



September 6, 2013

**Via Electronic Mail**

Marilyn Tavenner, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1601-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; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Proposed Rule (CMS-1601-P)**

Dear Ms. Tavenner:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Proposed Rule (CMS-1601-P) (*Federal Register*, Vol. 78, No. 139, Friday, July 19, 2013, p. 43534).

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.

AdvaMed appreciates the complexity in developing the OPSS rule. 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 not, however, able to replicate the changes in this year's rule due to a number of problems including significant data errors and insufficient information about the methodology used to develop proposed rates. Additionally, the effect of many of the proposals included in the rule will not be known for at least two years because it will take that long for CMS to have actual OPSS claims data that reflects the new policies. These problems, as will be

discussed in more detail throughout this letter, make it very difficult to understand the overall impact of many of the proposed policies on providers and beneficiaries.

During the Advisory Panel on Hospital Outpatient Payment (Panel) meeting, held on August 26<sup>th</sup>-27<sup>th</sup>, the panel members unanimously recommended that CMS delay implementation of the major proposals related to development of comprehensive APCs, implementation of the CCRs for CT and MRI, and the seven new packaging policies. AdvaMed also agrees that CMS should not implement the major changes incorporated in the proposed rule.

Following the Panel meeting, CMS released corrected OPPS claims data files-- late afternoon on Wednesday, August 28<sup>th</sup>. While AdvaMed appreciates CMS' decision to make the corrected data available to the public, the new data was issued too late to allow stakeholders to conduct comprehensive analysis and to provide meaningful comments on a number of the potentially critical proposals included in the rule prior to the September 6<sup>th</sup> comment deadline. Additionally, lack of transparency regarding the methodology used by CMS persists despite release of the corrected data. A number of noted consultants who model the OPPS rule each year share AdvaMed's opinion. Christopher Hogan, Ph.D. (Direct Research, LLC), Susan E. White, Ph.D., CHDA (Health Policy Analytics, LLC), Mary Jo Braid-Forbes (Braid-Forbes Health Research, LLC), and The Moran Company all experienced significant difficulty in modeling the rule this year and in understanding the methodology used to develop the various proposals-- even after CMS issued corrected data files.<sup>1</sup> These consultants also agree that modeling this complex rule is a time-consuming and tedious task, and that the time remaining after CMS issued corrected data files was insufficient for analysis to be completed. AdvaMed reiterates that CMS should not finalize major changes included in the proposed rule

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 and Use of Cost-to-Charge Ratios (CCRs)
    - iii. Proposed Calculation of Single Procedure APC Criteria-Based Costs
      - a. Device-Dependent APCs
      - b. Blood and Blood Products
    - iv. Proposed Establishment of Comprehensive APCs
    - v. Proposed Changes to Packaged Services
      - a. Proposed New Packaging Policies for CY 2014
        1. Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure—Skin Substitutes
        2. Clinical Diagnostic Laboratory Tests
        3. Procedures Described by Add-On Codes
        4. Ancillary Services (Status Indicator “X”)
        5. Device Removal Procedures
- II. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
  - A. Proposed OPPS APC-Specific Policies:

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<sup>1</sup> AdvaMed is attaching memoranda from each of these consultants regarding their difficulties in replicating the proposed CY 2014 OPPS rule.

- i. Disposable Negative Pressure Wound Therapy
    - ii. Subcutaneous Implantable Defibrillator (S-ICD) System (0319T) assignment to APC0107
  - B. Proposed OPPS Changes—Variations Within APCs
    - i. Proton Beam Radiation Therapy (APCs 0664 and 0667)
    - ii. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0066 and 0067)
- III. Proposed OPPS Payment for Devices—Proposed Adjustments to OPPS Payment for No Cost/Full Credit and Partial Credit Devices
- 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
- V. Hospital Outpatient Quality Reporting Program Updates
- VI. Hospital Value-based Purchasing (VBP) Program Updates
- VII. Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
  - A. Possible Hospital OQR Program Measure Topics for Future Consideration

## **I. Proposed Update Affecting OPPS Payments (for CY 2014)**

AdvaMed has a number of comments related to the proposed payment updates for OPPS services in CY 2014. 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 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 regard to coding for supplies. Code utilization data is 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 and Use of Cost-to-Charge Ratios (CCRs)

AdvaMed commends CMS's decision to continue using data from the implantable device cost center in setting the rates for certain OPSS services for CY 2014.

Even though reporting to the new cost center is expected to improve over time, AdvaMed believes that additional educational efforts are needed to ensure that more hospitals use the implantable cost center and that they report data to it accurately. This will improve the validity of payment weights based on estimated costs. Furthermore, AdvaMed believes that CMS should monitor the accuracy of the data collected through the new cost center.

