September 4, 2012

Via Electronic Mail

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations (Proposed Rule CMS-1589-P)

Dear Ms. Tavenner:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations (Proposed Rule CMS-1589-P) (Federal Register, Vol. 77, No. 146, Monday, July 30, 2012, p. 45061).

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 lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.
AdvaMed understands the complexity of the OPPS payment methodology and appreciates the considerable effort you and your staff have devoted to the development of the proposed CY 2013 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) rule. While we are pleased with some of the proposed changes, we remain concerned with other proposals and welcome the opportunity to provide several recommendations. Our comments will address the following issues:

I. Proposed Updates Affecting OPPS Payments (for CY 2013)
   A. Proposed Recalibration of APC Relative Weights
      i. Proposed Use of Single and Multiple Procedure Claims
      ii. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)
      iii. Proposed Calculation of Single Procedure APC Criteria-Based Costs
          a) Blood and Blood Products
          b) Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)
          c) Computed Tomography of Abdomen/Pelvis (APCs 0331 and 0334)
      iv. Proposed Geometric Mean-Based Relative Payment Weights

II. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
    A. Proposed OPPS APC-Specific Policies:
       i. Appropriate APC Placement for Laparoscopic Adjustable Gastric Band Procedure Codes
       ii. Appropriate APC Placement for Proton Therapy
       iii. Appropriate APC Level V Endoscopy Upper Airway

III. Proposed OPPS Payment for Devices – Proposed Pass-Through Payments for Devices

IV. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals—Without Pass-Through Status

V. Proposed Procedures That Would Be Paid Only as Inpatient Procedures
   A. Total Disc Arthroplasty
   B. Arthroplasty Knee

VI. Proposed Update of the Revised Ambulatory Surgical Center Payment System
    A. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services --CPT Codes 58541 and 58542

VII. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting
    A. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determination
    B. Removal or Suspension of Quality Measures from the Hospital Outpatient Quality Reporting Program Measure Set
C. Proposed Updates to the “Percent of residents who have pressure ulcers that are new or worsened” measure and adoption in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)

I. Proposed Update Affecting OPPS Payments (for CY 2013)

AdvaMed has a number of comments related to the proposed payment updates for OPPS services in CY 2013. 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

AdvaMed appreciates the significant effort on the part of CMS to stabilize variation in APC payment rates.

i. Proposed Use of Single and Multiple Procedure Claims

AdvaMed commends CMS on their decision to continue using the single and “pseudo” single procedure claims rate-setting methodology which has yielded data that appears to more accurately capture the estimated costs of procedures. We do, however, have concerns that all of the codes associated with a procedure are not being reported. This is especially a concern with regards to supply codes. The codes on claims are used by CMS to identify and estimate the resources associated with a procedure and ultimately to appropriately adjust the APC payment. It is therefore essential that the coding on claims is accurate.

- AdvaMed recommends that CMS continue to focus on coding education as it impacts the use of proper HCPCS supply codes so that these codes are appropriately reported by hospital coders.

ii. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

AdvaMed commends CMS’s decision to use data from the Medicare cost report implantable devices charged to patients cost center to create a distinct cost to charge ratio for outpatient services for 2013. We believe that use of this data will improve the accuracy of payment rates for these services. Additionally, AdvaMed supports CMS’ recommendation to not use the new standard cost centers for MRI, CT and cardiac catheterization in CY 2013 due to the agency’s inability to calculate distinct cost to charge ratios for these procedures and the inaccessibility of revised cost report forms in HCRIS.

AdvaMed encourages CMS to continue to engage in educational efforts related to the use of the new cost center so that hospitals are aware of the importance of accurately capturing this information on their claims. This will be especially important in light of the fact that the device cost center data will only be in effect for outpatient procedures in 2013 and will not include inpatient procedures. This will also be important for improving the validity of payment weights based on estimated costs.

AdvaMed believes that CMS should also continue to work to ensure the validity of the data collected through the new cost center. This can be achieved through the development of a Medicare
Administrative Contractors (MACs) audit program that would identify hospitals that have not reported data for the new cost center. CMS could also require that cost reporting software be modified to increase the error level in instances where information reported on a claims worksheet is not consistent with the absence of data reported for implantable devices.

