January 27, 2014

Via Electronic Mail

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1601-FC
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Final Rule (CMS-1601-FC)

Dear Ms. Tavenner:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the Final CY 2014 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Rule.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming healthcare delivery, improving access to life-saving medical devices, and making our healthcare system more effective. The AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring that the latest medical technology innovations are included in all payment systems in an appropriate manner.

AdvaMed appreciates and understands the complexities in developing the OPPS rule. In moving from the proposed rule to the final, CMS clarified several problematic data issues for which AdvaMed and others expressed concern. We appreciate this effort to help us replicate many of the changes using the methodology identified in CMS’s rule. Despite the additional clarification and explanation, we are still experiencing some difficulties in replicating certain aspects of the rule related to comprehensive APCs. These data concerns impact our ability to fully analyze the new comprehensive APCs. Given these difficulties, we urge CMS to
consider our recommendations for improving the transparency of the comprehensive APC methodology and process. Our comments provide further detail.

**Comprehensive APCs**

AdvaMed’s comments focus on the establishment of comprehensive APCs and the proposal in the final rule to establish a methodology for dealing with complex cases involving multiple device-dependent procedures.

The final CY 2014 OPPS rule delayed implementation of the proposal to convert 29 device-dependent APCs into “comprehensive APCs”. The comprehensive APC policy would encompass the procedures billed with the device-dependent APC along with any other charges that would typically appear on a claim associated with said APC. In the final rule, CMS decided to delay implementation of comprehensive APCs until January 1, 2015. AdvaMed supports this change and urges CMS to adopt other changes which will improve stakeholder understanding of the comprehensive APC process.

A change from device-dependent APCs to “comprehensive APCs” represents a major shift in the way that APCs are developed and paid. AdvaMed remains concerned about the potential impact that a conversion to comprehensive APCs could have on payment rates and on the ability of patients to continue to receive the technology and care that they require. Analysis of the final rule suggests that CMS resolved many of the comprehensive APC data concerns in the proposed rule. However, we continue to have concerns with projected impact of comprehensive APCs on several significant or specific procedures.

These concerns pertain specifically to APCs 0083 and 0229. The payment calculations for these APCs, which include several critical and commonly performed cardiovascular procedures, was very difficult to replicate in the proposed rule. We are experiencing similar difficulties understanding the final rule data for these APCs. We believe these payment calculation discrepancies may be linked to the method that was used by CMS to assign complex device procedures to APCs. AdvaMed’s review of the available data suggests that some of the procedures assigned to APC 0083 should be assigned to APC 0229 due to resource similarities. We are continuing our efforts to replicate the payment calculations for these APCs and would like the opportunity to present additional information to CMS, in advance of the CY 2015 proposed rule, once our analysis in complete.

AdvaMed continues to have concerns within this new policy since the anticipated impact of these changes cannot be fully modeled. In light of payment calculation concerns and our overarching concerns about comprehensive APCs:

- **We encourage CMS to further explore the impact of comprehensive APC changes on all affected codes.**

- **We also encourage CMS to examine the procedures that were assigned to APCs 0083 and 0229 to ensure that, in addition to satisfying the other CMS criteria, these assignments best reflect the procedures’ resource and clinical similarities.**
The final CY 2014 OPPS rule also includes a method for more accurately accounting for the costs associated with complex cases with multiple device-dependent procedures. In replicating this methodology, AdvaMed experienced difficulty in determining the APC to which the complex case claims will be assigned. This methodology was not discussed in the final rule and is not apparent from the associated tables—making it difficult for stakeholders to determine whether the new methodology assigns the complex procedures to appropriate APCs that adequately account for the costs associated with performing the procedures and which are clinically similar.

- **AdvaMed recommends that CMS clarify the APC to which the various complex procedures are being assigned and provide opportunity for comment.**

- **AdvaMed also recommends that CMS develop a comprehensive addendum that lists the key complexity APC reassignments. This reference would allow stakeholders to better understand the process for assigning complex procedures to various APCs.**

Lastly, AdvaMed would like to raise a concern related to the impact of CMS’s new add-on code packaging policy. Our analysis of the final rule suggests that the complexity APC procedures could be affected by the packaging of add-on codes. Data suggests that CMS’s treatment of add-on codes included in complexity re-assignment APCs may vary based on the procedure. However, the process used by CMS to determine how an add-on code should be evaluated under this methodology is not discussed. AdvaMed believes that any methodology that takes add-on codes into account should be applied consistently across procedures.

- **AdvaMed recommends that CMS clarify the methodology that it applied to add-on codes in the various complexity APC assignments.**

**Reinstatement of Device Edits**

Additionally, the final rule finalized a recommendation to eliminate procedure-to-device and device-to-procedure edits for all APCs. Device edits have historically been very useful in ensuring the collection of accurate cost data. AdvaMed is concerned that elimination of these edits, especially in an environment of increased bundling, will jeopardize data accuracy.

In finalizing the decision to remove these edits CMS suggested that it will continue to monitor claims to determine whether reinstatement of the edits is needed at some time in the future.

- **AdvaMed recommends that CMS monitor claims and that the agency reinstate the device edits in CY 2015 to coincide with the implementation of comprehensive APCs.**

**Conclusion**

AdvaMed greatly appreciates the opportunity to comment on the CY 2014 final OPPS and ASC rule with comment and urges CMS to consider and incorporate our recommendations in future rulemaking for these payment systems. We also encourage CMS to work with us and other
stakeholders as the agency moves forward with the implementation and development of comprehensive APCs. AdvaMed also urges CMS to consider comments from AdvaMed members and others who will be providing detailed recommendations on both the final rule.

We would be pleased to answer any questions regarding these comments. Please contact me or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

Don May
Executive Vice President,
Payment and Health Care Delivery