August 28, 2014

Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospital: Data Sources for Expansion Exception; Physician certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data Proposed Rule (CMS-1613-P)

Dear Ms. Tavenner:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the proposed CY 2015 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 Use of Single and Multiple Procedure Claims
      ii. Proposed Calculation of Single Procedure APC Criteria-Based Costs
          a. Device-Dependent APCs
          iii. Establishment of Comprehensive APCs
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 Use of Single and Multiple Procedure Claims

AdvaMed commends CMS on its decision to continue using, for recalibration of APC relative weights, the single and “pseudo” single procedure claims rate-setting methodology which has yielded data that appear to more accurately capture the estimated costs of procedures. We do have concerns however, that all of the codes associated with a procedure are not being reported. This is especially a concern with regard to coding for supplies. Code utilization data are used by CMS to identify the resources associated with a procedure and ultimately to appropriately adjust the APC relative weights. Therefore, it is imperative that all resource, equipment, and supplies associated with a code are accurately reported.

- **AdvaMed recommends that CMS continue to focus on coding education to ensure that HCPCS supply codes and revenue codes are appropriately reported by hospital coders.**

ii. 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 Dependent APCs

The elimination of procedure-to-device and device-to-procedure edits for use with any APCs was finalized in 2014. AdvaMed did not support this change and continues to have significant concerns regarding the implications of this policy. Device edits were implemented in 2005 for the purpose of ensuring the accuracy of OPPS payments for procedures, especially those involving device-dependent APCs. Device edits are critical in helping to flag inappropriately coded claims and in identifying instances where a device, or other critical service, associated with a procedure is not included on a claim. Other stakeholders echoed this sentiment in their public and written comments to CMS during the CY 2014 OPPS rulemaking cycle. Despite these concerns the agency decided to move forward with elimination of these edits. CMS did state however in the final rule that they will continue to monitor claims to determine if the device edits need to be reinstated in the future.

Device edits historically have been very useful in ensuring the collection of accurate cost data. AdvaMed is concerned that elimination of these edits, especially in an environment of increased bundling, will jeopardize data accuracy.

- **AdvaMed recommends that CMS monitor claims and that the agency reinstate the device edits in CY 2015 to coincide with the implementation of comprehensive APCs.**
iii. Establishment of Comprehensive APCs

CMS is proposing several changes to its methodology for establishing and determining payment rates for comprehensive APCs. The proposed CY 2015 OPPS rule includes information pertaining to the establishment of a proposal to create 28 “comprehensive APCs” that would encompass the procedures billed with the device-dependent APC along with any other charges that would typically appear on a claim associated with the APC. A change from device-dependent APCs to the proposed “comprehensive APCs” represents a major shift in the way that APCs are developed and paid.

AdvaMed appreciates the complexity in developing the OPPS rule. We commend CMS for the improvements to the methodology for creating and implementing the comprehensive APCs, particularly additional clarity and modifications regarding the approach for assignment of complex forms of primary procedures (status indicator “J1”) to a higher-paying APC, as well as the proposal to allow combinations of primary procedures and add-on codes to qualify for complexity adjustments.

In an effort to understand the proposed changes, we typically engage in the process of modeling the proposed rule so that we can replicate the proposed changes and understand their impact on a number of areas specific to our members. AdvaMed was able to replicate CMS’s data analysis rule this year and in doing so was able to more fully evaluate the potential impacts of the comprehensive APC changes. Even though we were able to model the rule we would note that the full effect of the comprehensive APC proposals will not be known for at least another year—when CMS will have actual OPPS claims data that reflect the new policies.

Analytical Findings and Alternatives – In an effort to understand the implications of the transition to comprehensive APCs, AdvaMed asked our consultant at Direct Research, LLC to analyze claims data to estimate the impact of the proposal on payments for services included in the comprehensive APCs. The information that was produced by Direct Research suggests that there may be some problems related to the identification of codes that were given complexity assignments.

Many procedure codes are associated with multiple APCs and could be complexity adjusted to a number of different services. Given this, CMS should assign codes that map to multiple APCs to the APC that is most frequently associated with use of the device to ensure adequate payment for any associated procedures whether it is a comprehensive or regular APC. In spite of this logic, the methodology used by CMS to determine the APC placement for complexity adjustment procedures remains unclear.

- **AdvaMed recommends that CMS revisit its complexity assignments to ensure that they are placing these procedure codes in the most appropriate APC.**

Similarly, CMS does not appear to account for the costs of some high-cost procedures that are part of the comprehensive APC assignments. Some comprehensive APC claims include CPT codes that pay more than the device-dependent code driving the comprehensive APC. This is
particularly true for some of the lower paying comprehensive APCs. Under the current proposal CMS packages these more expensive codes into less expensive APCs. This could result in underpayment for services rendered and compromise the ability of facilities performing these services to continue providing them.

