MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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

BY EMAIL: APCPanel@cms.hhs.gov

BY MAIL:
Ms. Carol Schwartz
Designated Federal Officer, HOP Panel
CMS/CM/HAPG/DOC
7500 Security Boulevard
Mail Stop: C4–04–25
Woodlawn, MD 21244–1850

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) 2017.[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 2016, the Centers for Medicare and Medicaid Services (CMS) finalized an additional nine new comprehensive Ambulatory Payment Classifications (C-APCs), for 37 total C-APCs for CY 2016. For CY 2017, CMS is proposing to continue to implement the C-APC payment policy methodology implemented in CY 2015, and to create 25 new C-APCs for CY 2017, including a new C-APC for Allogeneic Hematopoietic Stem Cell Transplantation. These current proposed changes, along with the changes implemented for CY 2016, means that CMS has developed 62 new C-APCs, representing a major overhaul of the outpatient payment system. Because this change is happening so quickly and on such a large scale, there has not been time or data available to understand the effect of these dramatic changes on utilization of or access to care.

In addition to creating new C-APCs, CMS is proposing to modify packaging policies for the following list of OPPS packaged items and services:[2]

- Conditional packaging status indicator logic – In the CY 2017 proposed rule, CMS proposes to align the packaging logic for all of the conditional packaging status indicators and change the logic for status indicators "Q1" and "Q2" so that packaging would occur at the claim level (instead of based on the date of service), which CMS admits would increase the packaging of conditionally packaged items and services; and

[1] 81 Fed. Reg. 45604 (July 14, 2016).
[2] *Id*. at 45628-45630.

- Clinical diagnostic laboratory tests – CMS proposes to end its "unrelated" laboratory test exception to its packaging policies and will package "any and all laboratory tests if they appear on the claim with other hospital outpatient services."[3] CMS also proposes to exclude molecular pathology tests and certain advanced diagnostic laboratory tests.[4]

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. CMS has also stated that the new device pass-through payment process will increase transparency and opportunities for stakeholder input. 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.

Before addressing CMS's proposals more specifically, we want to comment on the role of the HOP Panel in helping CMS and stakeholders achieve their shared goals.

- **CMS should schedule the HOP Panel meeting during the last week of the comment period, and should push back the deadlines for registration and submission of comments so stakeholders can have time to analyze the impact of the proposals before requesting to testify.**

As CMS expands packaging, it is even more critical than ever that the agency use the HOP Panel to review its proposals, verify the appropriateness of APC assignments, and provide a public forum for stakeholders to share concerns about CMS's methodologies and calculations. Yet, despite this need, CMS has diminished the role of the Panel and the opportunity for stakeholders to air their concerns before it. The early deadline for submissions for this meeting, combined with the increasing complexity of the OPPS methodology and the time needed for the few analysts who can replicate the payment rates to run their calculations, makes it nearly impossible to provide detailed comments to the Panel in our written statements.

MDMA urges CMS to restore the role of the Panel to hear concerns and provide recommendations to CMS about the OPPS. We continue to believe CMS should use the HOP Panel and the public meeting each year 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 in 2014, to allow sufficient time for refinement and implementation. CMS also should provide data on the effects of previously implemented expansions of packaging and should discuss ideas for future policies at the HOP Panel meeting.

[3] *Id*. at 45628.
[4] *Id*. at 45628-29.

To make the meeting more productive for the Panel, CMS, and stakeholders, MDMA therefore urges the Panel to recommend that CMS schedule the HOP Panel meeting during the last week of the comment period and push back the deadline to register until after the proposed rule comes out in early July to allow sufficient time for interested parties to review the proposals, consider the impact, and make meaningful presentations to the HOP Panel.

Turning to the substance of CMS's proposals, 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 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 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.**

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

CMS's proposed 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) and CY 2015 (procedures described by add-on codes; ancillary services; and prosthetic supplies) are now available and must be analyzed closely to determine their effects on access to innovative technologies before CMS expands packaging further.

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.[5] This is a recommendation we suggested and supported; we appreciate the HOP Panel recognizing its importance.

As we have 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

[5] Advisory Panel on Hospital Outpatient Payment, March 9, 2015, Final Recommendations, www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.

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 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.

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."[6] 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.[7]

We once 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 that 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. 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.

More clarity is needed around how CMS calculates the payment rate for APCs and C-APCs as the agency expands packaging and bundling. We are concerned that the larger payment bundles CMS has implemented in recent years may not produce rates that accurately reflect the costs of services provided. For example, we are concerned that the proposed comprehensive APC packaging of upper airway procedures, including sinus surgery in APC 5155, has the potential to significantly negatively impact payment for those services, subsequently impacting Medicare beneficiary access. We are concerned C-APC 5155 does not account for the diversity of sinus procedures that could be performed across the four sinuses, particularly if bilateral procedures are also considered. We need more time to analyze the proposed rates to verify that they are appropriate for procedures commonly performed on a bilateral basis.

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 and C-APCs.

---

[6] 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.

[7] 78 Fed. Reg. 74826, 748764 (Dec. 10, 2013).

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 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. For CY 2017, CMS is proposing to change the methodology used for assigning device-intensive status to calculate the device offset amount at the HCPCS code level rather than at the APC level so that device-intensive status is assigned to all device-intensive procedures that exceed the 40 percent threshold.[8] We thank CMS for addressing concerns on how device costs are packaged and support the proposal's finalization.

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.

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

Mark Leahey
President and CEO
Medical Device Manufacturers Association

[8] 81 Fed. Reg. at 45654-55.