MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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

October 5, 2020

Via Electronic Submission

Ms. Seema Verma Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 314-G
200 Independence Ave, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs: New Categories for Hospital Outpatient Department Prior Authorization Process: Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy: Overall Hospital Quality Star Rating Methodology: and Physician-Owned Hospitals (CMS-1736-P).

Dear Administrator Verma:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments to the proposed revisions under the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for calendar year (CY) 2021 (the "Proposed Rule").[1] MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

We understand that the Centers for Medicare and Medicaid Services' (CMS's) goals for its payment policies are to improve the accuracy of payment rates under the OPPS and provide hospitals with incentives to provide care efficiently. MDMA supports these goals, and we want to work with CMS and our member companies to ensure that these goals are met while protecting beneficiaries' access to life-saving 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.

In order to ensure that the OPPS continues to provide Medicare beneficiaries access to appropriate, innovative care, MDMA asks CMS to take the following actions:

[1] 85 Fed. Reg. 48772 (August 12, 2020).

I. CMS should assign Fractional Flow Reserve Derived from Computed Tomography (FFRct) to New Technology Ambulatory Payment Classification (APC) 1513
II. CMS should assign new code 9225X to APC 5734 or APC 5733 with status indicator S
III. CMS should approve the transitional pass-through payment application for SpineJack System
IV. CMS should approve the transitional pass-through payment application for Hemospray® Endoscopic Hemostat
V. CMS should finalize the transitional pass-through payment approval for EXALT Model D
VI. CMS should allow an extension of separate payment for devices with transitional pass-through status due to the Public Health Emergency
VII. CMS should review and adjust the APC device offset for 0424T
VIII. CMS should revise the process for determining and applying appropriate offset amounts for devices seeking and/or receiving transitional pass-through payment
IX. CMS should delay implementation of the elimination of the Inpatient Only (IPO) procedures list until the agency has had the opportunity to consult with appropriate specialty societies and stakeholders, carefully consider the impact of eliminating the Inpatient Only procedures list on beneficiary access and facility reimbursement, and better articulate its methodology for assigning previously IPO procedures to APCs in the outpatient hospital setting
X. CMS should not finalize the proposal to expand use of prior authorization for any service until it has studied the effects of the policy implemented on July 1, 2020, and it should not implement it for cervical fusion with disc removal procedures and implanted spinal neurostimulators
XI. CMS should ensure that the process for adding new procedures to ASC Covered Procedures List is transparent and deliberate
XII. CMS should provide additional guidance to physicians and beneficiaries if it adds Total Hip Arthroplasty to the ASC Covered Procedures List
XIII. CMS should restore the J8 ASC payment indicator for 0200T
XIV. CMS should require Medicare Administrative Contractors to publish a valuation methodology for transitional APC pass-through device payments in the ASC setting or recommend a uniform methodology to them
XV. CMS should outline a process and criteria for interested stakeholders to submit requests for inclusion in the proposed rule

The above issues are discussed in detail in the following comments.

I. CMS should assign Fractional Flow Reserve Derived from Computed Tomography (FFRct) to New Technology APC 1513

In the Proposed Rule, CMS proposes to reassign the FFRct service, described by Current Procedural Terminology (CPT®) Code 0503T, to New Technology APC 1510 with a payment rate of $850.50. For reasons explained below, MDMA opposes this proposed APC reassignment and instead suggests that CMS assign the FFRct service to New Technology APC 1513 with a payment rate of $1,150.50 to cover the costs hospitals incur to provide the service and payment

stability.

As explained in the Proposed Rule, CMS initially assigned the FFRct service to New Technology APC 1516 with a payment rate of $1,450.50 in CY 2018, and continued this assignment for CY 2019. For CY 2020, CMS initially proposed reassigning the FFRct service to New Technology APC 1509 with a payment rate of $750.50 based on 78 single frequency claims. Based on comments from MDMA and others, CMS decided to utilize their policy for "low-volume" services and used the arithmetic mean cost for CPT Code 0503T to assign the FFRct service to New Technology APC 1511 with a payment rate of $950.50. For CY 2021, CMS has proposed to reassign the FFRct service to New Technology APC 1510, which would reduce the payment for the service to $850.50.[2]

MDMA believes that the proposed reassignment is unjustified, that the current payment rate is inadequate to cover the cost incurred by facilities in providing the service, and that the instability in payment has restricted access to the FFRct service for Medicare beneficiaries, which would be exacerbated by further reduction in payment. As stated in its own policy on "low-volume" services, CMS worries the standard methodology it uses to estimate the cost of a procedure under the OPPS "may not generate an accurate estimate of the actual cost of the procedure" and "can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC."[3]

This is exactly what has happened to the FFRct service. Following a proposed 48 percent and final 34 percent payment reduction for CY 2020, CMS has proposed another $100 (11 percent) payment reduction for CY 2021. Current CMS methodology cannot generate an accurate estimate of the true costs of the FFRct service. Further, the wide variation in payment rates has led many facilities to abandon plans to integrate the FFRct service into clinical care and resulted in a reduction in utilization.

