

August 31, 2015

Via Electronic Submission

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System (CMS-1633-P)

Dear Acting Administrator Slavitt:

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 changes to the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for calendar year (CY) 2016 (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.

The Centers for Medicare and Medicaid Services (CMS) has explained that the proposed policies are intended to improve the accuracy of payment rates under the OPPS and provide hospitals with incentives to provide care efficiently. These are important and worthwhile goals, but because beneficiaries’ access to life-saving technologies depends on appropriate implementation of complicated rate-setting calculations, it is essential that CMS proceed cautiously in pursuing these goals. If Medicare’s payment rates do not accurately reflect the costs of providing appropriate care, hospitals will not be able to provide beneficiaries the best care available today and invest in the technologies that will allow care to continue to improve.

¹ 80 Fed. Reg. at 39200 (July 8, 2015).

For example, for CY 2015, CMS finalized 25 of the proposed comprehensive Ambulatory Payment Classifications (C-APCs), creating 12 clinical families. For CY 2016, CMS is proposing to continue to implement the C-APC payment policy methodology implemented in CY 2015, and to create nine additional new C-APCs for CY 2016, including some surgical APCs and a new C-APC for comprehensive observation services. These proposed changes for CY 2016, along with the changes implemented for CY 2015 means that CMS has developed 34 new C-ACPs, representing a major overhaul of the hospital outpatient payment system. Because this is happening so quickly, there has not been time or data available to understand the effect of these dramatic changes.

CMS is also proposing to continue to expand the packaging policy for the following list of OPSS packaged items and services:²

- Ancillary services – In the CY 2016 proposed rule, CMS identified services in certain APCs that meet specific criteria, and CMS did not apply the \$100 geometric mean cost threshold methodology that the agency used in CY 2015. CMS is proposing to expand the set of conditionally packaged ancillary services to include services in three APCs (5734, 5673, 5674);
- Drugs and biologicals that function as supplies when used in a surgical procedure; and
- Clinical diagnostic laboratory tests.

In order to ensure that the OPSS continues to provide Medicare beneficiaries access to appropriate, innovative care, we ask CMS to take the following actions:

- **CMS should evaluate the impact of all expansions of packaging and other recent policy changes on access to care prior to implementing any additional new packaging proposals.**
- **CMS should allow sufficient time for adequate data to be collected to better understand the impact of packaging changes and to verify that the proposed rates accurately reflect hospitals' costs.**
 - **CMS should not implement the proposed reduction in payment to offset packaging of laboratory services in CY 2014.**
 - **CMS should not implement the proposed reduction in payment for stereotactic body radiation therapy (SBRT) services.**
 - **CMS should work with hospitals to identify the least burdensome method of collecting data on services related to primary services in C-APCs.**
 - **CMS should not package payment for newly created codes for at least three years.**
 - **CMS should not increase the packaging threshold for drugs without pass-through status.**
 - **CMS should not implement the proposed restructuring of orthopedic APCs and assignment of spinal procedures to a C-APC with dissimilar procedures.**

² 80 Fed. Reg. at 39233-36.

- **CMS should ensure device costs are appropriately reflected when procedure codes are assigned to new C-APCs and thus reconsider the assignment of CPT code 0392T to C-APC 5362 or revise the payment rate for this C-APC.**
 - **CMS should not implement the proposed reassignment of Current Procedural Terminology (CPT®)³ codes 31295 and 31296 within the restructured airway endoscopy APCs.**
 - **CMS should not implement the proposed assigned of new CPT codes 3160A and 3160B to APC 5153, Level 3 Airway Endoscopy.**
 - **CMS should not implement the proposed Level IV Urology APC (APC 5374) within the Urology and Related Procedures clinical family.**
 - **CMS should continue to require complete and correct coding for packaged services to ensure that the agency has accurate data for use in setting future payment rates.**
 - **CMS should modernize the transitional pass-through payment for devices to encourage innovation.**
 - **CMS should expand the cost bands for the New Technology APCs to assure that this program reflects the growing number of procedures, services, and technologies that can be safely performed and delivered in the outpatient hospital setting. CMS should adopt its proposal to establish specific criterion to evaluate the newness of a candidate for New Technology Intraocular Lenses payment under the ASC payment system.**
 - **CMS should ensure that the total payment for a retinal prosthesis implant procedure covers the cost of the device and the surgical procedure.**
 - **CMS should change the inflation update to better reflect changes in the cost of providing care in the ASC setting and to prevent further divergence between ASC and OPPS payment rates.**
 - **CMS should change its method of determining whether a procedure qualifies for the rate-setting methodology for device-intensive procedures in the ASC setting.**
- I. CMS should be judicious with any further consolidation and restructuring of clinical APCs and any new packaging until CMS has more information on the impact that consolidation and packaging has on patients' access to outpatient services.**