AdvaMed therefore makes the following recommendations related to the use of the cost center:

- ***AdvaMed recommends that CMS initiate actions to undertake additional outreach and educational activities to ensure that hospitals and the Medicare Administrative Contractors (MACs) are educated fully about the cost center requirements to ensure common knowledge, consistent and accurate audit processes, and to ensure that cost report changes are implemented effectively and accurately.***
- ***AdvaMed recommends that CMS continue to monitor the accuracy of data reported under the cost center to ensure that it is correct and leads to more accurate rate-setting.***

While AdvaMed supports the use of the Implantable Devices and the Cardiac Catheterization cost centers, CMS should not implement the proposed new cost-to-charge ratios for CT scans and MRIs. Applying distinct cost-to-charge ratios (CCRs) for CT and MRI costs to 2014 hospital outpatient payments would have the effect of cutting payments by as much as 19% for outpatient MRI services and as much as 38% for CT services, according to CMS estimates in its 2014 outpatient prospective payment system proposed rule.<sup>2</sup> In addition, because federal law caps payments under the physician fee schedule for advanced imaging at the outpatient system levels, the imaging cuts would extend to all non-hospital settings as well.

CMS in the inpatient rule indicated that "We will separately evaluate the impacts of implementing any additional CCRs under the OPSS as part of the OPSS rulemaking". AdvaMed has ongoing concerns that the CCR data may not accurately reflect the charges for these important services and may adversely impact patient access to necessary medical technologies. We strongly urge CMS to consider these issues as the agency considers implementing the MRI and CT CCRs in CY 2014.

AdvaMed continues to be concerned about the accuracy of data in the CT and MRI cost centers. We asked our consultant, Direct Research LLC, to analyze CT and MRI capital reporting for IPPS hospitals reporting CT, MRI, and Other Radiology separately on the 2552-10 cost reports. The analysis found that many hospitals report little to no equipment capital cost for CT and MRI. Similar concerns related to the accuracy of the data used to determine the CT and MRI CCRs was also discussed during the Summer Advisory Panel on Hospital Outpatient Payment (Panel) meeting held on August 26<sup>th</sup> and 27<sup>th</sup>. Due to several uncertainties regarding the data used to determine these CCRs, the Panel recommended that CMS delay implementation of the CT and

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<sup>2</sup> See NPRM TABLE 3 Federal Register, Vol. 78, No. 139, Friday, July 19, 2013, p. 43549

MRI CCRs along with several other proposals until data supporting those proposals can be reviewed by the Panel at the Spring 2014 meeting. AdvaMed supports adoption of the Panel's recommendation.

We believe that using the data currently available from the new cost centers for CT and MRI will ultimately lead to cost estimates that are inaccurate as it produces similar payment amounts for both advanced and older imaging modalities. Specifically, our consultant found that the estimated costs for CT and X-ray studies were roughly equal when computed with single claim OPPS data from hospitals that used separate CT and MRI cost centers. For example, the estimated cost of a CT scan of the abdomen would be \$95 while the estimated cost of an X-ray of the abdomen would be \$93, and the cost of a CT scan of the head/brain would be \$84 while the estimated cost of an x-ray of the skull would be \$82. Such an outcome appears to be highly inaccurate, given that advanced imaging technologies require more substantial investments in equipment, have substantially larger service costs, require higher-skilled technologists, take longer to perform, have more diagnostic power, and yield results with greater clinical value.

Research conducted by the Research Triangle Institute, International (RTI) under contract with CMS to study the effects of charge compression anticipated the difficulty of establishing accurate cost-to-charge ratios for CT and MRI services. According to the report “[CT and MRI] services are very capital-intensive, and accurate cost ratios will depend on providers’ being able to assign actual equipment depreciation and lease costs directly to the cost centers, rather than the traditional method of allocating average capital costs based on square footage.”<sup>3</sup> When RTI examined data from hospitals that reported costs for CT and MRI services on nonstandard lines, they found that “many facilities had very low cost ratios on these nonstandard lines, including many below 0.05.”<sup>4</sup> RTI noted, “that this raises questions about the relative accuracy of [the hospitals’] cost finding.”<sup>5</sup>

Another source of potential data error is the fact that hospitals are still familiarizing themselves with various aspects of the new cost report form. More specifically, the 2552-10 Medicare cost report form was effective for cost reporting periods beginning on or after May 1, 2010, and many hospitals began reporting separately for MRI and CT cost centers during the first year of the new cost report form.<sup>6</sup> Hospitals’ lack of familiarity with these components of the cost reporting process may also generate cost reporting errors.

- ***AdvaMed recommends that CMS delay implementation of the MRI and CT CCRs in CY 2014.***

### **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.

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<sup>3</sup> RTI 2007, at p. 65, fn. 20.

<sup>4</sup> *Id.*, at p. 65.

<sup>5</sup> *Id.*

<sup>6</sup> 78 Fed. Reg. at 27506-07.

### **a. Device Dependent APCs**

The proposed rule includes a recommendation to eliminate the use of procedure-to-device and device-to- procedure edits for use with any APCs effective CY 2014. AdvaMed has significant concerns regarding the implications of this policy and recommends that CMS not move forward with its proposal. Device edits were implemented in 2005 for the purpose of ensuring the accuracy of OPPS payments for procedures, especially those involving the use of 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 left off a claim. Hospital representatives from the Provider Round Table echoed this sentiment in their public comments to CMS during the August 2013 CMS Advisory Panel on Hospital Outpatient Payment meeting during which they indicated that the device edits have been very helpful in enabling hospitals to submit accurate claims for device related procedures. While CMS suggests that the edits are no longer necessary and can therefore be eliminated, the agency does not point to any statistical drop in claims errors or any other data in support of its recommendation.

