



September 6, 2016

Via Electronic Mail Only

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health record (HER) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program (CMS-1656-P)

Dear Mr. Slavitt:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the proposed CY 2017 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 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. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Our comments will address the following issues:

- I. Proposed Updates Affecting OPPS Payments
 - A. Proposed Data Development Process and Calculation of Costs Used for Ratesetting
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 - ii. Complexity Adjustments
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 - 1. MRgFUS for Essential Tremor

- v. Proposed Calculation of Single Procedure APC Criteria-Based Costs
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- V. Proposed Procedures that Would Be Paid Only as Inpatient Procedures—Solicitation of Public Comments on Possible Removal of Total Knee Arthroplasty (TKA) Procedures from the IPO List
- VI. Proposed Nonrecurring Policy Changes— Section 603 of BBA Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider
- VII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
- VIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
- IX. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

I. Proposed Update Affecting OPPS Payments

AdvaMed has a number of comments related to the proposed payment updates for OPPS services in CY 2017. Our comments will cover a number of areas including claims data, APC development, and payment for devices. AdvaMed appreciates the ongoing effort on the part of CMS to stabilize the variation in APC payment rates. Comments on specific provisions are provided below.

A. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

i. Establishment of 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. AdvaMed has raised a number of concerns since the initial creation of these more bundled APCs including 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.

The claims data used to generate the CY 2017 OPSS rates represents 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 encourages CMS to 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 CMS to 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.***

The ability to replicate the methodologies used by CMS to make C-APC and other APC based changes in the proposed CY 2017 rule proved challenging using the claims data file and the methodology information that was made publicly available to stakeholders. AdvaMed's consultant at Direct Research, LLC was unable to replicate many of the C-APC payments, bilateral claims, and complexity adjustments included in the proposed rule. AdvaMed's analysis did suggest ongoing payment concerns for complex procedures that are done in a bilateral fashion under a comprehensive APC policy. These reductions may create disincentives for hospitals to perform complex cases and could impact patient access to the care they require.

The data analysis problems include:

- CMS not counting bilateral procedures billed with the 50 modifier as two services;
 - J1 status indicator codes being dropped/ignored for complexity adjustment
 - Inclusion of a third code with a "T" status indicator resulting in hospitals receiving lower payment – OPSS not paying the highest cost procedure on the claim
 - CMS failing to make its policy for establishing potential complexity code pairs publicly available
- ***Because of the problems with claim processing/programming, AdvaMed has grave concerns about the appropriateness of expanding C-APCs and urges CMS to maintain***

the current APC configurations and current status indicators and APC assignments for 2016 for the APCs that CMS proposed to designate as C-APCs for 2017.

- *AdvaMed supports and urges CMS to adopt the HOPs panel recommendation that CMS provide further information and data for stakeholders to review regarding how comprehensive APCs are created and their effects on outpatient payment.*
- *Prior to expansion of C-APCs, AdvaMed requests that CMS review 2015 and 2016 claims data to ensure appropriate payment and make available to stakeholders and the public all necessary data and other information (including methodology information) related to the proposed comprehensive APCs which will allow for an accurate assessment of their impact.*

ii. 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. We are pleased that CMS has proposed to discontinue the requirement that a code combination that qualifies for complexity adjustment must not create a 2 times violation in the new or higher level APC. AdvaMed views this as a positive step in ensuring appropriate application of the policy and resultant appropriate APC placement.

- *AdvaMed recommends that CMS finalize the proposal to discontinue the 2 times rule violation requirement as it applies to complexity adjustments for codes combinations.*

In analyzing the claims data for the proposed rule AdvaMed uncovered some anomalies regarding the application of complexity adjustments to bilateral claims. These anomalies impact CMS' determination regarding whether to assign a complexity payment adjustment and could result in differential payment for the same procedure depending upon whether it is billed using left and right codes on a claim or with the 50 modifier.