CMS's recently finalized and proposed expansions of packaging policies involve complex and interrelated changes to the rate-setting calculations. Each year, CMS' proposals build on prior changes to the OPPS, often before the effects of those earlier revisions on access to care can be measured. Piling on change after change without first understanding how these changes impact beneficiaries or providers is not appropriate. The claims data that reflect the expanded packaging policies implemented in CY 2014 (drugs, biologicals, and radiopharmaceuticals that function as supplies in a diagnostic test or procedure; drugs and biologicals that function as supplies or devices in a surgical procedure; clinical diagnostic laboratory tests; procedures described by add-on codes; and device removal procedures) and CY 2015 (procedures described by add-on codes;

³ CPT codes are the copyright of the American Medical Association (AMA).

ancillary services; and prosthetic supplies) will not be available for two to three years, making it extremely difficult to predict whether hospitals will continue to be able to invest in innovative technologies if additional packaging is implemented. As we have stated in previous comment letters, more time is needed to analyze hospitals' responses to these new incentives and the effect of these changes on beneficiaries' care before further changes to the OPSS are implemented.

We continue to ask CMS to report on the effects of its packaging proposals on access to items and services that are no longer separately reimbursed. This report should be shared with the Advisory Panel on Hospital Outpatient Payment (HOP Panel) and stakeholders before implementing any further packaging proposals so that the Panel and stakeholders can provide detailed comments on steps needed to ensure that the OPSS provides appropriate incentives to hospitals to furnish efficient, high quality care. We believe that annual reports on utilization of packaged items and services would help CMS identify and address any problems in beneficiary access to care.

II. CMS should allow sufficient time and adequate data to be collected to better understand the impact of packaging changes and to verify that the proposed rates accurately reflect hospitals' costs.

As noted above, for CY 2016, in addition to expanding packaging, CMS is proposing to restructure nine clinical APC families based on the following principles: (1) improved clinical and resource homogeneity; (2) reduced resource overlap in longstanding APCs; and (3) improved understandability of the OPSS APC structure.⁴ If finalized, CMS would eliminate more than 80 APCs. In some cases, such as for the airway APCs, the consolidation appears to be reasonable and MDMA generally supports such consolidation. MDMA, however, continues to have significant concerns about the resulting drastic payment reductions for some procedures in those APCs, as discussed in section II.G., below. In other cases, by contrast, such dramatic consolidation has the potential to exacerbate payment inequities and inaccuracies. In these instances, MDMA cannot support such consolidation. Therefore, MDMA recommends CMS move slowly with any further consolidation of clinical APCs until CMS has more information on the impact that consolidation and bundling has on patients' access to outpatient services.

Recognizing the complexity of CMS's proposed policies for CY 2014, the HOP Panel recommended that CMS delay implementation "until data can be reviewed by the Panel at its spring 2014 meeting regarding interactions between the proposals and their potential cumulative impact."⁵ We supported this recommendation, and applauded CMS for delaying implementation of the C-APCs for one year to allow both CMS and stakeholders more time to evaluate the agency's calculations and prepare for the new payment approach.⁶

⁴ 80 Fed. Reg. at 39257.

⁵ Advisory Panel on Hospital Outpatient Payment, August 26–27, 2013, Final Recommendations, <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/August-26-27-2013-AgendaRecommendations.zip>.

⁶ 78 Fed. Reg. at 74832.

We once again ask that CMS employ the same prudent approach to any further expansions of the packaging under the OPSS and delay implementation of the CY 2016 C-APC proposals. We continue to find that the 60-day comment period on the proposed rule often is not enough time to fully analyze CMS's proposals. Because the OPSS methodology is so complex, it is difficult for stakeholders to verify the accuracy of the proposed payment rates and provide detailed analysis during the comment period on the proposed rule. Once again, we expect that our members and other stakeholders would benefit from more time to analyze the proposals and assess their impact, as well as more clarity about how CMS calculates the payment rate for APCs and C-APCs as the agency expands packaging and bundling.