AdvaMed is especially concerned about the risk for data errors that may result now that CMS is also proposing to develop comprehensive APCs for many device-dependent APCs. The risk of coding errors can be expected to increase if all services for high cost device procedures are now encompassed on one APC grouping. While the agency suggests that comprehensive APCs will flag the device involved in a procedure, it fails to consider the lower cost devices that may be included on a device-intensive APC claim. It also does not take into consideration the presence of a second high-cost device on a claim, as in the case of comprehensive APC claims that include more than one device-dependent APC. In those cases, it is possible for another device that is significant to the overall procedure to be left off a claim.

AdvaMed is concerned that elimination of these edits, especially in an environment of increased bundling, will jeopardize data accuracy. CMS should minimize the potential for these types of data inaccuracies by continuing the edits.

- ***AdvaMed urges CMS to maintain the device-to-procedure and procedure-to-device edits in CY 2014 to ensure continued accuracy of the data reported by hospitals and captured by CMS.***

### **b. 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. The proposed rule has two parts affecting Medicare payments for blood and blood products: (1) bundling the costs of blood and blood products used in CMS's proposed twenty-nine comprehensive device-dependent APCs proposed by CMS and ending separate payment for blood in those instances; and (2) decreases in payment rates for certain blood APCs as a result of CMS using its hospital-specific, blood-specific CCR methodology.

***Bundling the Costs of Blood and Blood Products in the Proposed Comprehensive APCs--*** We believe that blood and blood components should not be included in the comprehensive APCs and should instead be valued independently as critical lifesaving medical inputs that help ensure

positive clinical outcomes for many patient populations. By bundling blood alongside other commodities used in medical procedures, CMS fails to take into account the unique, life-saving role of blood in enhancing outcomes for patients with conditions ranging from cancer to serious trauma. Bundling the costs of blood in the comprehensive APCs will put additional downward price pressures on blood at a time when hospitals are incurring higher costs for ensuring blood safety for their patients (see discussion below).

- ***AdvaMed recommends that CMS not include blood and blood products in its comprehensive APCs and not finalize its comprehensive APC proposal for the reasons discussed in the next section of this letter.***

***Decreases in Payment Rates for Certain Blood APCs--*** 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 March 2013) that hospitals have negative margins of approximately 10 percent for outpatient services provided to Medicare patients. 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. APC 967, Blood Split Unit, is an example of a blood product with high fixed costs. Splitting blood units is an important step to ensure safe transfusion for patients. With this process, a whole blood unit of blood is alliquotted into 20-30 CC' units which requires additional bags and centrifugation. The proposed rule would reduce the payment for this APC by 24.1 percent.

While technology is an essential component for ensuring a safe blood supply, blood centers must have in place other essential practices for the process. Blood centers must first recruit the safest blood donors and 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 do appropriate consultations and cross-matching to make certain the unit of blood is compatible with the patient. AdvaMed has heard that some community blood centers are using workers with lower skill levels and are reducing blood safety practices in order to address rising costs at a time when their payments are declining.

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 may be jeopardized.

- ***AdvaMed recommends that CMS review blood and blood product APCs with proposed payment reductions for CY 2014 to determine the appropriateness of the reductions in light of the high fixed costs for these APCs.***

#### **iv. Proposed Establishment of Comprehensive APCs**

The proposed CY 2014 OPSS rule includes a proposal to convert 29 device-dependent APCs into “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 believes that, before moving forward with this proposal, CMS needs to make available to stakeholders more information about both the data and methodology it used for constructing the proposed comprehensive APCs.

AdvaMed is concerned that, as proposed, the comprehensive APCs will have a serious negative impact on patients’ access to the technologies and services bundled into the proposed comprehensive APCs, and therefore believes that it is premature for CMS to finalize the proposal. Similar concerns related to the absence of data with which to make these determinations were raised during the summer Advisory Panel on Hospital Outpatient Payment (Panel) meeting held on August 26<sup>th</sup> and 27<sup>th</sup>. Following their discussion, the Panel recommended that CMS delay implementation of the comprehensive APC proposal, along with several other proposals, until data supporting those proposals can be reviewed at the Spring 2014 Panel meeting.

***Analytical Findings and Alternatives--*** In an effort to understand the possible implications of the change 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. Because detailed information about data and the methodologies used in formulating these specific APCs has not been provided by CMS, Direct Research was unable to replicate the payments that CMS has published for these comprehensive APCs in the proposed rule. However, Direct Research’s preliminary claims data analysis suggests that the comprehensive APCs will result in sizable reductions in Medicare payments for complex procedures, especially those that are done in a bilateral fashion or those that involve multiple vessels (as is the case with several vascular procedures). While the claims analysis shows modest increases for some simple procedures, it is hard to determine if these gains are the byproduct of historic coding errors or another cause. However, in the case of complex or bilateral procedures the claims data clearly shows that these procedures will see significant decreases under a comprehensive APC policy. These reductions will create significant disincentives for hospitals to perform complex cases and will, therefore, have a serious impact on patients’ access to the care they require.