- *AdvaMed recommends that CMS review its complexity criteria for bilateral claims and make adjustments as needed to ensure appropriate payment for bilateral procedures that are included in comprehensive APCs.*
- *AdvaMed recommends that CMS continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.*

iii. Impact on Pass-through Status

AdvaMed remains concerned about the impact of the comprehensive APC policy on devices seeking pass-through status. Pass-through status traditionally has been provided to high-cost devices that satisfy a number of criteria including meeting a “significant device cost” threshold where device cost exceeds 25% of the APC payment amount. AdvaMed historically has expressed concerns with the way applications for pass-through procedures are evaluated and approved. However, we have even greater concerns now that a system is being proposed that would require that devices be evaluated against an even larger bundle of costs.

AdvaMed is concerned that comprehensive APCs create even more hurdles for devices seeking pass-through status and recommends that CMS closely evaluate the impact that the development of expanded bundles and other payment policies have on these devices. We suggest CMS conduct an analysis to see how the transition from standard APCs to comprehensive APCs would have affected the eligibility for devices that received pass through status in past years. In addition, CMS should consider lowering the threshold for pass through status eligibility for devices within comprehensive APCs.

iv. Proposed Comprehensive APCs (C-APCs for CY 2017)

1. MRgFUS for Essential Tremor

For CY 2017 CMS is proposing to assign 0398T (Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to C-APC 5462, Level 2 Neurostimulator and Related Procedures APC reimbursed at \$5839.03. The procedure in question was only recently approved by the FDA (July 2016). Therefore, the proposed payment level was determined without the benefit of any claims data. The proposed payment rate for this procedure severely underestimates the resources necessary to offer intracranial MRgFUS as a treatment for essential tremor, creating an unsustainable situation in which facilities will lose money when the service is performed and potentially compromising patient access to much needed treatment.

- *AdvaMed recommends that CMS consider the resource and cost inputs associated with 0398T and that the code be placed in a more appropriate APC.*

v. Proposed Calculation of Single Procedure APC Criteria-Based Costs

AdvaMed has several comments related to single procedure APC costs based on our review of the proposed regulation.

1. 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 recommends that CMS continue to monitor claims to evaluate the need to reinstate all device edits.*

2. Brachytherapy Sources

For CY 2017, CMS will continue to pay separately for each type of brachytherapy device on a prospective basis based on the geometric mean cost of 2015 outpatient claims. There are longstanding problems with the CMS hospital outpatient claims data used to set the prospective brachytherapy device payments. Some examples of these problems include the following:

- High Dose Rate (HDR) brachytherapy devices are “renewable” because the device is decayed over a 90-day period. The source can be used to treat multiple patients during this 90-day period. As a result, the true cost of the device depends on the number of patients treated by a hospital within this time period, as well as the number of treatments required, and the intensity of the treatments. This unique characteristic makes it difficult to establish fair and adequate fixed reimbursement levels for all hospitals on a prospective basis.
- The data continue to show a huge variation in per unit cost reported on claims across hospitals, especially for low volume brachytherapy devices, which further validates our concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2017.
- Rank order anomalies continue to exist in proposed payments for brachytherapy devices. For example, High Activity Palladium-103 sources (C2635) always cost more than “low activity” Palladium-103 sources (i.e., C2640 & C2641); and stranded Palladium-103 sources (C2640) always cost more than non-stranded Palladium-103 sources (C2641). CMS’ data do not reflect this fact, in fact the data yield an inverse pattern, which indicates that CMS’ data may be inaccurate.

HCPCS Code & Descriptor	Geometric Mean Cost (2015 Hospital Claims)
C2641 Palladium-103, non-stranded	\$70
C2640 Palladium-103, stranded	\$77
C2635 High Activity Palladium-103	\$26

In addition, AdvaMed remains concerned that outpatient brachytherapy device payments proposed for CY 2017 continue to be unstable and fluctuate significantly. Proposed percentage

changes to payments from 2016 to 2017 ranges from -61% (C1719) to +1023% percent (A9527). In fact, seven of fourteen brachytherapy devices have proposed percentage changes of +/-10 percent, including A9527, C1716, C1719, C2634, C2635, C2636, and C2643.