We also find some of the proposed changes difficult to understand because CMS has not explained them in sufficient detail. For example, for CY 2016, CMS proposes to remove implantable biologicals from the skin substitutes cost group. CMS states that these products are typically used in internal surgical procedures to reinforce or repair soft tissues and are not typically used to promote wound healing on the skin. However, it is not clear how CMS arrived at this conclusion for each of these products or on what data CMS relied to make this determination. Stakeholders need information on the data used by CMS in order to adequately review the agency's rationale for proposed changes. In the context of all changes, CMS needs to post data files the agency is using for the changes, such as new offset files that show impact of specific devices with respect to new groupings/C-APCs, and allow stakeholders to comment on that information during a rulemaking cycle before the changes take effect.

We also believe that CMS should use the HOP Panel and its public meetings as opportunities to gather advice on potential expansions of packaging policies before deciding whether to include them in the proposed rule. After gathering comments on the proposed rule, CMS should delay implementation of any final policies for at least one year, as it did with the first set of C-APCs, to allow sufficient time for refinement and implementation.

We address our concerns about specific services, APCs, and related proposals below.

A. CMS should not implement the proposed reduction in payment to offset previous packaging of laboratory services.

MDMA has long been concerned that the larger payment bundles CMS has implemented in recent years may not produce rates that accurately reflect the costs of services provided, and the proposed rule shows that our concerns were well-founded. In the CY 2016 OPSS proposed rule, CMS notes that the agency packaged too much of the costs of laboratory services into payments in 2014 and is proposing a two percent reduction in payment for all APCs for 2015 to offset the mistake. This \$1 billion error has a significant impact on payment for all procedural APCs and the items and services packaged into them, causing reductions in rates that were increased last year. If similar mistakes are found in future year and additional offsets are proposed, payment rates would become unstable due solely to CMS's errors, not changes in hospitals' costs. We ask CMS to not apply this reduction now and to exercise caution to prevent future mistakes. We also

ask that CMS evaluate its data for potential underestimation of the costs of other packaged items and services.

B. CMS should not implement the proposed reduction in payment for SBRT services.

We continue to be troubled by the restructuring of APCs for multi-session stereotactic radiosurgery, known as (SRS) and SBRT, that were implemented in CY 2014. At that time, CMS replaced codes that differentiated services by type of technology and cost with a less specific code and reassigned services from three APCs into a single APC. The CPT code currently used for these services is 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) and is currently assigned to APC 66, which is proposed to be renumbered as APC 5625. This restructuring caused a deep cut in payment for services using the most advanced technology, and CMS proposes a further cut of 11 percent for CY 2016. If the proposed rate is implemented, Medicare's reimbursement for this service will have fallen by 40 percent since CY 2012.

These payment cuts are based on flawed data and are not justified by changes in hospitals' true costs for these services. When these services were identified with unique codes, their costs remained steady for years. When CMS combined these services into a single code, the cost suddenly appeared to be much lower, despite no immediate changes in the resources used. CMS's coding decision thus obscured true differences in hospitals' costs, causing the payment rate to drop inappropriately. Since the coding change, many hospitals have set their charges at levels that produce unbelievably low cost estimates according to CMS's standard methodology. Analysis of the 2014 claims data found that 32 percent of hospitals providing multi-session SBRT, accounting for 24 percent of claims, had costs that were less than 50 percent of the national average. If these hospitals had set their charges more appropriately, the payment rate for this code would increase by \$630 or 37 percent from the proposed rate.

These flaws in the data appear to reflect confusion about the resources associated with each service identified by the new codes. We also found evidence of confusion in some of the claims for single session cranial SRS. Out of 3,500 claims submitted with CPT code 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based), 500 were billed with other fractions of 77373 (a code which is supposed to be used for fractions 1-5 of multisession cranial or extracranial treatment). If CMS excluded these claims from rate setting, the geometric mean cost for 77372 of approximately \$5,400 would be reduced to \$4,900 for single session SRS delivery. This mean cost would still be much higher, according to CMS's calculations, than the mean cost of a single session spinal SBRT treatment, despite the fact that these services involve similar resources. This is another indicator of the inappropriateness of the proposed rates and underlying data.

We urge CMS not to implement further payment cuts that are based on flawed data. To do so would undermine CMS's efforts to ensure that the OPSS provides incentives to treat Medicare

beneficiaries with the most appropriate therapies. We urge CMS to increase the proposed payment rate of \$1,700 for APC 5625 by at least \$630 to more accurately capture the costs of providing this therapy. Alternatively, code 77373 should be placed into a stable APC, such as a new technology APC, for a period of 3 years to provide appropriate payment while stakeholders work with CMS to ensure that the agency has accurate cost data.

C. CMS should work with hospitals to identify the least burdensome method of collecting data on services related to primary services in C-APCs.

