MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

1333 H Street, NW
Suite 400W
Washington, DC 20005
Phone (202) 354-7171
Fax (202) 354-7176

June 9, 2023

Via Electronic Submission

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1785–P
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician- Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership [CMS-1785-P]

Dear Administrator Brooks-LaSure,

The Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, is submitting this letter in response to the proposed rule from the Centers for Medicare and Medicaid Services (CMS) setting forth proposed changes to the Medicare hospital inpatient prospective payment system (IPPS) and related policies for fiscal year (FY) 2024 (the "Proposed Rule").[1]

For nearly 30 years, MDMA has represented the medical device industry in Washington, DC, supporting policies that promote medical innovation and patient access to lifesaving and life-changing medical technologies. MDMA's membership is broad and diverse, ranging from small start-ups to multi-national medical device companies. It is a long and risky venture to develop novel medical innovations, and those that succeed have changed the face of medicine and redefined what is possible in the diagnosis and treatment of deadly diseases and prevalent conditions like cancer, heart disease, diabetes, and stroke.

We appreciate this opportunity to comment on the Proposed Rule. MDMA shares with CMS the goals of improving the accuracy of payment rates and providing hospitals with incentives to provide high quality care efficiently. We want to work with CMS and our member companies to

[1] 88 Fed. Reg. 26,658 (May 1, 2023).

ensure that these goals are met while protecting beneficiaries' access to lifesaving and life-enhancing technologies. Medicare's payment rates and bundles must accurately reflect the costs of providing appropriate care in order to ensure that hospitals can provide beneficiaries the best care available today and invest in the technologies that will allow care to continue to improve.

A. MDMA strongly opposes the proposed changes to the criteria and application process for New Technology Add-on Payment (NTAP), as they would undermine the clear purpose of the NTAP program and congressional intent—to quickly and effectively address payment disincentives that slow the adoption of new inpatient technologies that improve care and outcomes for beneficiaries.

The NTAP program represents a significant policy success for Medicare. As the only opportunity for incremental inpatient payment for qualifying new technologies and services, NTAP is critical to reducing payment disincentives for new technologies inherent in how the IPPS payment rates are otherwise established. Those disincentives create barriers to access for Medicare inpatients during the initial years after marketing authorization of a new medical device, drug, biologic or combination product by the U.S. Food and Drug Administration (FDA).

CMS is proposing two significant changes to the NTAP application and review process, which would be effective for the FY 2025 payment year application cycle and thereafter.[2] The first is that CMS will only accept NTAP applications for technologies that have not yet received FDA marketing authorization if they are "the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing of the request is provided to CMS" prior to the application deadline.[3] The second is a proposal to move the deadline for a technology to receive final FDA marketing authorization from July 1 to May 1—*i.e.,* from three months in advance of the start of NTAP payment to five months in advance.[4]

CMS states that these changes will "increase transparency, facilitate public input, and improve the review process,"[5] and suggests that they are necessary to manage "the increased complexity and volume of applications for new technology add-on payments."[6] However, **the changes will extend the period between market introduction and NTAP payment—*i.e.,* the period during which the payment disincentive that NTAP is designed to address remains in place—for some technologies *by a full year*, and also reduce the length of time that NTAP is in place for many technologies, *also by a full year*. Moreover, CMS has not demonstrated that the changes will actually produce any benefits in terms of transparency, public input, or the agency's ability to manage volume and complexity. For these reasons, we strongly oppose the proposed changes to section 412.87.**

It is not necessary to look far back into the history of the NTAP program to find an example of the additional delay in establishing adequate reimbursement for certain NTAP-eligible technologies that would result from the adoption of *either* of these proposed changes; in fact, one need only

[2] *Id.* at 26,961-26,963.
[3] *Id.* at 27,305 (proposed 42 C.F.R. § 412.87(e)(2)).
[4] *Id.* at 27,304 (proposed 42 C.F.R. § 412.87(f)(2)).
[5] *Id.* at 26,961.
[6] *Id.* at 26,962.

look to the FY 2023 IPPS rulemaking cycle. The iFuse Bedrock Granite® System ("Granite") was approved for NTAP beginning on October 1, 2022.[7] Had either proposed change been in place for the last NTAP application cycle, iFuse would have been denied NTAP payment for the FY 2023 IPPS payment year beginning October 1, 2022. NTAP payment for iFuse would not begin until October 2, 2023—more than 16 months after receiving FDA marketing authorization.