In preparing our comments on this proposed rule, our consultant was able to calculate the changes in overall APC costs for CY 2013 but was unable to replicate the impact of the new implantable device cost center on APC costs (as displayed in Table 2 of the proposed rule). We are available and open to discussing our efforts to replicate these calculations with you or your team.

In order to assure that the goals of the implantable device cost center are met AdvaMed makes the following additional recommendations:

- **CMS should initiate actions to undertake additional outreach and educational activities (beyond the distribution of Bulletins) to ensure that hospitals and the MACs are fully educated about the new cost center requirements to ensure common knowledge, consistent and accurate audit processes, and to ensure that cost report changes are implemented effectively and accurately.**

- **CMS should monitor the accuracy of data reported under the new cost center to ensure that it is correct and leads to more accurate rate-setting.**

- **CMS should provide additional information regarding the calculation of the percentage changes in APC costs attributable to the use of the implantable device cost center.**

### iii. Proposed Calculation of Single Procedure APC Criteria-Based Costs

AdvaMed would like to provide CMS with several comments related to single procedure APC costs in response to our review of the proposed regulation.

#### a) Blood and Blood Products

AdvaMed’s member companies produce a broad range of technologies for the collection, testing, safety assurance, processing, storage, and transfusion of blood. While AdvaMed is pleased that the proposed OPPS rule for CY 2013 would provide increased payments for half of the blood product codes, we are concerned that the rule would reduce payments for the other half of the codes.

These decreases come at a time when a number of significant changes in the U.S. market for blood products will result in payments for services that lag behind their actual costs. Transfusion Safety Officers are being hired in most major hospitals to address improper transfusion and inappropriate use of blood, resulting in higher hospital costs at a time when MedPAC reports in its latest report on hospital inpatient and outpatient services that Medicare payments are currently less than costs for the average hospital. In addition, blood centers continue to move away from the practice of collecting and storing surplus supplies of donor blood and are collecting exactly what they need to meet contractual agreements. This results in increased unit costs over time.

The proposed blood and blood product payment reductions can also jeopardize blood safety and the nation’s public health. Blood safety is very complex, entailing several levels of safety practices with
high fixed costs. First, it requires a blood center to recruit the safest blood donors and to take
detailed medical histories that include thorough documentation every time a donor gives blood.
Second, blood donation and handling require medical and technical expertise and oversight. Third,
blood and blood products require safe filtration and strict temperature storage. Fourth, blood needs
to be screened for infectious diseases both with serology and with nucleic acid testing technology.
Finally, safe transfusion includes many fixed costs, such as medical personnel who can perform
appropriate consultations and cross-matching to make certain the unit of blood is compatible with the
patient.

Advamed is concerned that reducing payment rates for many blood and blood products in the face of
rising costs for blood will result in many hospitals incurring significant financial losses in providing
blood and blood products to Medicare patients. Without adequate payment rates for blood and blood
products, the safety and availability of blood for America’s seniors and other individuals may be
jeopardized.

b) **Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)**

In the CY 2012 OPPS final rule, CMS moved a CPT base code (37221) involving primary iliac
artery stenting for an initial vessel from APC 0083 to APC 0229. In doing so, CMS failed to move
CPT code 37223, an iliac stenting add-on code for each additional vessel, to APC 0229, where the
base procedure code (37221) was reassigned. For a variety of reasons, we believe CPT 37223 should
be reclassified to APC 0229, and we recommend that CMS do so in the CY 2013 final rule.
Advamed has significant concerns related to the placement of CPT code 37223 in APC 0083 and
requests that CMS move that code to APC 0229, the APC in which the base code for this add-on
procedure is located. As discussed below, Advamed believes the clinical features of 37223 and its
geometric mean cost support its placement in APC 0229. Three considerations support Advamed’s
request to move CPT code 37223 from APC 0083 to APC 0229:

1) the CPT code descriptions and notes related to the CMS single procedure claim
methodology
2) the available CMS data and application of the payment discount to CPT code 37223; and
3) existing policy precedents regarding the assignment of add-on codes to the APC associated
with the base procedure code.