- **AdvaMed recommends that CMS treat high-cost procedure codes similar to codes that would qualify for a complexity adjustment and consider moving procedures containing these codes into higher level APCs where appropriate.**

CMS did not use some of the logical screens that are typically applied when selecting single-procedure claims. In particular, AdvaMed noted the failure to apply the screen for artificial charges. CMS’s failure to apply this screen may have resulted in the unnecessary inclusion of many low value charges for many of the claims that were incorporated into the comprehensive APC groupings. Inclusion of such low value charges could in some instances affect proper APC placement.

- **AdvaMed recommends that CMS apply the artificial charges screen to its comprehensive APC analysis to ensure more accurate procedure code placement.**

**Impact on Pass-through Status**—We remain 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 will create even more hurdles for devices seeking pass-through status.

**Complexity test for Eligible Add-On Codes – Endovascular Clinical Family Procedures**

The comprehensive APC policy includes a proposal to combine six existing endovascular procedure APCs into three APCs representing varying levels of these procedures. Many of the procedures that are housed within these newly combined APCs are subject to complexity adjustments and others involve add-on codes. While AdvaMed supports CMS’s proposal to restructure the Endovascular Family comprehensive APCs, which better reflects the cost of these services, we have ongoing concerns with the negative impact of comprehensive APCs on certain complex cases such as Level I Endovascular Procedures APC which experience a reduction of 11%.

Specifically, we continue to worry that multi-vessel peripheral revascularization procedures, typically billed using a combination of a primary procedure and add-on CPT-4 code, will be routinely under-paid when comprehensive APCs are implemented.
CMS is proposing to use two criteria to determine which combinations of codes (including combinations of J1 codes and a combination of a J1 code and certain add-on codes) trigger a complexity adjustment:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- The comprehensive geometric mean cost of the complex code combination is two times greater than the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the comprehensive APC (cost threshold).

Per our comments on the CY 2014 OPPS/ASC final rule with comment, we believe that the cost threshold is too restrictive and will leave a number of frequently performed complex vascular procedure combinations in APCs with inadequate payment. Under the proposed approach hospitals face significant underpayment for these procedures in cases where the comprehensive geometric mean cost of the complex code combination is 1.5 times higher than the geometric mean cost of the lowest significant HCPCS code in the comprehensive APC. AdvaMed is concerned that these cost disparities may impair access for patients who require complex multi-vessel procedures.

Therefore, we continue to recommend that CMS revise the cost threshold for complexity reassignment from two times to 1.5 times the geometric mean cost of claims reporting a single procedure. The cost threshold criterion is too restrictive and should be broadened to better reflect the most common complex peripheral revascularization procedures typically performed in the hospital outpatient setting, and which are significantly under-valued under the current methodology.

This slightly lower cost threshold would achieve several objectives. First, the threshold is still significant and thus would appropriately allow complexity reassignment only for cases that are meaningfully underpaid using the current methodology. The volume and clinical coherence criteria would also apply, further ensuring that only appropriate cases are reassigned to higher-paying APCs.

Furthermore, a 1.5 times cost threshold is consistent with CMS’s acknowledgment that hospitals can garner some efficiency when performing complex procedure combinations. A 1.5 times cost threshold would better capture cases that would cause financial hardship for hospitals and thus present a risk for beneficiary access. Applying a more relaxed cost criterion threshold for complexity adjustment, pursuant to the comprehensive APC payment methodology will still promote efficiencies among hospitals by increasing the payment bundle associated with these encounters and reducing the number of items and services that have historically been separately payable.
Proposed Changes to Packaged Items and Services – Proposed Revision of a Packaging Policy Established in CY 2014 – Procedures Described by Add-On Codes

The proposed rule includes a recommendation to package all of the add-on codes associated with a device-dependent procedure into what would become the comprehensive APC payment. AdvaMed has concerns related to this proposal as it could create significant financial burdens for hospitals, which may result in decreased beneficiary access to appropriate care. Below, we describe our concerns with CMS’s packaging proposal for add-on codes and provide a pathway for developing alternative solutions to address data issues related to setting OPPS payment rates for procedures represented by add-on codes.