- The manufacturer of Granite applied for NTAP payment under the Alternative NTAP Pathway for Transformative New Devices on October 7, 2021, in anticipation of receiving breakthrough designation from FDA, which occurred on November 23, 2021. The manufacturer filed its marketing authorization request with the FDA on January 20, 2022, and the FDA notified the manufacturer on February 9, 2022, that the submission had been accepted for review. Had CMS required documentation of a "complete and active FDA marketing authorization request" at the time of NTAP application, the NTAP application for iFuse would have been rejected by CMS, and hospitals would not currently be receiving NTAP payment for this breakthrough technology—likely leading to barriers to access for Medicare beneficiaries.

- FDA granted marketing authorization for Granite on May 26, 2021, more than five weeks before the current July 1 deadline for an NTAP-eligible technology to qualify for NTAP at the start of the next IPPS payment year. Yet, had the proposed May 1 deadline been in place in 2022, iFuse would have been denied NTAP for the FY 2023 payment year and hospitals would not currently be receiving NTAP payment for this breakthrough technology—likely leading to barriers to access for Medicare beneficiaries.

Not only would the proposed changes have delayed NTAP for Granite for an entire year, it also would have reduced the effective NTAP period for the technology by one year. The NTAP regulation provides that a technology will be considered "new"—one of the criteria for NTAP eligibility—only for the period "within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration)."[8] In general, CMS uses the date of FDA marketing authorization as the "newness start date" to calculate the 2 to 3 year NTAP payment period. That means that while the NTAP start date for Granite would have been delayed until October 1, 2023, the NTAP eligibility period (and NTAP payment) for iFuse would still be scheduled to expire on September 30, 2025 (*i.e.,* at the end of the FY 2025 IPPS payment year.)

The iFuse Granite System is not an isolated example of the adverse impact of the proposed changes on the timing and duration of NTAP for certain eligible technologies, including many designated as breakthrough devices by the FDA. **The adoption of the proposed May 1 deadline for FDA**

[7] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and 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, 87 Fed. Reg. 48,780, 48,969-48,974 (Aug. 10, 2022).
[8] 42 C.F.R. § 412.87(b)(2).

marketing authorization will significantly increase the number of technologies that will experience a long delay between market introduction and the implementation of NTAP. Table II.P.-01 in the Proposed Rule identifies 11 technologies that CMS is proposing to continue for FY 2024.[9] If this proposed policy had been in place when these technologies applied for NTAP, seven of the 11 technologies (64%) would have had their NTAP start one year later, as each received FDA approval after the proposed May 1 deadline; and with no corresponding change to the "3-year Anniversary of Entry onto U.S. Market" date, all six of those technologies would have seen their expected NTAP period reduced from three years to two years.

The earlier deadline for FDA marketing authorization also would significantly reduce the number of technologies that will receive NTAP for the maximum allowable period. Each year, in order to determine whether to extend NTAP for an additional year for each technology currently receiving NTAP, CMS looks to whether the technology received FDA marketing authorization in the first or second half of the fiscal year—*i.e.,* before or after April 1.[10] Under that current policy, new NTAP-eligible technologies that receive FDA marketing authorization between April 1 and the current deadline of July 1 generally will receive that third year of NTAP payment. CMS has not proposed to make any modifications to its current approach for determining whether extension of NTAP for currently-eligible technologies is appropriate, which means that only technologies approved between April 1 and May 1 are likely to receive the full three years of NTAP.

MDMA has two additional concerns related to the proposed requirement that a "complete and active FDA marketing authorization request" has been submitted to FDA prior to the NTAP application deadline, as set forth in proposed section 412.87(e)(2). In the preamble to the Proposed Rule, CMS provides the following clarifying information regarding the requirement:

> We propose that, for the purposes of this policy, submission of a request for marketing authorization by the FDA would mean that the applicant has submitted a complete application to FDA, and that the application has an active status with FDA (such as not in a Hold status or having received a Complete Response Letter). An applicant must provide documentation of the market authorization request at the time of submission of its new technology add-on payment application to CMS. We believe that requiring an FDA acceptance or filing letter would provide the clearest and most effective means of documenting that the applicant has submitted a complete request to FDA and are therefore proposing to require this approach to documentation. Under this proposal, the applicant would also indicate on the new technology add-on payment application whether the FDA request has an active status with FDA.[11]

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[9] 88 Fed. Reg. at 26,783.

[10] *Id.* at 26,782 ("Our policy is that a medical service or technology may continue to be considered 'new' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. *In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year* (70 FR 47362)." (emphasis added)).

