September 11, 2017

Via Electronic Mail Only
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-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 (CMS-1678-P)

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the proposed CY 2018 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
      i. Comprehensive APCs
      ii. Complexity Adjustments
      iii. Impact on Pass-through Status
      iv. Proposed Comprehensive APCs (C-APCs) for CY 2018—Brachytherapy Insertion Procedures

II. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
   A. Proposed OPPS APC-Specific Policies
      i. Imaging APCs
      ii. APC-specific comments
         1. Drug Coated Balloon Angioplasty Procedures
         2. MRgFUS
3. Endovenous Chemical Ablation for Lower Extremity Chronic Venous Disease
4. APC 5625 Level 5 Radiation Therapy - Proton Therapy
5. C-APC 5155 New CPT Codes that Combine Endoscopic Sinus Surgery Procedures
6. APCs for Multiple Endoscopic Sinus Surgery Procedures

III. Changes to the Device Edit Policy for CY 2017 and Subsequent Years
IV. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status – Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes
V. Proposed Procedures that Would Be Paid Only as Inpatient Procedures
   A. Proposed Changes to the Inpatient Only (IPO) List
   B. Solicitation of Public Comments on Possible Removal of Partial Hip Arthroplasty (PHA) and Total Hip Arthroplasty (THA) From the IPO List
VI. Potential Revisions to the Laboratory Date of Service Policy
VII. Changes to the HOPs Meeting Schedule
VIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
IX. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
X. Request for Information on CMS Flexibilities and Efficiencies

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. 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 CMS to 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.

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 supports the complexity adjustment as an important tool to help ensure payment under the comprehensive APC methodology is adequate. However, AdvaMed has repeatedly expressed concerns regarding appropriate application of complexity criteria and the resulting APC assignments for codes within the comprehensive APCs, and we believe that important opportunities to refine the methodology remain.

- AdvaMed requests that CMS continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.
- AdvaMed urges CMS to 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 that can be used in combination with other factors (e.g. clinical considerations) rather than a strict criteria.

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. CMS is proposing a code edit that would require use of a brachytherapy treatment code when a brachytherapy insertion code is billed beginning in CY 2018. AdvaMed does not support the proposed change because the CMS proposal does not account for the fact that many brachytherapy treatments are staged procedures.

Payments for high dose rate (HDR) brachytherapy should reflect the full scope of medically necessary services associated with its administration including insertion procedures and treatment services. This includes insertion services which are sometimes rendered in settings outside of the outpatient department or may be delivered by another department within the hospital. In all instances these procedures are billed to and paid by CMS. The current ways in which these procedures are billed and paid negate the need for the policy change that CMS is recommending in the proposed rule.

- AdvaMed recommends that CMS discontinue the C-APC payment policy for all brachytherapy insertion codes identified in the proposed CY 2018 rule. AdvaMed further recommends that CMS pay for brachytherapy separately and not package brachytherapy costs into the rate for surgery.
• Alternatively, CMS could pay for J1 brachytherapy insertion codes under the C-APC payment methodology but exclude all radiation oncology codes on the claim, and make separate payment for the brachytherapy treatment delivery and related planning and preparation services in addition to the C-APC payment.

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

A. Proposed OPPS APC-Specific Policies

i. Imaging APCs (5521-5525)

For CY 2018 CMS is proposing to add another level to the APC for imaging services without contrast to “more appropriately group certain imaging services with higher resource costs”. Addition of the new level will result in the shifting of procedure codes among the various levels and will lead to significant decreases in payment for a number of imaging procedures.

Medicare has not provided a clear rationale for adjusting the number of imaging APCs and did not offer any clinical basis for the reconfiguration. Deep payment cuts present potentially significant challenges to patient access. Appropriate payment is necessary to ensure that Medicare beneficiaries receive the right imaging procedure at the right time. CMS should recognize this and take steps to align payment policy to preserve beneficiary access to critical medical imaging services.

• AdvaMed requests a one year delay to allow stakeholders the opportunity to better understand the basis and implications of the addition of a payment level to the imaging APCs.

ii. APC-Specific Comments:

1. 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.

During the August 2017 meeting of the Advisory Panel on Hospital Outpatient Payment (HOPs) the Panel made two recommendations regarding the payment of drug coated balloons:
1. The Panel recommends that CMS continue to track HCPCS code 37224, Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty, with HCPCS code C2623, Catheter, transluminal angioplasty, drug-coated, non-laser, and that the appropriate Panel subcommittee review the Ambulatory Payment Classifications (APCs) for endovascular procedures to determine whether more granularity (i.e. more APCs) is warranted.

2. The Panel recommends that for CY 2018, CMS examine the number of APCs for endovascular procedures.

   • AdvaMed recommends that CMS accept both of the HOPs Panel recommendations.
   • Additionally, for 2018, AdvaMed recommends CMS create a new procedural HCPCS code to differentiate drug coated device procedures from non-drug coated device procedures and create more levels within the endovascular APC family to provide more adequate payment for drug coated device procedures.
   • AdvaMed further recommends that CMS continue to work with stakeholders to provide education regarding the need to bill the C-code and to ensure appropriate coding of these procedures to generate correct claims data for future rate setting.

2. MRgFUS

Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed (0398T) received FDA approval in July 2016. In CY 2017 the procedure was assigned to C-APC 1537 and reimbursed at $9750.50. This APC placement, which was determined without the benefit of any claims data, severely underestimates the resources needed to offer intracranial MRgFUS as a treatment for essential tremor and compromises the ability of the facilities which offer this procedure to make it available to future patients.

CMS is proposing that 0398T be included in C- APC 1537 for CY 2018 as well. AdvaMed is concerned by the continued implications that this payment rate has for patient access to this procedure. The lag in claims data used for ratesetting means that very few claims for 0398T appear in the 2016 OPPS claims data (used in setting rates for CY 2018). In fact, the CMS Cost Statistics File only includes one claim for 0398T from 2016 with a geometric mean cost of $27,500. Additionally, the claims data also closely aligns with costs associated with New Tech APC 1578 (Level 42) which pays $27,500.50. Despite the absence of a large number of claims in the data set AdvaMed believes that the costs reported to CMS to date for 0398T support placement of the code into an APC grouping other than C-APC 1537 which pays $9750.50.

   • AdvaMed recommends that CMS assign 0398T to new technology APC 1578 (New Technology – Level 42) with proposed payment rates of $27,500.50.
3. Endovenous Chemical Ablation for Lower Extremity Chronic Venous Disease

CMS is proposing assignment of two new endovenous ultrasound guided chemical ablation procedures described by CPT codes 364X5 (single vein) and 364X6 (multiple veins) to APC 5053 Level 3 Skin Procedures. AdvaMed believes that APC 5053 is not an appropriate APC for these new codes.

The Skin Procedures APCs are not appropriate for procedures that treat incompetent veins. APC 5053 (Level 3 Skin Procedures) contains procedures that are clinically and resource dissimilar to the procedures described by CPT codes 364X5 and 364X6. Furthermore, we believe that the recommended assignment of 364X5 and 364X6 to APC 5053 is in part based on the inappropriate assignment of CPT codes 36470 and 36471 to APC 5052.