Concerns With Packaging All Device-Dependent Add-On Codes

The goal of packaging is to create incentives for hospitals to provide care efficiently. However, unconditional packaging of add-on codes will not serve this purpose, because add-on codes are not ancillary, dependent services. Rather, many add-on codes describe clinical services and costs, which are often as resource intensive as the primary procedures with which they are associated, that are provided in conjunction with primary procedures. In some cases, the add-on code addresses specific costs relating to the use of a medical technology as part of the primary procedure. In addition, a number of procedures described by add-on codes address clinical needs that are independent from those addressed by their associated primary procedures. The add-on codes require fixed resources including labor, supplies, and equipment for which hospital efficiencies do not exist. The CMS proposal would result in packaging these services into APC payments that do not cover the fixed costs of the services including the use of a medical technology.

Consequently, hospitals will be faced with the option of continuing to do these add-on procedures at a loss, discontinuing the base and add-on services or use of medical technology, or selecting less complex patient cases to treat, in an effort to avoid the need for add-on procedures. All of these options raise concerns about patient access.

AdvaMed is concerned that the proposed CMS policy to package all device-dependent add-on codes may result in sizable reductions in Medicare payments for certain procedures and may have a negative impact on patients’ access to medical technologies.

- AdvaMed recommends that CMS review the data used to formulate the payment for each of these add-on codes to ensure that adequate costs for medical technologies are incorporated and that CMS permit exceptions to this packaging policy in cases where packaging the add-on costs could unreasonably impede patient access to new or existing devices, diagnostics, or other advanced medical technologies.
v. Ancillary Services (Status Indicator “X”)

CMS proposes to conditionally package certain items or services when the items or services are integral, ancillary, supportive, dependent or adjunctive to a primary service. Specifically, in CY 2015, CMS proposes to package select “ancillary” services assigned to APCs that have proposed APC 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 this packaging proposal are a number of physician pathology services—i.e., those assigned to the APCs for Level I Pathology (APC 0342) and Level II Pathology (APC 0433).

AdvaMed appreciates that CMS has revised its CY 2014 proposal that would have packaged all ancillary services. The Proposed Rule would conditionally package ancillary services in APCs where the geometric mean cost falls below $100 based upon costs calculated prior to conditional packaging. However, this proposal still creates serious risks of underpayment by packaging ancillary services with geometric mean costs substantially greater than the payments for the associated services into which such services would be packaged.

We understand that CMS is taking steps to move the OPPS to a more encounter-based prospective payment system, and CMS’s proposal to package ancillary services is intended to fit under that broader goal. However, the methodology set forth in the proposed rule threatens to compromise accurate payment for the procedures in question. Specifically, the methodology assumes that diagnostic services performed during an encounter are ancillary or integral to a therapeutic service or evaluation/management service performed during the same encounter. Diagnostic services may be performed for reasons altogether unrelated to a therapeutic or evaluation/management service performed during the same encounter. The relationship of ancillary services to other services performed during an individual patient encounter varies widely. While certain ancillary services may be integral to a therapeutic or evaluation/management service performed during the encounter such that the therapeutic or evaluation/management service is truly a “primary service” to which the other services are ancillary and integral, other ancillary services may be altogether unrelated to such therapeutic or evaluation/management service.

By packaging diagnostic services that are unrelated to therapeutic or evaluation/management services furnished during the same encounter, hospitals will incur substantial costs without adequate reimbursement. Hospitals will be disincentivized from performing ancillary services at the time of unrelated therapeutic or evaluation/management services even when providing such services at the same encounter would be efficient and offer patients the most appropriate care. As a result of the inadequate reimbursement under this packaging policy, hospitals may uncouple diagnostic services from therapeutic services and perform these during distinct encounters, or they may refer patients to obtain such services from different providers—increasing the potential for negative patient care.

- **AdvaMed recommends that CMS not proceed with its proposal to package ancillary services until the Agency has conducted a thorough analysis of the likely impact of such packaging on quality of care, efficiency of care, and overall programmatic costs.**
• If CMS does proceed with its proposal to package ancillary services, we urge CMS not to conditionally package any services with geometric mean costs (determined before or after conditional packaging) that exceed the geometric mean cost of any APC to which such “ancillary” service would be packaged.

Finally, AdvaMed notes 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. When that is the case, even if the geometric mean cost for a single unit of service falls below $100, the total geometric mean cost that could be packaged (considering multiple units of service) may substantially exceed $100.

• AdvaMed recommends that CMS not conditionally package any ancillary procedure if, when the service is performed in multiple units or in combinations of codes assigned to the same APC, the geometric mean cost would exceed $100.