[11] 88 Fed. Reg. at 26,962.

Our first concern is that requiring an FDA acceptance or filing letter actually pushes the effective FDA submission deadline even earlier than the NTAP submission deadline. The most recent performance goals under the Medical Device User Fee Act state that FDA will communicate with the applicant regarding whether the application has been accepted for filing review within 15 calendar days of receipt of the application—and that is a goal, not a requirement.[12] To be assured of receiving documentation of FDA acceptance prior to the NTAP deadline, an applicant will likely need to have its FDA submission ready in August or September—further increasing the number of technologies that will enter the market prior to the start of an IPPS payment year, but which miss out on NTAP for that year due to arbitrary application deadlines. This is likely to be especially true for the FY 2025 payment year, given that applicants planning to apply for NTAP during the upcoming application cycle will have only one to two months to prepare and submit a complete FDA marketing submission. **MDMA urges CMS not to move forward with adoption of proposed section 412.87(e)(2) at this time; but if the agency chooses to do so, the deadline for an FDA marketing authorization request should be no earlier than March 1.** That date provides ample time for CMS to modify the annual IPPS proposed rule prior to publication, while avoiding the likelihood that a technology will be excluded from NTAP consideration as a result of the FDA submission deadline yet still receive FDA marketing authorization prior to July 1.

Our second concern relates to the second prong of the FDA submission requirement—that the applicant attest that "the FDA request has an active status with the FDA" at the time the NTAP application is submitted. The problem is that a marketing authorization request that has been accepted by the FDA can go through periods of active and inactive status as a normal part of the FDA review process. As described by the FDA,

> When a submission contains insufficient information and a reviewer identifies a need for additional information, the reviewer will either call the submitter (Interactive Review) or prepare a letter outlining the additional information needed (Additional Information (AI) Letter). These letters include both formal letters sent via U.S. mail as well as "telephone hold" memos and e-mails. ... *Once an AI Letter is sent, the submission to which the letter pertains is placed on "hold" and is not considered to be under active review while the reviewer is waiting for a response.* In other words, the clock stops during this time.[13]

In short, a prospective NTAP applicant who has already filed a "complete" FDA marketing authorization submission and who is preparing to submit an NTAP application immediately prior to the deadline could find itself suddenly unable to satisfy the attestation requirement simply because the FDA sends an inconveniently timed AI Letter. Under proposed section 412.87(e)(2), that NTAP application would be rejected and the opportunity to establish adequate reimbursement for the technology would be delayed for an entire year—an arbitrary result that runs completely counter to the policy objective of the NTAP program. **CMS should either eliminate the required attestation regarding the status of the applicant's FDA marketing authorization request, or**

[12] U.S. Food and Drug Administration, "MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027", 5, 8 (available at https://www.fda.gov/media/158308/download).
[13] U.S. Food and Drug Administration, "Medical Device Pre-Market Programs: An Overview of FDA Actions", 6 (October 19, 2011) (available at https://www.fda.gov/media/81797/download) (emphasis added).

it should clearly define what qualifies as an "active" submission in a manner that is relevant to the NTAP criteria and review process.

We appreciate the effort and resources that CMS has dedicated to the management of the NTAP program, and we also acknowledge the increase in NTAP applications and that they do seem to have become more complex for certain technologies. Yet it is worth noting the details associated with the increase in NTAP applications. Most importantly, as shown in the chart below, while the relative number of NTAP applications for medical devices compared to pharmaceutical products has remained fairly steady since the FY 2021 application cycle, far more pharmaceutical products currently go through the traditional pathway compared to the alternative pathway.

		Traditional Pathway	Alternative Pathway	% Reviewed Under Traditional Pathway
FY 2023	Devices	2	17	11%
	Drugs	16	3	84%
FY 2022	Devices	11	15	42%
	Drugs	15	3	83%
FY 2021	Devices	7	3	70%
	Drugs	5	6	45%

Review of an NTAP application under the traditional pathway involves more complexity and requires substantially more staff time and other agency resources than a review conducted under the alternative pathway; and in FY 2023 CMS has had to analyze 12 drug applications under the traditional pathway compared to only three device applications. **Given the severe impact of the proposed changes on the timeliness and duration of NTAP for medical devices and the likely smaller contribution of device applications to the volume and complexity challenges cited by CMS, the agency should consider whether different approaches for device and drug applications are feasible and appropriate before moving forward with any changes.**

We support reasonable steps to improve the efficiency and capacity of the NTAP application and review process. For example, after CMS adjusted its original proposal in response to comments from MDMA and other stakeholders, we have supported CMS in its decision to publicly post complete NTAP applications as a means of securing better public input on complex issues and improving the allocation of staff time spent on review activities. Given this is the first year of NTAP applications being made public, it would be helpful to better understand from CMS how much time savings occurred from the elimination of previous work, such as the preparation of detailed summaries of each application in the annual IPPS proposed rule.