HCPCS Code	Long Descriptor	2016 Payment	2017 Proposed Payment	Percentage Change 2016-2017
A9527	Iodine-125, sodium iodide solution, therapeutic, per mCi	\$7.14	\$80.20	1023%
C1716	Gold-198	\$37.31	\$48.19	193%
C2634	High Activity Iodine-125	\$85.18	\$121.91	43%
C2636	Palladium-103, linear	\$14.24	\$18.11	27%
C2643	Cesium-131, non-stranded	\$52.18	\$60.07	15%
C2635	High Activity Palladium-103	\$35.24	\$25.01	-29%
C1719	Non-High Dose Rate Iridium-192	\$93.11	\$36.09	-61%

AdvaMed continues to have concerns regarding Medicare's data on brachytherapy devices. Brachytherapy device payments have fluctuated significantly since CMS implemented the prospective payment methodology based on median costs in 2010 and geometric mean costs beginning in 2013.

- *We continue to urge CMS to adopt policies which more accurately account for the costs associated with HDR brachytherapy treatment delivery and to limit the overall fluctuation in payment for brachytherapy devices.*

B. Proposed Clinical Diagnostic Laboratory Test Packaging Policy: Unrelated Laboratory and Molecular Pathology Test Exceptions

While AdvaMed understands the rationale underlying the proposed changes regarding the discontinued use of the L1 modifier, to identify unrelated laboratory devices, we remain uncertain as to the overall impact this change will have on setting appropriate rates for these services. Though we understand that several hospitals expressed difficulty in using the modifier we have concerns that lab services not provided secondary to another hospital service will be packaged with unrelated services on Medicare claims. As a general course of action we do not support packaging unrelated services as this does not comply with the standard practice of using packaging as a means to create a comprehensive payment for related services. If finalized, we strongly encourage CMS to monitor the impacts of this proposed change.

AdvaMed was, however, pleased to see that CMS will exclude ADLT and ADLT-like tests from the new packaging policy and will continue to evaluate these services separately from others included on a claim. This exception will help to further the objectives of PAMA and will allow accurate tracking of the payments associate with these unique laboratory tests.

- *AdvaMed supports finalization of the proposal to exempt molecular pathology tests from being packaged on Medicare outpatient claims.*

II. Proposed OPSS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPSS APC-Specific Policies

i. Imaging APCs

Currently, the imaging procedure APCs are grouped based on the imaging technology being used as well as whether or not contrast media are used. CMS is proposing consolidation of the 17 imaging APCs that were created in CY 2016 into 8 APCs (differentiated by level and the presence or absence of a contrast agent) for CY 2017. AdvaMed has concerns regarding the lack of stakeholder input that went into the development of the proposed APCs and we question the need for further consolidation of the imaging APCs at this time, especially given the restructuring changes made in CY 2016.

In CY 2016, CMS restructured the imaging APCs, reducing the number of imaging APCs from 54 to 17. The impact of the 2016 restructuring changes on patient access and providers is not yet known due in part to the existence of only one year's claims data and a data lag that prevents substantial analysis of the current groupings/changes. Consequently, the need for additional restructuring at this time is premature.

Additionally, the proposed changes negatively impact imaging services that are essential in the diagnosis and treatment of numerous health conditions. Specifically, the new APCs will result in reductions of 30% or more for many MRI procedures and will negatively impact reimbursement for many ultrasound and CT procedures. These impacts appear to be the result of the inappropriate consolidation of several procedures into APC groupings that are not resource and clinically similar. AdvaMed believes that the new APC proposal should be further vetted prior to implementation.

- *AdvaMed recommends that CMS delay implementation of the imaging APC consolidation proposal and that the agency work with interested stakeholders to determine the most appropriate grouping of these procedures.*
- *AdvaMed also asks CMS to not finalize the proposed payment cuts for ultrasound, CT, and MRI modalities that would be subjected to decrease in payment in excess of 20%.*

Additionally, there are significant unintended consequences of this imaging restructuring proposal that, if adopted, would have a negative impact on beneficiary access to preventive screening for osteoporosis. CMS is proposing to move the Axial Skeleton Dual Energy X-ray absorptiometry (DXA) (CPT 77080), a widely used method for conducting bone mineral density studies, from APC 5522 to APC 5521 for CY 2017. This would decrease the payment rate for Axial DXA by 38% or \$37, making it unaffordable for hospitals to perform this required baseline test in the outpatient setting for any patient being placed on osteoporosis therapy. Proposed APC 5521 would also group all bone mineral tests, along with unrelated services (such as chest x-rays) into the same APC without regard for clinical and resource differentiation among these modalities.

