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Carol Blackford
Director, Hospital and Ambulatory Policy Group

Jason Bennett
Director, Technology, Coding, and Pricing Group

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

Re: Comments in Advance of Fiscal Year (FY) 2023 Hospital Inpatient Prospective Payment System (IPPS) Notice of Proposed Rulemaking (NPRM)

Dear Ms. Blackford and Mr. Bennett,

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 FY 2023 Hospital Inpatient Prospective Payment System (IPPS) 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:

- Changing MS-DRG Assignments in the FY 2022 IPPS Final Rule Without Prior Proposals in Notice of Proposed Rulemaking
- Quality Measures
    - Global Malnutrition Composite Score
    - Hospital Harm Electronic Medical Record-Based Quality Measure for Pressure Injuries
- New Technology Add-On Payment Program

Changing MS-DRG Assignments in the FY 2022 IPPS Final Rule Without Prior Proposals in Notice of Proposed Rulemaking

Ensuring Alignment of Administrative Principles and Practices

As we brought to your attention in prior correspondence of August 18, 2021, in the FY 2022 IPPS Final Rule, CMS reassigned ICD-10 PCS codes D0Y0KZZ (LITT, Brain) and D0Y1KZZ (LITT, Brain Stem) from MS-DRGs 023, 024, 025, 026, 027 to MS-DRGs 040, 041, 042, without having proposed this change or providing a public comment opportunity. AdvaMed disagrees with the change in MS-DRG assignment made by CMS in the FY 2022 IPPS final rule, and we are even more concerned that CMS adopted this change without following the legal requirements of notice and comment rulemaking.[1] CMS's final rule policy was neither proposed nor adopted as a logical outgrowth of a public comment on a CMS proposal.[2] For this reason, consistent with section 1871(a)(4) of the Act, AdvaMed requests that CMS withdraw the reassignment of ICD-10 PCS codes D0Y0KZZ (LITT, Brain) and D0Y1KZZ (LITT, Brain Stem) from MS-DRGs 023, 024, 025, 026, 027 to MS-DRGs 040, 041, 042 effective for October 1, 2021.

The issues this final rule raises are technology/company/procedure agnostic and, as one would expect, we are concerned about the precedent this action sets for future rulemaking. AdvaMed is disappointed that we never heard from CMS as to why the Agency believes it did not need to follow the Administrative Procedures Act in reassigning codes in the final rule without opportunity for stakeholders to comment,

[1] Specifically, CMS's final rule decision is inconsistent with section 1871(a)(2) of the Social Security Act (the Act) that "no rule, requirement or other statement of policy…that establishes or changes a substantive legal standard governing…payment for services…shall take effect unless it is promulgated by the Secretary by regulation [notice and comment rulemaking]." Under section 1871(a)(4) of the Act, "if the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking…such provision shall be treated as a proposed regulation and…not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation."

[2] While CMS discussed other LITT procedures and MS-DRG assignments, the intracranial reassignments were not a logical outgrowth of the proposed rule because there was no way to divine from the proposed rule's LITT discussion that CMS was considering reassigning the LITT brain procedures.

and why it does not believe that it needs to issue a correction notice for the change included in the final rule.

The purpose of notice and comment rulemaking is to provide the public an opportunity to meaningfully review and provide comment on substantive policy changes under Agency consideration prior to their implementation. This is particularly critical in cases affecting Medicare payment, where a policy change may affect providers' ability to continue providing a service and, by extension, patients' access to that service. We therefore urge the Agency to ensure all substantive policy changes pertaining to the Medicare payment systems undergo this process moving forward.

Reversing MS-DRG Assignment of Select ICD-10-PCS Codes

As stated above, CMS's final rule policy was neither proposed nor adopted as a logical outgrowth of a public comment on a CMS proposal. While CMS discussed other LITT procedures and MS-DRG assignments, the intracranial reassignments were not a logical outgrowth of the proposed rule because there was no way to divine from the proposed rule's LITT discussion that CMS was considering reassigning the LITT brain procedures. For this reason, consistent with section 1871(a)(4) of the Act, AdvaMed requests that CMS withdraw the reassignment of ICD-10 PCS codes D0Y0KZZ (LITT, Brain) and D0Y1KZZ (LITT, Brain Stem) from MS-DRGs 023, 024, 025, 026, 027 to MS-DRGs 040, 041, 042 effective for October 1, 2021.

As a procedural matter, we recognize that CMS could properly pursue the change that was adopted in the FY 2022 IPPS final rule through notice and comment rulemaking in the FY 2023 IPPS proposed rule. However, before doing so, we urge CMS to take into account clinical and cost considerations related to the assignment of ICD-10-PCS codes D0Y0KZZ and D0Y1KZZ to MS-DRGs 023, 024, 025, 026, and 027.

