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

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

BY EMAIL: APCPanel@cms.hhs.gov

BY MAIL:
Ms. Carol Schwartz
Designated Federal Officer
7500 Security Boulevard
Mail Stop: C4–04–25
Woodlawn, MD 21244–1850

File code CMS–1649–N

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

The Medical Device Manufacturers Association (MDMA) appreciates the opportunity to address the Advisory Panel on Hospital Outpatient Payment (HOP Panel) regarding the Hospital Outpatient Prospective Payment System (OPPS) and the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights.[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.

For CY 2015, the Centers for Medicare and Medicaid Services (CMS) finalized 25 of the proposed comprehensive Ambulatory Payment Classifications (C-APCs), creating 12 clinical families. For CY 2016, CMS continues to expand use of the C-APC payment policy methodology implemented in CY 2015 by creating 9 new C-APCs, including some surgical APCs and a new C-APC for comprehensive observation services. These changes, along with the changes implemented for CY 2015, mean that CMS has developed 34 new C-ACPs, representing a major overhaul of the outpatient payment system. MDMA remains concerned that because this is happening so quickly, there has not been time or data available to understand the effect of these dramatic changes on access to care and appropriate utilization of innovative technologies.

The OPPS final rule for calendar year (CY) 2016 continued to expand the packaging policy for the following list of OPPS packaged items and services:[2]

- Ancillary services – For the CY 2016 final rule, CMS identified services in certain APCs that meet specific criteria, and CMS did not apply the $100 geometric mean cost threshold that the agency applied for CY 2015. CMS expanded 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

[1] 80 Fed. Reg. 70298 (Nov. 13, 2015).
[2] 80 Fed. Reg. at 70344-50.

- Clinical diagnostic laboratory tests.

CMS has explained that these packaging and bundling 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 and accurate bundling policies, it is essential that CMS continues to proceed cautiously in pursuing these objectives. If Medicare's payment rates and bundles do not accurately reflect the costs of providing appropriate care, hospitals will not be able to provide beneficiaries the best care available today, nor will they be able to 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, we ask the HOP Panel to make the following recommendations:

- **CMS should evaluate the impact of its most recent expansions of packaging on access to care before implementing any new packaging proposals.**
- **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.**
- **CMS should not package payment for newly created codes for at least three years.**
- **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 remain as transparent as possible about the data used to set payment rates.**

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

CMS's recently finalized 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. 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) are just becoming available, and data reflecting the changes implemented in CY 2015 (procedures described by add-on codes; 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 suggested in our comment letters and statements to this Panel, 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 OPPS are implemented.

Recognizing the importance of evaluating data on newly bundled services and the impact that bundling has had on those services, at the spring 2015 meeting, the HOP Panel requested that CMS provide utilization data on newly packaged services to the Data Subcommittee for review at its next meeting.[3] This is a recommendation we suggested and supported; we appreciate the HOP Panel recognizing its importance.

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.

We are concerned that the packaging of procedures has the potential to create perverse incentives. For example, the radiofrequency ablation of spinal metastases frequently requires the installation of bone cement to support the vertebral body. However, packaging these procedures puts the hospital at a financial disadvantage when these procedures are performed together. At the same time, not doing them together may put the patient at risk. No hospital or physician should be faced with a choice between financial wellbeing and patient wellbeing. Additional CMS analysis of such situations is needed before the program of comprehensive APC is continued.

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 finalized its proposal (with modifications) 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 OPPS APC structure.[4] By finalizing this proposal, CMS eliminated more than 80 APCs. In some cases, the consolidation appeared to be reasonable and MDMA generally supported such consolidation.

In other cases, by contrast, such dramatic consolidation has the potential to exacerbate payment inequities and inaccuracies. In these instances, MDMA did not support such consolidation. For example, MDMA was concerned about the resulting drastic payment reductions for some procedures in those APCs, specifically, the proposed reassignment of codes 31295 and 31296 within the restructured airway endoscopy APCs. MDMA provided comments on the proposed rule asking CMS to assign those codes to the Level 5 APC (APC 5155). We thank CMS for taking comments into consideration when restructuring the APCs by reassigning codes 31295 and 31296 to APC 5155 in the CY 2016 OPPS final rule. Consolidation drastically affected the

[3] Advisory Panel on Hospital Outpatient Payment, March 9, 2015, Final Recommendations, www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.
[4] 80 Fed. Reg. at 70380.

payment rates for other services in the final rule, however, and further consolidation would raise the concerns about inadequate payment rates. Therefore, MDMA again recommends CMS move slowly with any further consolidation of clinical APCs until the agency 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 applaud 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]

We again ask the HOP Panel to recommend that CMS employ the same cautious approach to any further expansions of the packaging under the OPPS. We continue to find the 60-day comment period on the proposed rule often is not enough time to fully analyze CMS's proposals. Because the OPPS 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. We are delighted that CMS released the claims data soon after the 2016 OPPS proposed rule was released, and that the agency worked with consultants to answer questions and help them replicate the ratesetting calculations. We urge CMS to take the same approach to the 2017 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 continue to 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 comprehensive APCs, to allow sufficient time for refinement and implementation.

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

We are troubled by CMS's decision 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 finalized its proposal 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). We ask the HOP Panel to recommend that CMS 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.

[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-Agenda-Recommendations.zip.
[6] 78 Fed. Reg. 74826, 748764 (Dec. 10, 2013).

IV. 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.

V. CMS should remain as transparent as possible about the data used to set payment rates.

We ask the HOP Panel to recommend that CMS 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 HCPCS codes are device-specific (for example, L8699, Unlisted orthopedic implant). We ask the HOP Panel to recommend that the data CMS uses in setting payment rates be 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 capturing the costs of devices, and we ask the HOP Panel to recommend that CMS continue to find ways to improve transparency between the agency and stakeholders to foster innovation.

Conclusion

In conclusion, MDMA is encouraged by the Panel's willingness 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