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Comments to the Centers for Medicare and Medicaid Services
Advisory Panel on Hospital Outpatient Payment

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to address the Advisory Panel on Hospital Outpatient Payment (HOP Panel) regarding the Hospital Outpatient Prospective Payment System (OPPS) proposed rule for calendar year (CY) 2018.[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.

In recent years, the Centers for Medicare and Medicaid Services (CMS) has expanded packaging within in the OPPS by creating 62 comprehensive Ambulatory Payment Classifications (C-APCs). CMS does not propose to create any new C-APCs or to make extensive changes to the methodology for CY 2018.[2] We support this pause in the development of C-APCs. Given the two-year lag in availability of claims data under the C-APCs, we are just now able to evaluate the effects of this new approach to setting OPPS rates for a substantial number of the C-APCs. It is critical that CMS and stakeholders take time to assess the effects of this rapid and substantial change to the OPPS on utilization of and access to care before further changes to the methodology are implemented.

We understand that 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.

[1] 82 Fed. Reg. 33558 (July 20, 2017).
[2] *Id.* at 33564.

We ask the HOP Panel to make the following recommendations to ensure that the OPPS continues to provide Medicare beneficiaries access to appropriate, innovative care:

- **CMS should evaluate the impact of all expansions of packaging on access to care before implementing any new packaging proposals.**
- **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 not package the costs of HCPCS code C1822 into procedure code 63685.**

I. CMS should evaluate the impact of all expansions of packaging on access to care before implementing any new packaging proposals.

CMS's recent expansions of packaging policies involve complex and interrelated changes to the rate-setting calculations. Each year's proposals build on prior changes to the OPPS, often before the effects of those earlier revisions on access to care can be measured. Piling change upon change without understanding how these changes impact beneficiaries or providers is not appropriate. As claims data become available two years after changes are implemented, CMS and stakeholders must analyze it carefully to determine each policy's effects on access to innovative technologies.

We are pleased that CMS accepted the HOP Panel's recommendation to analyze the effects of the C-APCs prior to release of the proposed rule for CY 2018.[3] CMS explains that it took a "broad approach in studying [Healthcare Common Procedure Coding System] HCPCS codes and [ambulatory payment classifications] APCs subject to the C–APC policy to determine whether aberrant trends in the data existed.'[4] CMS concludes, "Overall, we observed no such aberrancies and believe that the C–APC policy is working as intended."[5] In particular, CMS notes that it "observed an increase in claim line frequency, units billed, and Medicare payment," and CMS concludes that this "suggest[s] that the C–APC payment policy did not adversely affect access or reduce payments to hospitals."[6] CMS also reports that the "cost statistics of major separately payable codes (that is, HCPCS codes with status indicator ''S'', ''T'', or ''V'') that were packaged into a C–APC prospectively were consistent with the cost statistics of the codes packaged on the claim in actuality."[7]

We appreciate this analysis, but in light of the short amount of time between release of the proposed rule and related data and the deadline for submission of comments for the HOP Panel meeting, we have not had a chance to verify that these overall assessments of C-APCs are true for specific services. We remain particularly concerned about the effects of the C-APC methodology on access to innovative devices and payment for less commonly-performed procedures that lack sufficient volume to be counted when determining if a C-APC complies

[3] *Id*. at 33580.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*

with the two-times rule. It is possible for a procedure to have costs substantially above the geometric mean for a C-APC yet be included in that C-APC if it is not deemed to be a significant procedure. This appears to be an increasingly common occurrence as the number of services packaged into codes and assigned to a single APC expands.

As it has done in the past, we ask the HOP Panel to recommend that CMS report on the effects of its packaging proposals on access to items and services that no longer are separately reimbursed. This report should be shared with the 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 OPPS 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 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 OPPS, 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 when using data 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 cost of all the services in a given APC are truly representative of the cost of the device used in a particular procedure.

Further, we know that not all device 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 ask the HOP Panel to recommend that CMS continue to find ways to improve transparency between the agency and stakeholders to foster innovation.

III. CMS should not package the costs of HCPCS code C1822 into procedure code 63685.

In the proposed rule, CMS proposes to package the device costs of HCPCS code C1822 (generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), into the procedure associated with the device (Current Procedural Terminology (CPT®)[8] code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling), assigned to APC 5464) as of January 1, 2018.[9] This proposal would be inconsistent with CMS policies and lead to inaccurate cost

[8] CPT is a registered trademark of the American Medical Association.
[9] *Id.* at 33610.

calculations for this procedure. Consistent with the HOP Panel's authority to advise CMS on "packaging the cost of items and services, including drugs and devices, into procedures and services," we ask that the Panel recommend that CMS reverse its proposal to package the costs of HCPCS code C1822 into the procedure code and APC payment associated with the device.

Due to unique circumstances relevant to HCPCS code C1822, CMS lacks a sufficient volume of correctly coded claims for this code. Claim processing errors at the contractor level in 2016 created confusion for this particular code, resulting in a significant number of claims being denied or incorrectly submitted due to conflicting instructions and payment policies. These complications extended throughout the entire first year of claims submissions, and continue on some level even today.

A preliminary evaluation of the cost data from the CY 2016 OPPS rate-setting files, conducted by Watson Policy Analysis, demonstrates the pervasive inaccuracies in cost reporting for code C1822 in the first year the code was active:

- Facilities that frequently billed C1822 reported costs significantly below the amount at which the hospital purchased the device. For example, the three facilities with the highest utilization of C1822 in 2016 reported costs of only 50% - 70% of the actual price paid by the facility to acquire the device. These reported costs do not accurately reflect actual expenses associated with the device.

- Although there was only one company manufacturing and distributing the device described by C1822 in 2016, of the approximately 155 hospitals that reported the code in 2016, more than 25% of those facilities were not customers of that company. These facilities submitted code C1822 for devices that could not have been accurately described by C1822, because they did not purchase the only device described by that code in 2016. These reported costs are necessarily inaccurate.

- These inaccuracies were caused by lack of clear guidance and billing instructions, as well as the unfamiliarity of hospitals with the code and device in 2016.

In light of these circumstances, it would be inappropriate to package the costs of HCPCS code C1822 into CPT code 63685 (APC 5464) as of January 1, 2018. Deferring that packaging decision will allow additional cost data to be gathered (under improved claims processing conditions) that can be used to set appropriate rates in the future.

Moreover, delaying packaging would be consistent with CMS's stated policy goals. In the OPPS final rule for CY 2017, CMS stated that a three-year data collection period before packaging certain device costs into existing procedures will "better insure robust data collection and more representative procedure payments once the pass-through devices are packaged."[10] We agree with this goal and we supported CMS's change in policy. Without a full three years of cost data for devices described by HCPCS code C1822, packaging the costs of C1822 into existing

[10] 81 Fed. Reg. 79562, 79655 (Nov. 14, 2016).

payments will result in CMS establishing inaccurate cost and payment data for code 63685 and APC 5464.

We ask that the HOP Panel recommend that CMS reverse its proposal to package costs for HCPCS code C1822 into procedure code 63685 (APC 5464).

Conclusion

In conclusion, MDMA appreciates this opportunity to address the Panel, and we hope that our suggestions will improve the usefulness of the Panel's meetings and ensure the OPPS provides appropriate payment for high-quality care. We look forward to working with CMS in the future to continue to make improvements to this system.

Sincerely,

Mark Leahey

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