August 31, 2015

Via Electronic Mail Only
Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-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; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System (CMS-1633-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 2016 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 Recalibration of APC Relative Payment Weights
      i. Proposed Calculation of Single Procedure APC Criteria-Based Costs
      ii. Establishment of Comprehensive APCs
          - Impact on Pass-Through Status
          - Complexity Adjustments
   B. Proposed Comprehensive APCs (C-APCs for CY 2016)
   C. Proposed Calculation of Composite APC Criteria-Based Costs
      i. Proposed OPPS Payment for Brachytherapy Devices
      ii. Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)–Low Volume of Outpatient Claims Used For Rate Setting
D. Proposed Packaging Policies for CY 2016–Packaging Payment for Ancillary Services

II. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
   A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes
   B. Proposed New Technology APCs
      i. Proposed Additional New Technology APC Groups
      ii. Procedures assigned to New Tech APCs- Transprosthetic Urethral Implant Procedures
   C. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
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      ii. Orthopedic procedures
      iii. Urology and Related Services and Procedures
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   E. Proposed OPPS APC-Specific Policies
      i. Multi-session Stereotactic Body Radiation Therapy (APC 66 proposed renumbered APC 5625)
      ii. Disposable Negative Pressure Wound Therapy (NPWT) (APC 0015)
      iii. Placement of the combined EBUS/TBNA code (APC 5153)
      iv. Airway Endoscopy Procedures– Fiducial Marker Placement and Bronchoscopy/Lung Biopsy
      v. High Dose Rate Brachytherapy (APC 5641)
      vi. Brachytherapy Used in Gynecologic Procedures Proposed APC Reassignment of CPT 57155
      vii. Proposed APC Restructuring and Reassignment of Low Dose Rate Brachytherapy Codes

III. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals – Low Cost Skin Substitute (APCs 0327 and 0328 proposed renumbered APCs 5053, 5054, 5055)

IV. Proposed Nonrecurring Policy Changes– Changes for Payment for Computed Tomography

V. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System – Proposed Updates to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services– Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

VI. Short Inpatient Hospital Stays

I. Proposed Update Affecting OPPS Payments

AdvaMed has a number of comments related to the proposed payment updates for OPPS services in CY 2015. Our comments will cover a number of areas including claims data, charge compression, packaging, APC group policies, 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 Recalibration of APC Relative Weights

i. 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.

a. Device Edits

The elimination of procedure-to-device and device-to-procedure edits for use with any APC was finalized in 2014. 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 proposes that device codes be required on claims for devices assigned to a device-intensive APC.

- **AdvaMed is supportive of the decision to reinstate device edits for device-intensive procedures and recommends that CMS finalize the proposal.**

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

ii. Establishment of Comprehensive APCs

CMS is proposing to create nine additional comprehensive APCs for CY 2016.

Though CMS continues to make modifications to the C-APC policy, AdvaMed remains concerned that the rates associated with the comprehensive APC’s may not 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 recommends that CMS monitor and report on the impact of comprehensive APC changes on all affected codes and any potential impacts to patient access to services that are bundled under the comprehensive APCs.**

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.

Complexity Adjustments

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

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

B. Proposed Comprehensive APCs (C-APCs for CY 2016)

i. Comprehensive APC 5093 Level 3 Breast/Lymphatic Surgery and Related Procedures

For CY 2016, CMS will continue to implement the comprehensive APC payment policy which calculates a single payment for the entire hospital stay, defined by a single claim, regardless of the date of service span. AdvaMed appreciates the CMS’s efforts to develop a more accurate payment system. The CY 2016 C-APC policy applies to surgical services provided during brachytherapy treatment including breast brachytherapy catheter placement codes 19296 and 19298. AdvaMed is concerned that the current C-APC rate setting methodology may not capture all of the costs associated with the primary procedure.

An underlying assumption of the C-APC policy is that the hospital is reporting all services related to the primary service on a single claim. This assumption may not apply to radiation oncology services. The protocol for billing radiation oncology services varies by hospital as does the practice of packaging and billing for services. AdvaMed is concerned that variations within hospital billing practices make it impossible for CMS to establish accurate rates for these services pursuant to a C-APC policy.

For 2016, CMS is proposing to establish a HCPCS modifier to be reported with every code that is adjunctive to a comprehensive service, but is billed on a different claim. The modifier would be reported on UB-04 form (CMS Form 1450) for hospital outpatient services. Specifically, hospitals would report this modifier for services that are adjunctive to a primary procedure.
HCPCS code with status indicator “J1” and that are billed on a different claim than the primary service. The collection of this information would allow CMS to begin to assess the accuracy of the claims data used to set payment rates for C-APC services. While AdvaMed supports efforts to collect data for related adjunctive services that may lead to more accurate C-APC payments, we have several concerns regarding the modifier proposal.

- **AdvaMed recommends that CMS define the term “adjunctive service” and provide detailed instructions to insure that hospitals consistently and accurately report this data.**

Without details hospitals may under-report or inaccurately report adjunctive services that will lead to flawed C-APC payments.

- **CMS should also require hospitals to charge for all packaged services in order to obtain complete cost data.**

**C. Proposed Calculation of Composite APC Criteria-Based Costs**

**i. Proposed OPPS Payment for Brachytherapy Devices**

For 2016, CMS proposes to pay separately for each type of brachytherapy device on a prospective basis based on the geometric mean cost of 2014 outpatient claims. There are longstanding problems with the CMS hospital outpatient claims data used to set the prospective brachytherapy device payments based on median cost. These issues also occur under the geometric mean proposal. 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.