To avoid a further reduction in utilization and to cover the costs of the FFRct service, MDMA recommends that CMS instead reassign CPT Code 0503T to New Technology APC 1513 with a payment rate of $1,150.50. In addition to restoring stability to the payment rate for the service, this rate will also cover the costs that hospitals incur including the $1100 cost of the test, clinical support staff and resources needed to facilitate transfer of image data to the vendor, and quality control measures.

II. CMS should assign new code 9225X to APC 5734 with status indicator S

CMS proposes to assign the new code 9225X, Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral, to APC 5732 with status indicator Q1.[4] This new code describes use of artificial intelligence to interpret retinal images to diagnose diabetic retinopathy, a condition that puts millions of patients

[2] 85 Fed. Reg. at 48833-34.
[3] 84 Fed. Reg. at 39459.
[4] 85 Fed. Reg. at 58839.

with diabetes at risk for blindness. This technology helps to bring a recommended, but underutilized, diagnostic service to more patients by allowing it to be performed in a primary care setting.

MDMA commends CMS for taking this important step to establish payment for innovative digital health tools, but we recommend that CMS assign this code to a more appropriate APC, with a separately payable status indicator, to support adoption of and access to this important technology. Following CPT guidance, providers are currently billing for this service using code 92250. The new CPT code should be assigned to the same APC as 92250, not to a lower-paying APC as proposed. CMS should assign 9225X to APC 5734 until sufficient Medicare claims data can be collected by CMS to determine a future assignment.

MDMA also recommends that 9225X be assigned status indicator S so that it can be separately paid when performed with a clinic visit or other service. Conditionally packaging the service, as CMS has proposed to do, would discourage use of this service in the most efficient way, which is to perform the retina exam at the same time as another service instead of requiring the patient to make a second visit or schedule an appointment with a specialist. Separate payment is needed to support appropriate use of this innovative technology.

III. CMS should approve the transitional pass-through payment application for SpineJack System

MDMA asks CMS to approve the transitional pass-through payment application for the SpineJack system. The SpineJack system represents a significant advancement in the treatment of osteoporotic vertebral compression fractures (VCFs) and has recently received approval for a Medicare inpatient new technology add-on payment for FY 2021.

In the OPPS proposed rule, CMS requests comment on whether the SpineJack system meets the substantial clinical improvement (SCI) criteria and whether existing device pass-through payment category C1821 (interspinous process distraction device (implantable)) adequately describes the product.

The pass-through category identified by CMS does not provide an accurate description of the SpineJack device and does not take into account seven material differences that exist between the SpineJack system and interspinous spacers, which includes FDA submission type, intended use, mechanism of action, type of fixation, quantity of device used, location of device, and expansion of the device. MDMA believes that the SpineJack system is not appropriately described by any existing or previous category.

With regard to SCI, CMS raises concerns that the American Society for Bone and Mineral Research (ASBMR) guidelines do not support vertebral augmentation procedures, that only one randomized controlled trial (RCT) was provided to support SCI with SpineJack system and that the device was not studied against non-surgical management (NSM).

MDMA notes that while the ASBMR does not support vertebral augmentation, this finding is inconsistent with seven MAC local coverage determinations (LCDs) that appear in proposed or

final versions and indicate that earlier intervention for appropriate Medicare patients is supported by the body of clinical literature. MDMA contends that the LCDs for Percutaneous Vertebral Augmentation (PVA) demonstrate CMS willingness to cover PVA procedures for early treatment of appropriate Medicare patients. CMS also commented that the SpineJack system was not evaluated against NSM. MDMA does not believe this would have been a clinically appropriate comparator as almost all VCF patients first receive NSM, and then only those patients that do not respond to conservative care and may benefit from interventional treatment are considered for vertebral augmentation.

CMS further noted that only one RCT was provided to support the SCI criterion. MDMA is concerned that CMS may be holding medical devices to unreasonable clinical publication requirements. Additional RCTs for the same indication running at the same time are often not possible. Given the logistics to initiate, enroll and complete a second RCT for the same indication, it would most likely be in place after the newness period has expired for the technology.

Finally, MDMA notes that CMS's review and final determination in the Hospital Inpatient Prospective Payment System (IPPS) Final Rule for FY 2021 confirmed that the SpineJack system meets the SCI criterion.[5] Therefore, based on the clinical data available and clarification provided, MDMA urges CMS to approve the TPT application for the SpineJack system as it meets the newness, cost and SCI criteria.