***Future Designation of Device-Dependent APCs--*** AdvaMed has concerns regarding the impact of the comprehensive APC proposal on the future approval and evaluation of procedures that would traditionally be included in device-dependent APCs. Historically device-dependent APCs have received special payment consideration under the OPSS system because they require the implantation or use of a device. In the proposed rule, CMS acknowledges that not all device-dependent APC procedures are being considered for inclusion in comprehensive APCs. However, the majority of device-dependent APCs are included in the proposed policy. Given the

level of data currently available, AdvaMed is unable to determine, with any level of certainty, how this proposal will affect the consideration of implantable devices that would be considered for placement in either device-dependent or comprehensive APCs in the future.

***Impact on Pass-through Status--*** We have similar concerns related to the impact of this policy on devices seeking pass-through status. Pass-through status has traditionally 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 has historically 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 the transition to comprehensive APCs will create even more hurdles for devices seeking pass-through status.

Device-dependent APCs typically involve the use of sophisticated medical technology in a patient population with multiple and complex health problems. AdvaMed is concerned that the major reductions in payments for procedures in the proposed comprehensive APCs would have a serious negative impact on patient access to life-enhancing and saving technologies and procedures.

- ***AdvaMed recommends that CMS adopt the HOP Panel recommendation as it relates to delay of the CY 2014 comprehensive APC proposal and that the Agency not finalize the comprehensive APC proposal for CY 2014.***
- ***AdvaMed requests that CMS make available to stakeholders and the public all necessary data and other information (including methodology information) related to the proposed comprehensive APCs which will allow for an accurate assessment of its impact on patient care and the development of meaningful comments by interested stakeholders.***

#### **v. Proposed Changes to Packaged Services**

The proposed CY 2014 OPSS rule incorporates seven new APC packaging policies. While AdvaMed recognizes CMS’s rationale regarding packaging, we are concerned that the payment development process for packaged procedures is not transparent, may lead to inappropriate payments, and could compromise patient access to high quality care. Additionally, the lack of detailed information makes it difficult for stakeholders to assess and provide meaningful comments on the impact and appropriateness of these policies. CMS should make this information public to assure stakeholders that the data on which packaging decisions are based is accurate.

CMS has not added new packaging policies to the OPSS since 2008. Following the 2008 additions the Panel recommended that CMS analyze the impact of packaging on net payments for patient care before expanding packaging policies to other areas. The impact of the packaging proposal was the source of much discussion during the Summer Advisory Panel on Hospital Outpatient Payment (Panel) meeting held on August 26<sup>th</sup> and 27<sup>th</sup>. Due to several uncertainties regarding the interaction of the proposed policies and their impact the Panel recommended that CMS delay implementation of the packaging proposal along with several other proposals until data supporting those proposals can be reviewed by the Panel at the Spring 2014 meeting.

AdvaMed supports adoption of the Panel's recommendation. We also believe that CMS should not move forward with an expansion of packaging until it has first made available to the public an analysis of the impact of these changes on payment rates and patient access.

- ***AdvaMed urges CMS to delay implementation of the seven proposed packaging policies until the agency is able to provide more data to stakeholders to use in evaluating the impacts of these changes and to provide well-reasoned comments on the proposals.***

AdvaMed further recommends that CMS:

- ***Develop and communicate a clear and transparent method for identifying codes being considered for packaging.***
- ***Educate hospitals and coders on the importance of including all appropriate codes and charges on the claims form for those items included in packaged APCs.***
- ***Permit exceptions to any general packaging policy in cases where packaging could unreasonably impede patient access to new or existing devices, diagnostics, or other advanced medical technologies.***
- ***Increase transparency with regards to identifying the APC to which packaged devices will be added by providing a crosswalk indicating the volume of packaged claims for each type of packaged service that is provided with each principal procedure.***
- ***Make the data underlying payments for packaged services, including utilization rates and estimated mean costs, publicly available.***

#### **a. Proposed New Packaging Policies for CY 2014**

AdvaMed has several concerns related to the specific packaging proposals that we will discuss in greater detail below.

##### **i. Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure— Skin Substitutes**

The proposal to package drugs and biologicals that CMS believes function as supplies or devices when used in a surgical procedure is highly problematic for skin substitute products. These highly complex products, which consist of human, animal, and acellular dermal matrices, are used in the treatment of diabetic foot ulcers, venous leg ulcers, large wounds, surgical repairs, and severe burns. CMS is proposing to unconditionally package skin substitute products into their associated surgical procedures. This rationale is based on the use of these products “as a necessary supply” for surgical repair procedures.

In the proposal CMS also describes these products as wound dressings. However, in doing so CMS does not acknowledge the use of these products, in the management of wounds, not only as wound coverings but also as biologicals. In fact, skin substitute products may be covered with more traditional wound dressings. Although the FDA definition of wound dressings is very broad and encompasses everything from complex biologically active skin substitute technologies to synthetic dressings, the FDA's classification is not dispositive for Medicare purposes. Many

of the skin substitute products meet the Social Security Act definition of a biological and have been covered and paid as biologicals under Medicare Part B for many years.<sup>7</sup>

AdvaMed does not believe that packaging sophisticated skin substitute devices with more common wound care products such as bandages is appropriate. Nor do we believe that it is appropriate to treat these products as “surgical supplies.” Packaging skin substitute products under the proposal would not recognize the level of complex medical conditions for which they are used and would not acknowledge the substantial difference in costs associated with their use.