The assignment of CPT codes 36470 and 36471 to APC 5052 appears to be the result of the recent APC reorganization and consolidation, with assignment of both codes being based primarily on resource similarity (and not clinical similarity) to the other the procedures in APC 5052. The geometric mean costs of CPT codes 36470 and 36471 are probably considered too low for assignment to a more clinically appropriate vascular procedure APC. However, almost every procedure assigned to APC 5052 is for a skin treatment while CPT codes 36470 and 36471 describe clinically dissimilar vascular procedures. Because CPT codes 36470 and 36471 are not assigned to an APC series with clinically similar procedures, they should not be a basis of comparison for the APC assignment of the two new vascular procedure CPT codes 364X5 and 364X6.

- **AdvaMed requests that similar endovenous ablative procedures for the treatment of incompetent veins be assigned to the same APC -- APC 5183 (Level 3 Vascular Procedures).**
- **Given the clinical and resource similarity of the vein ablation procedures listed below, we request that the following codes be assigned to APC 5183 (Level 3 Vascular Procedures) in the 2018 OPPS final rule. We note that CPT codes 36473, 36475, and 36478 are currently assigned to APC 5183, and we request that 364X5 and 364X6 also be assigned to APC 5183.**

4. APC 5625 Level 5 Radiation Therapy - Proton Therapy

In the 2018 OPPS proposed rule, CMS proposes to decrease the reimbursement rate for APC 5625 by 5 percent. This reduction comes one year after the APC suffered a 14 percent payment rate reduction due to lower charges than anticipated for CPT code 77522 Proton Treatment, simple with compensation.
While CPT Code 77522 did not experience a significant reduction in charges, the code did experience a 20 percent decline in claims, from 8,260 in 2015 to 6,710 in 2016. CPT Code 77523 Proton Treatment, Intermediate experienced an 8 percent decline in geometric cost between 2015 and 2016, from $1,022 to $935. These year-to-year fluctuations in claims and geometric mean cost are creating instability.

- **AdvaMed recommends that CMS not finalize the reductions in payment to APC 5625 for CY 2018.**

### 5. C-APC 5155 New CPT Codes that Combine Endoscopic Sinus

The CPT Editorial Panel recently created four new CPT codes. Each new code describes a combination of two endoscopic sinus surgery services that are frequently performed together:

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Descriptor</th>
<th>Proposed APC Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>31XX2</td>
<td>Nasal/sinus endoscopy, surgical with <em>ethmoidectomy</em>; total (anterior and posterior), including <em>frontal</em> sinus exploration, with removal of tissue from frontal sinus, when performed</td>
<td>C-APC 5155</td>
</tr>
<tr>
<td></td>
<td><em>(Note: this code bundles CPT codes 31255 and 31276)</em></td>
<td></td>
</tr>
<tr>
<td>31XX3</td>
<td>Nasal/sinus endoscopy, surgical with <em>ethmoidectomy</em>; total (anterior and posterior), including <em>sphenoidotomy</em></td>
<td>C-APC 5155</td>
</tr>
<tr>
<td></td>
<td><em>(Note: this code bundles CPT codes 31255 and 31287)</em></td>
<td></td>
</tr>
<tr>
<td>31XX4</td>
<td>Nasal/sinus endoscopy, surgical with <em>ethmoidectomy</em>; total (anterior and posterior), including <em>sphenoidotomy</em>, with removal of tissue from the sphenoid sinus</td>
<td>$4,628.89</td>
</tr>
<tr>
<td></td>
<td><em>(Note: this code bundles CPT codes 31255 and 31288)</em></td>
<td></td>
</tr>
<tr>
<td>31XX5</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of <em>frontal</em> and <em>sphenoid</em> sinus ostia (e.g., balloon dilation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>(Note: this code bundles CPT codes 31296 and 31297)</em></td>
<td></td>
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</tbody>
</table>

CMS proposes to assign these new CPT codes to C-APC 5155 which would package them with all other procedures performed during the same patient encounter. When the combined procedures described by these new codes are performed in addition to other sinus surgery procedures, there is no additional payment to the hospital and there is no complexity adjustment. Moreover, there has not been adequate time for CMS to capture the geometric mean costs of these new CPT codes to accurately capture the combined expense associated with these codes.
• **AdvaMed recommends that the new combined sinus procedure codes described by CPT codes 31XX2, 31XX3, 31XX4, and 31XX5 not be added to C-APC 5155.**

Similarly, the proposed payment for sinus surgery procedures performed in the Ambulatory Surgery Center (ASC) setting is also inadequate. The multiple procedure reduction applies to endoscopic sinus surgery procedures when performed in an ASC. Under these rules, ASCs are paid at 100% for the highest ranking procedure and 50% for each subsequent procedure when performed in the same patient encounter. Provided below is a comparison of the proposed 2018 ASC payment versus the current 2017 ASC payment rate for the same encounter:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>2017 ASC Payment</th>
<th>Proposed 2018 ASC Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>31255</td>
<td>$1,708.23</td>
<td>N/A – if performed together in 2018, must be reported with 312XX@</td>
</tr>
<tr>
<td>31276</td>
<td>$854.12*</td>
<td>$1,756.84</td>
</tr>
<tr>
<td>31XX2 (replaces separate reporting of 31255 + 31276 in 2018)</td>
<td>N/A</td>
<td>$1,756.84</td>
</tr>
<tr>
<td>Total Payment</td>
<td>$2,562.35</td>
<td>$1,756.84</td>
</tr>
</tbody>
</table>

*Multiple reduction in payment rules apply ($1,708.23 x .50 = $854.12)

The 2018 proposed ASC payment for CPT 31XX2 represents a 32% reduction in payment. This reduction is magnified when these procedures are performed bilaterally, a typical presentation in operable sinus disease. We believe such dramatic payment cuts may negatively impact patient access to care, making provision of these services economically unfeasible for ASCs.

• **AdvaMed recommends that CMS consider an ASC payment rate for these newly bundled CPT codes that more closely aligns with the ASCs’ costs.**

**6. APCs for Multiple Endoscopic Sinus Surgery Procedures**

The APC into which sinus surgery procedures are assigned includes procedures that are not cohesive on a clinical or cost basis. Additionally, the C-APCs for endoscopic sinus surgery do not account for the fact that a majority of patient encounters for sinus surgery involve upwards of five surgical procedures.

CMS’ methodology for complexity adjustment only identifies two surgical procedures (i.e., pairs of codes). Since almost all sinus surgery encounters involve more than two procedures, many of which are bilateral, CMS’ current methodology does not capture the complexity of these sinus surgery encounters or the costs to ensure appropriate payment to hospitals.
In assigning procedures to C-APCs, we believe CMS must consider the number of multiple procedures furnished in a single patient encounter. AdvaMed is concerned that the costs of multiple sinus procedures are not appropriately factored into determining the APC payment rate. This shortfall in payment may adversely impact Medicare beneficiary access to care.

- AdvaMed recommend that CMS create a complexity adjustment for endoscopic sinus surgery claims that also includes a C code or a J code and that otherwise meet the complexity adjustment criteria to appropriately reflect resource intensity. Procedures with devices should be separate from claims without devices on the basis of clinical and resource dissimilarity.
- AdvaMed recommend that CMS consider modifications for the complexity adjustment to better reflect encounters in which the costs are driven by more than two procedures being performed.

III. Changes to the Device Edit Policy for CY 2017 and Subsequent Years–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 recommends that CMS continue to monitor claims to evaluate the need to reinstate all device edits.