CMS proposes to require hospitals to report modifiers to identify “every code that is adjunctive to a comprehensive service, but is billed on a different claim.”⁷ CMS says this data would allow it to “begin to assess the accuracy of the claims data used to set payment rates for C-APC services.”⁸ We are concerned that this requirement would be extremely burdensome for hospitals to implement. To use the modifier, hospitals would need to hold all claims to assess whether they are related to a primary procedure provided on another date. This would require hospitals to dedicate more staff to billing, instead of investing in clinical services, and would slow down hospitals’ claims submissions and payments. We urge CMS to work with hospitals to identify the least burdensome method of collecting useful cost data for CMS’s rate-setting purposes. If CMS decides to implement a modifier, it must provide clear instructions to hospitals on how to use the modifiers.

D. CMS should not package payment for newly created codes for at least three years.

We are troubled by CMS’s proposal to package payment for newly created codes, despite not having any cost or utilization data for those services. In addition to packaging payment for new add-on codes and codes for ancillary services, CMS proposes to package payment for several new codes, including 0406T (Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant) and 0407T (Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with polypectomy, biopsy or debridement). Furthermore, this proposal is without any explanation. If CMS has determined that these new codes for stand-alone procedures are in fact ancillary services or add-on codes, that conclusion would be incorrect. These codes should be separately reimbursed. We urge CMS to make separate payment for all codes that describe new services for at least three years to allow the agency time to gather the cost and utilization data needed to make appropriate APC assignments or packaging decisions.

E. CMS should not increase the packaging threshold for drugs without pass-through status.

We also recommend that CMS not increase the packaging threshold for drugs without pass-through status to \$100, as proposed.⁹ The packaging threshold has increased by 54 percent since

⁷ 80 Fed. Reg. at 39228.

⁸ *Id.*

⁹ *Id.* at 39275.

CY 2010, rising at a rate far faster than the OPPS update. We ask CMS to retain the threshold at \$95 and, at a minimum, not increase it by more than the OPPS update.

F. CMS should not implement the proposed restructuring of orthopedic APCs and assignment of spinal procedures to a C-APC with dissimilar procedures.

CMS proposes to restructure 24 orthopedic APCs into nine new APCs, and would move many services in these APCs into C-APCs.¹⁰ We are concerned that this restructuring results in significant payment reductions of 9.34 percent for some of these services, including spinal fusion and discectomy procedures (CPT codes 22551, 22554, 22612, and 22856). These codes are assigned to C-APC 5124 with many procedures that are completely dissimilar clinically, such as joint replacement procedures, and with respect to resource use. This proposed C-APC includes procedures with costs ranging from \$6,507 to \$18,675. Contrary to CMS's goals, there simply is no clinical or resource homogeneity among the codes assigned to this C-APC. We ask CMS to not implement this proposed restructuring of the orthopedic APCs.

G. CMS should ensure device costs are appropriately reflected when procedure codes are assigned to new C-APCs and thus reconsider the assignment of CPT code 0392T to C-APC 5362 or revise the payment rate for this C-APC.

CMS proposes to reassign CPT code 0392T (Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band) from APC 0174, Level IV Laparoscopy with a CY 2015 payment rate of \$8,069.91, to the proposed new C-APC 5362, Level 2 Laparoscopy with a proposed CY 2016 payment rate of \$6,940.91.¹¹ We are concerned that this reassignment results in a significant payment reduction of approximately 14 percent for CPT code 0392T and creates a situation where the device cost represents approximately 51 percent of the payment rate for APC 5362. For device-intensive CPT codes such as 0392T, CMS must ensure that device costs are appropriately accounted for when implementing new packaging policies. MDMA urges CMS to assign CPT code 0392T to a different APC with a more appropriate payment rate or, alternatively, revise the payment rate for the APC 5362 to appropriately reflect the cost of services described by 0392T.

H. CMS should not implement the proposed reassignment of codes 31295 and 31296 within the restructured airway endoscopy APCs.

CMS also proposes to restructure the APCs for airway endoscopy procedures, collapsing seven APCs into five APCs.¹² Although many of the reassignments appear to be reasonable, we are concerned about the reassignment of CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa) and 31296, (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)). These are two of only three codes from the current APC 75 that are proposed to be

¹⁰ *Id.* at 39261-62.

¹¹ *Id.* at 39252.