- *AdvaMed urges CMS to not finalize the proposed payment cut for CPT code 77080.*

ii. Strapping and Casting Applications (APCs 5101 and 5102)

In the 2017 OPPS proposed rule, CMS is proposing to change the status indicator (SI) for CPT codes 29581-29584 from “S” to “T”. These codes represent procedures that include the use of multi-layer compression bandaging, and map to APC 5101. The codes have historically been categorized with a SI of “S” and it does not seem reasonable, given their use that they would be subject to a multiple procedure reduction.

CMS did not provide substantive information in the proposed rule regarding the basis for the proposed change making it difficult for stakeholders to properly analyze the proposed change and to offer reasonable alternative proposals.

- *AdvaMed recommends that CMS not finalize the proposal to change the status indicator for CPT codes 29581-29584 from S to T, or change any status indicator without providing a methodology and rationale, and that the agency work with stakeholders to determine a more appropriate resolution.*

iii. Musculoskeletal APCs

In the CY 2016 final rule, AdvaMed was pleased that CMS revised the Musculoskeletal APC structure to add an additional APC to mitigate the dramatic payment shortfall for many musculoskeletal procedures, including percutaneous vertebral augmentation (PVA) procedures (CPT codes 22513-22514).

In the CY 2017 proposed rule, CMS has proposed substantial modifications to the Musculoskeletal APCs, including designating these APCs as C-APCs in 2017. The new Musculoskeletal APC structure in fact specifically reverses the creation of a mid-level APC grouping between approximately \$5,000 and \$9,000, which was finalized by CMS last year in response to comments.

As a result of these modifications procedures including unicompartmental knee replacements, hip arthroscopy procedures, and many spine procedures, including PVA, would be dramatically

underpaid relative to their costs. The reductions range from 26% to more than 30%. We believe setting rates so far below costs could restrict Medicare beneficiary access in this setting of care.

- ***AdvaMed recommends that CMS maintain the CY 2016 APC structure and status indicators for the Musculoskeletal APC groupings in 2017. This will give CMS time to reexamine its claims processing methodology, address the concerns raised in our comment letter, and consider other options for the Musculoskeletal APCs if warranted.***

iv. CRC Screening Colonoscopy (G0105 and G0121)

For CY 2017 CMS is proposing assignment of HCPCS codes G0105 and G0121 (for colorectal cancer screening colonoscopy) to APC 5525 – level 5 diagnostic radiology with contrast. Those two codes more appropriately map to APC 5312 – level 2 lower GI endoscopy procedure a radiologist does not perform these screening colonoscopy procedures and radiological equipment and/or methods are not used in their performance. We ask that the APC assignment for G0105 and G0121 remain aligned as a lower GI endoscopy procedure.

- ***AdvaMed urges CMS to not finalize the proposal to move HCPCS codes G0105 and G0121 (Colorectal Cancer Screening Colonoscopy) to CPA 5525 for CY 2017 and to instead retain the procedures in APC 5312 (Level 2 Lower GI Endoscopy Procedure).***

v. New Technology APC Assignment for Spine Add-on Codes

AdvaMed has ongoing concern regarding appropriate new-technology APC placement for add-on spine codes. For CY 2017, we recommend that CMS work with industry and stakeholders to gather cost information on which to base appropriate New Technology APC assignment for the following codes which have been or are proposed for movement to the outpatient setting and are assigned to status indicator N:.

20936 Sp bone agrft local add-on

20937 Sp bone agrft morsel add-on

20938 Sp bone agrft struct add-on

22840 Insert spine fixation device

22842 Insert spine fixation device

22845 Insert spine fixation device

The AMA CPT Editorial Panel has also created three new spine instrumentation CPT codes 22X81, 22X82, and 22X83 that have been assigned status indicator N. These codes represent a majority of the facility costs for the procedures in which they are used and include expensive implants.

