August 29, 2011

Via Electronic Mail

Donald M. Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-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; Ambulatory Surgical Center Payment System; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements (Proposed Rule CMS-1525-P)

Dear Dr. Berwick:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment System; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements (Proposed Rule CMS-1525-P) (Federal Register, Vol. 76, No. 137, Monday, July 18, 2011, p. 42170).

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 and support a system with payment weights and payment rates that include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient and ambulatory surgical center procedures.
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 2012 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:

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I. Proposed Updates Affecting OPPS Payments (for CY 2012)

AdvaMed identified a number of issues of interest or concern related to the proposed payment updates for OPPS services in CY 2012. Our comments in this section will cover a number of areas including claims data, charge compression, packaging, APC group policies, and payment for devices. AdvaMed appreciates the significant effort on the part of CMS to stabilize the variation in APC payment rates for CY 2011. In analyzing the proposed regulation, AdvaMed found some discrepancies in matching some of the CMS median claims data calculations related to the addition of procedures to the bypass list. We encourage CMS to make any needed corrections to the data when calculating final CY 2012 payments. Comments on other 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 and offers comments on five specific issue areas as described below.

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 appreciates the actions taken by CMS to implement a new Medicare cost report cost center for implantable medical devices to improve the accuracy of the data used in calculating the payment rates. In the proposed OPPS rule, CMS indicates that the agency does not have
sufficient data from hospitals using the new cost center to adjust payment rates for CY 2012, citing the fact that only 437 hospitals submitted claims using the “Implantable Devices Charged to Patients” cost center. CMS also states that it will not use data from the implantable device cost center to create a distinct CCR for use in calculating the CY 2012 OPPS relative weights because of inadequate data. CMS previously cited a similar rationale for not using CCRs derived from the new implantable device cost center in the FY 2012 hospital inpatient prospective payment system (IPPS) final rule. Using cost reports from an April 2011 update of HCRIS, AdvaMed’s consultant, Direct Research, found that nearly 800 hospitals were using the new cost center and estimates that 1000 hospitals will be using the new cost center by August 2011.

We wish to point out important distinctions between the use of cost center CCRs in the inpatient and outpatient prospective payment systems. The cost-based weights first adopted by CMS in IPPS in FY 2007 use an aggregated, average national CCR for each of 15 cost centers and apply the national CCRs to charges submitted on claims from all hospitals. In order to ensure that the national CCRs are reasonably representative of the full range of hospitals paid under IPPS, we understand that CMS may wish to have a robust number of hospitals reporting data under the new cost center before creating a national average CCR for implantable devices charged to patients.

For OPPS, however, CMS in general uses hospital-specific CCRs to estimate costs from the hospital’s charges. As noted on page 42181 of the proposed rule, “We applied the hospital-specific CCR to the hospital’s charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code.” For those hospitals that have submitted data under the new Implantable Devices Charged to Patients Cost Center, the data now represent the most detailed level of information possible for the estimation of hospital-specific costs of services involving implantable devices. An analysis of the overall national robustness of the hospital-specific CCR data for the new cost center is less significant in OPPS than it may be in IPPS. We therefore believe the use of the implantable device cost center CCR is warranted in OPPS for hospitals that have submitted information under the new cost report line and we recommend that CMS use such data from the cost center for reweighting the OPPS relative weights for CY 2012.

Beyond rate-setting for CY 2012, despite expected improvement from using the cost center over time, AdvaMed believes that additional educational efforts are needed to ensure that more hospitals complete the implantable device cost center, thereby improving the validity of payment weights based on estimated costs. Additionally, AdvaMed believes that CMS should 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.
AdvaMed therefore makes the following additional recommendations related to the use of the cost center. We recommend that CMS 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. AdvaMed also urges CMS to monitor the accuracy of data reported under the new cost center to ensure that it is correct and leads to more accurate rate-setting.

iii. Proposed Calculation of Single Procedure APC Criteria-Based Median Cost—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) Device-Dependent APCs—AdvaMed appreciates CMS’s recognition of the need to provide appropriate payment for devices used in procedures. We urge the agency to continue examining and refining the approach it uses to recognize the costs of the devices that are employed in device-dependent procedures in order to encourage the continued development and appropriate dissemination of new technology that can improve the care that Medicare beneficiaries receive.