**CPT Code Description and Notes**

Reliance by CMS on the 14 identified single procedure claims for APC assignment purposes is
inappropriate. The 14 single procedures were clearly billed in error as no single procedure claims for
37223 should have been submitted by hospitals. The descriptors and notes for CPT code 37223, as
included in the AMA’s CPT® 2012 Professional Edition, indicate that this code should only be
billed in conjunction with a base code (i.e. 37221). Therefore, there should not be any single
procedure claims identified for CPT code 37223.

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1 37223-Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with
   transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition
to code for primary procedure)
   - (Use 37223 in conjunction with 37221, 37229, 37231)
Available CMS data and application of the payment discount to CPT code 37223

Given the inherent challenges of determining single claims for add-on codes, AdvaMed recommends that CMS apply a complimentary methodology for use of the available claims data to more appropriately determine APC assignment for 37223. We believe CMS should focus on the 2011 claims data that shows 2,152 claims containing CPT code 37223. Among the 2,152 claims included in the 2011 data, 914 claims bill for CPT codes 37221 and 37223 only (based on an analysis by a consultant to AdvaMed). The number of claims containing lines for CPT code 37223 suggests that there is ample data available for use in determining appropriate APC placement.

Furthermore, CPT code 37223, similar to most add-on codes, is subject to multiple surgical procedure discounting. In accordance with the CMS Manual 100-04, Chapter 4 Part B Hospital, Section 10.5 – Discounting, multiple surgical procedures are subject to discounting. The full amount is paid for the highest weight APC and the remaining surgical procedures are discounted by 50 percent. CMS has assigned the “Status Indicator” of “T – Significant Procedure, Multiple Reduction Applies” to both CPT codes 37221 and 37223. Based on the CMS manual instructions and the Status Indicator assignment, CPT code 37223, currently assigned to APC 0083, when billed in accordance with the CPT code description and notes will always be discounted at 50 percent. Please see Attachment A for a full presentation of the data analysis.

Existing Policy Precedents Regarding the Assignment of Add-on Codes

AdvaMed would also note the inconsistency of CMS’ proposal to assign 37223 to APC 0083 rather than APC 0229, the APC the base CPT code (37221) is assigned to. We asked our consultant to analyze and review APC assignments for base CPT codes and their add-on codes. The results of the analysis suggest that CMS typically assigns an add-on CPT code to the same APC as its base CPT code. Of particular note are the coronary and endovascular interventions. (See Attachment A Table E)

- Based on the analysis outlined in Attachment A and previous CMS policies for CPT add-on codes, AdvaMed recommends that CMS consider the following factors and assign code 37223 to APC 0229 for CY 2013:
  1) In accordance with CPT coding description and notes, CPT code 37223 is always to be billed with CPT code 37221 which should result in no single procedure claims. Therefore, CMS should approach APC assignment of CPT code 37223 using claims that include 37221+37223.
  2) When CPT code 37223 is appropriately billed with CPT code 37221, the payment rate will always be discounted by 50 percent in accordance with the OPPS Status Indicator and CMS Manual instructions.
  3) If CPT code 37223 is assigned to APC 0229, the payment amount will be 95 percent of the implied geometric mean cost of 37223. Additionally, the procedures would be categorized to a more clinically coherent APC with similar geometric mean costs related to the payment amount.
  4) Continuing to place CPT code 32733 in APC 0083 results in a dramatic underpayment for the procedure of approximately $1,717.70. Moving the procedure into APC 0229 would result in a geometric mean cost (reflective of the discount applied to add-on codes) of $4,565 only slightly above 50 percent of the APC payment rate of $8,660.41.
c) Computed Tomography of Abdomen/Pelvis (APCs 0331 and 0334)

AdvaMed is troubled by CMS’s proposal to substantially reduce reimbursement for seven Computed Tomography (CT) procedures. CMS proposes to cut reimbursement by as much as 24.4 percent for some of these procedures. AdvaMed believes CMS should not implement this proposal without providing additional information regarding the basis for the proposed change and giving stakeholders a meaningful opportunity to comment.