- More than fifty percent of the current brachytherapy device APCs have proposed payment rates based on cost reporting data from 50 or fewer hospitals.

- **Rank order anomalies continue to exist in proposed payments for brachytherapy devices. High Activity Palladium-103 sources (C2635) should typically cost more than “low activity” Palladium-103 sources (i.e., C2640 & C2641); and stranded Palladium-103 sources (C2640) should typically cost more than non-stranded Palladium-103 sources (C2641). However, the CMS’ data yield an inverse pattern, which suggests potential inaccuracies.**
AdvaMed is concerned that OPPS brachytherapy device payments continue to be unstable and to fluctuate significantly. Brachytherapy device payments have experienced instability since CMS implemented the median cost based prospective payment methodology in 2010 and the geometric mean cost methodology in 2013. Proposed percentage changes from CY 2015 to CY 2016 payments range from -59.0 percent (A9527) to +239.8 percent (C2636). In fact, seven of fifteen brachytherapy devices have proposed percentage changes of +/-10 percent, including A9527, C1716, C1719, C2635, C2636, C2642 and C2643.

<table>
<thead>
<tr>
<th>HCPCS Code &amp; Descriptor</th>
<th>Geometric Mean Cost (2014 Hospital Claims)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2641 Palladium-103, non-stranded</td>
<td>$72</td>
</tr>
<tr>
<td>C2640 Palladium-103, stranded</td>
<td>$72</td>
</tr>
<tr>
<td>C2635 High Activity Palladium-103</td>
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</table>

AdvaMed supports the changes that CMS made several years ago, which permits the Agency to include data from multiple procedure claims within the database used by CMS for rate setting for radiation oncology codes. The methodology developed by CMS relies upon the “date of service” on the claims and a list of codes to be "bypassed" to create “pseudo-single” claims from multiple procedure claims. However, the existing methodology to create additional "pseudo" single claims from multiple procedure claims is not yielding a significant number of outpatient claims for LDR.

### ii. Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)—Low Volume of Outpatient Claims Used For Rate Setting

The typical brachytherapy encounter involves multiple services. As a result, exclusive reliance on "natural" single claims can be problematic for use in setting appropriate APC payment rates.
Brachytherapy procedures 77761, 77762, 77763, 77776, 77777, 77778 and LDR prostate brachytherapy composite APC 8001. This is a continuing trend that is worrisome as the other radiation oncology APCs seem to have a reasonable volume of data to determine payments. As shown in the table below, the number of single claims is sparse and continues to show a decrease in the number of LDR Brachytherapy procedures reported in the hospital outpatient setting. These numbers have continued to decrease since 2011.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>2016 Single Frequency Claims</th>
<th>2016 Total Frequency Claims</th>
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</thead>
<tbody>
<tr>
<td>77761</td>
<td>7</td>
<td>24</td>
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<tr>
<td>77762</td>
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<td>77777</td>
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<td>34</td>
</tr>
<tr>
<td>77778</td>
<td>70</td>
<td>2812</td>
</tr>
</tbody>
</table>

For 2016, CMS proposes to continue paying for LDR prostate brachytherapy services using the composite APC methodology implemented in 2008. That is, CMS is proposing to use 2014 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the Bypass List) to calculate the payment rate for composite APC 8001. The 2016 proposed payment rate for composite APC 8001 is based on 226 single outpatient claims, a significant decrease of 44 percent from 406 claims used for 2015 rate setting. It is very concerning that only a small proportion of the available outpatient claims are used for rate setting.

### Single Frequency Claims (2011-2016)

<table>
<thead>
<tr>
<th>Year</th>
<th>Single Frequency</th>
</tr>
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<tbody>
<tr>
<td>2011</td>
<td>849</td>
</tr>
<tr>
<td>2012</td>
<td>595</td>
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<tr>
<td>2013</td>
<td>677</td>
</tr>
<tr>
<td>2014</td>
<td>591</td>
</tr>
<tr>
<td>2015</td>
<td>406</td>
</tr>
<tr>
<td>2016</td>
<td>226</td>
</tr>
</tbody>
</table>

**D. Proposed Packaging Policies for CY 2016 - Packaging Payment for Ancillary Services**

In CY 2015, CMS packaged certain “ancillary” services based upon the procedures being identified as ancillary services and having APC-level geometric mean costs of less than or equal to $100 prior to application of the conditional packaging status indicator. Included among the services subject to packaging under this policy are a number of physician pathology services assigned to APCs Level 1 Pathology (APC 0342) and Level 2 Pathology (APC 0433).

For CY 2016, CMS proposes to expand the ancillary services policy to include APCs with geometric mean costs greater than $100 when services under these APCs are performed with another service with status indicator T. Under this expanded ancillary packaging proposal, CMS is proposing to package services assigned to Level 3 and Level 4 Pathology (APCs 5672 and 5673) when these are performed with services with status indicator T.
AdvaMed has concerns that the proposed expansion of the packaging policy will have the unintended consequence of impairing access to important ancillary services.