¹² *Id.* at 39257-58.

reassigned to APC 5154, Level 4 Airway Endoscopy, instead of APC 5155, Level 5 Airway Endoscopy. As a result of this change, the payment for these CPT codes would experience a 31 percent reduction with a proposed payment rate of \$2,105.97. These are the only codes in this proposed APC that have a significant device cost, and, the proposed payment rate is not reflective of the cost of all of the procedures' costs, including the devices used. We see no rational reason for this reassignment, and we are troubled by the fact that these reassignments are based on fewer than 40 claims for each code, which is less than five percent of all claims for these procedures. We thus ask CMS to assign these codes to the Level 5 APC (APC 5155), where they will be with the codes they currently share an APC with and where they will be reimbursed appropriately.

I. CMS should not implement the proposed assigned of new CPT codes 3160A and 3160B to APC 5153, Level 3 Airway Endoscopy

For CY 2016, CMS is proposing to implement two new CPT codes (3160 A and 3160B) for Endobronchial Ultrasound with transbronchial needle aspiration to replace CPT codes 31620 and 31629 (predecessor codes). Additionally, CMS is proposing to assign these new CPT codes to proposed APC 5153, Level 3 Airway Endoscopy while their predecessor codes were assigned to proposed APC 5154, Level 4 Airway Endoscopy.¹³ Although MDMA supports the creation of these new CPT codes, the proposed APC reassignment is inappropriate considering the costs and complexity of these procedures. Specifically, the proposed APC assignment represents a 49 percent reduction in the proposed 2016 payment rate for services that were previously reported by 31620 and 31629.

This request was presented at the August 24, 2015, HOP Panel meeting, where the panel voted unanimously to re-assign CPT codes 3160A and 3160B to APC 5154 Level 4 Airway Endoscopy. MDMA thus urges CMS to implement the Panel's recommendation and reassign CPT Codes 3160A and 3160B to APC 5154.

J. CMS should not implement the proposed Level IV Urology APC (APC 5374) within the Urology and Related Procedures clinical family

CMS also proposes to restructure the APCs in the Urology and Related Procedures clinical family, collapsing 16 APCs into seven APCs.¹⁴ Although many of the reassignments appear to be reasonable, we are concerned about the breadth of procedures that are proposed to be described by APC 5374, Level IV Urology and Related Services. Specifically, proposed APC 5374 will represents 43 percent of the total volume of all of the Urology clinical family procedures. Due to the volume of procedures proposed to be described by APC 5374, substantial payment misalignments relative to the cost of certain urologic procedures that utilize medical technologies will result at a frequency and magnitude far greater than what is acceptable under the APC system. MDMA thus urges CMS to not to implement APC 5374, as proposed, and

¹³ *Id.* at 39257-58.

¹⁴ *Id.* at 39263.

instead implement two new, smaller APCs that are better aligned from a resource intensity perspective that will decrease the frequency and magnitude of over- and underpayments.

III. CMS should continue to require complete and correct coding for packaged services to ensure that the agency has accurate data for use in setting future payment rates.

Regardless of whether CMS expands packaging within the OPSS, the agency's ability to calculate appropriate payment rates depends on the accuracy and completeness of the claims data. To ensure that the agency has the data it needs, we continue to urge CMS to require complete and correct coding for packaged services.

We also urge CMS to remain as transparent as possible about the data it uses to set APC payment rates. For example, for device-intensive procedures, we know that the cost of the device is included in the APC payment rate and represented in the APC offset file. However, it is unclear if the costs of all the services in a given APC are truly representative of the cost of particular procedure.

Further, we know that not all device Healthcare Common Procedure Coding System (HCPCS) codes are device-specific (for example, L8699, Unlisted orthopedic implant). We request that the data CMS uses in setting payment rates is returned with more transparency, so we can confirm that CMS is truly capturing which devices are being used and reported under the APC and the code(s) CMS wants hospitals to report.

We thank CMS for acknowledging concerns about transparency and recommend that CMS continue to find ways to improve transparency between the agency and stakeholders to foster innovation.

IV. CMS should modernize the transitional pass-through payment for devices to encourage innovation.

CMS has proposed to revise the pass-through device application process to enhance transparency and opportunities for stakeholder input.¹⁵ Beginning in CY 2016, CMS is proposing to add a rulemaking component to the current quarterly device pass-through payment application process. Specifically, CMS is proposing to supplement the quarterly process by including a description of applications received (whether they are approved or denied) as well as the agency's rationale for approving or denying the application in the next applicable OPSS proposed rule. CMS would accept public comments on the preliminary decisions and could change the decisions in the final rule in consideration of public comment. Applications that are denied during the quarterly application process could be revisited, with consideration of additional evidence, during the rulemaking process, and, if denied again, CMS would offer applicants an opportunity for reconsideration.