The seven impacted CT APC codes and the reduction from CY 2012 reimbursement are as follows:

- APC 0283 1% reduction
- APC 0332 9.4% reduction
- APC 0333 1% reduction
- APC 0331 24.4% reduction
- APC 0334 16.7% reduction
- APC 8005 6.9% reduction
- APC 8006 5.4% reduction

Dramatic reductions—such as the changes to APCs 0331 (24.4 percent) and 0334 (16.7 percent)—often suggest an underlying change in the estimation methodology, rather than a change in actual hospital costs. In reviewing the proposed rule, we did not find an analysis to support these significant reductions nor an analysis of the data used for CY 2012 compared to the data used for CY 2013 for these services.

AdvaMed is greatly concerned that these cuts, in light of the many other imaging cuts that have occurred in recent years, could fundamentally threaten adequate access to these diagnostic services that often permit earlier diagnosis and treatment thereby reducing program costs and improving quality of care.

- **AdvaMed recommends that CMS reconsider such reductions and provide further clarity on the causes underlying the significant proposed reductions in CT reimbursement.**

iv. Proposed Geometric Mean-Based Relative Payment Weights

For CY 2013, CMS is proposing to move to a geometric mean based claims analysis to determine OPPS relative weight payments. This is a deviation from CMS’s traditional median cost analysis. CMS suggests that movement to a geometric mean will create increased two times rule sensitivity and may also create better stability in the payment system.

- **AdvaMed recommends that CMS closely monitor the level of change created by use of geometric mean analysis over time, as compared to the median cost system, to ensure that the payment levels assigned via this method are both stable and appropriate.**

Proposed Reductions in Mechanical Thrombectomy Payment

AdvaMed is likewise concerned about the proposed reduction in reimbursement for mechanical thrombectomy by arteriovenous (AV) access (APC 0653). Mechanical thrombectomy by AV access
is an important procedure for dialysis patients who experience clotting. Despite the many benefits associated with mechanical thrombectomy by AV access, CMS nevertheless proposes to reduce CY 2013 reimbursement for this procedure by 19.7 percent from the CY 2012 rate. The proposed rule does not provide an explanation for this substantial decrease. AdvaMed is concerned that the proposed cut, given its size, carries the risk of ultimately affecting patient access to this important procedure.

AdvaMed believes that more information is necessary to provide stakeholders with a full opportunity to comment on the proposal. Accordingly, AdvaMed requests that CMS provide such information and delay its implementation of the proposal.

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

A. Proposed OPPS APC-Specific Policies

AdvaMed has several recommendations related to specific OPPS payment policies that we urge the agency to consider as it finalizes the CY 2012 rule. These are listed below.

i. Appropriate APC Placement for the Laparoscopic Adjustable Gastric Band Procedure Code

Beginning in CY 2012, CMS removed CPT 43770 [Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)] from the inpatient-only list. AdvaMed supports this decision. We are concerned that the current APC assignment of CPT 43770 to APC 0131 does not fully recognize the costs of the procedure. The geometric mean hospital outpatient department cost for Laparoscopic Adjustable Gastric Band (LAGB) surgery (CPT 43770) is estimated to be $7,359 in the CMS CY 2013 OPPS analytic file. This geometric mean cost is the third highest among all procedures in APC 0131, and more than double the geometric mean cost for all procedures in APC 0131 ($3,586).

There is no existing APC that is both comparable clinically and in terms of resource utilization. APC 0132 (“Level III Laparoscopy”) includes some procedures that are more clinically comparable to CPT 43770 than those in APC 0131, but the procedures in APC 0132 are not comparable to CPT code 43770 in terms of resource utilization. In fact, only one procedure currently assigned to APC 0132 has a geometric mean cost higher than CPT 43770.