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. While AdvaMed is pleased that CMS has proposed increased payments for some blood product codes, it is concerned that in many more instances it has proposed decreases for other blood product 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 hospitals are also seeing their Medicare payments for operating costs reduced as the result of health reform legislation and other regulatory changes. 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 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 cutting payment rates for blood and blood products in the face of rising costs for blood will result in most hospitals incurring a substantial financial loss 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.

iv. Proposed Calculation of Composite APC Criteria-Based Median Costs-- Multiple Imaging Composite APCs-- In its final outpatient payment rule for CY 2009, CMS finalized its proposal to pay for multiple images performed on the same patient on the same day through five multiple imaging composite APCs: APC 8004 (Ultrasound Composite); APC 8005 (CT and CTA without Contrast Composite); APC 8006 (CT and CTA with Contrast Composite); APC 8007 (MRI and MRA without Contrast Composite); and APC 8008 (MRI and MRA with Contrast Composite).

In the proposed 2011 OPPS/ASC rule CMS accepted the APC Panel’s (Panel) recommendation that they provide information to the Panel on the impact of the imaging composite APCs on services furnished to beneficiaries. This information was provided during the February/March 2011 Panel meeting. While AdvaMed appreciates the information that was shared with the Panel and meeting attendees, we continue to have concerns that the multiple imaging policy may result in inadequate hospital payment which could impact beneficiary access to necessary imaging procedures. We recommend that CMS continue to monitor costs, provide information on the impact of the multiple imaging composite APCs, and use information gained from monitoring of this issue to ensure continued beneficiary access to necessary imaging procedures. AdvaMed further recommends that CMS continue to evaluate whether the methodology used to establish existing composite APCs has resulted in payments that accurately reflect all of the resources needed to perform these services.

v. Proposed Changes to Packaged Services-- Packaged Services Addressed by the February 2011 APC Panel-- AdvaMed appreciates and supports CMS’s’s response to the APC Panel’s recommendation to analyze the impact of packaging on net payments for patient care. We also support the agency’s decision to not expand packaging policies to any additional categories of services for CY 2012. AdvaMed remains concerned that the implications of the packaging policies are not known and seeks greater transparency in rate setting. We recommend that CMS make the data
underlying payments for packaged services, including utilization rates and estimated median costs, publicly available.

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

A. Proposed OPPS APC-Specific Policies

AdvaMed has several recommendations related to OPPS specific payment policies for consideration as the agency moves forward with finalization of the CY 2012 rule.

i. Appropriate APC Placement for Endovascular Revascularization of the Lower Extremity Procedure Codes--AdvaMed would like to commend CMS on its proposal to move CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within same vessel, when performed) to APC 0229 for CY 2012. During the August 2011 APC Panel meeting the Panel recommended that CMS finalize this proposal. AdvaMed supports the recommendation from the APC Panel and urges CMS to finalize the proposal to move CPT code 37221 to APC 0229 for CY 2012.

CMS is proposing to leave CPT code 37223 (Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), including angioplasty within the same vessel, when performed), an add-on iliac stent procedure for each ipsilateral iliac vessel code, in APC 0083 for CY 2012. Although the single and pseudo single procedure claims methodology is appropriate for most median cost calculations it is not appropriate for determinations regarding “add-on” codes. “Add-on” codes should always be billed with a primary procedure code and will most often not be classified as a single or pseudo single procedure claim.