The ancillary packaging policy in the CY 2015 Final Rule as well as the expanded policy in this Proposed Rule assumes that ancillary services are typically integral, ancillary, supportive, dependent, or adjunctive to some therapeutic service or evaluation and management service furnished at the same encounter. The policy makes sense only insofar as the ancillary service is truly integral, ancillary, supportive, dependent, or adjunctive to a therapeutic or evaluation and management service performed during the same encounter AND only when the geometric cost of the APC to which the therapeutic or evaluation and management service is assigned is at least as great as the geometric mean cost of the APC to which the ancillary service, which is packaged together with the therapeutic or evaluation and management service, is assigned.

The current ancillary packaging policy and the proposed expansion are not effective in assuring that the packaged service is integral, ancillary, supportive, dependent, or adjunctive to the therapeutic or evaluation and management service to which the ancillary service is packaged. Additionally, these policies do not assure that the ancillary service is less costly than the service into which it is packaged.

AdvaMed is greatly concerned about the proposed expansion of the policy to ancillary services that are relatively high cost—regardless of the cost of the status T service to which the ancillary service would be packaged. The ancillary services proposed for packaging under the expanded packaging policy have geometric mean costs ranging from $98 to approximately $28,000. Among the 172 services identified 121 have geometric mean costs in excess of $500; 162/172 have geometric mean costs in excess of $200.

CMS is proposing to package relatively high cost services under this packaging proposal. The costs for procedures and services under status T ranges from $47 to approximately $23,000. Among these procedures and services 115 have geometric mean costs less than $200; 385 have geometric mean costs less than $500. Packaging services costing in excess of $200 with services costing less than $200 may penalize hospitals that choose to provide these ancillary services on the same date as a surgical service even if the surgical service is unrelated to the ancillary service.

We recognize that the APC payments for the “primary” procedures reflect packaging of the costs of the ancillary services. However, the incremental portion of the payments reflecting the ancillary services frequently will be substantially less than the cost of the ancillary services. Finally, we note that some of the services proposed for conditional packaging may be performed as more than one unit of service or as combinations of services falling under the same APC.

- **AdvaMed urges CMS not to conditionally package any ancillary procedure if the service is performed in multiple units or in combination with codes assigned to the same APC such that total costs is likely to substantially exceed the incremental payment determined from the overall packaging of a range of ancillary services to the primary therapeutic or evaluation and management procedure.**
By packaging unrelated or costly ancillary services to lower cost surgical services furnished during the same encounter, hospitals will incur substantial costs without adequate reimbursement.

- **We also urge CMS not to make any further changes to the ancillary packaging policy until the Agency has conducted a thorough analysis of the impact such packaging is currently having on quality of care, efficiency of care, and overall programmatic costs.**

If CMS intends to continue or expand the ancillary packaging policy, it should consider packaging only where the ancillary services are clinically coherent with the therapeutic or evaluation and management services to which the ancillary services are proposed to be packaged and only when the ancillary service APC has a geometric mean cost that is lower than the geometric mean cost of the APC to which the ancillary service is proposed to be packaged.

For the reasons summarized above, we also are very concerned with the proposal to expand packaging to include the higher cost ancillary services included under the Level 3 and Level 4 Pathology APCs. The geometric mean cost for the Level 3 Pathology APC is $221.31, and the geometric mean cost for the Level 4 APC is $464.78.

- **AdvaMed urges CMS not to finalize its proposal to expand the conditional packaging policy for ancillary services to include higher cost APCs, such as the Level 3 and Level 4 Pathology APCs (APCs 5673 and 5674, respectively).**

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

### A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes–

The proposed CY 2016 rule represents the first time that CMS has made information available for comment regarding the proposed APC placement and payment for new CPT codes. AdvaMed commends the agency on implementing a system that allows interested stakeholders to provide feedback on these proposed rates in advance of the final rule. AdvaMed also encourages CMS to continue considering approaches that will allow all codes that have gone through the CPT Editorial Panel and RUC review processes, in advance of publication of the proposed rule, to be included for comment.

### B. Proposed New Technology APCs

#### i. Proposed Additional New Technology APC Groups

AdvaMed is supportive of the CMS proposal to create several additional levels of New Technology APC groupings to accommodate the costs associated with recently approved devices. AdvaMed encourages CMS to remain open to the idea of creating new payment band levels, as needed, to accommodate future technologies. AdvaMed also recommends that CMS
add one dollar to the lower end of the payment range, for the various levels, to avoid pricing overlap.

**ii. Procedures Assigned to New Tech APCs—Transprostatic Urethral Implant Procedures**

AdvaMed supports CMS’s decision to retain HCPCS Code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) in New Technology APC 1564 for CY 2016. Leaving this procedure in a new technology APC for another year will allow CMS to continue collecting the claims data necessary to identify an appropriate APC assignment for the procedure. AdvaMed also supports the proposed change of this APC to device-intensive so that the ASC payment can be more appropriately determined. AdvaMed supports this new precedent that would recognize device-intensive procedures that are new to the OPPS system.

**C. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies**

In CY 2015 CMS began the process of restructuring APC groupings to better reflect costs and clinical homogeneity amongst the included procedures. For CY 2016 CMS is proposing to restructure nine additional APC groupings. AdvaMed urges CMS to be cognizant of the potential impact of these changes on reimbursement for procedures.

- We recommend that CMS implement a ceiling on the level of negative reductions in payment that a procedure subjected to the restructuring policy may experience.

AdvaMed also understands the potential cross-specialty impact of these changes. Restructuring APC groupings via the methods proposed by CMS will require transparency and a mechanism for soliciting direct feedback in order to achieve the desired outcome as many of the new groupings include codes that are performed by a variety of physician specialists.

