospital IQR Program on behalf of patient safety is timely, appropriate, and endorsed by AdvaMed.

Proposed Global Malnutrition Composite Score eCQM (NQF #3592e)

AdvaMed commends CMS for proposing the Global Malnutrition Composite Score in the 2023 Hospital IQR and requests that CMS finalize inclusion of this measure as proposed. The clinical and economic burden of malnutrition in hospitalized patients is well established, and early identification of hospitalized Medicare beneficiaries (both acute and long-term care) with or at risk for malnutrition remains a key gap area for quality improvement.

Prompt nutrition intervention and implementation of an effective care transition plan in malnourished patients are critical to improve patient safety and outcomes through reduction in complications such as infections, falls, and pressure ulcers. Addressing malnutrition through hospital quality measure reporting also provides an effective path toward improved clinical and economic outcomes in at-risk patients and provides a unique opportunity for CMS in its efforts to address health equity across populations and care settings. In recognition of the importance of proactively diagnosing and treating malnutrition, particularly within vulnerable populations, we further urge CMS to make reporting of this eCQM mandatory beginning with the CY 2024 reporting period/FY 2026 payment determination.

Proposed Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559)

CMS is proposing to adopt an eCQM Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PROM) following elective primary THA and/or TKA (THA/TKA PROM) for the Hospital IQR Program. CMS is proposing two voluntary reporting periods in CYs 2025 and 2026, followed by a mandatory reporting beginning July 1, 2025, which would impact payment beginning in FY 2028. The proposed THA/TKA PROM is based on a measure developed for and used in the Comprehensive Care for Joint Replacement (CJR) model beginning in 2015, which AdvaMed has supported and advocated for in that model.

AdvaMed strongly supports adoption of this proposed quality measure; however, we urge CMS to refine the measure's specifications to better capture patient-reported outcomes.

Additional Risk Variables. We believe that PROMs need to incorporate additional risk variables such as social determinants of health, body mass index, and smoking. It is only by incorporating risk variables such as these that PROMs will be able to accurately measure the outcomes reported by patients.

Functional Improvement Thresholds. CMS proposes that the measure outcome defines patient improvement as a binary outcome (yes/no) of meeting or exceeding an substantial clinical benefit between preoperative and postoperative assessments on the joint-specific PROMs as follows:

- For THA patients: meeting or exceeding the SCB threshold of 22 points on the HOOS, JR.
- For TKA patients: meeting or exceeding the SCB threshold of 20 points on the KOOS, JR.

While we are generally supportive of the proposed measure scores, we request that over the voluntary reporting period of the PRO-PM, CMS continues to assess the validity of the threshold by conducting analysis of available data to also assess alternative measure score calculation methodologies, such as average or median improvement scores. The purpose of this assessment is to ensure that the system is set up to achieve continued improvement for patient reported outcome and that the providers demonstrating varied outcomes can be sufficiently differentiated.

Post-Operative Timing of Outcomes Data Collection. While we recognize the importance of collecting PROM data for a longer timeframe than other Medicare total joint arthroplasty (TJA) quality measures tracking adverse events (TJA complications and readmissions), we are also concerned about the burden the longer timeframe for PROMs will have on physician practices. In the end, it is the physician practice that will be responsible for collecting and reporting PROM data following patients' discharge from the hospital. Many practices today are not prepared to collect this data over an extended period. We are especially concerned about this burden for small and rural practices. We have several recommendations for addressing these concerns.

For the proposed THA/TKA PROM, we suggest CMS use a shorter timeframe of 3 to 6 months for the data collection period, because this timing better aligns with most of the pain reduction and mobility gains experienced by patients. Capturing these scores 3 months post-discharge is already commonly performed and would not entail new data collection burdens. In addition, even when recovery takes longer, most patients show functional improvements on HOOS JR and KOOS JR scores of more than 20 and 22 points at one year. The two 2016 articles by Lyman et al. cited by CMS in the proposed rule shows that average two-year increases in scores were 40 for hips and 32 for knees. We do not expect the increases would vary all that much at the one-year mark, suggesting the proposed functional improvement thresholds are too low.

For tracking patient outcomes beyond the 3 to 6 months, we believe a more effective measure could use Medicare claims data to capture TJA revision and mortality rates at one year. This alternative would yield different but complementary data on performance and would have the benefit of relieving physicians of the burden of collecting data directly from patients.

Another alternative for relieving physician practices of the burden of collecting PROM data would be to create a pathway for reporting through registries, specifically the American Academy of Orthopaedic Surgeons' American Joint Replacement Registry, which has been incorporating PROs into its reporting on TKA/THA.

Finally, we recommend that CMS consider providing technical assistance to physician practices to help them with PROMs data reporting.

In summary, AdvaMed strongly supports the proposed THA/TKA PROM, but requests CMS: (1) incorporate additional risk adjustment variables (e.g., social determinants of health, body mass index, and smoking status) into the measure specifications to more accurately measure outcomes reported by patients; (2) shorten the period between pre-op and post-op measurement of functional improvement to 3 to 6 months; and (3) over the voluntary reporting period of the PRO-PM, CMS continues to assess the validity of the threshold by conducting analysis of available data to also assess alternative measure score calculation methodologies, such as average or median improvement scores. We also call upon CMS to make this hospital-level measure data publicly available as soon as possible on Hospital Compare or other comparable site so that patients can make informed decisions with their physicians about the settings that will offer the best outcomes following elective THA and TKA.