CMS recognized this in the agency’s APC assignment for CPT add-on codes 37206 and 37208. Placement of theses add-on codes in the same APC as their primary procedure codes is supported by three factors. First, the add-on codes are clinically coherent and use resources similar to their primary procedures, CPT codes 37205 and 37207. Second, these add-on codes are subject to the MPPR discount to recognize the efficiencies in performing treatment on an additional vessel in the same operative session. Third, because add-on codes are always billed with other primary procedure codes, not on the bypass list, no representative single or pseudo single claims will be included in the claims available for the median cost calculation methodology.

CMS placed CPT codes 37206 and 37208, the peripheral stent “add-on” codes, in APC 0229, “Level II Endovascular revascularization of the Lower Extremity” because these procedures are clinically coherent and use resources similar to their primary procedure CPT codes 37205 and 37207. The proposed OPPS CY 2012 CPT median cost file lists code 37206 with 17 single frequency claims which is only 0.2 percent of 8991 available claims. There are no single claims listed for 37208. Chris Hogan of Direct Research found 439 claims in the CY 2012 OPPS proposed rule file for CPT Code 37223. However, these could not be utilized as
single claims since there were multiple primary codes not on the bypass list that were also billed on the claim, in accordance with coding guidelines. Consequently, these claims did not meet the single or pseudo single claims criteria.

AdvaMed commends CMS on the appropriate categorization of previous CPT add-on procedure codes 37206 and 37208 in the OPPS methodology. In keeping with past precedent related to appropriate APC categorization, we recommend that CMS move CPT code 37223 to APC 0229 with its related primary procedure code (CPT code 37221) to ensure clinical coherence and resource similarity.

ii. APC Assignment for Lead Removal and Revision/Replacement Codes: 63661-6366--AdvaMed would also like to commend CMS for differentiating procedures for lead revisions and procedures for lead replacements to ensure appropriate payment rates for both types of procedures. Specifically, AdvaMed appreciates CMS’s proposal to remove CPT codes 63663 and 63664 from APC 0687 and to place the two codes in APC 0040 to more accurately reflect the resources associated with the procedures. We recommend that CMS finalize the proposal to place CPT codes 63663 and 63664 in APC 0040 and to change the title of APC 0040 to “Level I Implantation/Revision/Replacement of Neurostimulator Electrodes”.

iii. Appropriate APC Placement for Ureteroscopy with Lithotripsy--AdvaMed recommends moving CPT 52353 (Ureteroscopy with lithotripsy) from APC 0163 (Level IV Cystourethroscope and other Genitourinary Procedures) to APC 0169 (Lithotripsy) in CY 2012.

Currently, the only code in APC 0169 is CPT 50590 (Extracorporeal shockwave lithotripsy). Ureteroscopy with lithotripsy and shockwave lithotripsy represent the two predominant outpatient treatment methods for kidney and ureteral stones. Additionally, placing the only two outpatient procedures involving lithotripsy, in the upper urinary tract, into the APC designated for “Lithotripsy” would avoid potential incentives to use one procedure over the other. AdvaMed urges CMS to place CPT 52353 (Ureteroscopy with lithotripsy) in APC 0169 (lithotripsy).

iv. Proposed Payment for New Composite APC for Cardiac Resynchronization Therapy (CRT-D) and Implantable Cardiac Defibrillator (ICD) APC Procedures--In response to comments from AdvaMed and others, CMS is proposing to create a composite APC 8009 for use with CRT-D procedures CPT 33249 and CPT 33225 when performed on the same day. AdvaMed appreciates CMS’s consideration of a composite APC to address previously identified concerns related to fluctuation in the median costs for APC 0418 and CMS’s recognition that a composite methodology “would result in more accurate payment for these services because such a methodology is specifically designed to provide payment for two or more procedures when they are provided in the same encounter”.  