We believe that a more comprehensive approach should be taken by CMS. **CMS should not implement the proposed changes for the upcoming NTAP application cycle and, instead, include a request for information in the Final Rule to solicit recommendations that will improve the capacity and efficiency of the NTAP program without unnecessary burdens on applicants or delay in NTAP payment for eligible technologies.**

There have been various suggested proposals made over several years to improve the NTAP process that CMS has not discussed in rulemaking sufficiently. Some of those proposals, if implemented, would have substantially reduced the adverse consequences of the new requirements that CMS is proposing. These include the following recommendations made by MDMA in comment letters on previous IPPS proposed rules:

- **CMS should establish a bi-annual NTAP application cycle, aligned with the timing of issuance of new International Classification of Diseases, 10th Revision (ICD-10) codes, to allow more timely approvals.** Increasing the frequency of application cycles for NTAP would allow products that receive FDA marketing approval after the July 1 deadline the opportunity to receive reimbursement clarity much sooner and spur adoption of new technologies.[14]

- **CMS should provide conditional NTAP approval for technologies approved under the Alternative NTAP Pathway for Transformative New Devices that do not receive FDA marketing approval by July 1.** In the FY 2021 final rule, CMS amended the NTAP regulation to allow conditional NTAP approval for certain antimicrobial products that have not been granted FDA marketing authorization by the July 1 deadline. To further promote timely beneficiary access to important new technologies, CMS should extend this conditional approval policy to FDA-designated breakthrough devices approved for NTAP under the alternative pathway.[15]

- **CMS should include more regular communication with NTAP applicants during the review process.** As CMS identifies questions about the data submitted and the analytical methods used, the agency should bring those questions to the applicant so that the applicant can work with the agency to resolve these concerns or clarify its analysis before the annual proposed rule is released. This would simplify CMS's review, potentially narrow or revise the questions raised in the proposed rule, and facilitate more meaningful public comments on whether a new technology satisfies the criteria for NTAPs.[16] This would best be accomplished by incorporating two-way communication functionality in the Medicare Electronic Application Request Information System™ (MEARIS™), which also would create benefits in other Medicare coding and payment processes beyond NTAP.

B. MDMA is concerned that the proposed market basket update for FY 2024 is insufficient in light of current economic conditions for hospitals and could reduce the amount of

[14] Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services (June 17, 2022), 6, https://www.regulations.gov/comment/CMS-2022-0074-1209; Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services (June 28, 2021), 8, https://www.regulations.gov/comment/CMS-2021-0070-5650; Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Seema Verma, Administrator, Centers for Medicare and Medicaid Services (July 10, 2020), 3, https://www.regulations.gov/comment/CMS-2020-0052-0337.

[15] Letter from Mark Leahey (June 28, 2021), *supra* note 14, at 8; Letter from Mark Leahey (July 10, 2020), *supra* note 14, at 3.

[16] Letter from Mark Leahey (July 10, 2020), *supra* note 14, at 4.

resources available for investment in new services and technologies that improve care and outcomes for Medicare beneficiaries and other patients.

CMS is proposing the following applicable percentage increases to the national standardized amount for inpatient hospital operating costs:

- 2.8 percent for hospitals that submit quality data and are meaningful electronic health record (EHR) users;
- 0.55 percent for hospitals that submit quality data but are not meaningful EHR users;
- 2.05 percent for hospitals that are meaningful EHR users but fail to submit quality data; and
- -0.2 percent for hospitals that both fail to submit quality data and are not meaningful EHR users.[17]

While the most severe impacts of the COVID-19 pandemic appear to be receding, America's hospitals continue to face unprecedented financial pressures, including those due to expense pressures from workforce shortages and general economy-wide inflation. Recent IPPS updates have not adequately accounted for those financial pressures, largely because the market basket is a time-lagged estimate that is based on historical data.