- AdvaMed recommends that CMS engage all relevant stakeholders with codes that are subject to the various restructuring policies for feedback regarding clinical homogeneity and costs concerns.

**i. Airway Endoscopy Procedures**

For CY 2016 CMS is proposing to restructure the airway endoscopy procedures. Specifically, CMS is proposing to refine the number and composition of upper airway and lower airway APCs. AdvaMed is generally supportive of the idea of creating APCs within airway endoscopy procedures that allows for high cost procedures to be assigned to higher paying APCs. However, we would like to understand CMS’s rationale for grouping procedures that cross specialties into a single APC. For example, APC 5154 contains procedures performed by both otolaryngologists and pulmonologists. AdvaMed would also like to understand the process by which CMS will evaluate and come to consensus on the clinical homogeneity for a group of procedures that are performed in different anatomical locations and by different specialties. AdvaMed urges CMS to
continue to refine the number of APCs for airway endoscopy procedures and seek input from stakeholders as procedure types, volumes, and geometric mean costs change over time. AdvaMed is also aware of issues related to the application of CMS’s single procedure claims approach on the geometric means calculations for some of these codes, and urges careful attention to those issues.

**ii. Orthopedic procedures: Restructuring of Musculoskeletal APCs**

As a part of a comprehensive review of the overall structure of APCs and procedure code assignments for CY 2016, CMS proposes to restructure and consolidate APC groups for musculoskeletal and orthopedic surgery procedures. In the proposed rule, musculoskeletal and orthopedic procedures were identified for restructuring because of CMS’s concerns regarding the current level of granularity within the APCs representing these procedures. The proposed changes would reduce the number of APCs for these procedures by almost two-thirds – from 24 APCs to 9 APCs.

While there may be some opportunity for consolidation among the musculoskeletal APCs, AdvaMed is concerned that the proposed reduction in the number of APCs may be too expansive and may produce groupings that are too broad, creating APCs that do not accurately reflect resource distinctions among the higher and lower intensity procedures in the new APC groupings. For example, payments for some musculoskeletal procedures are reduced by nearly 35 percent under the proposed APCs. We are concerned that these reductions are too severe and may negatively impact patient access to certain procedures. While AdvaMed recognizes that the OPPS is a system of averages, significant reductions in payment rates for individual services without a commensurate decrease in costs can impede hospitals’ ability to provide those services.

- **AdvaMed recommends that CMS reassess the proposed new musculoskeletal APCs and develop an alternative proposal that results in a larger number of APCs that are more resource homogeneous.**

- **AdvaMed also recommends that CMS either delay implementation of the changes in CY 2016 or cap the percentage in negative value change associated with re-assigned procedures within the musculoskeletal APCs at 15 percent of their CY 2015 payment rate.**

By doing this, CMS can balance its goal of increasing bundling with that of maintaining sufficient stability in the payment rates such that patient access is not threatened.

**iii. Urology and Related Services and Procedures**

For CY 2016, CMS proposes to continue reducing the number of APCs in the Urology and Related Procedures clinical family from 16 APCs to 7 APCs. In CY 2015, the agency began this process of consolidation by performing a review of the grouping of APCs containing cystourethroscopy and other genitourinary procedures (APCs 0160-0163 and 0429), as well as,
APC 0169, extracorporeal shock wave lithotripsy (ESWL). Based on its review in 2014, the restructuring resulted in the use of four APCs for the CY 2015 OPPS update, as compared to the five APCs used for the CY 2014 OPPS update. CMS also eliminated APC 0169 (ESWL) and placed 50590 into APC 0163.

While there is some opportunity for consolidation among the clinical subcategories within the urology APCs, AdvaMed is concerned that the proposed Level IV Urology APC, APC 5374 may be too broad resulting in substantial payment misalignments relative to the cost of certain urologic procedures that utilize medical technologies.

Specifically, the proposed consolidation of procedures within APC 5374 (Level IV Urology and Related Services) now represents 43% of the total volume of all of the urology clinical family procedures. The overall payment is substantially misaligned due to the high relative volume of procedures on both the high and low ends of this APC. This misalignment results in several procedures with significant overpayments and underpayments as compared to their reported geometric mean costs. While overpayments and underpayments relative to cost are inherent to all APCs, AdvaMed is concerned about the magnitude of such discrepancies in this particular APC due to the number of procedures captured within it. Therefore AdvaMed urges CMS to consider dividing APC 5374 into two smaller APCs that would decrease the magnitude of such over- and underpayments and keep such intrinsic discrepancies in line with those occurring within the other APCs in the newly proposed Urology and Related Procedures clinical family.

