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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) 2019. 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.

Between CYs 2015-2017, the Centers for Medicare and Medicaid Services (CMS) overhauled the outpatient payment system by finalizing a total of 62 comprehensive Ambulatory Payment Classifications (C-APCs). Those changes happened rapidly and on such a large scale that there was no time or data available to understand the effect of those changes on utilization of or access to care. CMS did not propose any new C-APCs for CY 2018; MDMA appreciated the agency's recognition of the need to evaluate the impact these payment changes have had on beneficiaries. However, for CY 2019, CMS proposes three new C-APCs.

In addition to creating new C-ACPs, CMS proposes to modify packaging policies for non-opioid pain management therapy. MDMA appreciates that CMS is willing to pursue proposals to reduce payment obstacles to procedure alternatives to opioids and to the delivery of non-opioid anesthetics.

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.

As CMS considers changes to the outpatient prospective payment system, it is critical 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. This year, the comment deadline is only days after the release of the proposed rule. This quick turnaround is unacceptable; there is not enough time to review the rule, analyze payment implications, and provide thoughtful comments to the Panel.

MDMA continues to urge 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.

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 packaging policies 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.**
- **CMS should not implement the proposed reductions in payment for clinic visits and expanded clinical families of services at excepted off-campus departments.**

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

The last few years, CMS proposed significant expansions in the agency's packaging policies. Each year's proposals built upon 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.

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

As we have done in the past, we continue to 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 appreciate there were no C-APCs created last year; however, despite our recommendations, CMS is proposing three new C-APCs this year:

- Proposed C-APC 5163 (Level 3 ENT Procedures);
- Proposed C-APC 5183 (Level 3 Vascular Procedures); and
- Proposed C-APC 5184 (Level 4 Vascular Procedures).

Stakeholders need time to analyze the implications for these C-APC changes. MDMA urges to the panel to recommend that CMS provide stakeholders with the time and the data with which to do so.

II. CMS should allow sufficient time and adequate data to be collected to better understand the impact of packaging changes, including implementation of C-APCs, 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."[2] 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.[3] We also appreciate the agency's decision to not create any new C-APCs for CY 2018, allowing time for data to be collected on those that already exist. For CY 2019, CMS proposes to create three new C-APCs.

We once again ask the HOP Panel to recommend that CMS employ the same cautious approach to any future 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.

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

[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.

[3] 78 Fed. Reg. 74826, 748764 (Dec. 10, 2013).

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. As we anticipate that CMS will continue to package services and products in the future, 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.

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.

CMS's current interest in understanding the impact of packaging policies on the use of opioids and changes that need to be made to encourage non-opioid alternatives and procedure alternatives is an example of more thoughtful approach to C-APCs and the creation of C-APCs that MDMA has recommended in the past and continues to recommend going forward. MDMA appreciates the agency's recognition that packaging policies can discourage physicians from providing medically necessary, clinically appropriate services to beneficiaries and investment in the technologies that will allow care to continue to improve, and encourages CMS to continue to review its packaging policies in this context.

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, and CMS should finalize the proposed changes to the device-intensive criteria.

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 had been 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 changed 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.[4] For CY 2019, CMS proposes to modify the device-intensive criteria to:

[4] 81 Fed. Reg. at 79657-58.

1. Allow procedures that involve surgically inserted or implanted, single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure; and
2. Modify the criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive.

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.

IV. CMS should not implement the proposed reductions in payment for clinic visits and expanded clinical families of services at excepted off-campus departments.

Finally, we ask the HOP Panel to recommend that CMS not implement the proposed payment reductions for clinic visits and expanded clinical families of services in off-campus departments that are excepted from the provisions of Section 603 of the Bipartisan Budget Act of 2015. CMS proposes to reduce payment to 40 percent of the OPPS rate for these services, and to implement the reduction in clinic visit payments in a non-budget neutral manner, producing a cut in total payments under the OPPS of 1.2 percent. CMS proposes these payment reductions to help limit "unnecessary increases" in volume of procedures at these departments.

MDMA is troubled by the breadth of these proposals and their potential effects on payment for a wide range of procedures using innovative medical devices. We believe that a reimbursement cut of 60 percent would produce payment rates that would be too low to reimburse hospitals for the devices used in these procedures. We also are concerned that reducing payment for expanded clinical families of services will be difficult for hospitals to implement, because it will require a department-specific analysis of codes billed in a baseline period and their related APCs to determine whether the payment reduction applies to each service.

We ask the Panel to recommend that CMS (1) not implement these payment reductions, (2) continue to pay for these services in these excepted off-campus departments at the regular OPPS payment rates, and (3) receive and respond to comments on its ideas for methods for controlling unnecessary increases in volume of outpatient services before implementing any similar policies.

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
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