In its March 2023 report to Congress, MedPAC stated that overall Medicare hospital margins were negative 6.2% in 2021 after accounting for temporary COVID-19 relief funds. Without these funds, the overall Medicare margin for 2021 remained depressed at negative 8.3%. Moreover, MedPAC projects that

> hospitals' Medicare margins in 2023 will be lower than in 2021, driven in part by growth in hospitals' input costs, which exceeded the forecasts CMS used to set Medicare payment rate updates, and in part by the expected expiration of federal relief funds and temporary Medicare payment increases related to the public health emergency.[18]

On average, Medicare only pays 84 cents for every dollar hospitals spend providing care to Medicare beneficiaries. Moreover, overall median hospital operating margins were negative throughout 2022 and into the beginning of 2023. MedPAC projects that even for "relatively efficient" hospitals, Medicare margins will fall below break-even in 2023.[19]

It is essential that hospital margins both cover the costs of care *and* provide for adequate capitalization and investment so that hospitals can continue providing services needed by Medicare beneficiaries. MDMA urges CMS act within its administrative authority to support hospitals in this challenging period, including by using updated data (and potentially alternative data sources)

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[17] 88 Fed. Reg. at 27,0045-27,006

[18] Medicare Payment Advisory Commission (MedPAC). 2023. Report to Congress: Medicare Payment Policy, 56. Washington, DC: MedPAC. https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/.

[19] *Id.*

to determine whether a higher market basket and lower productivity adjustment for FY 2024 are warranted in the Final Rule.

C. CMS should delay the creation of new MS-DRG 173 (Ultrasound Accelerated Thrombolysis for Pulmonary Embolism), MS-DRG 278 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC) and MS-DRG 279 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures without MCC) while more data is collected.

In the Proposed Rule, CMS provided analyses regarding requests to reassign cases reporting ultrasound accelerated thrombolysis (USAT) of peripheral vascular structures procedures with the administration of thrombolytic(s) for deep venous thrombosis (DVT); and to reassign cases reporting USAT with the administration of thrombolytic(s) for the treatment of pulmonary embolism (PE). Based on the analyses, CMS proposed to create new MS-DRG 278 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC) and new MS-DRG 279 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures without MCC); and also proposed to create new base MS-DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism).[20] MDMA recommends that CMS not move forward with the implementation of either proposal at this time.

We are concerned that the inclusion of both conventional catheter-directed thrombolysis (CDT), also known as "standard infusion catheters", and USAT in the new MS-DRGs disregards fundamental clinical differences between the procedures. CDT generally relies on a multi-sidehole infusion catheter placed adjacent to the thrombus through which thrombolytics are delivered, typically over the course of 24 hours with the catheter in-dwelling, whereas USAT employs ultrasound to assist in thrombolysis, and the pulses of ultrasonic energy temporarily make the fibrin in the thrombus more porous and increase fluid flow within the thrombus. Standard CDT is the simple infusion of liquids into the vessel and should not map to the same root operation fragmentation codes as does USAT. CDT procedures are generally less complex clinically and consume significantly lower level of hospital resources as a result. We understand that an analysis of cost data being submitted to CMS shows that USAT DVT cases have total costs that are more than three times the cost of CDT, and that USAT procedures for PE cost more than CDT procedures for the sickest patients.

In addition, MDMA believes that it is premature to create new MS-DRGs for USAT for treatment of DVT and PE. The procedure volume data CMS relied on for the analyses are based on the recently implemented ICD-10-PCS data. Due to the lengthy processes for hospitals to adopt and accurately implement new coding, and the widely varying and conflicting coding advice available for utilization of the ICD-10-PCS for CDT and USAT, the number of cases is insufficient, most notably for the MCC thrombolysis cases. For example, we understand that CMS relied on data from just seven cases of CDT for PE. In short, the cases and related data selected by CMS for analysis cannot adequately compare the costs, complexity and utilization of USAT and CDT with a high confidence interval. CMS should reconsider the creation and potential composition of these new DRGs, re-evaluate at a later date when utilization volumes reach a threshold of significance, then propose for public display and comment in a future rule-making cycle.

[20] 88 Fed. Reg. at 26,684-26,691.

D. CMS should finalize the proposed creation of new MS-DRG 212 and also reassign cases involving a single open chest valve procedure (aortic or mitral) with a concomitant open surgical cardiac procedure to the new MS-DRG.