The proposal to package skin substitutes would create a one-size-fits-all approach to the selection of both the appropriate products for use with a wound and the size/amount of product required to treat the wound. This will create serious financial disincentives to the appropriate treatment of larger wounds or wounds for which more costly products may be medically appropriate.

Under the proposal a number of these products will see reductions in payment of 16% to 21%. This is due largely to the move from ASP payment, which was traditionally used to price these products, to OPSS payment methodologies. As noted in the analysis performed by Direct Research, LLC the high variance in cost of skin substitutes and the use of geometric mean instead of median cost disproportionately lowers the payments for the impacted procedures and Ambulatory Payment Classifications. Medicare typically pays about 88% of cost for payable procedures under OPSS. However, an analysis of the proposal suggests that, Medicare would pay the affected procedures an average of 77% of the former ASP costs for skin substitutes. Finalization of this OPSS proposal will likely result in hospitals receiving inadequate payment to procure these advanced products for use in procedures. Patients could lose access to technologies that will greatly enhance their care outcomes.

- *AdvaMed recommends that CMS not finalize the proposal to package skin substitutes as supplies or devices when used in a surgical procedure and to continue to pay these products at ASP for CY 2014.*
- *AdvaMed encourages CMS to work with stakeholders to address any concerns the Agency may have regarding appropriate utilization of skin substitute products for patients with complex wounds.*

## **ii. Clinical Diagnostic Laboratory Tests**

CMS is proposing to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the outpatient setting. Tests subject to the CMS proposal would be provided on the same date of service as the primary service **and** would be ordered by the same practitioner who ordered the primary service. CMS would not package a laboratory test if it is the only service provided on that date of service, was ordered for a different purpose by a different provider, or is a molecular diagnostic test.

Though AdvaMed understands the rationale for creating larger bundles by packaging the laboratory tests we have concerns regarding the implications of this change in Medicare beneficiary access to needed services. CMS acknowledges that packaging the laboratory tests

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<sup>7</sup> **See** Social Security Act §1861(t)(1)

has co-pay implications for beneficiaries. Because many of the clinical lab fee schedule (CLFS) tests that will now be packaged have historically been separately paid beneficiaries receiving these tests have not been responsible for a co-payment. CMS suggests that any changes to co-pay created by the packaging of laboratory test would be offset by the overall copayment limitation policy. However, we remain concerned that any increase in out-of-pocket costs, whether perceived or real, can have a detrimental impact on the decision of Medicare beneficiaries to seek out and to receive needed care including diagnostic testing.

Further, this proposal runs the risk of leading to duplicative payments. If the proposed packaging policy is finalized, physicians may decide to give patients prescriptions to have particular tests performed on a different date or outside the hospital, in lieu of testing on the date of the encounter at the hospital, to prevent the hospital from incurring the costs of performing the tests. Patients who are forced to go to an outside laboratory to obtain testing, may forego testing—including testing which may be critical in managing their care and improving their health outcomes. Additionally, Medicare could end up paying twice for tests: once because test payments would presumably be reflected in the rates set for the package under the OPDS, and again if the tests in question were performed elsewhere or on another date and paid under the Clinical Laboratory Fee Schedule. CMS has not described policies or mechanisms it might use to address such concerns.

- *AdvaMed urges CMS not to adopt the proposal to package clinical diagnostic laboratory services into the APC for other services performed at the same encounter in CY 2014.*

We also note that under the proposed packaging policy, CMS is proposing an exception for molecular pathology tests described by CPT codes 81200–81383; 81400–81408 and 81479. CMS has proposed such an exception because it believes that these tests “have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests” that CMS is proposing to package.

- *AdvaMed supports CMS’s decision to exempt molecular pathology codes from the packaging policy.*

### **iii. Procedures Described by Add-On Codes**

AdvaMed has concerns related to the proposal to package procedures described by add-on codes. The CMS proposal could create significant financial burdens for hospitals, which may result in decreased beneficiary access to appropriate care. Below, we describe our concerns with CMS’ packaging proposal for add-on codes and provide a pathway for developing alternative solutions to address data issues related to setting OPDS payment rates for procedures represented by add-on codes.

***Concerns With Unconditional Packaging of 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 eliminate all of the 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.***

#### **iv. Ancillary Services (Status Indicator "X")**

CMS currently pays separately for certain services that are assigned a status indicator "X", defined as ancillary services. For CY 2014, CMS is proposing to conditionally package all ancillary services, including physician pathology services that were previously assigned status indicator "X." These services would be assigned a new status indicator, "Q1," and would be packaged when they are provided with a service with status indicator "S," "T," or "V."

AdvaMed has concerns related to this proposal. We oppose CMS's proposal to package physician pathology services for the same reasons that we object to CMS's proposal to package clinical diagnostic laboratory tests. In short, physician pathology services are frequently performed absent a distinct "primary procedure." Packaging these physician pathology services may also create financial disincentives to perform medically necessary testing, or promote shifting to testing outside of the hospital setting.