IV. CMS should approve the transitional pass-through payment application for Hemospray® Endoscopic Hemostat

MDMA asks CMS to approve the transitional pass-through payment application for Hemospray® Endoscopic Hemostat based upon information submitted by the applicant supporting its satisfaction of the newness, cost and substantial clinical improvement criteria. Hemospray appears to offer a substantial clinical improvement in the care of patients with intractable bleeding where conventional dual therapy is ineffective. It also appears to prevent the need for more invasive procedures in bleeds that do not respond to conventional dual therapy, and in particular appears to be advantageous in treating bleeding arising from complications of malignancy in the GI tract.

Earlier this year, Hemospray was approved for new technology add-on payment in the hospital IPPS effective in FY 2021.

We wish to comment specifically on the agency's discussion in the proposed rule of adverse events associated with use of the device and a voluntary recall initiated by the manufacturer. Again, MDMA believes that ensuring that medical devices are safe and effective for their intended use is the primary role of the FDA. The FDA has extensive experience in supporting the

[5] Centers for Medicare & Medicaid Services Hospital Inpatient Prospective Payment System (IPPS) Final Rule, 42 C.F.R pts 405, 412, 413, 417, 476, 480, 484 and 495. (2020). Available at: https://www.federalregister.gov/documents/2020/09/18/2020-19637/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

safe and effective use of medical devices through a combination of premarket review, requirements for appropriate labeling and instructions for use, and post-marketing mechanisms such as adverse event reporting. The FDA has found Hemospray to be safe and effective for its intended use. The risks noted by CMS are risks of esophagogastroduodenoscopy for treatment of NVUGI bleeding, irrespective of treatment with Hemospray, and specific risks associated with the use of Hemospray are included in the labeling and instructions for use. They do not contradict a finding that Hemospray meets the newness, cost, and clinical improvement criteria required for device transitional pass-through payment. MDMA believes that denying eligibility for Hemospray based upon safety concerns, despite the FDA's approval of the device for marketing, would represent an inappropriate use of payment policy. The purpose of the transitional pass-through payment program is to address situations where inadequate payment creates disincentives for utilization of beneficial new technologies and barriers to access for Medicare beneficiaries to those new therapies. By denying pass-through eligibility for Hemospray over concerns about safety, in essence CMS would be maintaining the current payment disincentive to discourage the use of this technology, substituting the agency's judgment about the potential risk versus benefit of the therapy for that of the physician and patient. While we do not deny that CMS has the authority to set limits on access to FDA-approved therapies for Medicare beneficiaries based on clinical considerations, we do not believe this would represent an appropriate exercise of that authority.

The FDA cleared Hemospray to return to the market (K200972) after the manufacturer sufficiently addressed the issue that led to the cartridge exiting the handle. Hemospray has returned to the US market as of July 2020.

V. CMS should finalize the transitional pass-through payment approval for EXALT Model D

MDMA also asks that CMS finalize its proposal to approve transitional pass-through payment for single use endoscopes, including single use duodenoscopes like the EXALT Model D.[6] We also ask that CMS not apply the offset amounts associated with the CPT codes describing procedures where single use duodenoscopes are utilized when calculating payment, since these devices are not replacing any of the devices captured in the offset amount and are instead replacing a piece of depreciable capital equipment (i.e., reusable duodenoscopes).

VI. CMS should allow an extension of separate payment for devices with transitional pass-through status due to the Public Health Emergency

In many ways, 2020 has been unprecedented for our healthcare system due to the widespread impact of the COVID-19 pandemic. In addition to the challenges of diagnosing and treating a novel disease, healthcare providers and hospitals have seen significant declines in elective procedures and have struggled with reallocation of resources. Many Medicare beneficiaries have also lost significant access to novel technologies due to the Public Health Emergency (PHE). MDMA appreciates that CMS has recognized the impact that the PHE has had, and continues to

[6] 85 Fed. Reg. at 48847.

have, on utilization of and data collection for devices eligible for pass-through payment.[7]

MDMA supports the use of the agency's equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment after transitional pass-through status expires for devices for at least 10 months (*i.e.,* the duration of the PHE which began in January and is currently in place through October 2020). This extension would protect access to these devices while allowing CMS to collect additional claims data on costs and utilization of new technologies to support more accurate rate setting in the future. We also urge CMS to extend separate payment for devices newly receiving transitional pass-through status in CY 2021 for an amount of time equal to the beginning of their pass-through eligibility through the end of the PHE. There is likely to be a long runway until elective procedures once again reach pre-COVID volume and devices granted pass-through status for CY 2021 are likely to face many of the same challenges that the existing pass-through devices face. Extending the period where these products receive pass-through payments will support their adoption and beneficiary access.

MDMA urges the Division of Outpatient Care to coordinate with the Division of Acute Care to address the same issue as it relates to technologies with active new technology add-on payment (NTAP) or receiving NTAP during the PHE. While we recognize that NTAP is not the responsibility of the Division of Outpatient Care, a coordinated approach will ensure that there is no unintended site of service incentive created by providing relief for one site of service while not offering the same relief for another site of service.