IV. 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 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. Additionally, 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 in CY 2018-- to maintain consistency as the agency continues to evaluate the methodology for pricing skin substitutes. CMS is also soliciting feedback from stakeholders on the development of methodologies that used to create pricing thresholds and the payment groupings associated with skin substitute products. AdvaMed is appreciative of CMS’ efforts to ensure payment stability for these important devices.

- 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 CMS to finalize the recommendation.
V. Proposed Changes to the Inpatient Only List
   a. Total Knee Arthroplasty and 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).

This proposed assignment is based on 2016 OPPS claims data for TKA procedures. However, there is dramatic variation in cost depending upon whether the TKA claim includes the cost of the joint implant. In an analysis (below) of 2016 OPPS claims of TKA procedures by Chris Hogan of Direct Research Inc., the cost of TKA procedures with joint implants on the claim (based on presence of device C-codes) were roughly $10,000 more than TKA claims without joint implants.

<table>
<thead>
<tr>
<th>OPPS 2018 proposed rule, claims with total knee (CPT 27447).</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Treating these claims as J1 (comprehensive APC) claims</td>
<td>Cases</td>
<td>Geometric mean cost</td>
</tr>
<tr>
<td>Total, all claims</td>
<td>236</td>
<td>$8,602</td>
</tr>
<tr>
<td>No joint implant on the claim</td>
<td>87</td>
<td>$3,808</td>
</tr>
<tr>
<td>With joint implant on the claim</td>
<td>149</td>
<td>$13,843</td>
</tr>
</tbody>
</table>

When C-codes are used as a filter on TKA claims to identify correctly coded claims, assigning this procedure to APC 5116 (Level 6 Musculoskeletal Procedures) with other procedures utilizing similar resources is shown to be more appropriate.

Not including the cost of the joint implant used in a TKA procedure has erroneously led to the CMS recommendation to place TKA procedures in APC 5115 for CY 2018. We do not agree with this proposed APC assignment and urge CMS to follow its long-standing policy that only claims with device C-codes be used to set rates for device-dependent procedures. Because TKA procedures are by definition device-dependent, we ask that these procedures be treated in the same way as other procedures requiring the use of an implantable device.

- AdvaMed recommends that CMS only use OPPS claims data from TKA procedures which include the cost of the joint implant.
- AdvaMed recommends that CMS move TKA procedures to APC 5116 (Level 6 Musculoskeletal APCs for CY 2018) and that CMS only use OPPS claims data from TKA procedures which include the cost of the joint implant as the basis for moving TKA procedures to APC 5116 (Level 6 Musculoskeletal APCs for CY 2018) and to calculate that code’s contribution to the overall APC mean cost.
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 model, 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 but hospitals’ benchmarks would be based on historical costs that include less medically complex patients with lower costs now being treated outside of the inpatient setting.

We note that given the lack of a risk adjustment mechanism for use in the CJR, hospitals treating a large number of high-risk patients are already at a disadvantage in being able to reduce spending below their benchmarks, as pointed out in a recent study published in Health Affairs. This study, entitled “Medicare’s New Bundled Payment for Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients,” by Ellimoottil, et al, makes the case that adequate risk adjustment mechanisms are urgently needed if Medicare beneficiaries, especially those with high risk scores, are to have adequate access to high quality care. The authors of this study found that reconciliation payments for Michigan hospitals participating in CJR were reduced by $827 per episode for each standard-deviation increase in a hospital’s patient complexity.

- **AdvaMed recommends 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.**

For similar reasons, we are concerned that the increased movement of TKA to an outpatient setting could remove incentives for hospitals to participate in the Bundled Payments for Care Improvement (BPCI) program. Given CMS’ apparent plan to begin a “BPCI Advanced” program starting in calendar year 2018, hospitals and physician groups may not see any financial incentive to volunteer to participate in BPCI if they are already transitioning healthy patients to an outpatient setting and with benchmarks based on prior years’ data that reflect a mix of medically complex patients and less complex patients who would now be treated in the outpatient setting.

One possible solution to this problem would be expanding the definition of the Episode Initiator (EI) to also include episodes initiated in the outpatient setting and permitting both the inpatient and outpatient claims, in this case for TKA, to be represented in the payment model. Initial data analysis demonstrates that when comparing short stays (1-2 days) for inpatient TKA the total costs for DRG 470 is in the range of $13,271 to $13,946. As discussed above, based on 2016
OPPS data the mean cost of a TKA with the joint implant on the claim is $13,843. Considering how similar these cost estimates are, we believe there is enough stability in the data to include both inpatient and outpatient claims in the revised models. Expanding the definition of the EI would not only allow CMS to study model performance across sites of care, it would also avoid the need for a potentially complicated methodological approach to risk adjustment and stratification. Including both inpatient and outpatient claims will also assure that providers participating in these episode payment models will make determinations of surgical site selections based on clinical conditions and patient preferences, and not on reimbursement. AdvaMed urges that CMS put forth a proposal, with opportunity for comment, on how the relevant payment models will be amended to account for outpatient procedures before TKA is removed from the IPO list.

b. Solicitation of Public Comments on the Possible Removal of Partial Hip Arthroplasty (PHA) and Total Hip Arthroplasty (THA) Procedures From the IPO List

CMS is also soliciting stakeholder input regarding the removal of total and partial hip replacement procedures from the IPO. Similar to our comments regarding TKA, AdvaMed encourages CMS to be receptive to comments from the physician specialty societies and clinicians who are actively engaged in performing these procedures in assessing the feasibility of removing them from the IPO list. As with the consequences that could be observed in removing TKA from the IPO list, removing THA will have a significant impact on providers participating in the CJR model and the BPCI program. We also recommend that CMS only use total and partial hip replacement claims which include the cost of the joint implant in determining appropriate rate setting for these procedures.

VI. 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 recommends that the HOPs meeting statement submission deadlines published in the Federal Register 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.*
VII. Potential Revisions to the Laboratory Date of Service Policy

CMS is soliciting comments on proposed revisions to the Laboratory Date of Service (DOS) policy that would allow laboratories to bill Medicare directly for certain tests excluded from the OPPS packaging policy. Specifically, CMS is considering a revision under which the DOS for molecular pathology tests, and for tests that are considered to be advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act (Protecting Access to Medicare Act (PAMA, Sec. 216), will become the date the test was performed when certain criteria are met. Those criteria are:

- The physician orders the test following the date of a hospital outpatient’s discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter;
- It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

CMS is also considering revising the DOS policy to only apply to ADLTs meeting the above listed criteria.

AdvaMed is aware of concerns regarding the impact of the current DOS policy on the timely performance of life-saving and treatment determinative tests. The current DOS policy requires that the hospital, instead of the laboratory performing the test, bill for the test unless it is ordered at least 14-days after the patient is discharged from the hospital and other criteria are met (the “14-day rule”). The existing DOS policy also requires laboratories to seek payment from the hospital, unless the 14-day rule applies – in which case the performing laboratory may bill and be separately paid under Medicare Part B.

In the CY2016 OPPS final rule, CMS excluded molecular pathology tests from routine packaging because it believed that such tests have a different pattern of clinical use, making them generally less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that are packaged.