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

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes– Proposal to Modify the Current Process for Accepting Comments on New and Revised CPT Codes that are Effective January 1

The Proposed Changes
The proposed rule contains a lengthy discussion about the process for establishing values for potentially misvalued, new, and revised CPT codes. The proposal included in this year’s rule represents an effort on the part of CMS to provide an opportunity for stakeholders to comment on the proposed values for potentially misvalued, new and revised codes prior to their being used to determine APC rates. While AdvaMed appreciates CMS’s willingness to provide an opportunity for stakeholder feedback prior to finalization of these rates, we are very concerned with the additional delays related to use of new and revised code values and descriptor language, that would be created by the proposed changes.

The proposal would require CMS to include proposed values for all potentially misvalued, new, and revised code values in the proposed rule if they receive complete RUC recommendations by January 15th of the preceding year. This same proposal would delay revaluing of codes for which data are not received by the January deadline for one additional year. In these instances stakeholders would be provided an opportunity to comment on proposed values for potentially misvalued, new, and revised codes following publication of values in the final rule. In exchange for this comment opportunity, CMS would delay use of updated code values for potentially misvalued and revised codes for one year while they evaluate stakeholder comments.

In the case of revised codes, with proposed value changes, CMS would create G-codes to describe the predecessor to these codes and would use the values associated with those predecessor codes to price the code for an additional year. This proposed change also would delay use of revised code descriptor language. Similarly, potentially misvalued codes would
continue to have the same data values applied for an additional year pending CMS review of stakeholder comments. In the case of newly developed codes CMS would work with the RUC to include value recommendations in the proposed rule. However, if this were not possible CMS would establish values for the code during its initial year.

**Historic Process Concerns**

Historically, CMS has published the interim final RVU values for potentially misvalued, new, and revised codes in the final rule – leaving stakeholders unable to modify them for at least one year. In response to this, stakeholders have requested that CMS publish the proposed relative values for these codes in the proposed PFS or OPPS rules. Publication of these data in the proposed rules would provide an opportunity for stakeholder input prior to finalization of the data for the upcoming year.

AdvaMed’s members historically have had significant concerns regarding the ability of stakeholders to comment on the proposed values for new and revised CPT codes prior to publication of the final rule. Having an opportunity to do so is imperative in ensuring that the most accurate payment rate is set and available when a new or revised code is initially introduced. Our members also place a high priority on improving the speed with which they are able to access and use new codes and code values. Consequently, we are greatly concerned by any proposal that would add additional time to the, already lengthy, process for obtaining new and revised codes.

While AdvaMed understands CMS’s concerns regarding the ability to get value data in a timely manner, we would encourage CMS to continue working with the American Medical Association (AMA), stakeholders, and others to develop a process that provides an opportunity for publication of and comment on new values during the proposed rulemaking comment cycle whenever possible. Publication of the new values with release of the proposed rule provides the best opportunity for stakeholder feedback in a way that does not create potentially harmful delays in release and use of new and revised code values for services and procedures that benefit Medicare beneficiaries.

**Alternative Recommendations**

It is our understanding that the American Medical Association (AMA) provided CMS with recommendations in June of this year (see attachment) regarding ways to ensure the transmission of value data for new codes in time for publication in the proposed rule. AdvaMed is generally supportive of the AMA’s recommended approach for getting data to CMS in a timely enough manner to facilitate inclusion of proposed values in the proposed rule. We fully support the AMA’s recommendation to develop a data transmission schedule which coincides with the CPT and RUC meetings and which allows CMS to receive valuation data in a consistent manner that allows publication of proposed rates and temporary code descriptors in the proposed rule. We believe that the AMA’s approach addresses many of the concerns that our members traditionally have had regarding their ability to comment on proposed values.

AdvaMed does not, however, support the AMA’s recommendation to have the CPT Editorial Panel and the RUC limit their review of certain types of codes (especially high volume services)
deliberated during the February and April CPT and RUC meeting cycles. This change would prevent all of the code change applications deliberated during the February CPT Editorial Panel meeting from being considered for inclusion in proposed rulemaking – subjecting an unknown number of proposals to an additional 23-month delay. This level of additional delay would create too much uncertainty for stakeholders and providers regarding the anticipated availability of new and/or revised codes and would unnecessarily complicate the timetable and process for obtaining codes. In lieu of this, AdvaMed instead recommends that the AMA work with stakeholders and CMS to ensure that valuation data generated for potentially misvalued, new, and revised code requests considered during the May, October, and February CPT Editorial Panel meetings can be transmitted to CMS in time for inclusion in the proposed rule. AdvaMed strongly encourages CMS to consider the proposal submitted by the AMA, bearing in mind our recommendation regarding code proposals deliberated during the February and April CPT and RUC meetings.