VII. CMS should review and adjust the APC device offset for 0424T

CMS should address the APC device offset for CPT 0424T, Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator), currently set at 99.99 percent. This device offset leaves no payment for the non-device aspect of the implant procedure and effectively undoes the pass-through aspect of the Transitional Pass-Through Payment Program. This will create a strong disincentive and discourage the very access to care for Medicare beneficiaries that the Transitional Pass-through Payment Program is intended to facilitate. In addition, CMS has not provided a clear description of the methodology used to calculate the device offset for CPT code 0424T for CY 2021. The Claims Accounting Narrative does not provide a sufficiently detailed explanation for stakeholders to replicate how CMS determined the figures in the proposed rule. While it may simply be an error, sufficient details should be provided by CMS to allow others to recalculate CMS' figures in order to provide both a check and to provide more meaningful comments to CMS on these essentially quantitative matters.

VIII. CMS should revise the process for determining and applying appropriate offset amounts for devices seeking and/or receiving transitional pass-through payment

Currently, CMS requires that technologies meet several criteria in order to satisfy the cost test for transitional pass-through payment, including that the new device must exceed the cost of the

[7] *Id*. at 48862.

device-related portion of the APC payment amount for the service by at least 25 percent and the difference between the cost of the device seeking pass-through and the device-related portion exceeds 10 percent of the total APC payment.

In many cases, a device that meets the newness and significant clinical improvement criteria for transitional pass-through payment may only replace a portion of the devices included in the device-related portion. In some cases, the novel device may not replace any of the devices included in the device-related portion. In these cases, the device-related portion threshold a new device must meet is inappropriately high since many of the devices it includes will still be utilized in the procedure. Even if a new device not replacing all of the devices in a procedure meets the cost criteria and is awarded the transitional pass-through payment, the payment amount will be inappropriately low, since hospitals are still incurring the costs associated with the devices considered in the device-related portion yet this full amount will be subtracted from the final transitional pass-through payment amount.

MDMA asks that CMS solicit comments on revising the transitional pass-through cost test to recognize that new devices may not replace all devices currently utilized in a procedure both in its determination of whether a device meets the cost test and in its calculation of transitional pass-through payment for devices, including methodological options for the cost test and calculation of TPT payment, data needs and burden impact for those methodologies, and impact on beneficiary access to novel devices.

IX. CMS should delay implementation of the elimination of the Inpatient Only (IPO) procedures list until the agency has had the opportunity to consult with appropriate specialty societies and stakeholders, carefully consider the impact of eliminating the IPO procedures list on beneficiary access and facility reimbursement, and better articulate its methodology for assigning previously IPO procedures to APCs in the outpatient hospital setting

CMS proposes to eliminate the IPO list over a three-year transition period starting in CY 2021 and to allow physicians to determine site of care based on their clinical knowledge and judgement.[8]

A. CMS should delay implementation of elimination of the IPO list

Although we appreciate the initiative to allow providers to determine appropriate setting of care and provide more choices to beneficiaries, while taking safety into account, MDMA recommends that CMS delay implementation of this proposal until the agency has had the opportunity to consult closely with physicians and their representative organizations regarding the clinical suitability of removing all procedures from the IPO list and until the agency has provided greater detail regarding how it will determine APC assignments for procedures that have previously only been provided on an inpatient basis. More broadly, we are concerned that elimination of the IPO list may also create pressure for physicians to perform procedures in a lower acuity setting, without surgical backup or appropriate resources if a case turns out to be

[8] *Id*. at 48912.

more complex than anticipated.

We also are concerned that CMS' approach to APC assignment may not be aligned with resource use and could cause major changes—both increases AND decreases in reimbursement—from the inpatient rate, which could lead to physician behavioral changes, payment instability in the outpatient hospital setting, and unintended consequences for patients, including but not limited to increased patient co-payment amounts. CMS states that such concerns are mitigated because the services removed from the IPO list would likely be assigned to a comprehensive APC (C-APC), under which a beneficiary would face one copayment amount – capped at the inpatient deductible – for the entire hospital claim. However, beneficiaries who require more than one outpatient hospital procedure in separate episodes of care will still be subject to multiple copayments that may, in combination, exceed the inpatient deductible.

In addition, we are concerned about the appropriateness of OPPS payment rates for procedures that have, up to now, been paid only under the IPPS. CMS would not have historic charges for these procedures when performed on an outpatient basis. This concern underscores the need for interim rate setting policies, such as new technology APCs or rate floors for the two- to three-years that CMS gathers data to inform future rate setting.

B. CMS needs to address specific concerns about the musculoskeletal procedures that are proposed to be removed from the IPO list

CMS proposes to begin the three-year transition period of eliminating the IPO list starting in 2021 with a list of 266 musculoskeletal procedures. Some of these procedures have no data to support the appropriateness safety of their performance in the outpatient setting, such as amputations and various trauma repairs. The decision to remove all musculoskeletal procedures from the IPO list for CY 2021 will have significant unintended consequences for a number of procedures.