- **AdvaMed urges CMS to divide APC 5374 into two APCs, which would decrease the magnitude of the over- and underpayments arising from the number of procedures captured in the proposed APC, while maintaining the positive aspects of the proposed restructuring within the other APCs in this clinical family.**

**D. Proposed OPPS Payment for Devices**

**Proposed Revision to Application Process for Device Pass-through Payments**

CMS is proposing changes to the pass-through device application process that are intended to enhance transparency and opportunities for stakeholder input. Beginning in 2016, CMS proposes supplementing the current quarterly sub-regulatory application review process with an annual regulatory notice and comment opportunity. This new process would involve CMS including a description of applications received along with the agency’s decision to approve or deny the application, along with supporting rationale in the OPPS proposed rule. CMS would either uphold or modify its decision based in part on the comments received in response to the proposed rulemaking. If an application was approved during the quarterly process and a decision was made following the comment period to reverse the approval, the applicant could reapply with new information for consideration in advance of the following year’s proposed rule. However, pursuant to this change if an application is denied the submitter would be limited to either applying for reconsideration as part of the next year’s comment /rulemaking process or the applicant could withdraw their application from the rulemaking process with the understanding that no further reconsideration will be granted.
AdvaMed supports CMS’s efforts to make the device pass-through payment application and review process more transparent but is concerned with the limitations that would be placed on the ability of submitters to have their applications reconsidered in a timely manner, or at all. While we are supportive of the inclusion of important public comment opportunities we are wary of the alternative of sacrificing the timeliness with which an applicant could seek reconsideration of a denied application.

AdvaMed strongly supports CMS’s plan to maintain quarterly issuance of pass-through status determinations. As noted in the proposed rule CMS currently issues quarterly transmittals identifying which pass-through applications are approved. It is difficult to reconcile an annual comment opportunity with a quarterly approval process. In order to reconcile stakeholders need for information in a timely manner we would suggest that CMS consider implementing a process for disseminating information related to approval or denial of pass-through applications in a manner that works more efficiently with a quarterly determination process. For instance, CMS could maintain the quarterly transmittals and could incorporate information related to the approved and denied applications along with their rationale. Having this information would be of great assistance to applicants and future applicants as they consider applying for pass-through status or next steps related to re-consideration.

Likewise, AdvaMed would recommend that CMS allow applicants to apply for reconsideration in the same manner which is currently in place without limiting this process to annual rulemaking which could lead to lengthy gaps between receipt of a denial and the ability to submit additional documentation. We would like to maintain the ability to re-submit applications following a denial as soon as possible while maintaining the option for public comment. An applicant could foreseeably receive a denial and obtain additional information in support of a reconsideration request long before publication of the proposed OPPS rule. Consequently, the submitter should be allowed to resubmit their application for consideration when the data are available without having to wait for the OPPS rulemaking cycle.

The potential lags created by the CMS proposal, as it relates to re-consideration, will be critically important going forward – especially if CMS finalizes the proposal to cap the period during which a device may apply for pass-through status to 3-years following FDA approval or clearance. For example, a device that receives FDA approval in April 2015 and applies for pass-through status by the first business day in June 2015 could foreseeably receive a denial by October 1, 2015. Pursuant to the CMS proposal that applicant would have to apply for reconsideration as part of the rulemaking process which would not start until their denial was published in the proposed rule in July of 2016 and would not conclude until a decision, based on public comments and additional CMS feedback, is received in late October or November of 2016. At this stage the device will have lost 18-19 months of its “newness” assuming a 3-year cap is finalized. Even worse, if the decision included in the final OPPS rule is not favorable this same applicant will have lost 27-28 months of an available 36 month of “newness” before it could request a second reconsideration. The other, potentially undesirable, alternative (pursuant to the CMS proposal) would be to withdraw the application following receipt of the quarterly review determination thereby agreeing to no longer seek pass-through status.
• AdvaMed cannot support a proposal that could adversely impact the ability to submit legitimate reconsideration requests backed by additional clinical and other data developed subsequent to the initial submission(s). While we are fully supportive of increased transparency we strongly recommend that any process finalized by CMS provide as much flexibility and as few lengthy delays in submitting reconsideration requests as is possible.

AdvaMed shares CMS’s view that pass-through approval granted through the sub-regulatory process should rarely be reversed as a result of the public input process. There should be a high bar to reversing pass-through approval in light of the rigorous approval process, the greater weight that should be given to evidence presented by applicants most experienced with the technology in question, and the disruptions such reversal would cause.

• In the event of reversal of a previously approved pass-through application, AdvaMed recommends that CMS consider any subsequent reapplication on a quarterly basis.

Criterion for Newness
In the proposed rule CMS recommends changes in the newness criterion as it applies to devices seeking pass-through designation. Historically there has been no cap on the length of time that elapses between FDA approval of a device and submission of a pass-through designation application. CMS is recommending that devices which apply for pass-through status be limited to doing so within three years of obtaining FDA clearance or approval.

AdvaMed does not understand the need for this proposed change as we are unaware of a trend involving device manufacturers applying for pass-through status well in excess of three years past their FDA clearance and/or approval date.

• Given the nature of device innovation and development, AdvaMed recommends that CMS not finalize this proposal.

• Should CMS decide to move forward with the change we strongly advise the agency to develop necessary exceptions to accommodate devices for which the three year application deadline is unreasonable.

Examples of this might include a device that has very limited sales in its first few years that would prevent the generation of adequate claims data for purposes of determining appropriate APC placement if it were to receive this status when FDA approval was initially received.