1 CMS-1525-P, Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements, Display copy page 154.
AdvaMed, however, is extremely concerned with CMS’s decision to disregard its traditional method of determining composite and other APC payments by imposing a payment cap for APC 8009 that is not based on OPPS claims data. CMS is also proposing to use this same cap on payments for APC 0108. The CMS proposal would limit the payment rate for APC 8009 and APC 0108 to the non-capital portion of the inpatient Medicare-severity diagnosis-related group rate (MS-DRG 227) combining ICD and CRT-D system implantation procedures – approximately $26,364.93.

Other than certain exceptions during the early transitional years of the OPPS, CMS has been firm in its intent to use median costs derived from outpatient hospital claims data to establish payment for all OPPS services. As CMS has maintained in recent years, the integrity and stability of a prospective payment system lies heavily in its reliance on a standardized process applied to a standardized data source, consistent with nearly a decade of rate-setting practice under the OPPS. CMS has established claims data as the basis for OPPS rate-setting through discussions in OPPS payment rules, the deliberation of proposed changes to APC assignments, and through the approaches and policies (such as the bypass list, date splitting of claims, packaging, composite APCs and others) that the agency uses to increase the number of claims available for rate-setting. The concept of a payment cap based on the IPPS represents a sudden and substantial departure from CMS’s standard payment policy, introducing a significant level of uncertainty and unpredictability for stakeholders.

In light of this AdvaMed recommends that CMS use a method of rate-setting for APC 8009 and APC 0108 that is not tied to inpatient hospital rates and that establishes a payment rate based upon the clinical similarity and resource use of the procedures included in this composite APC. We further recommend that CMS work to ensure the integrity and stability of the outpatient prospective payment system by continuing to utilize outpatient claims data to determine the median costs for rate-setting and ask that CMS adopt the APC Panel’s recommendation that the rates for APC 8009 be determined using only outpatient claims data. It is imperative that rates in the outpatient setting use claims data from this setting if CMS is to maintain consistent weights and is to appropriately value these services. Lastly, in the event CMS is unable to arrive at rate-setting for the composite CRT-D APC based on outpatient claims data, we believe CMS should terminate the proposal to create APC 8009 and restore the previous APC structure and rate-setting practice for CRT-D and ICD implantation procedures in the final rule.

v. Retaining CPT Code 77338 in APC 0310--CMS is proposing to move CPT code 77338 (Multi-leaf collimator (MLC) device(s) for intensity modulated radiotherapy (IMRT), design and construction per IMRT plan) from APC 0310 to APC 0305. The proposed change would reduce the payment rate for this procedure from $926.74 to $256.92. This significant reduction in payment is not an accurate reflection of the actual costs to hospitals for this procedure. Reducing the payment for this procedure will negatively impact patient access to care as well as the financial viability of hospitals utilizing the technology. AdvaMed
therefore opposes the recommendation to move CPT code 77338 to APC 0305 and instead recommends that CMS retain the procedure in APC 0310 for CY 2012.

CPT code 77338 was introduced in CY 2010 to replace CPT code 77334 (Treatment devices, design and construction; complex – irregular blocks, special shields, compensators, wedges, molds or casts) when billing for IMRT MLC treatment devices. CPT code 77338 is utilized only for IMRT MLC devices. CMS initially proposed placing CPT code 77338 in APC 0303, the same APC as CPT 77334. Comments in response to the CY 2011 OPPS rule stated that keeping CPT code 77338 in APC 0303 would result in an inappropriate reduction in payment for these treatment devices. 2 CMS performed a cost analysis in response to comments received on the issue and determined a hypothetical cost per unit, for CPT code 77338, of approximately $792. Consequently, CMS assigned CPT code 77338 to APC 0310 because its rate was closest to the hypothetical cost per unit.

In the final CY 2011 OPPS rule CMS states that the CY 2012 rate for CPT code 77338 would be determined using claims data and the standard cost estimation process to establish a median cost for CPT code 77338. CMS also indicated that they would re-examine whether CPT code 77338 should remain in APC 0310 for CY 2012.