For example, CMS has included CPT code 27280 (open sacroiliac joint arthrodesis/fusion) for proposed removal from the IPO list. We believe that CPT code 27280 is not an appropriate candidate to be removed from the IPO list at this time because there is potential for minimally invasive SI joint fusion (CPT code 27279) procedures being miscoded as CPT code 27280. The typical patient profile, code descriptor and vignettes for 27280, as carefully debated by the American Medical Association (AMA), are all based on primarily hospital inpatient procedures. Based on the procedural descriptions of CPT code 27280 there is the presumption of a more morbid procedure, likely requiring inpatient care and careful discharge destination planning. The minimally invasive SI joint fusion code better identifies the appropriate procedure to be performed in the outpatient setting.

In another example, lumbar artificial disc replacement (LADR) procedures (described by CPT code 22857) are extremely low volume in the Medicare population, due in part, to a longstanding National Coverage Determination (NCD) that LADR is not a reasonable and necessary service for Medicare beneficiaries over the age of 60. As a result, there are few Medicare claims and hospital cost reports from all settings of care for CMS to accurately and fairly calculate the device offset percentage for LADR. This lack of claims data has led to a proposed device offset

percentage for LADR of 9 percent for 2021, while the proposed device offset percentage for cervical artificial disc replacement is 55 percent, even though an artificial cervical disc is generally recognized to be about half the cost of a lumbar disc.

These factors all point to the complexity of the decision regarding whether inpatient or outpatient is the most appropriate setting for a patient's musculoskeletal procedure. MDMA notes that in October 2018, the American Association of Hip and Knee Surgeons (AAHKS), the American Academy of Orthopaedic Surgeons (AAOS), The Hip Society, and The Knee Society issued a joint "Position Statement on Outpatient Joint Replacement." This statement includes "recommendations for outpatient hip and knee arthroplasty procedures to guide hospitals, surgeons and institutions in appropriate and safe patient care."[9] The document highlights a number of factors for surgeons and institutions considering discharge of either total knee arthroplasty (TKA) and/or total hip arthroplasty (THA) patients on a same-day outpatient basis (which could be applicable in either the hospital outpatient department or ASC setting). For instance, the policy references the need for the surgeon and institution to have appropriate insight and data regarding their performance and capability to perform early discharge THA and the need for "essential elements" focused on minimizing complications, such as policies on patient selection, evidence-based protocols and pathways for pain management and wound management, and protocols to respond to intraoperative and perioperative complications, to name just a few of the thoughtful best practices highlighted.

We therefore encourage the agency to consider delaying the removal of all musculoskeletal procedures from the IPO list until CMS can undertake a process to consult with physician specialties on procedures that are safe for the hospital outpatient setting and to ensure fair and adequate reimbursement levels that are capable of supporting patient access to these services in the hospital outpatient setting.

We also have concerns about the appropriateness of proposed payment rates for the musculoskeletal procedures. Many proposed APC assignments would pay 50 to 99 percent less than the IPPS rate.[10] An independent analysis from Braid-Forbes Health Research found no consistent use of cost data, either from outpatient or inpatient claims, to support the relative reduction in payment. This analysis instead found that procedures appeared to be assigned to APC groupings based on clinical similarity without regard to cost similarity. We are concerned with the lack of transparency in rate setting and that these rate differentials between the inpatient and outpatient setting can result in provider behavioral changes.

C. If CMS moves forward with eliminating the IPO list, it must implement several measures to ensure appropriate access to care and payment

If CMS does finalize the proposal to eliminate IPO list, CMS should grant a three-year

[9] AAHKS, Position Statement on Outpatient Joint Replacement, http://www.aahks.org/positionstatements/outpatient-joint-replacement/.

[10] See for instance CPT 27222, which could be assigned under the IPPS to MS-DRG 480 (FY 2021 payment = $19,439.70), and which would be assigned to APC 5111 (proposed 2021 payment = $214.47) under the proposed rule.

exemption from site-of-service denials and Recovery Audit Contractor (RAC) referrals to align with the proposed three-year transition period to eliminate the IPO list. While CMS proposes a two-year exemption period, we do not believe this is enough time. In conjunction with this policy, CMS should educate providers that Medicare policy allows for case-by-case exceptions to the "Two Midnights" rule based on patient history, co-morbidities and risk of adverse events. We also urge CMS to educate MACs, Medicare Advantage (MA) plan sponsors, the medical community, and patients that outpatient surgery is not mandated for any procedures being removed from the IPO list, and admission to the hospital as an inpatient is acceptable. We recommend CMS issue educational guidance to providers and Medicare contractors, similar to MLN Matters article (SE 190025), reinforcing that surgeons determine whether a particular procedure should be performed on an inpatient or outpatient basis, and there is no presumption that procedures should be performed on an outpatient basis. Similar guidance should be provided specifically to MA plan sponsors to ensure that physicians may select the appropriate site of surgery, inpatient or outpatient, for MA beneficiaries.