**CMS Proposals**

While AdvaMed is generally supportive of the AMA recommendations, we also want to provide feedback on the CMS proposals included in the rule. We believe that CMS’s proposal regarding revised code descriptors that do not impact value can work effectively. We do however, have concerns that the proposals related to potentially misvalued codes, revised codes, and wholly new services may create problems for our members. It is less than ideal to wait an additional year after going through the CPT and RUC processes to update the values for a revised or misvalued code. AdvaMed strongly encourages CMS to consider other alternatives which provide the option to include value data in the proposed rules and which do not create additional delay in accessing new and revised code value data and descriptors.

We also are concerned that the process of assigning G-codes for codes that would essentially be treated and reimbursed at the same level as the previous/unrevised codes will not add much value to the process and will be confusing for payers and others. AdvaMed strongly advises against the creation of G-codes in this situation. Lastly, CMS should clarify the process that the agency would use to assign values to newly created codes for the first year. In those instances, we recommend that the agency consider the input of affected stakeholders before finalizing values for any new codes. We further recommend that CMS consider applying this same approach to all potentially misvalued and revised codes for which they lack RUC recommended values in advance of publication of the proposed rule in lieu of using inaccurate value data for an additional year.

**AdvaMed Recommendations**

AdvaMed and its members strongly support approaches that provide an opportunity for inclusion of the proposed values for new and revised CPT codes in the proposed rule and that allow stakeholder comment prior to finalization of these rates. Adopting these types of approaches will ensure inclusion of more accurate rates in the final rule. We further support approaches, such as those advanced by the AMA, that allow for receipt of the proposed value data in time for publication in the proposed rule. In the event that the AMA is unable to provide valuation data for potentially misvalued, new, and revised codes in time for publication of the proposed rule, AdvaMed encourages CMS to work with stakeholders to establish appropriate valuation for the
first year.

AdvaMed strongly encourages CMS to consider options for gathering and disseminating value data in ways which do not result in additional delays and that provides an opportunity for stakeholder comment prior to release of the final rule. We are confident that this can be done in a way that allows comments to be collected in conjunction with publication of the proposed rules and encourage CMS to continue to work on this effort with a CY 2016 implementation timeline in mind.

B. Proposed OPPS APC-Specific Policies

i. Hysteroscopy Procedures (APCs 0190 and 0193)

CMS is proposing to restructure the hysteroscopy APCs. CMS proposes to reassign certain hysteroscopy procedures (CPT codes 58561 and 58563) from APC 0193 to APC 0190 in anticipation that this change will result in improved alignment of resource and clinical characteristics and more accurate payments.

AdvaMed is concerned with the impact of assigning certain hysteroscopy procedures (CPT codes 58561 and 58563) to APC 0190— which would pay approximately $1,000 less than the costs of these procedures per 2013 OPPS claims data. The discrepancies between cost and payment that may be created if these changes are finalized would threaten patient access to these procedures.

- *AdvaMed recommends that CMS consider two APCs for hysteroscopy procedures, one for lower-cost and less complex diagnostic hysteroscopy, and a second for more resource-intensive hysteroscopy procedures that use disposable devices.*

- *AdvaMed recommends that CMS continue to work with stakeholders to ensure appropriate APC payment and placement for hysteroscopic procedures that utilize a medical technology taking standard clinical practice and variation in use into consideration.*

ii. Female Reproductive Procedures Clinical Family (APC 0195 and APC 0202)

CMS is proposing to restructure the gynecologic female reproductive procedures APC clinical family. The proposed changes would result in the use of five female reproductive APCs for CY2015 OPPS, as compared to the seven APCs used for the CY 2014 OPPS. As part of the changes, CMS would reassign certain pelvic floor repair procedures that utilize an implantable medical device (CPT codes 57240, 57250, and 57260) from APC 0195 into APC 0202.

- *AdvaMed supports the reassignment of CPT codes 57240, 57250, and 57260 from APC 0195 into APC 0202 to better reflect clinical and resource homogeneity among similar procedures.*
CMS proposes to designate APC 0202 as a comprehensive APC and would bundle additional charges on a claim associated with a primary procedures into one payment for the hospital. CMS develops cost and volume criteria to designate certain “complex” procedures that include two primary procedures performed together. For 2015, CMS identifies three pairs of procedures that meet the current criteria for a complexity adjustment within APC 0202. Overall, APC 0202 includes a complicated grouping of miscellaneous gynecologic surgical procedures. Several of these procedures include the use of an implantable medical device and represent fixed costs for the hospital. Many of the surgical procedures in this APC relate to different female pelvic conditions that are interconnected and often performed together in various combinations.

