Comments to
Centers for Medicare and Medicaid Services
Advisory Panel on Hospital Outpatient Payment
March 14-15, 2016

Submitted By: DeChane L. Dorsey, Esq. January 29, 2016
On behalf of the
Advanced Medical Technology Association (AdvaMed)

AdvaMed appreciates the opportunity to address the Advisory Panel on Hospital Outpatient Payment (the Panel) and commends the Panel on its efforts to evaluate and improve the APC groups under the hospital outpatient prospective payment system (OPPS) and to ensure that Medicare beneficiaries have timely access to new technologies.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed is committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings and supports a system with payment weights and payment rates that include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient and ambulatory surgical center procedures.

Our comments today will address two key topics:

- **Reconfiguring APCs**
- **Comments on Specific APCs**

I. Reconfiguring APCs

There are several issues related to reconfiguring APCs that we would like to address.

Comprehensive APCs

CMS introduced the concept of comprehensive APCs (C-APCs) in the CY 2014 Outpatient Prospective Payment System rule. Since that time the agency has continued to create additional comprehensive APCs (C-APCs) and to make modifications to the policies governing development and use of these payment groupings.

C-APCs were first used on Medicare claims in CY 2015. The claims data that will be used to generate the CY 2017 OPPS rates will represent the first full year of claims data that has been

used for rate setting since establishment of C-APCs-- presenting the first real opportunity to see the impact of these changes on reimbursement for and utilization of these services.

AdvaMed has previously expressed concerns regarding whether the rates associated with the comprehensive APC's adequately or accurately reflect all of the procedures and costs associated with those APCs. This is of particular concern as CMS continues to expand the number of packaged and bundled services.

- ***AdvaMed encourages the Panel to recommend that CMS analyze the claims data and to provide a report on the impact of the conversion to C-APCs for the 25 C-APCs that went into effect on January 1, 2015.***
- ***AdvaMed encourages the Panel to recommend that CMS monitor and report on the impact of comprehensive APC changes on all affected codes and any potential impacts to patient access to services that are bundled under the comprehensive APCs.***

Complexity Adjustments

CMS has developed a process for identifying and applying complexity adjustments to certain combinations of codes as a part of the comprehensive APC policy. AdvaMed provided CMS with comments on this issue in response to the proposed CY 2015 rule and CMS refined the complexity criteria and the process for complexity assignment in the final rule. Despite these changes AdvaMed continues to have concerns regarding appropriate application of complexity criteria and the resulting APC assignments for codes within the comprehensive APCs.

- ***AdvaMed requests that the Panel recommend that CMS monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.***

Device Edits

AdvaMed has previously expressed concern regarding the elimination of device edits. Device edits have historically been very useful in ensuring the collection of accurate cost data.

CMS previously stated that it will monitor claims to determine whether reinstatement of the edits is needed at some time in the future. The CY 2016 rule finalized a proposal requiring device codes on claims for devices assigned to device-intensive APCs. AdvaMed is supportive of the decision to reinstate device edits for these procedures.

- ***AdvaMed requests that the Panel recommend that CMS continue to monitor claims to evaluate the need to reinstate all device edits.***

Restructuring APCs

CMS finalized the restructuring of nine APC clinical families in CY 2016. CMS also renumbered several APCs to improve understanding of the groupings. AdvaMed supports CMS's objectives of improving clinical homogeneity, resource homogeneity, reducing overlap within

APC families, and simplifying and improving understanding of APC structure. We are however concerned that any restructuring changes achieve the goals outlined by CMS while preserving stability and predictability within the payment system. Specifically, some of the restructuring proposals may result in wide variations in payment and may produce groupings that are too broad, creating APCs that do not appropriately reflect resource distinctions.

- ***AdvaMed urges the Panel to recommend that CMS staff engage with relevant stakeholders to solicit input related to restructuring APCs.***
- ***AdvaMed also urges the Panel to recommend that CMS monitor and report on the impacts of its APC restructuring policies.***

Packaging Items and Services Into APCs

Skin Substitute Products

For CY 2016 CMS is continuing its policy of packaging payment for skin substitute products and paying for these products via a low or high cost APC structure. However for CY 2016 CMS will consider either mean unit cost (MUC) **or** per day cost (PDC) in determining and identifying the appropriate cost threshold. AdvaMed is pleased with CMS's decision to revise its methodology in an effort to more accurately establish the low and high cost thresholds for skin substitute products but has concern with the impact of some of these changes in policy on low cost skin substitute products. AdvaMed continues to be concerned about the payment rates for low cost products when used to treat wounds less than 100 sq. cm.

- ***AdvaMed asks the Panel to recommend that CMS permit exceptions to any general packaging policy in cases where packaging could unreasonably impede patient access to new or existing devices, diagnostics, or other advanced medical technologies.***

- ***AdvaMed asks the Panel to recommend that CMS continue to monitor the impact of the high and low cost threshold pricing on the use and availability of skin substitute products and to continue considering other approaches for covering these products if necessary.***

- ***AdvaMed also asks the Panel to create an APC Group for the application of low cost skin substitutes for wounds less than 100 sq. cm that reflects the true cost of the low cost products and the work to apply them.***

- ***AdvaMed asks the Panel to recommend that CMS work with relevant stakeholders to obtain necessary data.***

II. Comments on Specific APCs

Multi-session Stereotactic Body Radiation Therapy (APC 5625)

AdvaMed is concerned that the payment rates for multiple session stereotactic body radiation therapy (SBRT) continue to decrease. The rate for these services for CY 2016 is approximately 11 percent below the payment for these same services in CY 2015. We do not believe that these payments are reflective of the actual costs of providing these services. AdvaMed is concerned that continued decreases in the payments for these services will impair beneficiary access to what could potentially be the most appropriate and safe treatment option. We are further concerned about the future impact of inaccurate rates for these procedures as CMS continues to expand packaging of services.

- ***AdvaMed asks the Panel to recommend that CMS continue to work with stakeholders to ensure appropriate payment for SBRT procedures in APC 5625***.

Disposable Negative Pressure Wound Therapy (NPWT) (APC 0015)

Given coding confusion for various disposable NPWT product types and near absence of hospital reporting of the disposable device that is required for each procedure, OPPS claims data inadequately reflects device costs for this service. In addition, because of the recent introduction of the NPWT CPT codes many OPPS claims do not capture the cost differences between traditional NPWT and disposable NPWT. AdvaMed is concerned that current rates do not cover the cost of the disposable device used in these services, and that this may impair patient access to these innovative technologies.

- ***AdvaMed asks the Panel to recommend that CMS continue to work with stakeholders to gain better cost data in order to guide the appropriate APC assignment for disposable NPWT.***

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AdvaMed encourages the Panel to continue to recognize the unique challenges associated with device-dependent procedures and urges the Panel and CMS to carefully consider the timeliness, adequacy, and accuracy of the data and the unique perspective that manufacturers bring to these issues.

Thank you.

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