- **AdvaMed recommends that CMS reassign the LAGB procedure (CPT 43770) from APC 0131 and establish a new single code APC for the procedure.**

ii. Appropriate APC Placement for Proton Therapy

The CY 2013 proposed rule includes changes to the APCs for proton beam therapy (APCs 0664 and 0667) which result in significant payment decreases (see chart below).
<table>
<thead>
<tr>
<th>HCPCS</th>
<th>2012 APC</th>
<th>2012 Payment Rate</th>
<th>2013 Proposed APC</th>
<th>2013 Proposed Payment Rate</th>
<th>Proposed Change in Payment</th>
<th>Proposed Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>77520</td>
<td>0664</td>
<td>$1,183.77</td>
<td>0664</td>
<td>$450.40</td>
<td>-$733.37</td>
<td>-62%</td>
</tr>
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<td>77522</td>
<td>0664</td>
<td>$1,183.77</td>
<td>0667</td>
<td>$1,110.23</td>
<td>-$73.54</td>
<td>-6.2%</td>
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<tr>
<td>77523</td>
<td>0667</td>
<td>$1,548.54</td>
<td>0667</td>
<td>$1,110.23</td>
<td>-$438.31</td>
<td>-28.3%</td>
</tr>
<tr>
<td>77525</td>
<td>0667</td>
<td>$1,548.54</td>
<td>0664</td>
<td>$450.40</td>
<td>-$1,098.14</td>
<td>-70.9%</td>
</tr>
</tbody>
</table>

Given the limited number of hospitals currently providing proton beam therapy, and the even more limited number of cost reports and claims available to CMS for calculating proposed rates, we strongly encourage the agency to re-examine the data before moving forward with such significant reductions that could compromise beneficiary access to care. The issues and concerns cited by AdvaMed were discussed during the August 27, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (HOPs Panel). During that meeting the HOPs Panel made a recommendation that AdvaMed supports and would recommend to CMS.

- **AdvaMed recommends that CMS accept the HOPs Panel recommendation that CPT codes 77520, 77522, 77523, and 77525 remain in their current APCs for CY 2013 and that the CY 2012 payment rates associated with the APCs for those codes remain in effect for CY 2013.**

**iii. Appropriate APC Level V Endoscopy Upper Airway**

For 2013, CMS is proposing to assign CPT code 31541 (Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis) to APC 0075 (from APC 0074: Level IV Endoscopy Upper Airway). In the proposed rule, CMS has not provided an explanation for this proposed reassignment. This lack of information is especially concerning given that CPT 31541 would become the highest volume procedure in APC 0075 and significantly impact the proposed payment, reducing it by over 4 percent. Given that no explanation is offered for moving CPT 31541, AdvaMed cannot comment on whether the change and the resulting negative impact are appropriate. Consequently, we request that CMS reverse its proposal to move CPT 31541 to APC 0075 and, instead, recommend keeping the code in APC 0074 for CY 2013.

**III. Proposed OPPS Payment for Devices-- Proposed Pass-Through Payments for Devices**

In the proposed CY 2013 OPPS proposed rule, CMS does not identify any new device categories as eligible for pass-through payment for CY 2013 and proposes expiration of pass-through status for three existing categories on December 31, 2013. Over the past several years, there has been a steady decline in the number of devices that have been approved for pass-through status.
- AdvaMed recommends that CMS re-evaluate the criteria and approval process currently applied to the evaluation of devices for pass-through status to ensure adequate access to and support for innovative new technologies that improve health care.

- AdvaMed also recommends that CMS publish an annual list of all devices for which pass-through status was requested along with the rationale supporting their decision to grant or deny pass-through status.

IV. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals Without PassThrough Status

AdvaMed believes that stability in the payment for diagnostic radiopharmaceuticals is necessary to ensure availability of these important agents for use in nuclear medicine procedures.

- AdvaMed does not support CMS’ proposal to continue packaging the payment for diagnostic radiopharmaceuticals that do not have pass-through status.

V. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Total Disc Arthroplasty

CMS proposes to remove cervical disc arthroplasty from the list of procedures that Medicare will only pay as an inpatient procedure. AdvaMed believes this proposal appropriately recognizes the clinical similarity between the cervical disc arthroplasty procedure (CPT 22856) and other cervical fusion procedures for which Medicare makes payment in the outpatient setting, and strongly recommends that CMS finalize its proposal.