- ***AdvaMed recommends that CMS not package ancillary services with status indicator X in CY 2014.***
- ***AdvaMed recommends that as CMS considers creation of an ancillary services policy that the Agency consider exempting molecular pathology tests from any such policy.***

Should CMS proceed with this proposal, however, we would recommend that CMS exempt from packaging those physician pathology services that involve molecular pathology procedures. Likewise, we would recommend CMS extend its proposed exemption of molecular pathology procedures from the proposed packaging policy to physician pathology services—especially molecular physician pathology services. Just as CMS noted that molecular pathology tests have a different pattern of use and may be less tied to a "primary service" performed during

a hospital encounter, the same rationale applies to molecular pathology services that require physician interpretation, such as in situ hybridization procedures (which target DNA within cells). These services also should be exempt from any packaging proposal adopted in the final rule.

#### **v. Device Removal Procedures**

The CMS packaging proposals include a recommendation to conditionally package the costs for device removal and revision or replacement procedures. CMS notes that it is “proposing that services be conditionally packaged so that if they are provided without other services, there will be a separate payment for the service.” Under the CMS proposal, conditionally packaged OPPS procedures will be assigned the modifier Q2.

While AdvaMed appreciates CMS’s taking steps to accommodate payment for separate services in the OPPS setting, we note that the proposal creates problems for procedures that require the removal of a device but do not require the subsequent replacement or revision of that device when performed in the ASC. This is due to the absence of a mechanism or a modifier for conditionally packaging ASC procedures. The ASC modifier (N1-- Packaged service/item; no separate payment made) that has been assigned to many of the packaged codes that were conditionally packaged in the OPPS reflects full packaging for these procedures when performed in the ASC. Because the ASC modifier indicates that the total procedure is packaged no payment can be made when only a device removal procedure is performed in this setting. This essentially prevents providers who perform these same procedures in the ASC from receiving any payment for the service. AdvaMed does not believe that this is reasonable given the ability, per CMS regulations, to perform these services in either the OPPS or ASC settings.

- *AdvaMed recommends that CMS create a method for conditionally packaging ASC services.*
- *We further recommend that CMS create a modifier to reflect conditional packaging in the ASC setting thereby allowing those procedures that are conditionally packaged in the OPPS, using modifier Q2, to be subject to this same level of conditional packaging in the ASC setting.*

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

### **A. Proposed OPPS APC-Specific Policies**

#### **i. Appropriate APC Placement for Disposable Negative Wound Pressure Therapy G Codes**

AdvaMed requests that CMS reassign the G codes created on January 1, 2013 for disposable negative pressure wound therapy (NPWT) from APC 0016 (Level IV Debridement & Destruction) to APC 0186 (Level III Skin Repair). The G codes and their descriptors are shown below.

G0456 Negative pressure wound therapy, (e. g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including

provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters

G0457 Negative pressure wound therapy, (e. g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

Moving these G codes to APC 0186 (Level III Skin Repair) would better group these procedures, which use single-use disposable device systems, with an APC that includes other similar wound care codes describing treatment of complicated wounds (CPT codes 13100, 13101) and cleaning and preparation of viable wound surfaces for substitute skin grafting (CPT codes 15002, 15003). APC 0186 also includes a procedure for closing split wounds (CPT code 12020), a service similar to the wound healing objective of disposable NPWT.

The G codes are now mapped to APC 0016 (Level IV Debridement and Destruction). This APC contains medical services involving destruction of skin lesions, removal of foreign bodies, and debriding subcutaneous tissue. While APC 0016 broadly relates to skin care, its procedures are more closely related to extraction, ablation, and removal of foreign bodies. Disposable NPWT is the application of suction on different types of wounds using various energy sources to remove exudate and promote healing, which aligns more with the wound care services contained in APC 0186.

Because the G code APC assignments are interim in nature for 2013, CMS could reclassify these codes in 2014, and once actual hospital outpatient claims for these services become available, the assignment could be revisited if future claims data suggests another APC assignment would be more appropriate.

- *AdvaMed requests that CMS reclassify G codes G0456 and G0457 to APC 0186, as this would be a more appropriate grouping from a resource and clinical homogeneity perspective.*

#### **ii. Subcutaneous Implantable Defibrillator (S-ICD) System (0319T) assignment to APC0107**

AdvaMed disagrees with CMS on the assignment of Category III CPT Code 0319T (insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode) to APC 0107. Code 0319T includes insertion or replacement of the subcutaneous implantable cardio defibrillator (S-ICD) System which includes the pulse generator and the lead. APC 0107 is generally reserved for procedures (i.e., 0321T, 0323T, 33230, 33231, 33240, 33262, 33263, and 33264) that involve ICD pulse generators only. Therefore, placement of 0319T into APC 0107 would not fully recognize the costs of the pulse generator **and** the lead.

CMS is also obligated to consider clinical similarities when assigning new procedures to an APC. The lead and pulse generator placement procedures involved in the S-ICD system implant are more similar to procedures found in APC 0108 which includes codes for implantation of both the ICD pulse generator and lead(s).

- *AdvaMed recommends reassignment of the S-ICD system implant (0319T) to APC 0108 due to clinical and resource similarity.*

## **B. Proposed OPPS Changes—Variations Within APCs**

### **i. Proton Beam Radiation Therapy (APCs 0664 and 0667)**

The proposed CY 2014 rule includes a proposal to delete APC 0664 and to move CPT codes 77520 and 77522 from APC 0664 to APC 0667 based on a violation of the two times rule. CMS also proposes revising the title of APC 0667 to Proton Beam Radiation Therapy. If CMS moves forward with the proposal APC 0667 would include all proton beam radiation therapy services including simple, intermediate, and complex treatments. APC groupings are required to be both resource and clinically similar. AdvaMed is concerned that moving all of the proton beam radiation therapy procedure codes into a single APC may not allow adequate distinctions among the resources involved in doing the various procedures.