With respect to cost, the costs of these cases are much more clearly aligned to MS-DRGs 025-027 than to MS-DRGs 040-042 based on a review of the most recent claims and cost report data used for rate setting. Specifically, in the FY 2019 Final MedPAR dataset, 159 cases involving LITT procedures of the brain and brain stem were identified that were assigned to MS-DRGs 025-027, with fewer than 11 assigned to MS-DRG 023, and none assigned to MS-DRG 024. Using the FY 2019 Final MedPAR, the FY 2020 Proposed MedPAR, and the FY 2021 and FY 2022 Final IPPS Impact Files, we found that the mean cost of cases involving the procedures described by D0Y0KZZ and D0Y1KZZ assigned to MS-DRG 025 in FY 2019 was $47,304, which is within $1,200 of the overall mean cost of MS-DRG 025 of $48,482. In contrast, the overall mean cost of MS-DRG 040 is over $5,000 less, at $42,256. While the cost of LITT procedures of the brain and brain stem assigned to MS-DRGs 026 and 027 exceeded the overall mean costs of those MS-DRGs by over $7,000 and $3,500, respectively, the magnitude of the difference is much less than

the difference when comparing those cases to the overall mean costs of MS-DRGs 041 and 042 ($14,493 and $9,547, respectively). These data clearly show that while the LITT procedures of the brain and brain stem assigned to MS-DRGs 026 and 027 in FY 2019 were more costly on average than other cases assigned to those MS-DRGs, they were significantly more costly than the other procedures assigned to MS-DRGs 041 and 042.

As stated previously, the intracranial LITT procedures are most similar to the procedures assigned to the craniotomy MS-DRGs 023 - 027. Like LITT, the cases assigned to those MS-DRGs involve intracranial procedures and include procedures to treat patients with brain cancer and epilepsy. In the FY 2022 final rule, CMS stated that "The technique to perform the LITT procedure on these structures is considered minimally invasive and does not involve a craniotomy, therefore, continued assignment to the craniotomy MS–DRGs is not clinically appropriate." From a clinical standpoint, we note that although minimally invasive, LITT procedures of the brain and brain stem involve a twist drill or burr hole through the skull to access the precise location that has been determined using planning software. These procedures are very similar to other non-craniotomy procedures assigned to MS-DRGs 025-027 and are therefore better aligned within these MS-DRGs. LITT is a complex surgical procedure performed by a neurosurgeon in an operating room and is more clinically similar to craniotomies than it is to the procedures in MS-DRGs 040 - 042.

Finally, LITT and craniotomy are in fact very clinically similar; both procedures are intended to remove and destroy the targeted tumor and/or lesion with a different surgical tool used (scalpel vs heated ablation probe). As described above, the brain LITT procedures involve insertion of laser probes into the brain which requires opening both the skull and dura, similar to a craniotomy. Craniotomy and LITT share several procedural characteristics. Both craniotomy and LITT:

- Require an operating room;
- Performed under general anesthesia;
- Require creation of burr holes and invasive skull fixation;
- Require a sterile field, incision, opening of the skull and dura;
- Cause tissue to be immediately destroyed or excised;
- Carry a risk of immediate intracranial bleeding;
- Require closure of the scalp wound;
- Risk intracranial infection; and
- Require a hospital stay of one or more nights.

In conclusion, we respectfully request that CMS reverse the reassignment of ICD-10-PCS codes D0Y0KZZ and D0Y1KZZ to MS-DRGs 040-042 (Peripheral, Cranial Nerve, and Other Nervous System Procedures) that took place in the FY 2022 IPPS final rule, and instead restore the MS-DRG assignments that were in place in FY 2021 (MS-DRGs 023, 024, 025, 026, and 027).

Quality Measures

Adopting the Global Malnutrition Composite Score

AdvaMed continues to urge the Agency to prioritize inclusion of the Global Malnutrition Composite Score as soon as feasible in the Hospital Inpatient Quality Reporting (IQR) Program, as well as for future consideration in the Long-Term Care Hospital and Skilled Nursing Facility Quality Reporting Programs. 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. Malnutrition is also linked to food insecurity, an important social determinant of health affecting many communities and older adults. Addressing malnutrition through hospital quality measure reporting can provide an effective path toward improved clinical and economic outcomes and can be a key component for ensuring health equity in at-risk patients.

Adopting the Hospital Harm – Pressure Injury Electronic Medical Record-Based Quality Measure

While CMS did not propose this measure in the FY 2022 IPPS Proposed Rule, we understand the Agency is continuing to validate this measure and may include this measure in upcoming IPPS rulemaking. We support CMS' consideration of this measure and ask that the Agency implement this measure at the earliest available opportunity. Multiple studies have shown that adherence to evidence-based protocols and use of various pressure injury prevention technologies can significantly reduce the risk of these hospital-acquired conditions (HAC). More tracking of this key HAC adverse event will better organize hospital care around those practices that can lower the frequency of these debilitating wounds.