We also recommend that CMS assign CPT procedure code 22856 to APC 0425 Level II Arthroplasty or Implantation with Prosthesis to better reflect the resources necessary to perform the procedure. CMS proposes assignment of CPT code 22856 to APC 0208. While it is appropriate to remove CPT code 22856 from the inpatient list, the resource requirements to perform cervical disc arthroplasty are significantly greater than those represented in APC 0208. The cervical disc arthroplasty procedure is considered a device-dependent procedure because it uses an artificial disc. APC 0208 is not a device-dependent APC and does not adequately reflect the total estimated cost of performing the service. Therefore, AdvaMed recommends that the cervical disc arthroplasty procedure be assigned to APC 0425 for CY 2013.

B. Arthroplasty Knee

With respect to the CMS proposal to remove total knee arthroplasty (CPT code 27447) from the inpatient only list, AdvaMed is concerned that assigning this procedure to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis) as currently configured would establish an inappropriate payment rate for this surgical procedure.

The 2013 proposed rate of $8,950 for APC 0425 is far below CMS’ 2011 geometric mean cost ($11,286) for the most comparable procedure, a uni-compartmental knee replacement (CPT code 27446). Total knee replacement is more resource-intensive given that it is typically a longer, more invasive procedure. AdvaMed understands that CMS is somewhat constrained because of the lack of
OPPS cost data to guide its classification of total knee arthroplasty. Nonetheless, we recommend a split of APC 0425 to allow the two knee reconstruction procedures to be grouped together in a newly created APC, or with other similar orthopedic arthroplasty procedures in APC 0425. This would greatly improve clinical homogeneity and would better align the resource consumption of the procedures within the newly crafted APCs.

VII. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting

A. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In this rule, CMS is proposing that once a measure is adopted for the hospital OQR program for a payment determination year it will automatically be adopted for subsequent years until CMS proposes to remove, suspend or replace it. In previous rulemaking, CMS has proposed to retain previously adopted measures on a year-by-year basis.

- AdvaMed agrees with CMS’s approach concerning the automatic adoption procedure proposed for the purposes of streamlining the rulemaking process.

B. Removal or Suspension of Quality Measures from the Hospital Outpatient Quality Reporting Program Measure Set

CMS has proposed to apply the Hospital Inpatient Quality Reporting Program (IQR) measure removal criteria that were finalized in the FY 2011 IPPS/LTCH PPS final rule when determining measures to be removed from the Hospital Outpatient Quality Reporting Program (OQR). These seven criteria involve (1) high and unvarying measure performance among hospitals (“topped out” measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a lack of alignment with current clinical guidelines or practice; (4) availability of a more broadly applicable measure; (5) availability of a measure that is more proximal in time to desired patient outcomes; (6) availability of a measure that is more strongly associated with desired patient outcomes; and (7) collection or public reporting of the measure leads to negative unintended consequences such as patient harm.

AdvaMed agrees with CMS’s attempts to align the inpatient and outpatient processes regarding the removal/suspension of quality measures in each reporting program. AdvaMed agrees that the IPPS/LTCH criteria are also applicable in evaluating the Hospital OQR Program quality measures for removal. The detailed criteria set-forth and previously applied in the IQR program will bring additional consistency to the Hospital OQR Program.

- AdvaMed recommends that CMS establish criteria through the regulatory process for resuming data collection of any quality measures that are temporarily suspended or removed from any Quality Reporting Program (IQR, OQR, IRF, or QRP).

C. Proposed Updates to the "Percent of residents who have pressure ulcers that are new or worsened" measure and adoption in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP).
In the FY 2012 IRF PPS final rule CMS used their endorsement exception authority to adopt an application of the ‘Percent of Residents with Pressure Ulcers that Are New or Worsened’ measure (NQF #0678). CMS notes that they selected this measure because there was no other NQF-endorsed measure available to assess the percentage of patients with pressure ulcers that are new or worsened in the IRF setting at that time. CMS notes that they recognized that the NQF endorsement of this measure was, at that time, limited to short-stay nursing home patients, but believed that this measure was highly relevant to patients in any setting who are at risk of pressure ulcer development and a high priority quality issue. Subsequently, in the FY 2012 IRF PPS final rule, CMS finalized the adoption of an application of the NQF-endorsed #0678 pressure ulcer measure. CMS also requested that the NQF extend its endorsement of this short-stay nursing home pressure ulcer measure to the IRF setting.