AdvaMed’s analysis of CY 2010 claims data shows that only 13 percent of hospitals submitted claims, in-line with CMS expectations, for CPT code 77338. It is clear that hospitals are in need of guidance when billing for this procedure code. Therefore, AdvaMed urges CMS to keep CPT code 77338 in APC 0310 for CY 2012, while additional claims data is collected, and to issue guidance to ensure that hospitals appropriately bill for this new code.

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

In the CY 2012 OPPS proposed rule, CMS states that only one device category is eligible for pass-through payment for CY 2012 and that there are no categories for which CMS would propose expiration of pass-through status. Over the past several years, there has been a steady decline in the number of devices that have been approved for pass-through status. To ensure that adequate support is provided for desirable new technologies, AdvaMed recommends that CMS reevaluate the criteria and approval process currently applied to the evaluation of devices for pass-through status. 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.

2 Prior to the creation of CPT 77338, hospitals reported and were paid for three to nine units of CPT 77334 for each of the two treatments received. CMS found that the median number of units of CPT 77334 that were furnished to patients who received IMRT in CY 2009 was eight.
IV. Proposed Update of the Revised Ambulatory Surgical Center Payment System

AdvaMed welcomes the opportunity to provide comments on the proposed update of the Ambulatory Surgical Center payment system and provides recommendations and comments on several key issues.

A. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

AdvaMed’s comments will focus on five specific topics as described in detail below.

i. CPT Codes 37205 and 3720--AdvaMed commends CMS for adding CPT codes 37221 and 372223, two Endovascular Revascularization codes, to the list of ASC approved procedures. Following the adoption of these new codes, CPT codes 37205 and 37206 were revised as follows:

37205 – Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel
37206 – each additional vessel

In the CY 2011 OPPS rule CMS proposed including CPT codes 37205 and 37206 on the ASC approved procedure list but deleted them following approval and implementation of the new Endovascular Revascularization codes. AdvaMed recommends that CPT codes 37205 and 37206 be added to the ASC approved procedure list for treating upper extremity vessels. These procedures are similar in clinical complexity and resource utilization as CPT codes 37221 and 37223.

ii. CPT Codes 58541 and 5854--CMS has approved CPT codes 58550 (Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g of less) and 58552 (Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tubes (s) and/or ovary (s)), more commonly known as a laparoscopic assisted vaginal hysterectomy (LAVH), for use in the ASC setting. However, CMS does not allow Laparoscopic Supracervical Hysterectomy (LSH) which is commonly billed with CPT codes 58541 and 58542, to be performed in an ASC setting. Laparoscopic Supracervical Hysterectomy (LSH) meets CMS’ current ASC criteria for approved procedures (presents a low safety risk and does not require an overnight stay). Additionally, LSH is an approved surgical procedure in the Medicare Hospital outpatient setting. The LSH procedures are very similar to the LAVH procedures in terms of clinical use, procedure time, and patient length of stay. Therefore, AdvaMed recommends that the agency consider adding LSH procedures approved for use in the Ambulatory Surgery setting.
V. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting

AdvaMed’s member companies develop and manufacture devices and diagnostics that improve the quality of care provided to millions of patients and across all health care settings. AdvaMed has been engaged and supportive of CMS’s effort to improve the quality of care for Medicare beneficiaries and appreciates the opportunity to provide comments on topics related to the hospital quality reporting program.