This same rationale supports AdvaMed’s recommendation regarding the proposed revision to the DOS rule. Molecular pathology tests and advanced diagnostic laboratory tests meeting the requirements of PAMA are less frequently connected to an underlying hospital service and should not be bundled into hospital payment but instead should be billed separately by the performing laboratory.

AdvaMed supports policies that promote patient access to appropriate diagnostic testing and medical care.

- *AdvaMed recommend that CMS finalize the proposed revision and also*
encourage CMS to apply this policy to both molecular pathology tests and
ADLTs payable under the Clinical Laboratory Fee Schedule (CLFS), as well as
to the technical component of molecular pathology procedures payable under
the Physician Fee Schedule as the DOS rule also applies to the technical
component of these procedures.

- Relevant PFS molecular pathology procedures and applicable CPT codes
  include:
  - Flow cytometry - 88120, 88121, 88184, 88185
  - Immunohistochemistry - 88341, 88342, 88344, 88360, 88361
  - In situ hybridization - 88364, 88365, 88366, 88367, 88368, 88369,
    88373, 88374, 88377.

VIII. 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 2018 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 index 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’ 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 rate of approximately 55%. Therefore, in addition to
stopping the growing disparity by using the MB inflation update for both the ASC and OPPS
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 index 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 OPPS systems in CY 2018.**

- **AdvaMed recommends that CMS re-establish the relativity between the ASC and OPPS systems by updating ASC payments to reflect the initial, overall comparison rate of 65% of the HOPPS rate.**

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

#### A. Proposed Adoption of ASC–17 Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination.

CMS is proposing to adopt ASC–17: “Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures” beginning with the CY 2022 payment determination based on the increasing prevalence of orthopedic surgery in the ASC setting. AdvaMed agrees with CMS that it is important to minimize adverse patient outcomes associated with surgical orthopedic procedures in this setting. CMS expects that the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting measure information would make the rate of unplanned hospital visits (emergency department visits, observation stays, and unplanned inpatient admissions) following orthopedic surgery atASCs more visible to both ASCs and patients and would incentivize ASCs to incorporate quality improvement activities to reduce these unplanned hospital visits.

The proposed ASC–17 measure, however, is not currently NQF-endorsed. The Measure Application Partnership (MAP) reviewed this measure (MUC16–152) during the last cycle and recommended this measure be refined and resubmitted prior to adoption, stating that testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting. MAP also recommended that this measure be submitted to NQF for review and endorsement. At the time of the MAP’s review, this measure was still undergoing field testing. CMS notes that they intend to submit this measure for review and endorsement by NQF once an appropriate NQF project has a call for measures.

- **AdvaMed recommends that this measure be submitted for NQF endorsement and review by the MAP for review of testing, including validity and reliability, in the ambulatory care setting before adoption into this program.**

#### B. Proposed Adoption of ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination.
CMS is proposing to adopt ASC–18: “Hospital Visits After Urology Ambulatory Surgical Center Procedures” beginning with the CY 2022 payment determination based on the increasing prevalence of urology procedures in the ASC setting. CMS notes that some studies indicate that urology procedures account for nearly 5 percent of unanticipated admissions, and that urology surgery patients were almost twice as likely as orthopedics, plastic surgery, or neurosurgery to be admitted following surgery. AdvaMed agrees with CMS that it is important to minimize adverse patient outcomes associated with surgical urology procedures in this setting.

The proposed ASC-18 measure, however, is not currently NQF-endorsed. MAP reviewed this measure (MUC16–153) during the previous cycle and recommended that this measure be refined and resubmitted prior to adoption by the ASCQR Program because, at the time of the MAP’s review, this measure was still undergoing field testing. The Workgroup stated testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting, and recommended this measure be submitted to NQF for review and endorsement. CMS notes that they intend to submit this measure for review and endorsement by NQF once an appropriate NQF project has a call for measures.

- **AdvaMed recommends that this measure be submitted for NQF endorsement and review by the MAP for review of testing, including validity and reliability, in the ambulatory care setting before adoption into this program.**

C. Proposed Inclusion of Ambulatory Breast Procedure Surgical Site Infection Outcome measure (NQF #3025) in Future ASCQR Rulemaking

CMS is inviting public comment on the inclusion in future rulemaking for the ASCQR of one measure developed by the CDC: Ambulatory Breast Procedure Surgical Site Infection Outcomes Measure (NQF #3025). CMS notes that Surgical site infection (SSI) is one of the most common Healthcare-associated infections (HAIs), comprising approximately 22 percent of all HAIs, and contribute greatly to the mortality and cost burden of HAIs. Moreover, breast SSIs represent a substantial proportion of SSIs overall in inpatient settings, and have one of the highest infection risks of any procedure type in outpatient settings. Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting, these have not yet been developed for outpatient surgeries in ASCs, which comprise a fast-growing proportion of all surgeries performed in the United States. AdvaMed agrees that post-operative surgical site infection complications can significantly contribute to unnecessary poor outcomes including readmission rates due to wound infections, dehiscence and other complications, including death.

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure was included on the 2016 MUC list and reviewed by the MAP. The MAP Workgroup conditionally supported MUC16-155 Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure pending NQF endorsement and additional testing and monitoring before use in a value-based purchasing (VBP) program.
• AdvaMed recommends that this measure be submitted for NQF endorsement and review by the MAP for review of additional testing, including validity and reliability, in the ambulatory care setting before adoption into this program.

X. Request for Information on CMS Flexibilities and Efficiencies

AdvaMed applauds CMS’ decision to seek information on potential regulatory reform to improve the Medicare program and reduce unnecessary burdens on hospitals, physicians, and most importantly patients. Medicare’s historic mission has been to assure affordable access to the best care the U.S. health care system can offer. As the federal government’s largest health program, Medicare should also support the national mission to advance medical progress. A number of Medicare’s regulations, policies, and procedures place unnecessary burdens on medical technology companies’ ability to provide, and Medicare patients’ ability to benefit from, new technology-based treatments, diagnostics, and cures. These burdens not only deprive Medicare beneficiaries of prompt access to appropriate treatments for their conditions but have also contributed to a significant slow-down in early stage investment in the treatments and cures of the future. We submit the following problems and recommendations for your consideration.

1. CMS Public Meetings

CMS hosts a variety of public meeting that provide an opportunity for stakeholders to weigh in on proposed policy and coverage changes. The current structure of the public meetings frequently does not allow adequate time for stakeholders to prepare or to present comments on issues that are critical to ensuring access to technologies by Medicare beneficiaries. Additionally, the structure of many of the panels which hear public comments does not allow adequate opportunity for outside stakeholder participation. AdvaMed believes that is very important to hear perspectives and to provide opportunities for stakeholders outside of CMS to provide feedback on the various proposals being considered by the Agency.

Recommendation: AdvaMed recommend that panels provide more opportunities for non-CMS membership. We also recommend that CMS be required to always provide a minimum of 21 business days for comments to be submitted in advance of public meetings. All public meetings should provide an opportunity not only for stakeholders to attend via teleconference or some other web-based means but should also provide attendees who avail themselves of these means to make comments. Lastly, we recommend that the results from the public meetings be made publicly available within 60 days of the conclusion of the meeting and that no changes can be finalized prior to the issuance of the final comments and feedback from the related public meeting.