New Technology Add-On Payment (NTAP) Program

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

In the FY 2022 IPPS Final Rule, CMS used its authority under section 1886(d)(5)(I) of the Act to provide a one-year extension for new technology add-on payments for technologies approved for FY 2021 that would be discontinued beginning FY 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 NTAPs during a time when many elective procedures in many parts of the country have been canceled and/or postponed. 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 new technology add-on payments that otherwise would be discontinued beginning with FY 2022. Our companies with technologies approved for NTAPs have continued to observe low volume of procedures with NTAPs during the resurgence of COVID-19 and we argue that another extension is required to allow time to collect claims and cost data that align more closely with typical patterns of care.

AdvaMed also notes that with the PHE very likely to continue at least through the end of FY 2022, and many hospitals' admissions still impacted by the PHE, CMS will need to extend NTAP payments beyond the one-year proposed in the FY 2022 IPPS Final Rule. We also recommend that CMS not extend NTAP payments for technologies that have received add-on payments for three or more years prior to the beginning of the PHE.

Implementing a New NTAP Review Process

NTAP's analog for medical devices under the Outpatient Prospective Payment System (OPPS) is the 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.[3]

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

[3] 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.

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 now for NTAP applications that do not receive FDA approval by July 1.

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 second 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 (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 a 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).[4] 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

[4] 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.

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.

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 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 be 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.

Providing Conditional Approval for NTAP Alternative Pathway Applications

Under the alternative pathway for NTAP, an FDA-approved breakthrough technology will be 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.

Addressing Technologies Using Software as a Medical Device

AdvaMed is very pleased to see CMS's approval of NTAP applications for technologies that use software as a medical device (SaMD), and specifically those using artificial or augmented intelligence (AI). The field of digital health has opened new frontiers in care delivery and health management and innovation is occurring at a rapid pace. By digital technologies, we refer to apps, algorithms, AI, and software as a medical device that facilitate the electronic or mobile collection and analysis of data used to inform health care decision-making or behaviors and to support the provision of care on a remote basis.

We also believe that updating Medicare's coverage pathways is necessary to accommodate advances in health care delivery through the application of digital health technologies and argue that this can be accomplished through changes to benefit category regulations rather than through the creation of new benefit categories in Medicare statute. CMS's approval of NTAP applications using SaMD

shows that Medicare can accommodate new digital technologies so long as the program takes a broad view of how that can be done.

We have two recommendations with regard to the Agency's recognition of NTAP applications with AI and SaMD components. First, we ask that CMS appropriately take into account, as it evaluates an application meeting NTAP's cost criterion, the costs of utilizing and maintaining AI and SaMD used in a technology diagnosing or treating specific conditions. We recognize that the variety of different AI and software algorithmic technologies used in health care delivery, with their different designs and intended uses, makes it difficult to generalize about their costs. However, it is critical that CMS appropriately assess individual technologies with AI and SaMD for the costs these digital components add to a technology and their associated services. We note that many AI- and software algorithmic-powered technologies provide analysis that otherwise could not be practically performed by a human expert due to cost, time, and fatigue considerations. In addition, the cost of maintaining and improving software is a complex and continuous enterprise and may require constant revision as providers use and apply the technologies in patient care. It is critical that CMS recognize the costs of AI and SaMD in NTAP technologies if patients are to continue to see the benefits of their incorporation into health care delivery.

Our second recommendation with regard to NTAP and technologies with AI and SaMD components pertains to follow-on products coming on the market after an approved NTAP application. The NTAP program does allow FDA-approved/cleared follow-on products under certain circumstances to qualify for add-on payments, following approval of an application. We believe that CMS intends for an FDA-approved/cleared follow-on product to receive NTAP only if the follow-on product's mechanism of action is substantially similar to an approved applicant's mechanism of action, but CMS has not addressed what manufacturers of follow-on technologies with digital components, such as AI, are required to do to ensure they qualify. Given the fact that the development lifecycle for SaMD is much shorter than that for other medical devices, we recommend that CMS establish an expedited process for assessing similarity for FDA-approved/cleared follow-on technologies with SaMD, where manufacturers, who want to avail themselves of the approved NTAP for their follow-on product, would submit a request to CMS for assessment. CMS would be required to issue preliminary determinations subject to public comment within specified, relatively short timeframes, and CMS would then issue a final determination within another short period of time after the public comment period closes. This final determination would provide guidance to hospitals and health systems on how to determine what software is applicable to the issued ICD-10-PCS.

We appreciate this opportunity to share our recommendations for your consideration in preparation for the FY 2023 IPPS 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 & Health Care Delivery Policy