- *AdvaMed recommends that CMS not merge APCs 0664 and 0667 without further evaluation of the clinical differences among the CPT codes and to ensure the accuracy of the claims data that was used to determine the presence of a two times rule violation.*

### **ii. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0066 and 0067)**

CMS is proposing in CY 2014 to replace the four existing SRS HCPCS G-codes (G0173, G0251, G0339, and G0340), with SRS CPT codes 77372 and 77373.<sup>8</sup> CMS is proposing to assign CPT code 77373 to APC 0066 “Level I Stereotactic Radiosurgery” and both single session cranial treatment codes (CPT codes 77371 and 77372) to APC 0067 (Level II Stereotactic Radiosurgery).

- *AdvaMed supports the proposal to consolidate the HCPCS SRS G-Codes and to place the remaining SRS codes into two separate ambulatory payment classifications (APCs). The consolidation of these codes will eliminate confusion among providers and reduce redundancy.*

## **III. Proposed OPPS Payment for Devices—Proposed Adjustments to OPPS Payment for No Cost/Full Credit and Partial Credit Devices**

For CY 2014 CMS is proposing to modify its policy regarding the reporting of full and partial credit for replaced devices whose costs exceed 40 percent of the APC cost. Since 2007 hospitals have been required to report whether they have received a full or partial credit for a replacement device on their claims forms using modifier FB (full credit ) or FC (partial credit). This system, while requiring the use of a modifier did not require specific cost information. The current proposal would eliminate the use of the FB and FC modifiers and would instead require hospitals to report the amount of the credit on the claim when they receive a credit that is 50 percent or more than the cost of the device. This information would be reported in the amount portion for value code “FD” (Credit Received from the Manufacture for a Replaced Medical Device).

AdvaMed agrees with this proposal given that it is closely aligned with the approach for full and partial credits under IPPS. Nevertheless, we have some concerns with the APCs to which the policy is applied. In the proposed rule, CMS states that it is “not proposing any changes to the APCs and devices to which this proposed modified policy would apply,” however, Table 17 indicates that a number of APCs would be covered by the no cost/full credit policy for the first time in 2014, including the following:

0082 ....	Coronary or Non-Coronary Atherectomy.
0083 ....	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0104 .....	Transcatheter Placement of Intracoronary Stents.
0229 .....	Level II Endovascular Revascularization of the Lower Extremity.
0319 .....	Level III Endovascular Revascularization of the Lower Extremity
0656 .....	Transcatheter Placement of Intracoronary Drug-Eluting Stents

We do not believe that it is appropriate for CMS to extend the replaced device credit policy to these angioplasty, atherectomy, and stenting APCs. Angioplasty and atherectomy procedures do not involve an implanted device that stays in the body, which is one of the three criteria for determining the APCs to which the modified no cost/full credit policy applies. 42 C.F.R. section 419.45(a). Likewise, stent procedures involve devices that remain in the body permanently and are never removed or replaced, making the replacement device policy inapplicable. CMS states that the purpose of this policy is to ensure equitable payment when the hospital replaces an implanted device at no cost or with a credit.<sup>9</sup> This may occur with neurostimulator generators, pacemakers, implantable cardioverter defibrillators, and other products listed on Table 18, but not with angioplasty, atherectomy, and stenting procedures. Atherectomy and angioplasty do not involve implanted devices and stent procedures do not involve replaced devices. Therefore, there are no credits provided to the hospitals for these services. Including 0082, 0083, 0104, 0229, 0319, and 0656 does not achieve CMS’s policy objective. As a general provision the device replacement policy should apply only to “implantable devices” and/or implantable devices that can be replaced.

AdvaMed would also note that CMS does not include any of the C codes that would be used with these APCs in the listing of devices to which the proposed modified no cost/full credit and partial credit device payment adjustment policy would apply in CY 2014 (Table 18). Table 18 lists those products that CMS believes can be implanted, replaced, and have a credit applied. Table 17 should be consistent with Table 18 by eliminating the angioplasty, atherectomy and stent APCs. CMS should also remove APCs 0082, 0083 0104, 0229, 0319, and 0656 from the final listing of APCs covered by the no cost/full credit policy.

- ***AdvaMed recommends that CMS move forward with the proposal to eliminate the FB and FC modifiers and implement the FD modifier (Credit Received from the Manufacture for a Replaced Medical Device).***
- ***AdvaMed recommends that CMS remove APCs 0082, 0083 0104, 0229, 0319, and 0656 from the final listing of APCs covered by the no cost/full credit policy.***

#### **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 2014 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 respectfully request that CMS 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 2014.*

#### **V. Hospital Outpatient Quality Reporting Program Updates**

CMS proposes to remove two measures from the OQR Program beginning with the 2016 payment determination. Both of these measures have been the subject of previous actions to defer or delay reporting requirements. The measures are:

- *OP-19: Transition Record with Specified Elements Received by Discharged Patients; and*
- *OP-24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting.*

Concerning OP-19, CMS has concluded that this measure cannot be implemented with the degree of specificity needed to fully address the concerns of stakeholders without being overly burdensome. In addition, CMS states that they cannot ensure the consistency of data submissions across hospitals or the accuracy of measure results. Regarding OP-24, CMS proposes to remove the measure from the OQR Program because of ongoing issues in adopting the measure specifications for the hospital outpatient setting.