In April 2012, CMS filed an ad hoc request for review of the NQF #0678 short-stay pressure ulcer measure with the NQF. In addition, CMS also requested an expansion of this measure to other care settings. CMS noted that this measure is highly applicable to all post-acute care settings, including IRFs. CMS anticipates that if the pressure ulcer measure is revised by the NQF, it will be re-titled ‘Percent of Patients or Residents with Pressure Ulcers That Are New or Worsened’ (NQF #0678) so as to reflect the expansion in the scope of the applicable patient population. As of the publication of the proposed rule, the NQF review process for the NQF #0678 pressure ulcer measure expansion request was still in progress. If the NQF expands the scope of endorsement for this measure to the IRF setting, without any substantive changes, CMS is proposing to adopt and use the revised pressure ulcer measure in the IRF QRP.

- AdvaMed supports CMS’s proposal to adopt the revised pressure ulcer measure in the Inpatient Rehabilitation Facility quality reporting program (IRF QRP) for FY 2014 payment determinations and all subsequent fiscal year payment determinations, if the NQF expands the scope of endorsement for the measure to the Inpatient Rehabilitation Facility setting.

Conclusion

AdvaMed greatly appreciates the opportunity to comment on the CY 2013 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 give consideration to 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,

Ann-Marie Lynch
Executive Vice President,
Payment and Health Care Delivery
Attachment A

The following analysis supports AdvaMed’s recommendation to assign code 37223 to APC 0229 for CY 2013:

**TABLE A—CMS Data as Presented in the Proposed Rule**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Geometric Mean Cost (GMC)</th>
<th>APC</th>
<th>APC Payment Rate</th>
<th>Payment Discount Rate %</th>
<th>Total Payment</th>
<th>Total Claims</th>
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<tr>
<td>37221</td>
<td>$7,958.53</td>
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<td>37223</td>
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<td>0083</td>
<td>$4,057.25</td>
<td>50%</td>
<td>$2,028.62</td>
<td>14</td>
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</table>

Since CPT code 37223 should not be associated with any single procedure claims, AdvaMed asked a consultant to simulate the geometric mean for CPT code 37223. Claims were identified that included both CPT codes 37221 and 37223 with stent C-codes. The simulated total geometric mean cost for the 914 claims was estimated to be $12,406.74. The geometric mean cost for single-procedure claims of CPT code 37221 was recalculated to be $7,842.04. Therefore, the simulated geometric mean cost of CPT code 37223 was $4,564.70 ($12,406.74 minus $7,842.04).

In assigning CPT code 37223 to APC 0229, the payment amount for 37223 is 95 percent of the simulated geometric mean cost of 37223 as shown in Table B below.

**TABLE B—Consultant Analysis**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Geometric Mean Cost</th>
<th>APC</th>
<th>APC Payment Rate</th>
<th>Payment Discount Rate %</th>
<th>Total Payment</th>
<th>Total Claims</th>
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<td>$7,842.04</td>
<td>0229</td>
<td>$8,660.41</td>
<td>100%</td>
<td>$8,660.41</td>
<td>5,480</td>
</tr>
<tr>
<td>37223</td>
<td>$4,564.70</td>
<td>0083</td>
<td>$4,057.25</td>
<td>50%</td>
<td>$2,028.62</td>
<td>914</td>
</tr>
</tbody>
</table>

Tables C and D illustrate the payment impact of keeping 37223 in APC 0083 vs. moving it to APC 0229.