E. Proposed OPPS APC-Specific Policies

i. Multi-session Stereotactic Body Radiation Therapy (APC 66 proposed renumbered APC 5625)

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

- **AdvaMed recommends that CMS work with stakeholders to ensure appropriate payment for SBRT procedures in APC 66 (proposed to be re-numbered 5625).**

  **ii. Disposable Negative Pressure Wound Therapy (NPWT) (APC 0015)**

In CY 2015, CMS moved the two G-codes (G0456 and G0457) for disposable negative pressure wound therapy (NPWT) from APC 0016 to APC 0015, with a payment rate of $146.08. For CY 2016, CMS proposes to assign these services, now reported with CPT codes 97607 and 97608, to APC 5052 (Level 2 Skin Procedures), with a proposed 2016 APC rate of $165.76. Given coding confusion for various disposable NPWT product types and near absence of hospital reporting of the disposable device that is required for each procedure, OPPS claims data inadequately reflects device costs for this service. In addition, because of the recent introduction of the NPWT CPT codes and the near identical nature of the code descriptors for traditional and disposable NPWT, many hospitals have not updated their charge masters to differentiate the cost differences between these services. AdvaMed is concerned that current and proposed payment rates do not cover the cost of the disposable device used in these services, and that this is restricting Medicare beneficiary access to these innovative technologies. As a result, we believe single-use NPWT should be assigned to proposed APC 5053, as it is a better fit from a resource and clinical perspective.

- **AdvaMed recommends that CMS assign disposable NPWT to proposed APC 5053.**
- **AdvaMed also recommends that CMS explore how to best identify subsets of disposable NPWT OPPS claims that have devices on the claims, to assist CMS in differentiating costs between traditional and disposable NPWT**

  **iv. Placement of the combined EBUS-TBNA code (APC 5153)**

For CY 2016 CMS is proposing to place the newly created EBUS-TBNA codes into APC 5153 with a proposed payment of $1078.38. While AdvaMed understands and supports the creation of the new code we have concerns regarding its placement in this APC as we do not believe that APC 5153 adequately reflects the costs associated with the procedures. In CY 2015, EBUS and TBNA, when performed together, mapped to APC 415 with a payment of $2,257. The 2016 proposed APC assignment for the new EBUS-TBNA procedure codes is APC 5153 while TBNA alone is assigned to APC 5154. The payment rate for APC 5154 is $2,016. Under Medicare’s proposal payment for EBUS-TBNA would be almost 50% lower than the payment associated with performing TBNA without EBUS. AdvaMed is concerned that the payment rate for EBUS-TBNA procedures does not account for the costs of TBNA which is a critical part of the procedure.
AdvaMed recommends that CMS assign the EBUS-TBNA codes 3160A and 3160B to APC 5154 instead of APC 5153 to better reflect clinical homogeneity and costs associated with providing similar TBNA procedures.

v. Airway Endoscopy Procedures

We are pleased with the CMS decision to create the new APC 5154 (Level 4 Airway Endoscopy), which better represents several low volume, but high cost procedures in terms of clinical and resource homogeneity. However, additional modifications to the Upper Airway APCs are necessary to fully address clinical and resource homogeneity concerns within this group of APCs.

Fiducial marker placement (bronchoscopy) code 31626 (Bronchoscopy w/markers)

CMS proposes to assign CPT 31626 to APC 5154 (Level 4 Airway Endoscopy). However, bronchoscopy with fiducial marker placement is more appropriately assigned to APC 5155 (Level 5 Airway Endoscopy), based on both clinical and cost homogeneity. From a clinical perspective, unlike most of the procedures assigned to APC 5154, bronchoscopy with fiducial marker placement is specifically performed to enhance the effectiveness of lung cancer treatment. The procedure is a key step in ensuring therapeutic treatments achieve their desired goal – efficient and effective delivery of a therapy optimizing the chances that the intervention will work as intended. Thus, the procedure is a better fit clinically with the therapeutic procedures assigned to APC 5155 as opposed to the diagnostic procedures assigned to APC 5154.

From a cost perspective, fiducial market placement is also better aligned with APC 5155. The geometric mean cost of CPT 31626 is $3,183.26. This is over $1,000 higher than the APC payment amount, and $995 above the geometric mean cost of the APC. By comparison, the geometric mean cost of bronchoscopy/lung biopsy ($1,636.70), one of the highest in APC 5153.

Bronchoscopy/Lung Biopsy Code 31628 (Bronchoscopy/lung bx each)

CMS proposes to place CPT code 31628 in APC 5153 (Level 3 Airway Endoscopy). However, APC 5153 does not reflect the costs associated with this procedure. The geometric mean cost of bronchoscopy/lung biopsy ($1,636.70), one of the highest in APC 5153. The geometric mean cost of bronchoscopy/lung biopsy is well within the range of the geometric mean costs of the procedures CMS proposes to assign to APC 5154. Moreover, placement of this procedure in APC 5153 as proposed would result in significant hospital losses of almost $560 per procedure. The volume of this procedure is relatively small, but still important (2,217 single procedures or 6% of the total single procedure volume in the APC) given the nature of the
procedure. Creation of an economic disincentive to offer this service – even if volumes are limited – is contrary to the notion of promoting value-based care for Medicare beneficiaries.

- AdvaMed recommends that CMS place CPT code 31626 in APC 5155 (Level 5 Airway Endoscopy) to better reflect clinical homogeneity and costs associated with providing this procedure.

**v. High Dose Rate Brachytherapy (APC 5641)**

New CPT codes 7778C, 7778D and 7778E are proposed for assignment to APC 5641 Brachytherapy (see below). The new High Dose Rate (HDR) brachytherapy procedure codes are based on predecessor codes 77785, 77786 and 77787 and will bundle the basic radiation dosimetry calculation described by CPT 77300.

Based on the outpatient claims data analysis it appears that CMS may have used the 2015 codes (i.e. 77785, 77786 and 77787) without adjusting for the cost of the, now-bundled, basic radiation dosimetry calculation code 77300.