- *AdvaMed recommends that the agency continue to work with stakeholders to further study and better understand how its proposed policies impact the broad variety of female pelvic surgical procedure combinations included in this intricate APC clinical family (female reproductive procedures) to ensure adequate payments, and associated complexity adjustments, for these procedures.*

### iii. Urogenital Procedures (APC 0385)

In the CY 2014 OPPS final rule, CMS renames APC 0385 to Level I Urogenital Procedures and APC 0386 to Level II Urogenital Procedures. This clinical family was previously named Level I Prosthetic Urology (APC 0385) and Level II Prosthetic Urology (APC 0386) and includes cancer and reconstructive male urological surgical procedures that all utilize an expensive medical technology and are typically performed by subspecialist surgeons.

As part of its new comprehensive APC proposed policy, some procedure codes are given complexity adjustments if the codes represent complex pairs of two primary procedures performed together and meet other criteria. CMS identifies three pairs of procedure codes within APC 0202 that meet its complexity adjustment criteria (7282A, 7283A, and 7285A) and the agency proposes to reassign these pairs into APC 0385 in CY 2015.

From both a clinical and hospital resource perspective, the male urological surgical procedures within APC 0385 vastly differ from the female reproductive procedure complexity pairs and other gynecologic surgical procedures within APC 0202.

- *AdvaMed recommends that CMS not reassign the APC 0202 complexity adjustment pairs into APC 0385.*

- *AdvaMed further recommends that CMS work with stakeholders to identify the appropriate placement of any proposed complexity reassignments from APC 0202 into another APC that better aligns clinical and resource homogeneity.*

### iv. Cystourethroscopy and Other Genitourinary Procedures (APC 0163)

CMS is proposing to restructure the Cystourethroscopy and Other Genitourinary Procedures
clinical family and reassign several procedures from APC 0429 into APC 0163 (Level IV Cystourethroscopy and other Genitourinary Procedures) for the CY 2015 OPPS update. In addition, CMS is proposing to delete APC 0169, *Extracorporeal Shock Wave Lithotripsy* (ESWL), and reassign CPT code 50590 into APC 0163.

ESWL is classified as a non-invasive therapy and is not comparable clinically and with respect to resource use to the other more invasive surgical urological procedures that are proposed to be included in APC 0163. CMS recognizes these differences in the acute inpatient hospital setting and assigns the procedure into its own unique MS-DRG grouping. (MS-DRG 691, Urinary Stones with ESW Lithotripsy with CC/MCC and MS-DRG 692, Urinary Stones with ESW Lithotripsy with CC/MCC)

- **AdvaMed recommends that CMS not move CPT code 50590 into APC 0163 and to retain the code in APC 0169, Extracorporeal Shock Wave Lithotripsy (ESWL).**

**v. Image-Guided Breast Biopsy Procedures (APC 0005)**

In prior comments to CMS AdvaMed requested that CMS address concerns related to the payment of breast biopsy codes included in APCs 0005 and 0037. We are pleased that the proposed rule appears to take our concerns into account and that CMS is proposing to increase the payment rate for APC 0005 for CY 2015.

- **AdvaMed recommends that CMS finalize its proposal to delete APC 0037 and to increase the payment for APC 0005.**

**vi. Wound Treatments and Services (APCs 0015 and 0327)**

**a. Epidermal Autograft (APC 0327)**

CMS is proposing to reassign CPT 15110 (Epidermal autograft, trunk, arms, legs; first 100 sq cm or less) from APC 0329 (Level IV Skin Procedures) to APC 0327 (Level II Skin Procedures). In 2014 the average reimbursement rate for APC 0329 was $2,260. Moving CPT code 15110 to APC 0327 as proposed would result in an average reimbursement rate of $431. In CMS’s analysis the geometric mean for CPT 15110 was $774.

<table>
<thead>
<tr>
<th>APC</th>
<th>Descriptor</th>
<th>Cost Range</th>
<th>Geometric Mean</th>
<th>2014 Medicare Reimbursement</th>
<th>2015 Proposed Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>0327</td>
<td>Level II Skin Procedures</td>
<td>$85 to 2,798</td>
<td>$451.14</td>
<td>$409.41</td>
<td>$430.89</td>
</tr>
<tr>
<td>0328</td>
<td>Level III Skin Procedures</td>
<td>$688 to $3,901</td>
<td>$1,474.20</td>
<td>$1,371.19</td>
<td>$1,408.02</td>
</tr>
<tr>
<td>0329</td>
<td>Level IV Skin Procedures</td>
<td>$1,262 to $8,660</td>
<td>$2,369.50</td>
<td>$2,260.46</td>
<td>$2,263.12</td>
</tr>
</tbody>
</table>
Reassigning CPT code 15110 to APC 0327 would result in a drastic (80 percent) reduction in reimbursement that could negatively impact patient care. CPT code 15110 is neither clinically nor resource similar to the codes in APC 0327 and is closer in resource and clinical characteristics to codes found in APC 0328. Consequently, AdvaMed recommends moving CPT code 15110 from APC 0329 to APC 0328. In support of this recommendation AdvaMed would like to point out that:

- APC 0327 has a cost range from $85 to $2,798, however 99% of the claims in that APC are less than $774.
- The cost range for APC 0328 is from $688 to $3,901.