- ***Because CMS does not have outpatient cost information on which to base APC assignment for these codes AdvaMed recommends that CPT codes 22X81, 22X82, and 22X83 be placed in New-Technology APC bands until appropriate cost data is gathered.***

B. OPSS Payment for Devices

i. Proposed Pass-Through Payment for Devices

CMS is proposing three changes related to pass-through payment for CY 2017 including: using the implantable devices cost-to-charge ratio (CCR) to determine pass-through payment for implantable devices, beginning pass-through payments on the date payment is first made, and ending pass-through payments on a quarterly basis.

“Pass-through” payments are generally for new medical devices that have cost and charge data that are not yet reflected in the data that Medicare uses to set OPSS rates. To make payment for implantable medical devices approved for pass-through, Medicare determines the device’s cost by reducing the hospital’s charge for the device by its hospital-wide CCR. CMS is proposing to use the implantable device CCR that was first adopted in the FY 2009 IPPS rule and first used for determining relative weights for the IPPS in FY 2013 to determine pass-through payments for implantable medical devices.

- ***AdvaMed agrees with CMS’ proposal and believes that using the more specific “implantable devices charged to patients” CCR will result in a more accurate measurement of costs for pass-through medical devices.***

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPSS, a category of devices be eligible for transitional pass-through payments for at least two years, but not more than three years. For CY 2017, CMS makes two proposals that are intended to make payment for implantable medical devices for the maximum amount of time specified by the statute. By starting the two to three years on the date CMS first makes pass-through payment rather than when the device is first eligible for pass-through payment, the proposed policy will avoid a portion of the two to three years being used when the pass-through payments are not being made (e.g. if there are delays in marketing the pass-through device).

- ***This proposal is in line with comments made by AdvaMed in last year’s rule to improve the pass-through process. AdvaMed supports finalization of this proposal.***

CMS’ second proposal would end pass-through payment on a quarterly basis rather than an annual basis. Under current policy, pass-through payment expires at the end of the calendar year in which the medical device has already received at least two years of pass-through payment. Thus, a device that first starts receiving pass-through payment on April 1, 2014 would stop receiving pass-through payment on December 31, 2016—receiving two years and nine months of pass-through payments. A device that first starts receiving pass-through payments on October 1, 2014 would also stop receiving pass-through payments on December 31, 2016—receiving two

years and three months of pass-through payments. By expiring pass-through payments at the end of a calendar quarter, CMS' proposal will result in both of these devices receiving the full 36 months of pass-through payments.

- *AdvaMed agrees with CMS' proposal and commends the agency for continuing to implement changes to improve its pass-through payment policy.*

ii. Device-Intensive APCs/Procedures

For CY 2017, CMS proposes that the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims for all procedures in the APC be based on the median cost instead of the geometric mean cost.

AdvaMed agrees that this statistical approach for low volume APC claims can reduce unnecessary payment rate fluctuations.

- *AdvaMed recommends that CMS determine payment rates based on median cost for an APC with fewer than 100 total claims.*

CMS also proposes to revise the device intensive calculation methodology to calculate the device offset amount at the HCPCS code level rather than at the APC level-- to ensure that device intensive status is properly assigned to all device-intensive procedures.

AdvaMed proposed this change in comments on the CY 2016 proposed rule. Though AdvaMed has been unsuccessful in replicating the new methodology in a way that shows the actual impact of the proposed change, it will likely result in more accurate ASC payment for device intensive procedures, particularly those recently assigned to non-intensive APCs. Since the ASC list payment rates are determined at the HCPCS level, assignment of device intensity at this level is both logical and efficient.

AdvaMed also supports CMS' proposal to assign a default level of at least 41 percent device offset to new procedures that are device-intensive until claims data are available to calculate the actual device offset for the new code.

- *AdvaMed recommends that CMS finalize the proposal to calculate device offset at the HCPCS level and that the agency amend the applicable regulations to reflect that CMS would no longer be designating APCs as device-intensive, and instead would be designating procedures as device-intensive.*

- *AdvaMed also recommends that CMS finalize the proposal to assign a default device offset of at least 41 percent to new HCPCS procedures that involve implantation of medical devices but do not have associated claims data. We further recommend that device offset be calculated during the first rule year for which sufficient claims data are available.*

III. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status– Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

For CY 2017 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.

Despite changes to the method for calculating the thresholds, AdvaMed continues to be concerned about the payment rates for low cost products when used to treat wounds less than 100 sq. cm.