A. Proposed New Quality Measures for the CY 2014 and CY 2015 Payment Determinations
AdvaMed’s comments on proposed new quality measures focus on 5 key issue areas and are detailed below.

i. Proposed New Claims for CY 201--CMS proposes to add several new measures to the measure set for the 2014 payment determination including: Surgical Site Infection – a National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Measure (NQF#0299), five Diabetes Care Measures (NQF #0059, NQF #0064, NQF #0061, NQF #0055, and NQF #0062), and Cardiac Rehabilitation: Patient Referral From an Outpatient Setting (NQF #0643). AdvaMed supports the adoption of these important NQF-endorsed measures into the Hospital OQR Program, especially those related to HAI/Surgical Site Infections. AdvaMed recognizes the significant negative impact of healthcare associated conditions on ALL patients in ALL settings and would encourage CMS to include more HAI quality measures in the Hospital OQR Program in the future.

ii. Proposed New Claims for FY 2015--For the first time, CMS proposes Hospital OQR Program measures for the 2015 payment determination. In addition to continuing the 32 measures for 2014, one additional measure is proposed: “Influenza Vaccination Coverage among Healthcare Personnel” (NQF #0431). This measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. It would be reported via the NHSN infrastructure and protocol for immunizations from October 1, 2013 through March 31, 2014. AdvaMed supports the proposal for the implementation of this NQF-endorsed measure, as it is important for healthcare personnel to have immunity to influenza so as to limit its transmission in healthcare settings.

B. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS: Proposed Data Validation Approach for the CY 2013 Payment Determination
For CY 2013, CMS proposes several significant changes to the Hospital OQR Program data validation requirements. First, CMS proposes to reduce the number of randomly selected hospitals from 800 to 450. CMS states that it has found that hospitals are consistently reporting high accuracy rates for chart abstracted measures and there is little variation among hospitals. Therefore, CMS believes a smaller sample size will still provide sufficient case numbers for the purposes of validation. Second, CMS proposes to select up to 50 additional hospitals for validation based on targeting criteria. For 2013, the proposed criteria would include hospitals that either fail the
validation requirement for the 2012 payment determination or have an outlier value based on the data they submit. Third, CMS proposes to continue the same medical record documentation submission procedures finalized for the 2012 payment determination, except that the time period given to hospitals to submit medical record documentation to the CMS contractor would be shortened from 45 days to 30 days.

It is our understanding that last year, CMS selected this approach specifically to parallel their own proposal for the FY 2012 RHQDAPU program, to validate data from 800 randomly selected hospitals – representing approximately 20 percent of all participating HOP QDRP hospitals – each year. Advamed believes that validating a larger number of cases from a sample of hospitals has advantages over sampling a smaller number of cases from a pool of all hospitals participating in the Hospital QQR. Advamed believes that the total number of hospitals subject to validation (500) will remain adequate to assess the reporting accuracy of various types of hospitals.

C. 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs
Under the American Recovery and Reinvestment Act of 2009, eligible hospitals and Critical Access Hospitals (CAHs) may quality for incentive payments if they demonstrate meaningful use of certified EHR technology. Implementing regulations established requirements for meaningful use, including the electronic reporting of clinical quality measures (CQMs). However, CMS has acknowledged that it does not yet have the capacity to receive the CQM data electronically. Therefore, reporting in 2011 has been required through only attestation. In this rule, CMS proposes to modify the requirement that CQM reporting must be done electronically and to establish an electronic reporting pilot for eligible hospitals and CAHs. For 2012 and subsequent years, eligible hospitals would be able to continue to report CQMs as calculated by EHRs through attestation. Alternatively, for the 2012 payment year, they could participate in a proposed FY 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs. Data for the Pilot would be submitted during the period from October 1st through November 30th, 2012 (60 days following the close of the measurement period). CMS plans to offer a test period beginning July 1, 2012 to allow eligible hospitals and CAHs or their designee to submit CQM data to CMS. Advamed supports use of Pilot programs, and specifically CMS’s proposal for the Medicare EHR Incentive Pilot for Eligible Hospitals and CAHs, which could be instrumental in shaping and facilitating the mechanisms for electronic reporting by eligible facilities in the near future.