¹⁵ *Id.* at 39265.

We commend and support CMS for its efforts to increase transparency through the agency's proposed updates to the process for pass-through payments for devices; this is a critical step toward improving equity and predictability in the process. MDMA supports the proposals to include in a list of applications received, outcome, and rationale in the subsequent OPSS proposed rule. This release of information will improve the predictability and consistency in application of criteria. We also support the continued use of a quarterly application process because it allows devices to be considered for pass-through status in a timely manner.

CMS also has proposed a newness criterion for device pass-through applications. Under the proposal, a device will only be eligible for transitional pass-through payment under the OPSS if the date of original Food and Drug Administration (FDA) approval or clearance and U.S. market availability is within three years from the date of the application for transitional pass-through payment. MDMA recommends that CMS measure newness from the date of first sale, not the date of FDA approval or clearance, because some products require additional regulatory approvals from other agencies, such as the Federal Communications Commission, or encounter delays in marketing following approval.

We also believe that additional changes are needed to ensure that pass-through status achieves its intended purpose of “allow[ing] for adequate payment of new innovative technology while [CMS] collected the necessary data to incorporate the costs for these devices into the base APC rate.”¹⁶ Because CMS currently reviews candidates for pass-through status under extremely broad pass-through categories, it fails to recognize as “new” many innovative devices that are substantially different from the products for which that category was created years earlier. This leads to CMS denying pass-through status for new devices or new uses of existing devices that required entirely new FDA approval or clearance and are used with different procedures or on different parts of the anatomy than prior devices, even though these devices could not have been included in CMS's cost data for the relevant base APC (or any APC) prior to their approval because they were not marketed at that time. The extreme narrowness of CMS's approach to identifying new devices is reflected in the very small number of new device categories created in recent years – only eight in five years.

For example, in 2013, CMS denied pass-through status for the Zilver PTX Drug-Eluting Stent because CMS determined that it was described by an existing category, and it did not satisfy the cost tests. The Zilver PTX Drug-Eluting stent is intended for use in the treatment of symptomatic vascular disease of the above-the-knee femoropopliteal arteries (superficial femoral arteries). It is the only FDA-approved drug-eluting stent with an indication for non-coronary artery use. When the FDA approved this device under a Pre-Market Approval (PMA) application, it assigned it a unique product code, NIU, which is defined as “stent, superficial femoral artery, drug-eluting.” In other words, the FDA determined that the Zilver PTX device was the first device of its kind of technology and indication. Because no devices like it were previously available, the cost of this device could not have been reflected in the claims data for

¹⁶ *Id.* at 39266.

the APCs for the procedures using this device, and this should not have been a basis for denial of this application.

In contrast to the FDA's judgment, CMS determined that the Zilver PTX device was described by an existing pass-through category: C1874, stent, coated/covered, with delivery system. None of the products in this category were similar to the Zilver PTX, however. The devices in this category were used for different parts of the anatomy and/or used different technology and were identified with different FDA product codes than the Zilver PTX. At the time of Cook's application, this category included vascular and non-vascular (i.e., esophageal, colonic, biliary, and urethral) stents that may have a drug coating, but were not drug-eluting. Because these products differed so greatly from the Zilver PTX, to the extent that any of the cost of products in this category were reflected in the claims data for the femoral artery revascularization procedures, it simply is not accurate to conclude that the claims data included the cost of the Zilver PTX.

We urge CMS to revise its criterion to be consistent with the FDA's standards for recognizing new devices. For example, if FDA determines a device must be cleared through a de novo 510(k) or requires PMA approval, such a product should meet CMS' criteria as "new." Similarly, if FDA determines a device requires creation of a new product code, such a product should meet CMS' criteria as "new." We also recommend that CMS create a new device pass-through category for any device for which the FDA creates a new product code.

In addition, we recommend that CMS change its test of whether a device's cost is "not insignificant in relation to the APC payment amount for the service related to the category of devices" to use a specific dollar threshold, such as \$100, rather than a percentage of costs relative to the APC's payment or device-related payment. As CMS expands packaging, creates C-APCs, and consolidates APCs to include larger bundles of costs, it becomes more difficult for devices to meet CMS's current thresholds for "not insignificant" cost, even if they represent a substantial cost to hospitals. These changes in APCs' structures also cause fluctuations in payment for procedures from year to year, which causes unpredictability for manufacturers who are trying to determine if their device would meet the cost threshold. Using a specific dollar threshold would provide greater clarity and predictability about whether a new device qualifies for pass-through status.