2. ASC Update Factor

As stated in the above comments the use of different inflation updates for the OPPS and ASC systems creates misalignment in the rate calculations for these payment systems. CMS uses 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 index 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’ 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 approximately 55%. Therefore, in addition to stopping the growing disparity by using the MB inflation update for both the ASC and OPPS 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 index 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.

**Recommendation:** AdvaMed recommends that CMS apply the Market Basket inflation update to both the ASC and OPPS systems in CY 2018. We also recommend that CMS re-establish the relativity between the ASC and OPPS systems by updating ASC payments to reflect the initial, overall comparison rate of 65% of the HOPPS rate.

3. **HCPCS Level II Codes**

The assignment of a HCPCS code is often times critical in ensuring adoption, use, and payment of a device or procedure. The significance of coding has led to AdvaMed’s longstanding efforts to improve the transparency and effectiveness of the Level II HCPCS coding system. Our members have long had concerns with the limited transparency associated with the process along with the available options for challenging a decision made by CMS regarding the need for a new or revised code. We recently signed on to a letter submitted by the Alliance for HCPCS II Code Reform (Alliance). The letter (see attachment) spells out a number of concerns with the process but also provides several recommendations for improving the process including: increased transparency (including a process for obtaining input from Medicaid, the Veterans Administration, and commercial payers; timely notice of coding decisions; detailed reasons for
denial of a code request; creating mechanisms for providing comments if a stakeholder does not attend a meeting in-person; opportunities for CMS staff consultation and feedback; a clear process for deleting codes; and the ability to withdraw a code application), clearly explaining the criteria used to establish new HCPCS codes (including modifying the coverage tree to not require that marketing requirements, that are not required for drugs seeking a code, also be eliminated for devices), creating a formal appeals process (including establishing an appeals board), and improving interaction with the Medicare Pricing, Data, Analysis, and Coding contractor (PDAC).

**Recommendation:** AdvaMed recommends that consideration be given to the various recommendations included in the Alliance letter as these changes will significantly impact appropriate identification and payment for innovative technologies that benefit Medicare beneficiaries.

In addition to the list of recommendations included in the Alliance letter AdvaMed also believes that CMS can improve Medicare beneficiary access to technologies requiring a HCPCS code by allowing applications to be submitted more frequently than once per year. The ability to submit applications more frequently will give submitters additional opportunities to correct/address concerns raised by CMS staff while reducing access delays by beneficiaries and other patients who may benefit from a new technology.

**Recommendation:** AdvaMed recommends that stakeholders should be allowed to apply for HCPCS Level II codes twice per year.

### 4. Quality Measures Approval

AdvaMed has long advocated for the adoption and use of quality measures to assess the impact of care on Medicare patient populations. As part of our advocacy we have been engaged in the work of the NQF and other quality measure development organizations. Despite this work we continue to have concerns regarding the process for developing and adopting quality measures. AdvaMed believes that the quality measures that are adopted by CMS for use in the Medicare program should translate to what providers do in their actual patient treatment practice.

**Recommendation:** We encourage CMS to adopt measures that are either NQF endorsed or are seeking endorsement from NQF or another reputable measure developer. We are also supportive of CMS testing and using quality measures that relieve burdens and promote access to innovative technologies.

### 5. APC Development

AdvaMed has concerns related to APC placement relates to the strict criteria applied to device codes that are in an APC. Typically a code cannot be placed into a higher paying APC unless it violates the two times criteria. We do not believe that this is an appropriate application of the two times rule; rather than being used as an organizing principle within the OPPS, it should be used as a minimum standard to ensure procedures are not vastly underpaid. The range of payment and
the types of codes assigned to an APC are supposed to be clinically and resource similar. However, the range of costs included in an APC can be quite vast. In many instances though there is no actual two times violation between the mean cost for the highest paid code in an APC and the lowest paid code, the difference in payment can be very close to a two times violation (within a few dollars). However, the absence of a two times violation does not mean that the procedure is appropriately assigned to the APC. The procedures’ resource costs may be more similar to procedures in the next higher-level APC and should be assigned there as long as the reassignment does not create a two times violation in the higher paying APC. Appropriate payment for innovative technologies is essential to incentivize hospitals and providers to make innovative and life-changing technologies available to their patients.

**Recommendation:** AdvaMed encourages CMS to be more flexible in considering criteria and factors outside of a two-times rule violation in determining the need to place devices into a different and/or higher paying APC.

Additionally, in CY 2014 CMS introduced the concept of comprehensive APCs (C-APCs). C-APCs were developed with the intent of providing one payment to the outpatient department that appropriately captures the cost of all related treatments and services received by a patient during an outpatient visit. AdvaMed continues to have concerns regarding the methods used by CMS to develop the various C-APCs and the assignment of rates to these groupings. We have made repeated requests at the formerly bi-annual and now annual (HOPs) meetings for monitoring and reporting on the impact of the C-APCs on access to technologies.

**Recommendation:** AdvaMed remain very interested in the overall impact of C-APCs on patient access and further urge CMS to continue to provide more information regarding the data and the process that is used to develop these groupings. We believe this added level of transparency will provide stakeholders with the necessary information to intelligently comment on the impact of new and future proposed APCs. Providing this additional information will also allow stakeholders to more effectively work with the Agency to assist in the development of policies that allow Medicare beneficiaries to have access to necessary technologies.

Lastly, AdvaMed continues to have concerns related to the methods used by CMS to develop APCs. While we appreciate CMS’ efforts to create forums to address concerns and to raise questions regarding the placement of procedures in APCs from year to year there is still a fair amount of uncertainty as to the methods used to group procedures into APCs and calculate the rates associated with the various APCs. Additionally, our members continue to be challenged by the ways in which technologies, especially newly developed technologies, are assigned to APCs.

The lag in the claims data used in setting rates poses a huge problem for appropriate APC placement. The data currently used for outpatient ratesetting lags behind by two years (meaning CY 2016 OPPS claims data is used to set rates for procedure that will be paid under the OPPS in CY 2018). This data lag, for example, poses significant concerns for newly developed technology, that is being identified via a HCPCS code and paid under OPPS for the first time in CY 2018, due to the absence of sufficient, and in many cases, no claims data to use in setting a payment rate. While new technology APC placement and pass-through payment are helpful in
establishing appropriate payment for some new technologies, not all technologies satisfy the strict criteria that must be satisfied to qualify for these designations.

**Recommendation:** CMS should be required to work with the manufacturers of new technologies for which insufficient claims data exist to establish rates during the initial years the devices are paid under Medicare.

6. **Coverage of clinical trials**

Access to clinical trials offers important benefits to patients and is critical to supporting the research endeavor that drives medical progress. A CMS regulation in 1995 and a presidential executive order in 2000, as well as congressional legislation in 2003 established the principle that Medicare patients should have access to clinical trials and that Medicare should cover at least part of the costs.\(^1\) CMS deems FDA-approved drug trials as automatically meeting Medicare’s criteria for coverage, but has chosen to require a separate CMS review and approval of FDA-approved device trials.

Until recently, CMS approved about 97 percent of the applications for coverage of investigational device exemption (IDE) clinical trials that were approved by the FDA. With the institution of a new, centralized review process, however, AdvaMed’s member companies have seen increasing denials by CMS of coverage for certain IDE clinical trials, particularly early feasibility, or first-in-human trials.