The correct methodology would be to treat the old code combinations as “composite APCs”, then identify the geometric mean cost of these composite APCs and use that cost. This approach would include the cost of the now-bundled CPT 77300. This would ensure costs based on a single unit of each HDR brachytherapy code plus a single unit of the basic radiation dosimetry calculation code.

Identification of claims that should count as “composites” produces the following results (see table below):

| OPPS 2016 proposed rule, revised estimate of APC 5641 payment rate |
|-----------------------------|-----------------|-----------------|-----------------|
| HCPCS | SI | APC | Payment Rate | Single Frequency | Geometric Mean Cost |
|-----------------------------|-----------------|-----------------|-----------------|
| As calculated by CMS       |                 |                 |                 |
| 0182T                     | S               | 5641            | $697.05         | 132 $ 894.98      |
| 77778                     | Q3              | 5641            | $697.05         | 70 $ 917.40       |
| 77785                     | S               | 5641            | $697.05         | 8,320 $ 687.81    |
| 77786                     | S               | 5641            | $697.05         | 6,945 $ 790.07    |
| 77787                     | S               | 5641            | $697.05         | 557 $ 788.84      |
| Weighted average (APC geometric mean) |                 |                 | 16,024 $ 736.40 |

Revised based on cost of new codes calculated as composites

| Revised based on cost of new codes calculated as composites |
|-----------------------------|-----------------|-----------------|
| HCPCS | SI | APC | Payment Rate | Single Frequency | Geometric Mean Cost |
|-----------------------------|-----------------|-----------------|
| 0182T                     | S               | 5641            | $772.54         | 132 $ 894.98      |
| 77778                     | Q3              | 5641            | $772.54         | 70 $ 917.40       |
| 7778C                     | S               | 5641            | $772.54         | 6,006 $ 809.88    |
| 7778D                     | S               | 5641            | $772.54         | 1,887 $ 830.73    |
| 7778E                     | S               | 5641            | $772.54         | 428 $ 802.19      |
| Revised APC geometric mean |                 |                 | 8,523 $ 816.16  |
Calculating the geometric mean of these claims by CPT code, and recalculating the proposed 2016 payment for APC 5641 Brachytherapy increases the geometric mean cost approximately $80, from $736 to $816, a 10 percent increase in the proposed payment of $772 for APC 5641 Brachytherapy.

- **AdvaMed requests that CMS reprice the HDR claims by treating a combination of one unit of 77785 (or 77786 or 77787) plus one unit of 77300 as one payable code, then processing as it would normally for identification of single-procedure claims.**

  *vi. Brachytherapy Used in Gynecologic Procedures Proposed APC Reassignment of CPT 57155*

For 2016, CMS proposes to reassign CPT 57155 Insertion of uterine tandem and/or ovoids for clinical brachytherapy from APC 5413 Level 3 Gynecologic Procedures to APC 5414 Level 4 Gynecologic Procedures. This insertion code for brachytherapy is a frequently used and established treatment standard for gynecological cancer.

- **AdvaMed supports reassignment of CPT 57155 to APC 5414 Level 4 Gynecologic Procedures in 2016.**

  *vii. Proposed APC Restructuring and Reassignment of Low Dose Rate Brachytherapy Codes*

For 2016, CMS proposes to delete LDR Brachytherapy APCs 312 Radioelement Applications and APC 651 Complex Interstitial Radiation Source Application. CMS proposes to reassign the LDR brachytherapy codes as follows:

- LDR intracavitary code 77762 is being reassigned to APC 5622 Level 2 Radiation Therapy.
- LDR intracavitary codes 77761 and 77763 are being reassigned to APC 5623 Level 3 Radiation Therapy.
- LDR interstitial brachytherapy codes 77776 and 77777 are proposed for deletion effective January 1, 2016.
- LDR interstitial brachytherapy code 77778 is being reassigned to APC 5641 Brachytherapy. Reimbursement for APC 5641 will only occur when CPT 77778 is not billed on the same date of service as CPT 55875.
- Unlisted brachytherapy procedure code 77779 is being reassigned to APC 5621 Level 1 Radiation Therapy.

In 2015 and prior years, LDR intracavitary brachytherapy codes 77761, 77762 and 77763 were assigned to the same APC (0312 Radioelement Applications). For CY 2016, CMS proposes splitting the LDR intracavitary radiation source codes into two distinct APCs. CMS is proposing to assign CPT codes 77761 and 77763 to APC 5623 Level 3 Radiation Therapy and CPT code 77762 to APC 5622 Level 2 Radiation Therapy. As noted above, the number of LDR Brachytherapy claims used for 2016 rate setting is extremely low. In fact, CMS reports no claims available for CPT 77762 for 2016 HOPPS rate setting. The costs associated with intermediate
LDR intracavitary code 77762 to place five to ten sources is typically greater than the simple LDR intracavitary code 77761, which involves placement of one to four sources.

- **AdvaMed recommends that CMS reassign CPT 77762 to APC 5623 Level 3 Radiation Therapy, with CPT codes 77761 and 77763.**

### III. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals – Low Cost Skin Substitute (APCs 0327 and 0328 proposed renumbered APCs 5053, 5054, 5055)

AdvaMed appreciates efforts by CMS to account for the increased cost of applying low cost products to wounds equal to or greater than 100 sq cm (C5277 to APC 5054; C5273 to APC 5055) but continues to be concerned about the payment rates for these same products when used to treat wounds less than 100 sq cm.