- ***AdvaMed agrees with the removal of measures OP-19 and OP-24, as each measure appears to have significant issues regarding its implementation and additional action to correct these concerns does not seem feasible.***

CMS proposes to add five new measures to the OQR data set for the 2016 payment. Four of these measures have NQF endorsement, but the endorsement is time-limited. They are:

- Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564);
- Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- Endoscopy/Polysurveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659); and
- Cataracts: Improvement in Patient’s Visional Function within 90 Days Following Cataract Surgery (NQF #1536).

NQF time-limited endorsement refers to measures that are endorsed for a limited period of time by NQF, provided that the proposed consensus standard meets the NQF-endorsed evaluation criteria, *with the exception of not having been adequately field tested*. Time limited endorsement is in effect for a period of 12-24 months, during which time the consensus standards “owner” must provide evidence and results from the testing to the Consensus Standards Approval Committee (CSAC) of the NQF. Upon completion of adequate testing and provision of the results, the CSAC may remove the time limitation on the endorsement.

- ***AdvaMed strongly recommends that these measures complete field testing by the measure steward, and, in addition -- be submitted to NQF and receive NQF endorsement -- prior to being placed into the Hospital Outpatient Quality Reporting Program. Field-testing is an essential component of the evaluation of a measure and a requirement for full NQF endorsement. Field-testing addresses essential, hands-on issues with measure implementation such as feasibility challenges, demonstration of reliability of the data, necessary adjustments that need to be made to facilitate obtaining measure results, estimation of the costs or burden of data collection and analysis, and validity, among others. AdvaMed strongly avers that proposed measures should complete the NQF “endorsement lifecycle”-- including field-testing -- prior to their selection for implementation in specific programs.***

AdvaMed urges the Agency to adopt quality measures tracking radiation dose exposure in the Hospital OQR Program. The incentives of hospitals and physicians performing advanced diagnostic imaging are not aligned, as radiologists, who are eligible to participate in PQRS and choose to submit radiation dose optimization measures, may require access to software or capital

equipment to automate the collection of these data. Hospitals, on the other hand, have no financial or quality report incentive to invest in such software or equipment. AdvaMed urges CMS to align incentives and harmonize quality reporting metrics for all advanced diagnostic imaging providers to optimize patient safety and quality of care.

## **VI. Hospital Value-Based Purchasing (VBP) Program Update**

CMS is proposing to implement an independent review that will provide for an additional appeal process available to hospitals participating in the value-based purchasing (VBP) Program, beyond the existing review and corrections process. Under the proposal, a hospital that is dissatisfied with the result of the appeals process already in place under §412.167(b) could request an independent CMS review. CMS indicates that it intends to complete such reviews within 90 calendar days following a request, although the proposed regulatory text (§412.167(c)) does not specify a timeframe.

- *AdvaMed agrees with the proposal to implement an additional hospital appeals process. However, we recommend that CMS amend the proposed regulatory text to specifically include the 90-day timeframe following a request to complete such a review.*

## **VII. Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program**

CMS proposes to add four new measures to the existing ASCQR Program quality measures. All measures except for NQF #0654, *Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures*, are NQF endorsed for the ASC setting. CMS states, that despite the lack of endorsement for that setting, the cataract complication measure is appropriate for the ASCQR Program because the procedure is commonly performed in ASCs and the measure identifies important patient care issues.

- *AdvaMed recommends that CMS request the measure steward to submit measure NQF #0654 for NQF endorsement as these measures should be specified, endorsed and tested for the appropriate facility level of analysis before they are finalized for inclusion in quality reporting.*

### **A. ASCQR Program Measure Topics for Future Consideration**

CMS invites comments on potential future measures. CMS should consider comprehensive wound care measures that could be aligned across all settings. Wound care measures are relevant across numerous populations, including adult and pediatric surgical, medical, and geriatric. Wound care measures would be an essential tool in containing and preventing infections and would significantly contribute to the reduction of hospital readmissions, emergency department visits, and repeat visits in other settings for evaluation by health professionals.

In the proposed rule, CMS also states that it is considering using the following measure domains for future measures in the OQR program: clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency.

AdvaMed agrees that this domain structure would serve to align the OQR Program with the IQR Program and the ASC Quality Reporting Program. However, CMS does not mention how these domains will be weighted in the final calculation of a Quality of Care Composite.

- ***AdvaMed strongly recommends that CMS not consider assigning equal weights to each proposed domain in the calculation of the Quality of Care Composite or similar type of composite. Implementation of this approach would have the effect of diluting: (1) the importance of delivering effective care and treatment practices for patients (clinical care domain), and (2) the significance of efforts to make care safer by reducing harms caused in the delivery of care (patient safety domain).***

### **Conclusion**

AdvaMed greatly appreciates the opportunity to comment on the CY 2014 proposed OPPI 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,

/s/

Richard J. Price  
Senior Vice President,  
Payment and Health Care Delivery

Enclosures