To ensure that any procedures that are removed from the IPO list are reimbursed appropriately under the OPPS, we recommend:

- In no case, should the OPPS rate be less than the lowest severity-adjusted IPPS rate during a proposed two- to three-year transition period to support data collection to support accurate future rate-setting.
- Alternatively, MDMA recommends that CMS assign any procedures moved off the IPO list to *new technology APCs* on an interim basis. Such interim assignments for these newly outpatient procedures would enable CMS to collect claims data on which to base permanent clinical APC assignment."
- CMS should implement a limit to the total payment change from current inpatient payment rate to outpatient payment rate of no more than 20 percent per year.
- CMS should create quality measures to monitor rates of complications and/or 30-day readmissions to minimize unintended negative impact on patient outcomes and experience as procedures migrate to the outpatient setting.
- Because CMS lacks data on the device costs for these procedures, CMS should assign a default 31 percent device offset value initially to any procedures that are moved off of the IPO list that are a) identified as low-volume procedure codes and b) are moved into a device-intensive APC. CMS should monitor their costs over the subsequent three years to determine whether the offset should be changed.
- CMS should consider extending the transition period for any procedures removed from the IPO list from three years to five to seven years to minimize payment disruption in the outpatient hospital setting.

X. CMS should not finalize the proposal to expand use of prior authorization

A. CMS should not expand use of prior authorization for any service until it has studied the effects of the policy implemented on July 1, 2020

In the CY 2020 OPPS rule CMS finalized a proposal to require prior authorization for five service categories that the agency identified as having "unnecessary increases in volume" in the

hospital outpatient setting. The five service categories consisted of procedures with both cosmetic and therapeutic indications, and the requirement for prior authorization became effective on July 1, 2020. For CY 2021, CMS proposes to require prior authorization to two additional procedures—cervical fusion with disc removal and implanted spinal neurostimulators—effective on July 1, 2021.[11]

MDMA has serious concerns that CMS's expansion of prior authorization policy will severely restrict patient access for beneficiaries to medically necessary procedures and add undue administrative and cost burden to providers. CMS has provided no analysis or evidence supporting a conclusion that changes in utilization of the two therapies is the result of unnecessary use, nor has the agency provided a clear explanation of the general factors that the agency considers in proposals to implement prior authorization. Prior authorization, which inherently increases burden and cost for providers and beneficiaries, should not be based on unsupported assumptions or arbitrary and non-transparent decision-making. To do so would be to prioritize paperwork over patients.

MDMA also questions whether MACs are prepared to efficiently administer increased demand for prior authorization. In fact, it is our understanding that MACs are struggling to administer prior authorization for the five OPD service categories implemented just a few months ago on July 1, 2020. Manufacturers have reported beneficiaries being subjected to significant wait times for certain services, causing unnecessary pain and suffering. Palmetto GBA, the MAC for Jurisdiction M, acknowledged that some providers who submitted prior authorization requests going back as far as August 24, 2020 still had not received responses as of September 22, 2020.[12] Any consideration of expansion to other service categories should wait until a comprehensive analysis of the 2020 initiative can be completed.

Especially in the time of the COVID-19 PHE, CMS should not add barriers to access for medically necessary procedures, particularly for those procedures for which access is already governed by national and/or local coverage determinations. CMS should not expand the use of prior authorization for any procedure, including finalizing the proposed prior authorization requirement for cervical fusion with disc removal and implanted spinal neurostimulators, until:

- the agency has conducted a thorough analysis of the impact of prior authorization for the five procedures for which it was implemented in July 2020, including the extent to which the MACs have been able to meet the timeframes for processing prior authorization requests, and the cost and other burdens imposed upon providers and beneficiaries relative to the benefit to the Medicare program of reducing inappropriate utilization; and

- the agency has established specific criteria, through a transparent process incorporating feedback from beneficiaries and other stakeholders, to guide its decision-making related to the use of prior authorization.

[11] 85 Fed. Reg. at 49028.

[12] Palmetto GBA E-mail Update: Tuesday, September 22, 2020 (referring to Palmetto GBA to Address Outpatient Department (OPD) Prior Authorization (PA) Requests That Have Not Yet Received a Response, https://www.palmettogba.com/palmetto/providers.nsf/vMasterDID/BTNQZ67284?opendocument).

B. CMS should not require prior authorization for cervical fusion with disc removal procedures and implanted spinal neurostimulators

MDMA also opposes use of prior authorization for cervical fusion with disc removal procedures and implanted spinal neurostimulators in particular. MDMA has concerns regarding the lack of transparency in the analytical approach and the difficulty in accessing the data set used by CMS to determine that these procedures had rates of growth that suggested inappropriate use. It was not possible to replicate CMS' methodology so that stakeholders could provide a fully informed response to CMS' proposal, which is inconsistent with the objectives of a public and transparent process.