Finally, we also ask CMS to clarify, and ideally eliminate, its "substantial clinical improvement" criterion. This terminology is far too vague and subjective and as a result, has been applied inconsistently and unpredictably. CMS's current pass-through application requires that the device "substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to *all available treatments or diagnostic tests.*"¹⁷ Quite frankly, this is almost impossible, particularly in therapeutic areas such as wound care with dozens of treatments on the market or for many of our small, resource-constrained medical device manufacturers. Congress created the device and drug pass-through provisions to ensure

¹⁷ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service/Payment/HospitalOutpatientPPS/Downloads/catapp.pdf> (emphasis added).

Medicare beneficiaries have access to innovative therapies. CMS's creation and application of the "substantial clinical improvement" criterion is impeding that access. At a minimum, if such a criterion remains, the agency should establish much more clear guidelines and apply those guidelines consistently across all applications. If an applicant fails to meet the criterion, CMS should explain in depth why and what precisely the applicant can do to meet it in the future. The agency's current one-line response that the device "did not demonstrate a substantial clinical improvement" is inadequate and unhelpful and ultimately denies Medicare beneficiaries access to new innovations.

We urge CMS to make these changes to foster innovation and to ensure that new life-saving technologies are accessible to Medicare beneficiaries in a timely manner.

V. CMS should expand the cost bands for the New Technology APCs to assure that this program reflects the growing number of procedures, services, and technologies that can be safely performed and delivered in the outpatient hospital setting

CMS is proposing to expand the New Technology APC groups by adding nine more levels, New Technology Levels 38 through 46 (1585 through 1593, status indicator T).¹⁸ Levels 38-46 will accommodate New Technologies and related procedures at higher incremental payment levels over \$10,000. CMS explains that "every year we receive several requests for higher payment amounts under the New Technology APCs for specific procedures paid under the OPSS because they require the use of expensive equipment."¹⁹ To this end, MDMA supports the creation of the new cost bands and believes that this expansion represents an opportunity for the collection of more accurate claims data that will assure a more accurate transition of technologies and procedures out of the New Technology APC cost bands to clinical APCs. We further urge CMS to allow for more seamless expansion of new technology cost bands in the future, as needed, so as not to arbitrarily cap the high cost band payment and limit access to new innovations.

VI. CMS should adopt its proposal to establish specific criterion to evaluate the newness of a candidate for New Technology Intraocular Lenses (NTIOL) payment under the ASC payment system.

CMS is proposing to establish a specific criterion to evaluate the newness of a candidate for NTIOL payment under the ASC payment system. Specifically, CMS is proposing that, beginning in CY 2016, an application will only be evaluated by CMS for a new IOL class if the IOL has received initial FDA premarket approval within the three (3) years prior to the NTIOL application submission date.²⁰

MDMA supports this proposal to establish a clear standard for defining "new" technology that is eligible for consideration as a new class of NTIOL. The proposed three-year period would allow

¹⁸ 80 Fed. Reg. at 39255-56.

¹⁹ *Id.* at 39255.

²⁰ *Id.* at 39320.

sufficient time for any required clinical studies to be completed in support of FDA labeling for NTIOL application. It also would be aligned with the current Inpatient Prospective Payment System (IPPS) new technology add-on newness standard and the proposed OPSS pass-through payment newness standard. We recommend that CMS adopt this proposal in the final rule.

VII. CMS should ensure that the total payment for a retinal prosthesis implant procedure covers the cost of the device and the surgical procedure.

MDMA is pleased that CMS recognizes the need to assign retinal prosthesis implant procedures to an APC with appropriate payment once pass-through status expires for this device, and we ask the agency to clarify its proposed payment rate. This procedure is coded using CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy), and the retinal prosthesis device is identified by code C1841 (Retinal prosthesis, includes all internal and external components). For CY 2015, this surgical procedure was assigned to APC 0673, and the device has had pass-through status since October 1, 2013.

In the CY 2016 proposed rule, CMS proposes to expire pass-through status for HCPCS code C1841 on December 31, 2015.²¹ CMS states that due to the newness of this surgical procedure and limited historical claims data, it is proposing to reassign CPT code 0100T from existing APC 0673 (Level III Intraocular Procedures, with a CY payment rate of \$3,123) to the proposed newly established New Technology APC 1593 (New Technology—Level 46 (\$70,000–\$80,000)).

We applaud CMS for understanding that the payment rate for APC 0673 would be inappropriate given hospital costs for performing the surgical procedure and implanting the prosthetic. Thus, we welcome CMS’s approach to reassign CPT code 0100T from existing APC 0673 to a New Technology APC.

