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 several topics:

- Reconfiguring APCs
- Comments on Specific APCs
- HOPs Meeting Schedule

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 CY 2017 OPPS rates represented the first full year of claims data used for rate setting since establishment of C-APCs. 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 continue to analyze the claims data and to 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 has repeatedly expressed 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 continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs and consider alternative methodologies, such as lowering the two times cost threshold currently required to qualify for complexity adjustment, or using it as a general guideline rather than a strict criteria.**

**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.

The CY 2016 and 2017 rules finalized proposals requiring device codes on claims for devices assigned to device-intensive APCs. AdvaMed supported the decision to reinstate device edits for device-intensive procedures.

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

**Brachytherapy Insertion (High Dose Rate)**

CMS should take steps to ensure that fair and adequate payment is provided as the Agency transitions reimbursement for High Dose Rate (HDR) brachytherapy to a bundled payment under the comprehensive APC (C-APC) methodology. Payments for HDR brachytherapy should reflect the full scope of medically necessary services associated with its administration including insertion procedures and treatment services.

The CMS proposal would result in significant and counterproductive cuts to reimbursement that would threaten patient access to this valuable intervention for cancer treatment. In the proposed rule, CMS acknowledged, that many brachytherapy insertion procedure codes (CPT codes
571555, 205555, 31643, 41019, 43241, 55920, and 58346) are billed without a brachytherapy treatment code (CPT codes 77750 – 77799) on the same claim. CMS is proposing a code edit that would require use of a brachytherapy treatment code when a brachytherapy insertion code is billed.

AdvaMed supports steps that will ensure the long term integrity of the bundled payment methodology. However, the proposal, if finalized, would reduce HDR brachytherapy rates by more than 30 percent in 2018. This cut will threaten access to this important technology for cancer patients. Because the code edit will not appear in rate-setting data for two years, it will also result in a payment rate that does not accurately reflect the full cost of services, which conflicts with the intent and design of C-APCs. AdvaMed urges CMS to identify a solution that protects patient access to this important technology.

- **AdvaMed requests that the Panel recommend that CMS not use brachytherapy C-APCs associated with the identified insertion procedure codes for at least two years until correctly coded claims data are available for rate-setting purposes.**

**Packaging Items and Services into APCs**

**Skin Substitute Products**

For CY 2018 CMS is proposing to continue its policy of packaging payment for skin substitute products and paying for these products via a low or high cost APC structure. The agency will continue to consider either mean unit cost (MUC) or per day cost (PDC) in determining and identifying the appropriate cost threshold. For CY 2018 CMS is proposing to retain skin substitute products that had been placed in the high cost group in CY 2017, but no longer exceed the applicable MUC or PDC thresholds, as high cost products-- to maintain consistency as the agency continues to evaluate the methodology for pricing skin substitutes.

- **AdvaMed supports CMS’ recommendation to maintain skin substitutes that were in the high cost group in CY 2017 in that group for CY 2018 and asks the Panel to recommend that CMS finalize the recommendation.**

**II. Comments on Specific APCs**

**Drug Coated Balloon Angioplasty Procedures**

Beginning in April 2015, CMS recognized the significant clinical benefit of drug coated balloons (DCBs) in the treatment of peripheral artery disease (PAD) with the approval of transitional pass-through payment (TPT). Pass-through payment for DCBs is set to expire on December 31, 2017. Beginning in CY 2018, payment for DCBs will be packaged into the APC payments for the associated revascularization procedures in which they are used. AdvaMed is particularly concerned that the proposed payment for femoropopliteal angioplasty procedures (described by CPT code 37224) of approximately $4,999 (APC 5192 Level 2 Endovascular Procedures), is significantly less than the historical cost of cases involving DCB, estimated at $8,483. Unless
CMS reassigns these cases to a higher level APC, the Medicare payment will be inadequate to ensure continued patient access to this important technology.

- **AdvaMed requests that the Panel recommend to CMS that DCB angioplasty procedures qualify for a complexity adjustment and be reassigned to APC 5193 Level 3 Endovascular Procedures APC in order to improve alignment between payment and costs in CY 2018.**

**Musculoskeletal APCs**

CMS is proposing removal of total knee arthroplasty (TKA) from the inpatient only list, and assigning the TKA procedure (CPT code 27447) to APC 5115 (Level 5 Musculoskeletal Procedures).

- **AdvaMed asks the Panel to recommend to CMS that any final rate for TKA be based on grouping this code with similar device-intensive orthopedic procedures.**

Additionally, while we appreciate that CMS has given much thought to the decision to make TKA payable as a HOPD procedure, we are concerned that the proposed rule does not address or respond to issues raised in last year’s proposed rule regarding the implications of removing TKA from the inpatient only (IPO) list for hospitals, providers, and practices currently participating in the Comprehensive Care for Joint Replacement (CJR) model. The consequences of removing TKA from the IPO list are especially critical for providers participating in the CJR, given the program’s lack of a mechanism to adjust risks for patient health and medical condition. As we noted in our OPPS comment letter last year, if more TKA procedures are moved to an outpatient setting, hospitals participating in the CJR may be left with a more acutely ill patient population needing TKA. Because the inpatient admission for TKA establishes the starting point for calculation of CJR benchmarks and actual spending, this change would likely affect participating providers’ ability to reduce spending below their benchmark or target price—since many of their healthier patients would now be treated outside of the episode. CMS would have to consider adjustments to a hospital’s benchmark to account for the higher risk profile of patients receiving TKA as an inpatient procedure.

- **AdvaMed requests that the Panel recommend that CMS provide information to the public regarding how removal of TKA from the inpatient only list will impact participants in the CJR prior to finalizing this policy.**

**III. Changes to the HOPs Meeting Schedule**

The announcement for the HOPs meeting along with the deadline for submitting statements is typically published in the Federal Register several months prior to display or publication of the proposed rule. In recent years delayed release of the proposed rule has led to a truncated period of time for stakeholders to develop comments for the Panel meeting--necessitating the extension of the deadline by which to submit statements. While stakeholders are appreciative of these extensions, and the flexibility shown by CMS in granting them, we would recommend that the
approach to setting deadlines for the meeting statements be modified so as to avoid this situation from arising in the future.

- **AdvaMed asks that the Panel recommend to CMS that the HOPs meeting statement submission deadlines be changed from a firm date to 21 days from the display of the proposed rule to permit definitive time for claims analysis and statement development.**

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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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