- *AdvaMed recommends that CMS permit exceptions to any general packaging policy if the resulting packaging could unreasonably impede patient access to new or existing devices, diagnostics, or other advanced medical technologies.*
- *AdvaMed also asks CMS to create a new APC Grouping 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.*

It appears that inaccurate reporting of skin substitute utilization and costs are the underlying cause of the incorrect assignment of packaged skin substitute procedures to APCs that substantially underpay for the actual cost of the products used in these procedures. While some of the negative impacts, due to inaccurate reporting, on the pricing for skin substitute products appear to have been helped by the changes implemented for CY 2016, AdvaMed is concerned by the level of payment cuts that will be applied to both high and low cost products for CY 2017. These substantial decreases in payment will result in packaged payment rates that do not cover the procurement and other costs for many of these products and could create access issues for Medicare beneficiaries. For example, the changes in the prices for some products are expected to result in decreases in payment of more than \$700. These changes impact products in APC packaged procedures 15277 and C5273 which will see a change in price from \$2137.49 to \$1411.92 and APC packaged procedure C5277 which will see a decrease from \$1411.21 to \$453.92. Other low and high cost products see more modest decreases in payment. However, taken in its totality the scope of this proposed change causes AdvaMed great concern.

- *AdvaMed recommends 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 recommends that CMS implement changes to ensure continued beneficiary access to these products and to establish an APC structure that limits the extent of changes in the reimbursement of these products from year-to-year.*
- *AdvaMed recommends that CMS work with relevant stakeholders to obtain data regarding the actual cost of high and low cost products included in the various packages.*

IV. Changes to the HOPs Meeting Schedule

Effective CY 2017 the meetings of the Advisory Panel on Hospital Outpatient Payment (HOPs) will occur only once per calendar year. This will significantly impact the ability of stakeholders to raise comments and concerns related to changes included in the final OPSS rule to CMS. In light of this change it is imperative that the comments that stakeholders submit for consideration during future HOPs meetings be adequately vetted and reflect the available claims data. Unfortunately, the current scheduling and deadline requirements for the HOPs meeting, coupled with the timing for the release of the claims data file, do not allow adequate time for analysis of proposed OPSS changes in advance of the meeting.

- *AdvaMed asks that the HOPs meeting date and the statement submission deadlines be more closely aligned with release of the rule (and associated comment deadlines) to permit adequate time for release and analysis of the claims data.*

AdvaMed's request is supported by a request coming out of the August 22, 2016 HOPs panel meeting in which Panel members recommended that CMS provide more time for the public to review information regarding the creation of APCs and to make proposals to the Panel.

V. Proposed Procedures that Would Be Paid Only as Inpatient Procedures—Solicitation of Public Comments on Possible Removal of Total Knee Arthroplasty (TKA) Procedures from the IPO List—

In its proposed rule, CMS asks for public comment on whether the agency should remove total knee arthroplasty (TKA) or total knee replacement, CPT code 27447, from the inpatient only (IPO) list and allow the procedure to be done in outpatient settings, including hospital outpatient departments and ambulatory centers (ASCs). CMS observes that recent innovations in the procedure, including minimally invasive techniques, improved perioperative anesthesia, alternative post-operative pain management, and expedited rehabilitation protocols, have reduced and continue to reduce the average length of stay for an uncomplicated TKA procedure. The innovations in care delivery have also resulted in more TKA procedures being done in an outpatient setting for the under-65 population. CMS also notes that procedures not on the IPO list can be and are very often performed either in the inpatient or outpatient setting.

AdvaMed supports CMS exploring this policy change. However, we recommend that CMS do so with careful and thorough deliberation, since any policy change in this area must start from the premise that Medicare patients are more complex than the under-65 population. In addition, as the proposed rule notes, TKA must be tailored to the individual patient's needs and for the Medicare population, this is necessarily more challenging. We encourage and anticipate that CMS will consult with all affected stakeholders on any policy change that would allow TKA to be done on an outpatient basis for Medicare patients, including physician societies, surgeons, and hospitals but also with device manufacturers since our companies have played a major role in the innovations that have led to shorter lengths of stay for TKA and the more procedures being done in outpatient settings.