To its credit, CMS leadership is working with the FDA to address this issue and to find a way to cover early feasibility studies. But the requirement that CMS re-review and approve clinical trials that have already been approved by the FDA should be eliminated. Before any medical technology trial can be conducted, it must be approved both by the FDA and by an institutional review board (IRB) as scientifically sound and meeting ethical requirements for protection of human subjects and for informed consent. Separate CMS review of device trials is redundant, sets up an unnecessary bureaucratic barrier to research, extends the time required to get a trial underway, and discourages small companies, in particular, from conducting trials in the United States—denying Medicare patients the opportunity to participate in trials that the executive orders and legislation were intended to achieve. Importantly, it diverts CMS coverage division resources from more important activities.

**Recommendation:** CMS should treat medical technology trials the same way it treats drug trials and deem FDA-approved IDE trials automatically approved for CMS coverage.

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\(^1\) 60 Fed Reg 48417; “Memorandum on Increasing Participation of Medicare Beneficiaries in Clinical Trials,” June 7, 2000; Medicare Modernization Act of 2003 (section 1862(m) of the Social Security Act. For clinical trials of novel devices, Medicare covers the routine costs of the trials, but not the cost of the device itself. For clinical trials of devices that are improvements of existing treatments and the original treatment would be a covered service, Medicare pays for provision of the improved device at the same level and using the same mechanism that would be applied if a patient were treated using the prior device.
7. Coverage of breakthrough technologies.

The 1997 Food and Drug Administration Modernization Act (FDAMA) legislation established a category of medical devices and diagnostics that are eligible for priority FDA review. To qualify, products must be designated by the clinical experts at FDA as offering the potential for significant improvements in diagnosis or treatment of the most serious illnesses—those that are life-threatening or irreversibly debilitating. Because these products are typically truly novel technologies, only about half the products that receive this designation are actually approved by the FDA—an average of about three a year. The processes by which products meeting the statutory standard for priority treatment are considered by the FDA were spelled out in greater detail in FDA’s Expedited Access Program (EAP), and in the recently passed 21st Century Cures legislation. A review of eighteen of these products that were approved by the FDA over the last ten years found that almost all were ultimately granted Medicare coverage, but some faced significant delays, depriving patients of timely access to important treatment. It is not surprising that almost all of these products were ultimately found to be “reasonable and necessary,” since the FDA’s criteria for the designation assures that the treatments or diagnostics were effective in treating the most serious illnesses and were superior to existing alternatives.

**Recommendation:** After FDA approves a device or diagnostic under one of the authorities noted above, CMS should provide immediate transitional coverage and coding for the indications approved by FDA. During the transitional period, CMS could require collection of additional data, if necessary, to make a final determination as to whether the device meets the reasonable and necessary standard. This transitional coverage approach would provide Medicare beneficiaries more rapid access to breakthrough technologies and would also encourage investment in development of these technologies.

8. CMS Timing for Accepting National Coverage Decisions (NCDs)

CMS follows clear time-lines and processes for national coverage decisions. These timelines and processes have generally worked well in providing a transparent process with reasonable completion times. When a company requests an NCD, however, there is no clear timeline as to when the NCD process will begin and no transparency to the company as to when or on what basis a decision to commence the process will be made. This is frustrating to companies and unnecessarily delays the availability of reasonable and necessary therapies to Medicare patients.

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2 The study, which was conducted internally by AdvaMed, did not analyze whether delays were due to time needed to gain a coverage decision, a new code, or some combination of the two. Even when access was finally granted, it was not necessarily for all the FDA approved indications or in all areas of the country, since many product coverage decisions are made by local Medicare carriers rather than through national coverage decisions and the study characterized the technology as receiving a favorable coverage decision if it was covered anywhere. The technologies that were covered without any delay typically fit into an existing code and payment category, so no special Medicare coverage decision was required. The analysis excluded technologies that did not receive Medicare coverage because they were not approved by FDA for the elderly population or because they were deemed outside the scope of services covered under the Medicare statute.
**Recommendation:** CMS should establish clear time lines and transparent processes for commencing an NCD requested by external stakeholders such as technology developers.

9. **Transparency and fairness in local coverage decisions (LCDs)**

Most new technologies do not go through a national coverage decision. In some cases, coverage decisions are made by the Medicare Administrative Contractor (the MAC, or local Medicare contractors that process claims). These decisions often lack the transparency and procedural fairness of an NCD and sometimes are made based on inadequate or faulty data.

**Recommendation:** CMS’ Program Integrity Manual describes a procedure that MACs must follow in making an LCD. However, there is no standardized process for applying the manual procedure and all MACs do not follow the same process for developing LCDs. CMS should enforce the requirements in the Program Integrity Manual.

10. **Monitoring Issuance and Updates to LCDs**

AdvaMed members continue to have concerns regarding the process for notifying stakeholders of proposed revisions to, and drafting of, new LCDs. For example, it is difficult to locate and monitor the development of local coverage policies. Consequently, stakeholders frequently miss the opportunity to comment on draft and revised LCDs because there is no standardized process for announcing the issuance of a draft or proposed LCD. The lack of a standardized process for notification also forces stakeholders to check the websites of the various MACs on an almost daily basis for any changes. Checking websites is made even more difficult because contractor web sites are often poorly organized or designed. AdvaMed members also note that, although contractors have list serves, key policy changes are often not mentioned in list serve e-mails. This process in highly ineffective and deprives stakeholders of the opportunity to actively engage in the comment development process for these critical coverage documents.

**Recommendation:** AdvaMed recommends that CMS be required to work with local MACs to develop a system, similar to the one used by the Coverage and Analysis Group, that posts proposed/draft and revised LCDs on the CMS website and that simultaneously provides notice to stakeholders.

11. **Streamlining CMS/AMA Processes for Coding**

CMS’ lengthy process for assigning payment codes to new treatments is a major barrier to timely coverage. The absence of a code that can be used by providers to bill for a new treatment can compromise patient access to the treatment. Many new technologies are similar enough to existing technologies to be billed with an existing code, but most novel and important treatments will likely require a new code before patients can actually receive the treatment. CMS is responsible for providing codes for inpatient procedures, for durable medical equipment, and for hospital outpatient services that are not provided by a physician, as well as care in some other settings. The AMA provides codes for physician and laboratory services provided in all settings. CMS has the flexibility to establish codes for these services as well in order to meet their needs.
and when the AMA has not established a code. CMS provides codes for other Part B services such as durable medical equipment, surgical dressings, etc. Adoption of a new code by CMS or the AMA takes a minimum of eighteen months and a maximum of two years, even if there are no problems during the application process.

**Recommendation:** CMS should examine its coding processes and work with the AMA and the stakeholder community to find ways to speed up the process for issuing and making codes effective for providing patients access to new treatments and technologies. The new system for coding diagnostic tests under the Protecting Access to Medicare Act (PAMA) could provide a model for code development for other medical technologies.

### 12. Medicare Administrative Contractors (MAC) Treatment of Category III codes

The AMA has a process for the assigning temporary (Category III) codes. Category III codes are established for tracking new technology that may have insufficient utilization or that otherwise does not meet the standards to receive a Category I code. Most MACs have chosen to treat technologies assigned a temporary code as experimental and automatically deny them coverage, even though the treatments may be FDA approved and are, therefore, not experimental. Moreover, a technology that is eventually moved from Category III to a Category I (permanent) code may continue to experience coverage difficulties because of Medicare contractor reluctance to remove the technology from the non-covered services list.