Patients with diabetic foot ulcers are challenged to find options to effectively close their wounds. Newly developed autologous epidermal harvesting techniques provide additional options for treating these wounds. Moving CPT code 15110 to APC 0327 could compromise the ability of providers to continue making this therapy available to patients – including Medicare beneficiaries.

CPT 15110 is more clinically similar to the procedures in 0328 (Level III Skin Procedures). The procedures in APC 0328 include:

- CPT 13160 Late closure of wound
- CPT 14000-14061 Adjunctive Tissue transfer
- CPT 15115 Epidermal autografting face/neck/hands/feet
- CPT 15135 Dermal autograft of face/neck/hands/ feet
- CPT 15220-15260 Full skin grafts
- CPT 15650 Transfer skin pedicle flap

Conversely, procedures in APC 0327 are not clinically similar. These procedures include:

- CPT 11950-11952 Treatment of contour defects
- CPT 12035-12307 Intermediate layer closures
- CPT 15002 – 15003 Wound preparation
- CPT 15050 Skin pinch graft

The frequency of CPT code 15110 in the Medicare claims data is artificially low and the costs are not representative for this procedure. We believe providers may be coding this procedure improperly and that additional provider education is needed. This may result in more accurate information for CMS to use for rate setting in future years.

The proposed APC re-assignment of CPT 15110 significantly lowers the payment for this procedure. This change would have profound impact on providers who, due to financial limitations, might be unable to afford to offer this procedure. Patients with these challenging wounds would no longer be able to benefit from this clinically effective procedure to close their wounds. We recommend that CPT 15110 be re-assigned to APC 0328 instead of APC 0327.
APC 0328 has more clinically similar procedures to auto epidermal grafting and falls within a more appropriate cost range.

- **AdvaMed recommends that CMS continue to work with stakeholders to ensure appropriate APC placement and payment of epidermal grafting procedures and to ensure appropriate coding by providers.**

- **AdvaMed also recommends that CMS move CPT code 15110 to APC 0328 because of the resource and clinical similarities between the code and the other codes included in that APC.**

### b. Disposable Negative Pressure Wound Therapy (NPWT) (APC 0015)

For CY 2015 CMS is proposing to move two NPWT G-codes (G0456 and G0457) from APC 0016 to APC 0015 and to rename APC 0015 (Level II Debridement and Destruction). AdvaMed is concerned that the movement of the NPWT G-codes from APC 0016 to APC 0015, and the resulting payment reduction, will result in a payment rate that does not cover the cost of the disposable devices used in these services and may adversely affect patient access to these innovative technologies. This is of particular concern as the prior payment under APC 0016 was already insufficient to cover the device costs.

The two G-codes that are proposed to be moved from APC 0016 (G0456 and G0457) are billed for NPWT services utilizing a disposable device. These same G-codes will be converted to CPT codes in 2015. Although the G-codes were established in 2013 they have experienced low utilization due to lack of clarity regarding their use due in part to the failure of the G-code descriptors to explicitly include both mechanically-powered and electrical devices— an issue which should be resolved in the descriptors for permanent CPT codes. Use of the G-codes has also been impacted by the anticipated issuance of permanent CPT codes.

Significant confusion linked to the wording of the G-code descriptors has persisted since introduction of these codes in 2013. Though the codes were intended to be used with both mechanical and disposable NPWT devices, inclusion of the words “mechanical” disposable NPWT caused confusion among providers regarding their ability to use the codes to bill for **electrical** disposable NPWT products. As a result, the claims data does not accurately reflect all of the charges for this treatment and the devices used.

- **AdvaMed recommends that CMS not move G0456 and G0457 to APC 0015 and that the two G-codes remain in APC 0016 until additional claims data is collected, preferably using claims from the new disposable NPWT CPT codes that will likely be implemented in 2015.**

- **AdvaMed also recommends that CMS continue to work with stakeholders to ensure appropriate APC payment and placement for these procedures.**
vii. Laminotomies and Laminectomies (APC 0208)

AdvaMed has concerns related to the inclusion of Cervical Artificial Disc procedure (CPT 22856) in a non-device dependent APC 0208. We have concerns that payment inadequacies associated with the proposed APC placement of this procedure may hamper its use in an outpatient setting. AdvaMed supports moving this procedure code, which involves implantation of a device, out of APC 0208 into a more clinically and resource appropriate device-dependent APC that will ensure coverage of its associated device costs.