The changes included in the proposed rule will place the low cost products in APC groupings (C5271 and C5275 to APC 5053) that will result in payment reductions of 29% for CY 2016. AdvaMed is concerned that this change, if finalized will create barriers for use of these low cost products.

- **AdvaMed recommends that CMS remove the low cost skin substitute application codes, C5271 and C5275 along with other procedures at the high end of the cost spectrum from APC 5053.**

- **AdvaMed recommends that CMS create a new APC Group for the application of low cost skin substitutes, C5271 and C5275 together with other procedures at the upper end of proposed APC 5053, that reflects the true cost of the low cost products and the work to apply them. The geometric mean cost of this new APC is $603.53.**

- **AdvaMed recommends that CMS work with relevant stakeholders to obtain necessary data.**

### IV. Proposed Nonrecurring Policy Changes – Changes for Payment for Computed Tomography

Section 218(a)(1) of the Protecting Access to Medicare Act (PAMA) of 2014 included a provision to reduce the technical component payment for certain computed tomography (CT) services furnished using equipment that fails to meet NEMA standard XR-29-2013. Pursuant to the PAMA provision, effective January 1, 2016 certain CT services which do not satisfy the NEMA standard will experience reductions in payment of -5% in 2016 and -15% in 2017 and subsequent years.

The proposed rule includes a proposal to establish a modifier to be used on claims which will allow CMS to identify and reduce the payment for “non-XR-29-2013 compliant” CT services.
AdvaMed supports the development and use of a modifier by CMS to impose appropriate payment reductions. We also recommend that CMS monitor claims to assess the overall impact of the PAMA requirement and to ascertain the shift in usage patterns of providers to CT equipment which emits reduced levels of radiation.

V. 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 2016 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.

MedPAC states in a March 2013 Report to Congress that:
“Although CMS has historically used the CPI–U as the basis for Medicare’s annual updates to ASC payments, the mix of goods and services in this price index probably does not reflect ASC inputs. The CPI–U is based on a sample of prices for a broad mix of goods and services, including food, housing, apparel, transportation, medical care, recreation, personal care, education, and energy (IHS Global Insight 2009). The weight of each item is based on spending for that item by a sample of urban consumers during the survey period. Although some of these items are probably used by ASCs, their share of spending on each item is likely very different from the CPI–U weight. For example, housing accounts for 43.4 percent of the entire CPI–U (Bureau of Labor Statistics 2009).”

CMS’s use of CPI-U for ASC payments builds in a growing disparity in updates between the ASC and OPPPS payments that is not consistent with Congressional intent to align payments between the two settings. 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) 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 2016.

AdvaMed believes that using the device-intensity of the entire APC is less accurate than using the device-intensity of each procedure separately. Under the current system, patient access to ASC procedures whose device-intensity is more than the average of the APC is limited because the payment is below the procedure’s cost. Less device-intensive procedures within an APC receive higher payment than may be appropriate. Since the device-intensity of each procedure (as designated by HCPCS code) is calculable, the incentives would be better aligned and payments more appropriate if the device-intensity is calculated at the procedure (rather than APC) level.

The current method for pricing device-intensive procedures in the ASC takes into account the reality that ASCs pay the same amount for devices as hospitals; therefore, the system provides similar payments to hospitals and ASCs for this portion of device-intensive procedures. However, in the current system, device-intensity is calculated at the APC level and not for specific HCPCS codes. Though HCPCS codes are assigned to APCs because of similarity in clinical application and cost the device-intensity of the assigned codes can vary greatly. AdvaMed recommends a change in the methodology that would allow device-intensive procedure codes to be assigned to an APC that is not classified as device-intensive as a whole, but would instead permit HCPCS-level device-intensity assessment via use of a payment indicator, which would permit use in the ASC setting. By determining and designating device-intensity at the HCPCS level, a) payment levels to ASCs will be more accurate for each procedure; b) CMS may realize reduced overall payment by more accurately leveraging ASC efficiency of services; and c) Medicare beneficiary access to treatment in the ASC will be increased.

- **AdvaMed recommends that device-intensity be calculated on a HCPCS code level rather than the APC level.**

A. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services – Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

AdvaMed supports CMS’s decision to include transprostatic urethral implants on the list of ASC procedures which will be designated as device-intensive for CY 2016. We are also supportive of the decision to assign payment indicator J8 to the procedure C9740–making the packaged device payment amount the same as under the OPPS, with only the service portion of the rate being subject to the ASC standard ratesetting methodology.

VI. Short Inpatient Hospital Stays

CMS addresses several concerns related to the Two-Midnight policy in the CY 2016 proposed rule. This policy has been the source of many questions and concerns since its implementation in 2012. While CMS notes concerns raised by the policy that have been cited by MedPAC, AHA, and others it ultimately did not adopt any of the policies put forth by outside stakeholder
groups. Instead, CMS proposes to modify the existing policy to create more flexibility in accommodating physician judgment in determining the anticipated length of stays for individuals presenting to hospital inpatient and outpatient departments for care.

- **AdvaMed is supportive of the proposed changes regarding the Two-Midnight policy and encourages CMS to continue working with interested stakeholders to address issues related to overall implementation of this policy.**

**Conclusion**

AdvaMed greatly appreciates the opportunity to comment on the CY 2016 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