**Recommendation:** Medicare contractors should be prohibited from automatically treating technologies and services that are assigned Category III codes as experimental and should be required to go through a formal, transparent coverage determination process if they choose to deny coverage. Medicare contractors should be required to automatically remove technologies that have transitioned from a temporary to a permanent code from the non-covered category, unless they provide a rationale, which includes detail regarding the data and evidence that was considered, for continued non-coverage.

### 13. New Technology Add-On Payment Program (NTAP)

Congress adopted the NTAP program in 2000 to overcome disincentives in the hospital prospective payment system for rapid adoption of clinically superior technologies with higher short-term costs to providers. If a new technology used in treatment is substantially more expensive than the technologies in the MS-DRG to which it is first assigned, hospitals suffer financial losses from using it—even if the treatment reduces overall costs to the Medicare program or significantly improves patient outcomes. As data accumulate over time, CMS may adjust its payments to reflect the cost of the new treatment, but this can take several years to accomplish. (A similar program, called the Transitional Pass-through Payment Program, was established for hospital outpatient treatments.)

The NTAP addresses this problem by providing interim payment adjustments based on the actual cost of the treatment for technologies that CMS judges to be novel and providing significant clinical improvements for patients. After data on the actual cost of the treatment have been
accumulated for two-to-three years, CMS makes whatever adjustments are needed to the DRG payment, including creating a new DRG for that technology when necessary.

Unfortunately, the program has been less than effective in achieving its objectives. Only slightly more than a third of applications (26 of 72) have been approved since 2003. While the U.S. was the first country to adopt special payment mechanisms for important new technologies, a recent article in *Health Affairs* found considerably fewer treatments qualify under NTAP than qualify in other countries with similar programs.\(^3\)

Moreover, in the current environment of cost-containment, CMS’ level of payment for the technologies it does identify (50 percent of the difference between the hospital’s actual cost for the new treatment and the payment for the established treatment) is too low to effectively eliminate disincentives to providing beneficiaries access to important but more costly treatments. Manufacturers increasingly report that hospitals are declining to purchase NTAP technologies because of the financial losses they would face from inadequate Medicare reimbursement.

**Recommendations:**

a) The add-on payment level for approved NTAPs should be increased from 50 to 80 percent of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology. An analysis by Avalere Health LLC found that despite receiving $40.5 million in NTAP payments between FY 2006 and FY 2013, hospitals also received $23.2 million in outlier payments on these same cases. The fact that so many NTAP cases also qualify for outlier payments highlights how inadequate the NTAP payment is to achieve the program’s objectives.

b) Local MACs should be prohibited from denying coverage and add-on payments for new medical services or technologies approved for NTAPs by the Secretary. During 2015, two local MACs issued non-coverage determinations for a medical technology that CMS had approved for NTAP, effectively denying beneficiaries in many States access to a new technology that met each of the three criteria CMS considers in making decisions for NTAP approval, and by implication approval for coverage and payment. With an approved NTAP application, the treatment or technology should be covered by Medicare for all beneficiaries, both during the add-on period and following that period.

c) The criteria for “newness” should be modified to take a broader view of a new mechanism of action to recognize an innovative deployment mechanism as substantially different.

d) The criteria applied in making substantial improvement determinations should be broadened to require, in addition to existing criteria, that the Secretary consider whether

the new technology or medical service meets one or more of the following criteria: (a) results in a reduction of the length of a hospital stay; (b) improves patient quality of life; (c) creates long-term clinical efficiencies in treatment; (d) addresses patient-centered objectives as defined by the Secretary; or (e) meets such other criteria as the Secretary may specify.

e) An entity that submits an application for NTAP payments should be entitled to administrative review of an adverse determination by an official of the Department of Health and Human Services (other than an official of the Centers for Medicare & Medicaid Services). This will provide a safeguard both for the manufacturer submitting an application as well as to the beneficiary for ensuring access to innovative technologies that improve patient care outcomes. AdvaMed further recommends that administrative review of an adverse determination should not preclude resubmission of a modified application at a later point in the future.

14. Medical technology manufacturers as collaborators in episode payment models (EPMs)

CMS has recognized that EPM participants may want to engage with organizations that are neither providers nor suppliers to assist with matters such as episode data analysis, local provider and supplier engagement, care redesign planning and implementation, beneficiary care coordination and management, and other related activities. The agency, however, has not authorized manufacturers of medical devices and diagnostics to serve in the role as collaborator. Many medical technology companies have in-depth knowledge of patient care protocols, best practices, and treatments that lead to improved patient outcomes. They are ideally suited to collaborate with EPM participants by integrating data analytics infrastructure and services to optimize care to achieve quality goals, by providing services that streamline the supply chain to reduce cost, or by sharing risk for the performance of innovative technologies used by EPMs to meet their savings and/or efficiencies goals in care delivery.

**Recommendation:** CMS should permit medical technology manufacturers to serve as collaborators in EPMs and clarify the specific circumstances under which manufacturers can do so.

15. Promoting risk-sharing arrangements between medical technology manufacturers and episode payment model (EPM) participants through Fraud and Abuse law waivers

Regulatory uncertainty concerning the application of the criminal Anti-Kickback Statute to EPM participants and medical technology companies chills innovative collaborations and value-based arrangements. Further, the current Anti-Kickback Statute (AKS) safe harbors are narrowly constructed. While there are ways to construct some limited engagements currently, they do not offer the fluidity that would be possible with new value-based AKS safe harbors (see AdvaMed safe harbor proposals for value-based arrangements at [http://www.advamed.org/resource-center/advamed-aks-safe-harbor-proposals-value-based-arrangements](http://www.advamed.org/resource-center/advamed-aks-safe-harbor-proposals-value-based-arrangements)).
Current safe harbor protection is afforded only to those arrangements that meet all of the conditions set forth in the safe harbor regulations. Unfortunately, the safe harbor constructs are narrowly fashioned around fee-for-service payment models and this serves to inhibit using delivery reform models that have the potential for improving both quality and efficiency of care delivery. For example, the provision of items and services that are not reimbursed under the same payment methodology may not qualify for protection under Discount Safe Harbor includes the limitation that the bundled good or service be reimbursed by the Federal health care program using the same methodology and be earned based on purchases of that same good or service within a single fiscal year. The “same methodology” limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value because of the uncertainty around what items or services would be considered to fall under the “same methodology.” Furthermore, one episode of care may span two fiscal years, which would also disqualify an arrangement from protection. Additionally, the warranty safe harbor does not expressly allow a seller to provide anything as part of a warranty in excess of the cost of the item itself. As such, the warranty safe harbor was intended to address defective products, rather than a warranted outcome not being achieved. Until new value-based safe harbors are issued, we believe that it would be beneficial for CMMI to use its fraud and abuse law waiver authority to promote greater investments in more fulsome value-based solutions.

Integral to developing and executing value-based arrangements between delivery reform participants and medical technology company collaborators is the need for manufacturers to be able to communicate with providers, payers and other stakeholders about clinical goals, efficiency measures, and economic performance terms and collaborative with one another on meaningful value-based arrangements. Starting points for these goals, measures, and terms may originate from economic and clinical data (with varying levels of support) that may not be specified in the approved or cleared label of the device. However, this scientific and health care economic information will be needed to both establish and optimize the clinical and economic goals of the value-based collaboration.