However, we want to verify that the proposed payment will be sufficient to cover the device costs. CMS is aware that the device cost is greater than \$144,000 (based on the IPPS new technology add-on payment of \$72,028.75, which is 50 percent of the device costs).

In the preamble, CMS states the following:

“We are proposing a CY 2016 OPSS payment of approximately \$75,000 for proposed new APC 1593, which would be the payment for CPT code 0100T (not including the retinal prosthesis), **plus** the proposed maximum FY 2016 IPPS new technology add-on payment for a case involving the Argus® II Retinal Prosthesis System of \$72,028.75 (80 FR 24425).”

We interpret the statement from CMS as proposing to pay:

(1) \$75,000 for APC 1593; **plus**

²¹ *Id.* at 39264.

(2) an additional payment equal to the IPPS new technology payment amount of \$72,028.75.

This would result in a total procedure payment of \$147,028.75. This approach would result in a total payment per procedure that covers the cost of the device and provides additional payment for the surgical procedure. This payment policy should remain in effect until adequate claims data are available from the OPPS claims database. We ask CMS to clarify that it will make this payment in the final rule.

VIII. CMS should change the inflation update to better reflect changes in the cost of providing care in the ASC setting and to prevent further divergence between ASC and OPPS payment rates.

MDMA is concerned about the growing payment gap between the ASC payment system and the OPPS. The ASC payment system is based on the relative weights determined under the OPPS and a lower conversion factor, initially set to ensure budget neutrality with the prior ASC payment system.²² Over time, rates in the ASC system have increased at a much lower rate than in the OPPS due to use of different update factors, despite a lack of evidence that inflation has been lower in the ASC setting. From 2010 through 2015, the OPPS update has been higher than the ASC update. The proposed update for CY 2016 is higher in the ASC payment system than in the OPPS due to an unusual negative update in the OPPS. Since 2010, the cumulative update in the OPPS has been 11.55 percent, while the cumulative update in the ASC setting has been only 6.6 percent.

The growing gap in ASC and OPPS payment rates is caused by the use of different update factors under these systems. The OPPS uses the hospital inpatient market basket and the ASC payment system uses the Consumer Price Index (CPI-U). Section 1833(i)(2)(C)(i) of the Social Security Act requires that “if the Secretary has not updated amounts established” under the ASC payment system during a 12-month period, such amounts shall be increased by the “percentage increase in the Consumer Price Index for all urban consumers.” In the proposed rule, CMS acknowledges that “the statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update.”²³

We ask CMS to use the hospital market basket instead of the CPI-U for the ASC update. The CPI-U does not appropriately reflect changes in ASC’s costs because it is based on prices across all sectors of the economy, including food and beverage, housing, education and communication, and recreation, as well as medical care. In fact, medical care constitutes only 7.7 percent of the CPI-U.²⁴ In contrast, the hospital market basket measures inflation in the costs of goods and services related to healthcare. The CPI-U also is inappropriate because it

²² *Id.* at 39321.

²³ *Id.* at 39323.

²⁴ http://www.bls.gov/cpi/cpiri_2014.pdf.

includes a productivity adjustment which is unnecessary because the ASC payment system is subject to a separate multifactor productivity adjustment by law. The hospital market basket does not include a duplicative productivity adjustment. We ask CMS to adopt the hospital market basket as the update factor for ASCs.

IX. CMS should change its method of determining whether a procedure qualifies for the rate-setting methodology for device-intensive procedures in the ASC setting.

The existing APC payment methodology for device-intensive procedures provides for application of a modified payment formula in the ASC setting when the device-intensity of an APC is greater than 40 percent. Determination of device-intensity at the APC level, however, results in over- and under-payments of device-intensive HCPCS codes in two ways. First, within APCs determined to be device-intensive, less device-intensive procedures may be overpaid and more device-intensive procedures may be underpaid as determined by the volume weighted procedural frequency. Second, device-intensive procedures that are assigned to a non-device intensive APC may be inappropriately underpaid as a result of heterogeneity within the APC with respect to device-intensity.

MDMA thus recommends that device-intensity determination for purposes of payment in the ASC setting be made at the individual HCPCS code level, rather than the APC level. MDMA further recommends that such device-intensive procedures require the concurrent reporting of a device code to permit for appropriate data collection and tracking.

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In conclusion, MDMA is encouraged by CMS's efforts to address important issues in the OPPS, and we look forward to working with CMS in the future to continue to make improvements to this system.

Sincerely,

Mark Leahey

Mark Leahey
President and CEO
Medical Device Manufacturers Association