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**Comments to the Centers for Medicare & 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 (the HOP Panel) on important changes in the Hospital Outpatient Prospective Payment System (OPPS). 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 OPPS final rule for calendar year (CY) 2014 made significant changes to payment for procedures using medical devices, and CMS plans to implement more revisions in CY 2015. For CY 2014, CMS expanded packaging to include five new categories of items and services:

1. Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;
2. Drugs and biologicals that function as supplies or devices when used in a surgical procedure;
3. Certain clinical diagnostic laboratory tests;
4. Procedures described by add-on codes, excluding drug administration services; and

5. Device removal procedures.¹

For 2015, CMS plans to create 29 new comprehensive ambulatory payment classifications (APCs) to pay for certain device-dependent procedures. Each comprehensive APC will include not only all of the items and services that are packaged under the current OPPS rule, but also nearly all adjunctive items and services, such as:

- all services packaged, conditionally or unconditionally, elsewhere under the OPPS;
- all adjunctive services provided during the delivery of the comprehensive service; and
- all hospital-administered drugs pursuant to a physician order, excluding pass-through drugs.

CMS would continue to pay separately for mammography services, brachytherapy seeds, and pass-through drugs and devices, and ambulance services as non-OPPS services, regardless of whether they are reported as part of a comprehensive service.

CMS has explained that these 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 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 at least one year between proposing any expanded packaging and implementing any such policies to allow stakeholders and the HOP Panel sufficient**

¹ 78 Fed. Reg. 74826, 74832 (Dec. 10, 2013).

time to study CMS’s methodology and assess the appropriateness of the proposed APCs and payment rates.

- **CMS should 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 its most recent expansions of packaging on access to care before implementing any new packaging proposals.

MDMA and other stakeholders joined the HOP Panel in urging CMS to delay implementation of its proposals for CY 2014 to allow more time for all parties to conduct a thorough analysis of CMS’s rate-setting methodology and calculations and to assess the impact of these changes on access to care. We recognized that these changes to OPPS payment policies involve complex and interrelated changes to the rate-setting calculations, and stakeholders found it difficult to verify the accuracy of the proposed payment rates and provide detailed comments during the comment period on the proposed rule. In many cases, the proposed rates reflected dramatic and unpredictable changes in payment, ranging from – 5 percent to +189 percent compared to the CY 2013 rates. Consultants identified several significant errors in the proposed rates, and there was little time to assess the appropriateness of the proposed payment rates when CMS released corrected files shortly before the end of the comment period. We supported the HOP Panel’s recommendation to 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.”²

Despite these recommendations, CMS decided to implement most of its proposals for expanded packaging. Now that these policies have been implemented, CMS should not expand packaging further until the agency has evaluated the effects of these policies on access to care. At this point, it is too early to make such an assessment. These policy changes will have been in effect for only one month before the deadline for submission of testimony for the HOP Panel meeting, and will have been in place for just over two months when the meeting is held. More time is

² 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>.

needed to analyze hospitals' response to these new incentives and their effects on beneficiaries' care. 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 are no longer 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 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 at least one year between proposing any expanded packaging and implementing any such policies to allow stakeholders and the HOP Panel sufficient time to study CMS's methodology and assess the appropriateness of the proposed APCs and payment rates.

CMS finalized its comprehensive APC proposal with modifications, but agreed to delay implementation for one year to allow both CMS and hospitals more time to evaluate the agency's calculations and prepare for the new payment approach.³ We commend this decision and ask the HOP Panel to recommend that CMS employ the same cautious approach to any further expansions of the packaging under the OPSS. Indeed, we 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 has done with the comprehensive APCs, to allow sufficient time for refinement and implementation.

³ 78 Fed. Reg. at 74832.

III. CMS should 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 have urged CMS to require complete and correct coding for packaged services. We have seen that hospitals are much more likely to report all codes and costs for packaged services when there is a requirement to do so. In the CY 2014 proposed rule, CMS recognized this fact, explaining that since device-dependent APCs were created, employing device-to-procedure and procedure-to-device edits, CMS has seen a "significant improvement and stabilization in reporting of costs."⁴

CMS proposed to remove the edits on the basis that "hospitals are now fully accustomed to appropriate cost reporting under the OPPS such that special billing constraints are unnecessary."⁵ CMS did not implement its proposal and is further assessing the need to continue claims processing edits requiring a device code to be on the claim under the comprehensive APCs in CY 2015.

We do not share CMS's confidence that hospitals will continue to report codes for packaged items and services if they no longer are required to do so. Although CMS believes that hospitals are accustomed to reporting these codes, the agency also describes the edits as a burden on hospitals.⁶ We are concerned that hospitals might seek to improve their claims filing efficiency in the short term by not reporting codes that are needed for appropriate rate-setting in the long term. MDMA asks the HOP Panel to recommend that CMS require complete and correct coding for packaged services and continue to employ device-to-procedure and procedure-to-device edits.

⁴ 78 Fed. Reg. 43534, 43695 (July 19, 2013).

⁵ Id.

⁶ 78 Fed. Reg. at 74857.

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.