MDMA supports CMS's proposal to create new MS-DRG 212 (Concomitant Mitral and Aortic Valve Procedures) to recognize the incoherence of the current grouping of multiple open valve/chest procedures performed in one inpatient hospital visit.[21] As we have expressed in our two most recent IPPS comment letters,[22] hospital underpayment for concomitant open chest procedures makes it less likely that patients will have multiple clinical issues addressed during one open chest procedure and instead will require a subsequent admission for additional treatment, unnecessarily increasing Medicare expenditures and patient risk.

As written, the proposed MS-DRG 212 requires both an open mitral valve replacement (MVR) and aortic valve replacement (AVR) to be performed in addition to a third procedure for assignment to the proposed MS-DRG 212. This requirement severely limits the number of patients who could benefit from other concomitant open cardiac procedures, as a much larger percentage of patients undergo one open valve (open MVR or AVR) procedure with other non-valve cardiac procedures, such as open surgical ablation for atrial fibrillation (AF).

While the creation of MS-DRG 212 is a step in the right direction, we encourage CMS to allow grouping of a single open chest valve procedure (open AVR or MVR) performed with an open surgical procedure to MS-DRG 212 in the Final Rule. As an alternative, CMS could regroup open single valve (MVR or AVR) with open surgical ablation for AF into higher weighted MS-DRGs 216-218 with a DRG name change. We understand that medical society guidelines support the treatment of multiple clinical problems during one hospital visit, such as the addition of surgical ablation for atrial fibrillation, as patient mortality is significantly improved if AF is treated at the same time of other open-heart procedures. Delay in addressing the biggest patient segment with open valve replacement (MVR or AVR) and other concomitant procedures (*e.g.,* surgical ablation for AF) risks limiting lifesaving access to therapies for CMS beneficiaries.

E. CMS should finalize the proposed clarification of MS-DRG assignment for open procedures and external heart assist devices.

We continue to support CMS's efforts to ensure clinical coherence in the external heart assist category and support technical clarifications proposed by CMS in the Proposed Rule to align cases using the open surgical ICD-10 code with the MS-DRGs designed for open procedures,[23] as intended under existing coding nomenclature. This clarification ensures cases that would ordinarily map to these appropriate MS-DRGs are not misassigned.

Creating a new code to distinguish the surgical insertion with a graft or conduit for external heart assist will allow physicians, hospitals, and researchers to differentiate these cases. We agree with

[21] 88 Fed. Reg. at 26,691-26,695.
[22] Letter from Mark Leahey (June 17, 2022), *supra* note 14, at 3; Letter from Mark Leahey (June 28, 2021), *supra* note 14, at 3-4.
[23] 88 Fed. Reg. at 26,695-26,700.

CMS that the indications and clinical characteristics of these axillary and open external heart assist cases are similar and more closely aligned with MS-DRGs 001-002.

We appreciate CMS's continued efforts to ensure that surgical axillary and open procedures that are clinically homogenous are aligned and continue to be assigned within appropriate MS-DRGs matching their clinical coherence.

F. MDMA supports the creation of new MS-DRGs 323-325 to provide adequate reimbursement for Coronary Intravascular Lithotripsy following the expiration of NTAP.

As stated earlier, the NTAP program represents a significant policy success for Medicare that helps facilitate beneficiary access to new technologies in the hospital inpatient setting. We applaud CMS for evaluating the claims associated with intravascular lithotripsy (IVL) as its NTAP eligibility expires to determine the most appropriate MS-DRG assignment for FY 2024, including the proposal to create three new MS-DRGs.[24]

Proactively conducting an analysis of claims data collected during the NTAP period is a critical, final step in the NTAP process in order to provide appropriate MS-DRG assignment and rate setting that reflects the cost of the new technology. As part of that process, it is important for CMS to evaluate various options for providing adequate reimbursement, including potential MS-DRG reassignment, creation or revision. Based on the analysis presented in the preamble to the Proposed Rule, we agree with CMS's proposal to create these three new MS-DRGs for IVL.

We acknowledge concerns expressed by some of our members that the proposed MS-DRGs may not reflect the full range of treatment options for severely calcified coronary lesions. We encourage CMS to evaluate other technologies used in the treatment of severely calcified coronary lesions (such as atherectomy) for potential MS-DRG reassignment, based upon clinical coherence and consistency of hospital resource consumption.

Conclusion

MDMA appreciates this opportunity to comment on the FY 2024 IPPS proposed rule. As always, MDMA looks forward to working with the agency to improve access for Medicare beneficiaries to the best and most innovative technologies that our industry has to offer.

Sincerely,

Mark Leahey
President and CEO
Medical Device Manufacturers Association

[24] 88 Fed. Reg. at 26,706-26712.