For cervical fusion with disc removal procedures, we believe that much of the increase in hospital outpatient volume may be attributed to shifting site of care for these procedures. For example, for cervical fusion procedures described by CPT codes 22551 and 22552, data analysis by Braid-Forbes Health Research determined that in 2017 and 2018, the increase in outpatient cases was almost identical to the decrease in inpatient cases. This shift was also expected and in fact encouraged by CMS policy. CPT code 22551 was removed from the IPO list as of January 1, 2012 (76 FR 74355). However, CPT 22552, which is an add-on code to procedure code 22251, was not removed from the IPO list until 2016. As the policy of allowing a base code to be performed outpatient and its add-on code to be performed inpatient-only was flawed, CMS provided a correction in the CY 2016 OPPS rule (80 FR 70467), allowing CPT code 22552 to be performed outpatient. The removal of these procedures from the IPO list and the shift from inpatient to outpatient utilization explains the increase that CMS is observing and why these procedures should not be subject to prior authorization. A similar shift is evident for CPT 22554, but the overall volume of these cases is decreasing overall.

For implanted spinal neurostimulators, specifically spinal cord stimulators (SCS) are already considered a "last resort" therapy and beneficiaries must fail, or be deemed unsuitable for, a series of alternative treatment modalities before even being eligible for an SCS trial, which does not always result in a permanent implant. Prior authorization for implanted spinal neurostimulators, ultimately, would not reduce procedure volume as the National Coverage Determination (NCD 160.7) guarantees access to beneficiaries for whom the technology will provide a therapeutic benefit. SCS is an opioid sparing technology and prior authorization would create a barrier to a non-opioid alternative and is inconsistent with HHS & CMS pain management policies. Additionally, it could increase opioid use, abuse, and death among beneficiaries. It is the improvements in outcomes and the dire need for opioid alternatives that has led to the increase in SCS volume in the last five to eight years, and as such this does not constitute "an unnecessary increase in volume."

XI. CMS should ensure that the process for adding new procedures to ASC Covered Procedures List is transparent and deliberate

CMS is considering two additional, alternative reforms to expand the ASC covered procedures list (ASC-CPL): (1) a nomination process for adding new procedures to the ASC-CPL, along with criteria replaced by revised "parameters"; or (2) a new approach under which CMS would

dramatically streamline the regulatory criteria for evaluating potential additions to the ASC-CPL, resulting in the immediate transition of approximately 270 procedures to the list of ASC covered services.[13] MDMA appreciates CMS's interest in ensuring that procedures that are safe and effective for use in an ASC can be performed in that setting. However, we are concerned that any such process for moving codes be subject to informed clinical judgments about safety and efficacy and that the clinical and stakeholder community be involved in the selection of such codes. We also have questions about the need for a new process.

First, we question the need for a new nomination process for the ASC-CPL list since CMS already accepts such nominations from stakeholders as part of the annual OPPS/ASC rulemaking process. We also question the benefit under option one of replacing regulatory criteria with "parameters" that "are meant as general guidelines, not requirements." This change appears to introduce more variability and less predictability in the standard for inclusion of a procedure on the ASC-CPL, which ultimately may be less protective for beneficiaries.

In whatever manner CMS proceeds, we recommend that CMS ensure that changes to the ASC-CPL list are made in a transparent, deliberative manner with the input of the relevant experts. We further recommend that CMS affirm that manufacturers also would have standing to nominate procedures for the ASC-CPL under this process, given their depth of knowledge about the technologies used in medical procedures.

XII. CMS should provide additional guidance to physicians and beneficiaries if it adds Total Hip Arthroplasty to the ASC Covered Procedures List

CMS proposes to add 11 procedures to the ASC-CPL for CY 2021 under its "standard review process," including total hip arthroplasty (THA) CPT code 27130.[14] CMS stated that "physicians should have the flexibility to determine the most appropriate site of care for their patients' surgery." MDMA agrees that physicians should have the flexibility to determine the most appropriate site of care for their patients' surgery, and also believes that tools are needed, in the form of appropriate patient selection criteria, to help physicians "identify the subset of Medicare beneficiaries who may be suitable candidates to receive THA procedures in an ASC setting based on the beneficiaries' clinical characteristics."

As noted earlier, AAHKS, AAOS and other orthopedic specialty societies have issued a "Position Statement on Outpatient Joint Replacement"[15] that includes recommendations for surgeons and institutions considering same-day outpatient TKA or THA surgery in the hospital outpatient department or ASC. We recommend that CMS review these recommendations in providing guidance on patient selection for physicians determining setting of care for beneficiaries receiving THA.

[13] 85 Fed. Reg. at 48957.
[14] *Id*. at 48957-58.
[15] *See* http://www.aahks.org/wp-content/uploads/2018/12/AAHKS-Outpatient-Position-Statement-101018.pdf.