It is the physician-surgeon who must be responsible for making decisions about the most appropriate setting for a TKA procedure, based on an assessment both of the patient's overall health status as well as the care expected to be needed following the procedure--and Medicare's coverage of that care. Medicare beneficiaries having outpatient TKA would, of course, not be eligible for Medicare's skilled nursing facility benefit, because they would not meet the 3-day inpatient hospital stay requirement for Medicare to cover that care. Access to physical therapy services is less problematic for the Medicare beneficiary: the patient would have to be either sufficiently ambulatory to travel to an outpatient facility for therapy or be determined to be homebound in order to qualify for physical therapy through Medicare's home health benefit. Medicare's eligibility rules for covered benefits should and must be factored into decisions by the surgeon for deciding which site will be more appropriate for the patient's well-being.

As the proposed rule notes, CMS has no claims history for beneficiaries receiving TKA on an outpatient basis. As a result, if CMS were to remove TKA from the IPO list, the agency must determine what to pay for the procedure in the outpatient basis. This will require extensive data gathering and analysis. At a minimum, AdvaMed recommends that the APC for TKA procedures should be categorized as device-intensive, so that payment is sufficient to cover the cost of the device, thereby ensuring appropriate patient access in the outpatient setting.

The proposed rule also asks for comments on how removing TKA from the IPO list might affect the CJR model demonstration and specifically target price calculations used in the CJR. 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. This in turn would affect their ability to reduce spending below their benchmark or target price, likely making it more difficult for them to do so, since many of their healthier patients would now be treated outside of the episode where the anchor is the inpatient stay. 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.

All of these issues—a more complex Medicare population, data needs for developing an appropriate payment amount for TKA as an outpatient procedure, necessary adjustments to CJR benchmarks to reflect a changing population—require careful deliberation and thorough data analysis before CMS moves forward with removing TKA from the IPO list.

- *We urge CMS to proceed cautiously and not implement a change in policy without first proposing specific changes in a formal Notice of Proposed Rulemaking.*

VI. Proposed Nonrecurring Policy Changes— Section 603 of BBA Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

AdvaMed supports legislative policies that ensure continued access by patients, regardless of their location, to the most appropriate health care to address their individual needs. This specifically extends to policies that impact the ability of patients to access appropriate medical technologies.

Section 603 of the Bipartisan Budget Act of 2015 establishes new rules that determine which Medicare fee schedules--the OPPS or PFS fee-schedules-- will be used to pay for items and services furnished by certain off- campus departments of a hospital. AdvaMed encourages Congress, CMS, and others to adopt policies that ensure that the site of service changes included in section 603 of the BBA do not impede the ability of Medicare beneficiaries to access the care that they need.

CMS has focused on the concept of clinical families in defining whether an off-campus department has expanded the scope of its services beyond those offered on November 2, 2015. Preserving ongoing patient access to necessary outpatient department services, such as radiation therapy, requires planning for future innovation. Therefore, AdvaMed recommends that CMS finalize the policy to map new HCPCS codes and APCs to specific clinical families, thereby allowing new services to be reimbursed under the OPPS. We also encourage CMS to ensure that policies related to the operation of off-campus departments allow those facilities to continue to adopt the technological advancements necessary to serve the patients receiving care in this setting.

VII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System – Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

The use of different inflation updates for the OPPS and ASC systems creates misalignment in the rate calculations for these payment systems. For CY 2017 CMS proposes to continue using the Consumer Price Index (CPI-U) to update ASC rates for inflation while OPPS rate updates are based on the Hospital Market Basket (MB) index. AdvaMed does not believe it is appropriate to use different inflation update mechanisms for the OPPS and ASC systems. We urge CMS to adopt the MB index as the update mechanism for the ASC system.

The MB more accurately reflects the types of health-related goods and services that are typically consumed in the ASC than does the CPI-U. The CPI-U measures changes in the prices of goods and services purchased by households (with housing and food costs making up more than half of

the CPI's weight); it does not accurately reflect the costs incurred by ASCs.