D. Proposed ASC Quality Reporting Program
CMS is proposing to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination, with data collection beginning in CY 2012 for most of the measures to be used for the CY 2014 payment determination. CMS is also proposing a multi-year approach to adopt measures and proposes specific measures for CYs 2014, 2015, and 2016 payment determinations. CMS notes that it may revise or add measures in future rulemaking cycles to address program needs arising from new legislation or changes in HHS or CMS priorities. Advamed agrees with and applauds CMS for utilizing this multi-year approach, which will likely limit the burden on ASCs and assist ASCs in planning for quality reporting, as well as provide time for CMS to
further develop the infrastructure for collecting quality data on ASCs and making payment determinations.

In the proposed rule, CMS identifies four principles that it applies in developing the ASC Quality Reporting Program, as well as other quality reporting programs. The principles include: 1) use of a mix of standards, processes, outcomes and patient experience of care measures, with a goal of moving to use primarily outcomes and patient experience of care measures, 2) alignment of measures across public reporting and payment systems under Medicare and Medicaid, 3) minimizing collection of information burden on providers, and 4) endorsement of measures by a national, multi-stakeholder organization, to the extent practicable and feasible and recognizing differences in statutory authorities. AdvaMed agrees that, in general, these are well-developed principles, as applied to the development of the ASC Reporting Program, and other quality reporting programs. However, we have some concerns regarding the fourth principle dealing with endorsement of measures. **AdvaMed strongly believes that all measures chosen for quality reporting programs should have NQF approval prior to implementation.** Importantly, the NQF Consensus Development Process includes an option for an Expedited Review. This was established by the NQF Board of Directors to allow for accelerated endorsement for projects with associated time-sensitive legislative or regulatory requirements. It is our understanding that this expedited process usually takes considerably less time (i.e. several months) to complete and avoids the sometimes lengthier wait times for traditional NQF review. If however, CMS chooses quality measures that have been endorsed by other national multi-stakeholder organizations, AdvaMed strongly urges CMS to immediately submit these selected measures for expedited review and subsequent endorsement by NQF. If NQF reviews and does not endorse these measures, CMS should consider placing the implementation of these measures on hold or, depending upon the recommendations by NQF, decline to implement the measure.

E. Proposed Quality Measures for ASCs for CY 2014 Payment Determination

CMS proposes an initial measure set for the ASC Quality Reporting Program consisting of measures addressing outcomes and infection control processes. Six measures were developed by the ASC Quality Collaborative (ASC QC), and are NQF-endorsed. **AdvaMed is pleased that the NQF-endorsed specifications for these 6 measures include all ASC admissions and that CMS has received communication from NQF indicating that the proposal to use Medicare claims reporting to collect information on these measures is an appropriate application of the NQF-endorsed measures.** In addition to the six ASC QC measures, CMS proposes to add “Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin” – ASC-7, an NQF-endorsed measure currently used in the PQRS. CMS notes that the proposed measure is not specifically NQF-endorsed for the ASC setting, but it believes it is highly relevant for use in the ASCs because it assesses adherence to best practices for outpatient surgery. **AdvaMed cautions that measures sets should be endorsed by NQF for their particular setting (i.e., Inpatient, Outpatient, ASC, LTCF, etc.) ASCs may structurally and organizationally differ significantly from hospital outpatient facilities. The ownership structure, accrediting/licensing organizations and processes, rules regarding record
keeping/auditing of records, and standards of medical care may be vastly different. The impact of these proposed measures could ultimately create a more substantial burden upon the ASC. Therefore, in order to provide the optimum benefit, the opportunity for accurate implementation, as well as collection of data, and reduced waste/time/frustration at the facility and patient level, AdvaMed believes that these quality measures should ultimately be developed or modified for their specific clinical setting.

VI. Additional Proposals for the Hospital Inpatient Value-Based Purchasing (Hospital VBP) Program

As noted above, AdvaMed has been actively engaged and supportive of CMS’s effort to improve the quality of care for Medicare beneficiaries and appreciates the opportunity to provide comments on topics related to the hospital inpatient value-based purchasing.