- **AdvaMed urges CMS to move CPT code 22856 from APC 0208 to a more appropriate, device-dependent, APC assignment such as APC 0425 (Level V Musculoskeletal Procedures Except Hand and Foot).**

viii. Optical Coherence Tomography of Breast CPT

CMS proposes to package two Category III CPT codes (0351T and 0353T) that describe optical coherence tomography (OCT) procedures of the breast. AdvaMed has concerns regarding the implications of this assignment on hospitals and physicians who perform the procedures.

CPT codes 0351T and 0353T describe a new method for assessing surgical margins and the microstructure of tissue during the same patient encounter as tumor removal surgery. The proposed rule assigns a status indicator N to these two codes and indicates that they are intraoperative procedures. AdvaMed believes that CPT codes 0351T and 0353T represent unique, independent services that merit their own APC assignment.

- **We recommend assignment of CPT codes 0351T and 0353T to APC 0028 (Level I Breast and Skin Surgery), APC 0029 (Level II Breast and Skin Surgery), or APC 0030 (Level III Breast and Skin Surgery).**

III. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals– Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals; Proposed High/Low Cost Threshold for Packaged Skin Substitutes

CMS has historically treated skin substitute products as biologicals and has required them to go through the pass-through process for drugs and biologicals. The proposed rules do not recommend that skin substitutes be reclassified as something other than a biological yet it requests that these products no longer go through the pass-through payment process associated with this category of devices. The rationale for the proposal suggests that skin substitutes are similar to implantable biologicals (which are surgically inserted or implanted through a surgical incision or natural orifice). AdvaMed disagrees with the assertion that skin substitutes are
similar to implantable biologicals noting that most skin substitutes are not implanted via an incision or natural orifice. Consequently, it does not seem necessary to re-classify the method that should be used for skin substitute products to get pass-through status.

AdvaMed strongly opposes CMS’s proposal to use the device pass-through evaluation process for skin substitutes and similar products that aid wound healing. We fail to find any statutory or regulatory authority for treating drugs and biologicals as devices for purposes of the pass-through process. Moreover, treating skin substitutes as devices is inconsistent with the longstanding treatment of these therapies for purposes of pass-through payment, and may impede further development of technology in this field. Treating biologicals as devices is inconsistent with the statutory provision for pass-through payments, congressional intent, and the treatment of other similar biological products.

- **AdvaMed recommends that CMS continue to allow skin substitutes to use the pass-through process for drugs and biologicals, and that CMS not finalize the proposal to require them to go through the device pass-through process.**

**IV. 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 2015 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 HOPPS 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 MB inflation update to both the ASC and OPPS systems in CY 2015.**

V. Hospital Outpatient Quality Reporting Program Updates

CMS proposes the addition of one new claims-based measure to begin with the 2017 payment determination in both the Hospital OQR, as well as the Ambulatory Surgical Center Quality Reporting Programs: Facility Seven Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, proposed as measure number OP-32. The measure was submitted for National Quality Forum (NQF) endorsement in February 2014. It is our understanding that the measure has been recommended for endorsement by the NQF All-Cause Admission and Readmissions Standing Committee and is currently submitted for NQF member voting for final endorsement, which ends on October 20, 2014.

- **AdvaMed recommends that this measure receive full NQF endorsement – prior to being placed into the Hospital Outpatient Quality Reporting Program and/or the Ambulatory Surgical Center Quality Reporting Program.**

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

CMS proposes the addition of one new claims-based measure to begin with the 2017 payment determination in both the Hospital OQR, as well as the Ambulatory Surgical Center Quality Reporting Programs: Facility Seven Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, proposed as measure number OP-32. The measure was submitted for National Quality Forum (NQF) endorsement in February 2014. It is our understanding that the measure has been recommended for endorsement by the NQF All-Cause Admission and Readmissions Standing Committee and is currently submitted for NQF member voting for final endorsement, which ends on October 20, 2014.

- **AdvaMed recommends that this measure receive full NQF endorsement – prior to being placed into the Hospital Outpatient Quality Reporting Program and/or the Ambulatory Surgical Center Quality Reporting Program.**
Conclusion

AdvaMed greatly appreciates the opportunity to comment on the CY 2015 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 comprehensive APCs 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 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

Enclosures