**Recommendation:** In light of the challenges noted above and until new value-based safe harbors are issued, we believe it would be beneficial for CMMI to use its waiver authority in the context of ACO and episode payment models being tested by the agency to:

- Create a waiver that will maintain protections for patients and Federal health care programs while allowing for greater involvement and investment in EPMs, by allowing:
  - Value-Based Pricing Arrangements (VBPA) – that accommodate Value-Based Price Adjustments dependent on the achievement of a measurable clinical and/or cost outcome and for the bundling of Value-Based Services (analysis, software, equipment, information and/or services provided to providers / patients—at no charge for the purposes of (1) determining the terms of the VBPA; (2) measuring collecting, calculating and reporting the metrics upon which the VBPA is based or the resulting adjustment that is payable; (3) optimizing the effectiveness and clinical utility of the reimbursable items and services; and (4) otherwise achieving clinical/cost outcomes.
• Value-Based Price Adjustments would include a payment made by a seller to a buyer, or by a buyer to a seller, as a reduction to or increase in such buyer’s price or net cost for one or more reimbursable items and/or services under a VBPA. The terms and conditions of the VB Price Adjustment must be fixed and disclosed in writing in advance (e.g., fixed if the formula or other objective mechanism for determining the amount of the adjustment is set forth in writing).

• This would allow for Risk-sharing between ACO and EPM participants and medical technology company collaborators that incentivize and reward improvements in clinical outcomes and/or reductions in cost.
  
  o Value-Based Warranties – that allow manufacturers of products to make certain clinical and/or cost outcome assurances, and provide an appropriate remedy where such outcomes are not achieved. Similar to VBPA, this would also allow for the bundling of Value-Based Services and require that the terms and conditions of the Value-Based Warranty remedy be fixed and disclosed in writing in advance.

  • This would allow for Outcome warranties that specifically address warranting an outcome instead of a product failure and protect payments for bundled products and services provided when an outcome is not met. For example, this would provide a targeted approach to addressing scenarios where a medical device company agrees to reimburse a hospital not only its aggregate purchase price for the implant device acquisition costs, but also unreimbursed products and services if a patient is readmitted to the hospital within 90 days following the surgical procedure because the surgical site is infected or a revision surgery is needed. Currently when this occurs, there is arguably protection under the safe harbor warranty for only the device cost when the device fails.

  o Communications on efficiency (e.g., performance/throughput claims), population outcomes/cost, and economics that are not specifically part of the product labelling to develop and operationalize value-based arrangements in ACOs and EPMs. We recommend that guidance be issued that clarifies that these communications are necessary and permissible and that varying levels of supportive data are acceptable (e.g., case study, big-data analytics).

16. Telehealth

CMS and CMMI have provided, under a number of different value-based models initiatives, waivers of the telehealth originating site and geographic site requirements that allow services to be covered in urban areas and permit in-home telehealth visits for beneficiaries being served under these programs. AdvaMed has strongly supported these waivers and agrees with CMS that the waivers will support care coordination and timely access to high quality care for all EPM beneficiaries.

However, we do not believe that the waivers go far enough in testing the efficiencies, care coordination, and quality of care improvement potential of telehealth technologies, and believe
that CMS and its Innovation Center are missing an opportunity, through their existing waiver authorities, to use delivery reform models for creatively testing situations where additional flexibility in the provision of telehealth services would increase overall care efficiency and/or improve care quality.

**Recommendation:** AdvaMed encourages CMS and its Innovation Center to undertake demonstrations, through its delivery reform models, to determine whether and under what circumstances expanded coverage of telehealth can improve patient to physician interaction, and also physician to physician care management and collaboration that may have the potential to be cost-effective and/or improve quality of care for Medicare beneficiaries. The demonstrations might focus on covering expanded telehealth services, beyond those on the Medicare approved list, and targeted at specific population groups, for example, persons with multiple chronic conditions. These services could be provided through a broader array of technologies than the interactive telecommunications systems allowed under current law, such as store and forward technologies, remote monitoring technologies, physiologic and behavioral monitoring, and point-of-care testing. The demonstrations could also test alternative methods for paying for telehealth beyond fee-for-service, and include, for instance, capitation that would pay a delivery reform model participant a specified amount per month for telehealth services. If necessary, the demonstrations could be limited to models with two-sided risk.

CMS has clearly signaled that it believes that delivery reform models should be expanded to improve efficiency, care coordination, and quality of care delivery for Medicare beneficiaries. These goals can only be achieved with providers committed to care redesign and infrastructure changes necessary to support greater coordination and care management during a defined episode. Telehealth services can be, and, from our point of view, should be, central in any plan for redesigning care for payment across an episode of care. Waivers of the originating site and geographic site requirements that apply to telehealth services are a step in the right direction. But they are insufficient for allowing providers to maximize the potential of the various telehealth technologies to reduce the cost of care and improve health care outcomes. CMS’ delivery reform models offer the ideal scenario for testing and defining how these services can be cost-effective and AdvaMed urges CMS to actively pursue using delivery reform models for such purposes.

**17. Telehealth Benefit Expansion**

CMS has also expressed significant interest in improving coordination of care among providers to ensure that beneficiaries are receiving the best possible care. One way of achieving this coordination is through telehealth services, including provider to provider telecommunication. The types of health care improvements that are possible through use of digital and telehealth technologies is rapidly expanding. Unfortunately, the CMS telemedicine benefit category is limited in the number and types of these technologies and services that it will cover and make available to Medicare beneficiaries.

**Recommendation:** AdvaMed recommends that CMS re-examine its telehealth benefit category to provide more coverage of new and emerging digital and telehealth care options that can improve the life of Medicare beneficiaries. The expansion of the benefit will become even more
important, especially in the treatment of patients in rural areas, as the pool of physicians continues to dwindle in the future. Adopting Medicare policies to address these concerns will be instrumental in ensuring the efficacy and efficiency of the system in future years. AdvaMed also encourages CMS and CMMI to undertake demonstrations, under both the traditional fee-for-service program and APMs, focused on specific services beyond those on the current Telehealth Services List, or configurations of services, which target specific population groups, e.g., persons with multiple chronic conditions, to determine whether these services can be cost effective and improve quality of care for Medicare beneficiaries.

18. Promoting Long-Term Quality for Total Joint Arthroplasty (TJA) Procedures

AdvaMed continues to support the goals of CMMI’s payment and delivery reform models, which seek to improve both the efficiency and quality of health care through enhanced care coordination and redesigned care processes. However, we believe that one of these models, specifically the Comprehensive Care for Joint Replacement (CJR) model, could be improved with the development of incentives that would promote long-term quality and value outside the 90-day bundle.

**Recommendation:** AdvaMed believes that a useful path to pursue would be to establish incentives for hospitals and physicians to lower long-term revision rates after total joint replacement during the initial episode. Initially, the focus could be on one-, three-, and five-year revision rates. Ultimately, CMS should strive to include measurements of revision rates over longer periods of time. We will be submitting more detailed proposals in the near future.

**Conclusion**

AdvaMed appreciates the opportunity to comment on the CY 2018 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,

Donald May  
Executive Vice President  
Payment and Health Care Delivery

Enclosures