A. Proposed Review and Correction Process for Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)
CMS is proposing a two-phase process for hospitals to review and correct the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data submitted in the HVBP program. For the Phase 1 review of HCAHPS, CMS proposes to reduce the HCAHPS submission deadline under the Hospital IQR Program by one week in order to create a 1-week period for hospitals to review and correct their HCAHPS data. During the proposed 1-week review and correction period, hospitals would be able to provide any missing data or replace incorrect data that they submitted to the Quality Improvement Organization (QIO) Clinical Warehouse. They would have the opportunity to review frequency distributions of all their submitted data items, including hospital summary information, patient administrative data, and patient survey responses. The second phase would allow for review of the patient-mix and mode adjusted HCAHPS scores on those dimensions that are used to score hospitals under the VBP Program. If a hospital believes its scores were miscalculated, CMS would check the calculation and recalculate the scores if necessary. AdvaMed strongly supports these proposed processes which will provide hospitals opportunities to evaluate and rectify submitted HCAHPS data, as well as review the calculated HCAHPS scoring and query CMS for recalculation of the scores.

B. Ensuring HAC Reporting Accuracy
In the proposed rule, CMS is considering a specific validation process for HACs that would target a subset of hospitals that report zero or an aberrantly low percentage of HACs on Medicare fee-for-service IPPS claims relative to the national average of HACs. CMS believes that HAC rates may be under-reported on claims data. AdvaMed supports the efforts by CMS to provide a validation process designed to ensure more accurate reporting of HACs.

C. Proposed Domain Weighting for FY 2014 Hospital VBP Program
As finalized in previous rulemaking, for the FY 2013 Hospital VBP Program, CMS will weight a hospital’s score for the clinical process of care domain at 70 percent of the total performance score,
with the remaining 30 percent weight given to the patient experience of care domain. In this rule, CMS proposes that for FY 2014, the following domain weights would apply in calculating a hospital’s total performance score: Outcome = 30 percent, Clinical process of care = 20 percent, Patient experience of care = 30 percent, and Efficiency = 20 percent.

Under this scheme clinical-care related domains (process of care and outcome) would constitute 50 percent of the performance score, followed by patient experience of care at 30 percent, and efficiency at 20 percent. Over time, CMS believes that scoring methodologies should be weighted more toward outcomes, patient experience of care, and functional status measures (e.g. measures assessing physical and mental capacity, capability, well-being and improvement). **AdvaMed agrees that in the future, scoring methodologies should be weighted more toward outcomes, patient experience of care, and functional status measures. AdvaMed supports the addition and weighting of the outcome domain, as this is essential in the development of future measures. AdvaMed does have concerns regarding the implementation of the efficiency domain. AdvaMed believes that all measures – especially those pertaining to efficiency/resource use – adopted into the HVB Program, should be submitted for endorsement by NOF and sufficiently field tested prior to adoption.**

In developing efficiency measures, CMS must identify an appropriate episode of care which includes a sufficient period of time to assess the overall value of the services provided. Efficiency — and measures dealing with efficiency — should be defined to include the overall value of the service, including both quality and cost. One could easily draw erroneous conclusions about the relative value of care if an inappropriate time period is used. For example, a provider may have a choice between a lower-cost medical device which is expected to need replacement within a few years, necessitating another hospitalization, and a higher-cost device which will last many more years. If resource use, or costs, are measured based on an episode of care that only considers the hospitalization and perhaps a 90-day period post-discharge, the “total” cost of the episode may appear on its face to be a better value because the initial cost of the device was lower. However, this assessment would be inaccurate as it would not consider the additional costs associated with a subsequent readmission, surgical costs, and device replacement costs that could have been delayed or avoided if the higher-cost, longer lasting device was initially chosen. Even a one-year period might be insufficient to assess the value of many new technologies to patients and/or the health care system overall.

**Conclusion**

AdvaMed greatly appreciates the opportunity to comment on the CY 2012 OPPS and ASC proposed 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,

[Signature]

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