We also recommend that CMS carefully monitor the results of ASC-17, (NQF 3470) Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, for increasing incidence of unplanned hospital visits following THA procedures.

Finally, we recommend that CMS ensure that beneficiaries are fully informed of the financial implications of ASC selection when choosing the site of service for their procedure. In the outpatient hospital department, the beneficiary copayment (including THA) is capped at the inpatient deductible. As CMS is aware, this cap does not apply in an ASC. As a result, beneficiaries would pay hundreds of dollars more for a THA procedure performed in an ASC versus an outpatient hospital department (approximately $1,785 versus $1,408 under the proposed 2021 rule). It is imperative that beneficiaries understand this cost implication when choosing their setting of care. We therefore recommend that CMS encourage physicians to discuss the financial implications of the site of surgery, which could include notifying beneficiaries of the availability of the CMS Outpatient Procedure Price Lookup tool.

XIII. CMS should restore the J8 ASC payment indicator for 0200T

CMS proposes to revise the ASC payment indicator from J8, device intensive procedure, to G2, relative weights calculated solely based on the OPPS relative payment weight, for the following procedure:

> 0200T Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed

However, in the OPPS Addendum P, 0200T is listed as J1 (device-intensive) with a 30.06 percent device offset and a $1,914.40 device cost. MDMA highlights the disconnect between the device-intensive determination for OPPS payment purposes but not in the ASC setting. We recommend that CMS reexamine this assignment and restore the J8 payment indicator to 0200T in the final rule.

XIV. CMS should require MACs to publish a valuation methodology for transitional APC pass-through device payments in the ASC setting or recommend a uniform methodology to them

In some instances, select implantable medical devices qualify for both payment in the ASC setting and transitional pass-through payment status from CMS. Impulse Dynamics' device, the Optimizer® system (HCPCS C1824), is an example of such a device. Optimizer® achieved transitional pass-through payment status in OPPS 2020. The CPT code describing Optimizer® implants (0408T) also qualifies for payment in the surgery center setting per the addenda from the same rule. Only a very small handful of devices fit both criteria, either historically or currently.

CMS has published its method for valuing pass-through devices implanted in the hospital outpatient setting clearly in the Federal Register. CMS also has communicated that, in the surgery center setting, payment for a qualifying procedure and the associated pass-through

device should be paid separately.[16] However, CMS has left valuation of pass-through devices implanted in the ASC setting as "contractor priced."[17] To date, no Medicare contractor has published or otherwise clearly communicated its valuation methodology or how to represent "actual cost of the device"[18] on a claim including a pass-through device submitted from surgery center as the place of service.

Even if they can perform a particular procedure safely and effectively in the surgery center setting, providers are unlikely to offer it to patients if they do not have clarity on payment. Fee schedule payments and incremental payment valuation methodologies are readily available to hospital outpatient departments. Surgery centers should expect the same level of clarity for procedures they perform. We therefore recommend that CMS solicit comments from stakeholders regarding development of a more transparent and consistent policy regarding valuation of pass-through devices implanted in the ASC setting.

XV. CMS should outline a process and criteria for interested stakeholders to submit requests for inclusion in the proposed rule

Finally, during the course of the CY 2021 rulemaking cycle, we were informed of a request made by a coalition of device manufacturers to CMS regarding changes to a clinical APC family that included the creation of a new APC level. It is our understanding this request was provided to CMS in a timely manner for inclusion in the proposed rule. However, this specific request was not included in the CY 2021 proposed rule, denying the stakeholders the opportunity to see CMS's analysis of the request and allow for interested stakeholder comments. We are disappointed and concerned that CMS choose not to include this request in the proposed rule for public comment, regardless of CMS' ultimate decision on the request. It also leads us to question what other requests CMS may have also received that were not included in the proposed rule for discussion.

Moving forward, we request CMS outline a process and criteria that CMS will utilize to determine which requests are included in the OPPS rule. We are concerned that CMS is unilaterally deciding which requests are included or excluded from the rulemaking cycle. For those requests that are excluded, CMS is making a de facto decision against the request, eliminating the opportunity for stakeholder comment in the final rule. We believe that these are important steps to ensure transparency and stakeholder input in the hospital outpatient prospective payment program.

Conclusion

MDMA appreciates this opportunity to comment on the CY 2021 OPPS Proposed Rule. We urge CMS to consider our recommendations carefully and make the changes necessary to ensure that Medicare beneficiaries have access to state-of-the-art care. As always, MDMA looks forward to

[16] MLN Booklet, Ambulatory Surgical Center Payment System, March 2020, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AmbSurgCtrFeepymtfctsht508-09.pdf.
[17] 42 C.F.R. § 416.171(b)(1).
[18] *Id*. § 419.66(h).

working with the agency in the future to improve access to the best and innovative technologies that our industry has to offer. If we can provide any additional information, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahy
President and CEO
Medical Device Manufacturers Association