CMS's use of CPI-U for ASC payments builds in a growing disparity in updates between the ASC and HOPPS payments that is not consistent with Congressional intent to align payments between the two settings. This is reflected in the comparison of ASC and HOPPS payments since the establishment of the ASC Payment System for CY 2008. CMS initially set ASC payment rates at approximately 65% of HOPPS rates. The use of CPI-U for the annual ASC payment updates has caused this percentage to fall to a current approximate 50%. Therefore, in addition to stopping the growing disparity by using the MB inflation update for both the ASC and OPSS systems, CMS needs to re-establish the relativity between the two systems that was identified and targeted in the CY 2008 ASC Payment System Final Rule.

Greater alignment between the HOPD and ASC updates will help promote site-of-care decisions that are based on patient treatment needs and reduce the potential influence of payment differentials. Accurate payment updates for the ASC setting are particularly important given that Congress has updated ASC rates infrequently over a period spanning more than two decades. AdvaMed believes that standardizing the inflation update mechanism (to the more appropriate MB update), and returning ASC payment rates to the initially targeted relativity between the two systems, will aid in promoting beneficiary access to continued, high-quality care in the ASC setting, which in turn promotes savings to the Medicare system.

- *AdvaMed recommends that CMS apply the Market Basket inflation update to both the ASC and OPSS systems in CY 2017.*
- *AdvaMed recommends that CMS re-establish the relativity between the ASC and OPSS systems by updating ASC payments to reflect the initial, overall comparison rate of 65% of the HOPPS rate.*

As stated earlier in these comments AdvaMed is pleased that CMS accepted our recommendation to revise the device intensive calculation methodology to calculate the device offset amount at the HCPCS code level rather than at the APC level-- to ensure that device intensive status is properly assigned to all device-intensive procedures. AdvaMed believes that this adjustment will be beneficial in appropriately accounting for the costs of high-cost implantable devices used in procedures performed in ASCs.

- *AdvaMed recommends that CMS finalize the proposal to calculate device-intensity on a HCPCS code level.*

VIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

For 2020 payment determination and subsequent years, CMS is proposing to add five new measures that were derived from the existing Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) which began voluntary implementation in January 2016. These include three OAS CAHPS composite survey-based

measures (OP-37a-c), which each consist of six or more questions, and two global survey-based measures (OP-37d-e), which are comprised of a single question:

- OP-37a: OAS CAHPS – About Facilities and Staff
- OP-37b: OAS CAHPS – Communication About Procedure
- OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
- OP-37d: OAS CAHPS – Overall Rating of Facility
- OP-37e: OAS CAHPS – Recommendation of Facility

AdvaMed understands the important value of patient experience data and supports the adoption of these CAHPS for use in the hospital outpatient setting.

- *AdvaMed recommends that the CAHPS measures evolve quickly to include patient surveys that assess whether or not patients thought that they were provided sufficient and timely access to medical innovation and technology during their care in this setting.*

IX. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

For 2020 payment determination and subsequent years, CMS is proposing to add five new measures that were derived from the existing Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) which began voluntary implementation in January 2016. These include three OAS CAHPS composite survey-based measures (ASC-15a-c), which each consist of six or more questions, and two global survey-based measures (ASC-15d-e), which are comprised of a single question:

- ASC-15a: OAS CAHPS – About Facilities and Staff
- ASC-15b: OAS CAHPS – Communication About Procedure
- ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery
- ASC-15d: OAS CAHPS – Overall Rating of Facility
- ASC-15e: OAS CAHPS – Recommendation of Facility

AdvaMed understands the important value of patient experience data and supports the adoption of these CAHPS for use in the ambulatory surgical setting.

- *AdvaMed recommends that the CAHPS measures evolve quickly to include patient surveys that assess whether or not patients thought that they were provided sufficient and timely access to medical innovation and technology during their care in this setting.*

Conclusion

AdvaMed appreciates the opportunity to comment on the CY 2017 proposed OPPS and ASC rules and urges CMS to consider and incorporate our recommendations into the final rules for these payment systems. We also urge CMS to work with us and other stakeholders as the agency moves forward with the implementation and development of new and modified payment policies and to consider comments from AdvaMed members and others who will be providing detailed recommendations on both of these rules.

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,

/s/

Donald May
Executive Vice President,
Payment and Health Care Delivery