**TABLE C—Consultant Analysis**

CPT 37223 assigned to APC 0083

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Geometric Mean Cost (GMC)*</th>
<th>APC</th>
<th>APC Payment Rate</th>
<th>Payment Adjudication Rate %</th>
<th>Total Adjudication Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>37221</td>
<td>$7,842.04</td>
<td>0229</td>
<td>$8,660.41</td>
<td>100%</td>
<td>$8,660.41</td>
</tr>
<tr>
<td>37223</td>
<td>$4,564.70</td>
<td>0083</td>
<td>$4,057.25</td>
<td>50%</td>
<td>$2,028.63</td>
</tr>
<tr>
<td>Total</td>
<td>$12,406.74</td>
<td></td>
<td></td>
<td></td>
<td>$10,689.04</td>
</tr>
<tr>
<td>Over/(under) payment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$(1,717.70)</td>
</tr>
</tbody>
</table>
### TABLE D — Consultant Analysis

CPT 37223 assigned to APC 0229

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Geometric Mean Cost (GMC)*</th>
<th>APC</th>
<th>APC Payment Rate</th>
<th>Payment Adjudication Rate %</th>
<th>Total Adjudication Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>37221</td>
<td>$7,842.04</td>
<td>0229</td>
<td>$8,660.41</td>
<td>100%</td>
<td>$8,660.41</td>
</tr>
<tr>
<td>37223</td>
<td>$4,564.70</td>
<td>0229</td>
<td>$8,660.41</td>
<td>50%</td>
<td>$4,330.21</td>
</tr>
</tbody>
</table>

Total $12,406.74

Over/(under) payment $12,990.62 $583.88

* 37221 (single-procedure claims), 37223 simulated geometric mean cost from consultant analysis.

Table E illustrates CMS’ typical approach to APC assignment for add-on CPT codes

<table>
<thead>
<tr>
<th>Base CPT</th>
<th>Add-on CPT</th>
<th>Principal APC</th>
<th>Add-on APC</th>
<th>Base CPT Description</th>
<th>Add-on CPT Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>92995</td>
<td>92996</td>
<td>0082</td>
<td>0082</td>
<td>Coronary atherectomy</td>
<td>Coronary atherectomy add-on</td>
</tr>
<tr>
<td>37205</td>
<td>37206</td>
<td>0229</td>
<td>0229</td>
<td>Transcathe IV stent, precut</td>
<td>Transcathe IV stent, percult, addl</td>
</tr>
<tr>
<td>37207</td>
<td>37208</td>
<td>0229</td>
<td>0229</td>
<td>Transcathe IV stent, open</td>
<td>Transcathe IV stent, open, addl</td>
</tr>
<tr>
<td>37220</td>
<td>37222</td>
<td>0083</td>
<td>0083</td>
<td>Iliac revasc</td>
<td>Iliac revasc add-on</td>
</tr>
<tr>
<td>37228</td>
<td>37232</td>
<td>0083</td>
<td>0083</td>
<td>Tib/per revasc w/tla</td>
<td>Tib/per revasc add-on</td>
</tr>
<tr>
<td>92982</td>
<td>92984</td>
<td>0083</td>
<td>0083</td>
<td>Coronary artery dilation</td>
<td>Coronary artery dilation</td>
</tr>
<tr>
<td>92997</td>
<td>92998</td>
<td>0083</td>
<td>0083</td>
<td>Pul art balloon repr precut</td>
<td>Pul art balloon repr percut</td>
</tr>
<tr>
<td>37184</td>
<td>37185</td>
<td>0088</td>
<td>0088</td>
<td>Prim art mech thrombectomy</td>
<td>Prim art m-thrombect add-on</td>
</tr>
<tr>
<td>37184</td>
<td>37186</td>
<td>0088</td>
<td>0088</td>
<td>Prim art mech thrombectomy</td>
<td>Sec art m-thrombect add-on</td>
</tr>
<tr>
<td>36478</td>
<td>36479</td>
<td>0092</td>
<td>0092</td>
<td>Endovenous laser 1st vein</td>
<td>Endovenous laser vein addon</td>
</tr>
<tr>
<td>92980</td>
<td>92981</td>
<td>0104</td>
<td>0104</td>
<td>Insert intracoronary stent</td>
<td>Insert intracoronary stent</td>
</tr>
</tbody>
</table>