Proposed Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (THA/TKA Complication Measure) (NQF #1550) Beginning with FY 2024 Payment Determination

CMS is proposing the addition of a refined version of the claims-based THA/TKA Complication Measure to the Hospital IQR Program measure set beginning with the FY 2024 payment determination. The prior, original version was removed from the Program beginning during FY 2018 IPPS rulemaking after routine triennial measure maintenance review as part of a CMS initiative to reduce provider burden. When removed from the Hospital IQR Program, the original version was not simultaneously removed from the Hospital Value-Based Purchasing (VBP) Program measure set, where it had been adopted previously into the Clinical Outcomes domain.

The Agency lays out a plan to propose replacement of the original measure in the Hospital VBP Program measure set with the refined measure in the future, once the statutory requirement for use and public reporting of the refined measure as part of the Hospital IQR Program are met.

AdvaMed agrees with CMS that it is critically important to assess the quality of care provided to Medicare beneficiaries for THA and TKA, especially given the current and projected numbers of these procedures being done and the impact complications can have on beneficiaries' lives as well as on program spending. Measuring and reporting risk-standardized complication rates will guide providers in identifying problems and improving care outcomes and will inform patients' decisions about where to seek care.

We are concerned, however, about the absence of discussion in the proposed rule of the need to incorporate social risk factors into the complication rate measures. Doing so is essential for the measures to accurately capture quality of care and patient outcomes for THA and TKA. We request that CMS incorporate social risk factors into the measures as the Agency moves forward with implementation of complications rate measures into the Hospital IQR Program. We also recommend that the social risk factors included in the complication rate risk adjustment be consistent across other measures, such as PROMs (discussed above) and the complication rate measure already in the Hospital VBP Program.

Proposed Establishment of a Publicly-Reported Hospital Designation to Capture the Quality and Safety of Maternity Care

CMS introduced the Maternal Morbidity Structural measure in FY 2022. The Agency is now proposing to grant a special designation to hospitals answering "Yes" to structural measure questions, which identify facilities as participating in perinatal collaboratives and in implementing patient safety practices. This designation would be put on a public-facing CMS website in recognition of hospitals' demonstrated commitment to improving maternal health. AdvaMed supports this initiative by CMS to empower patients and the broader public to make informed decisions about the quality of maternity care provided at a hospital through available comparative data on overall maternal mortality rates, morbidity rates, and health outcomes.

Implementation of this policy represents a positive step in promoting and advancing the Agency's health equity strategic pillar and has the potential to facilitate improvements in the maternal health disparities experienced by far too many women in the United States. As currently drafted, the proposal does not impose any additional requirements on facilities but will hopefully lay the groundwork for more facilities to examine the care they provide to patients receiving maternity care and to acquire this designation in the future.

As CMS proposes more robust criteria for this designation over time, AdvaMed encourages the Agency to use this data to inform the development of strategies, resources, and tools to improve maternity care. CMS should also continue building upon the information available to patients as they evaluate and make choices about their maternity care. Additionally, as CMS works to implement policies aimed at improving the outcomes of women seeking maternity care, we encourage the Agency to continue stakeholder outreach and engagement to gain their perspectives on the value of reporting the structural measures, lessons learned, data shortcomings, and additional data that will enhance patients' decision-making about where to find the highest quality of care in their communities.

Condition of Participation (CoP) Requirements for Hospitals and CAHs to Report Data Elements to Address Any Future Pandemics and Epidemics as Determined by the Secretary

CMS is proposing to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs Conditions of Participation (CoPs) to extend the current COVID-19 reporting requirements and to establish new reporting requirements for any future PHEs related to a specific infectious disease or pathogen. In establishing these electronic reporting requirements for COVID-19 PHE and future PHEs, CMS is proposing to require hospitals and CAHs to report "suspected and confirmed" infections among patients and staff on a daily basis, or other reporting frequency as dictated by the state of the relevant PHE and ongoing risks.

We are concerned mandating daily reporting of both suspected and confirmed infections during a PHE will increase burden and strain resource allocation on hospitals working to ensure patient health and safety. In addition, we believe developing an enforcement mechanism for this reporting is inconsistent with CMS' experience throughout the ongoing COVID-19 PHE, where the majority of hospitals voluntarily reported critical PHE-related data to the Agency. As demonstrated throughout the COVID-19 PHE, proactive testing and early identification of positive cases is critical to minimizing spread. By collaboratively developing processes and infrastructure to support streamlined voluntary reporting, we believe CMS can accomplish its public health goals more effectively than with a mandate. We urge CMS to take these concerns into consideration before finalizing these changes to the CoPs.

Continued Financial Relief for Providers and Beneficiaries

AdvaMed supports continued financial relief for providers to address the ongoing impact of COVID-19. In addition to supporting the extension of NTAP for certain innovative technologies and suspension of payment penalties under the Hospital VBP and HAC Reduction Programs, AdvaMed supports a moratorium or further delay of Medicare sequestration cuts, which are scheduled to return in full on July 1. While we recognize this issue is largely within Congressional control, we urge CMS to advocate on behalf of all Medicare participants—providers and beneficiaries—to avoid additional financial hardship and the downstream issues that follow. We encourage CMS to offer (or pursue) this financial relief through the end of the fiscal year in which the PHE ends.

We appreciate this opportunity to comment on the proposed rule. If you have any questions, please contact Richard Price (rprice@advamed.org) and Kirsten Tullia (ktullia@advamed.org).

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy