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October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445–G, HHH Bldg.
200 Independence Ave., SW
Washington, D.C. 20201

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List (CMS-1506-P)

Dear Dr. McClellan:

St. Jude Medical appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Hospital Outpatient Prospective Payment System (OPPS) and 2007 Payment Rates and 2007 Updates to the Ambulatory Surgical Center Covered Procedures List (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49506). St. Jude Medical is dedicated to making life better for cardiac, neurological and chronic pain patients worldwide through excellence in medical device technology and services. The Company has five major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiac surgery, cardiology and neuromodulation.

St. Jude Medical appreciates the considerable effort you and your staff have put into the development of the OPPS. We also appreciate CMS' efforts to address the industry's concerns as it updates and refines the OPPS. While we are pleased with some of the proposed changes, we remain concerned with the accuracy of the APC payment rates, which are the focus of our comments.

Device-Dependent APCs

Since implementation of the Medicare hospital outpatient prospective payment system, CMS has found that the medians calculated from hospital charge data would result in payments for some device-dependent APCs that would not even compensate the hospital for the cost of the device. While the numerous coding and data problems associated with the outpatient system have shown significant improvement, the fundamental problems still

exist. While we appreciate the significant effort on the part of CMS to stabilize variation in APC payment rates for CY 2007, we continue to have concerns regarding the accuracy of the data used to set rates, especially for device-dependent procedures.

For CY 2007, CMS proposes to base the device-dependent APC medians on CY 2005 claims, the most current available. St. Jude Medical commends CMS on its decision to bypass specific codes that do not have significant packaged costs in order to use more data from multiple procedure claims. CMS' new single- and "pseudo"-single procedure claims rate-setting methodology has yielded data that appears to more accurately capture the costs of procedures. We recommend that CMS continues to refine these methodologies to improve the accuracy of estimates for the costs of devices included in multiple procedure claims. We are also pleased with the CMS decision to use only correctly coded claims that include the appropriate C-code for all device-related APCs and do not contain token charges in setting payment rates. Use of this methodology results in payment rates that more appropriately reflect the costs associated with these procedures.

While the medians for some device-dependent APCs have gone up using this methodology, we are concerned that CMS' proposal does not do enough to ensure that payment rates are adequate to protect beneficiary access to devices. For many devices, the CY 2007 OPPS rates still do not provide adequate reimbursement for the full cost of the device and the associated procedure. For example, procedures involving the insertion or replacement of neurostimulator pulse generators or receivers and system components (i.e., external transmitters, patient programmers and extensions) are grouped to APC 0222. The proposed CY 2007 reimbursement rate for APC 0222, based on CY 2005 claims, is $10,964, of which 78.1 percent, or $8,563, is the device-related portion. In 2005, radio-frequency (RF) receiver and non-rechargeable pulse generator systems were implanted predominantly, since rechargeable pulse generator systems were just being introduced to the market. For CY 2006, rechargeable pulse generators qualified for, and presently receive, the new technology pass-through payment, which will continue through CY 2007. According to IMS Health[1], for the first three quarters of 2005, the median hospital acquisition cost for RF receivers and non-rechargeable pulse generators was $11,596. Thus, the total proposed payment of $10,964 does not cover the hospital acquisition cost of the RF receivers and non-rechargeable pulse generators, let alone the system components or any procedure-related costs.

Improvements are still needed to ensure accuracy in the overall payment for device-dependent procedures. Until CMS has addressed charge compression (discussed below) and other problems with the accuracy of claims data, St. Jude Medical urges CMS to set a floor on the CY 2007 device-related APC rates at no less than 100 percent of the CY 2006 rates plus the market basket update for all device-related APCs. Although this change will not

1 IMS Health, Health Supply Index of non-federal, short-term acute care hospital purchase from January 1 through September 20, 2005.

alleviate the underpayment for many device-dependent procedures, it will provide a greater level of stability to hospitals that provide these procedures.

Charge Compression

We believe that the cost estimates for many higher cost devices have been understated by CMS' cost calculation methodology to the extent that they are significantly below the hospital's actual acquisition costs. Generally, CMS multiplies charges by hospital-specific cost-to-charge ratios (CCRs) to calculate hospitals' costs for all services in a single revenue center, which decreases the charges by a constant factor. This methodology is based on the assumption that each hospital marks up its costs by a uniform percentage within each department to set each service's charge. However, within a revenue center, some hospitals mark up inexpensive products more than they do expensive products. Yet, CMS' methodology does not recognize hospitals' variability in setting charges. If CMS uses a single CCR to estimate costs, the approach will generally lead to an underestimate of hospitals' costs for higher cost items – a phenomenon known as "charge compression."

To the extent that hospitals' markup practices for high-cost devices are systematically out of line with the hospitals' markup practices for other items and services, the payment levels for APCs corresponding to these devices are likely to be underweighted and underpaid. The effect on the APC may be especially pronounced when the charge for the device accounts for a high percentage of the total charges associated with an APC, as it would for many implantable devices with high-unit costs.

The table[2] below illustrates the variation in markup in charges for certain implantable devices in a single revenue center. The markup for implantable cardioverter-defibrillator (ICD) pulse generators is 79 percent lower than for other less costly devices, leading to charge compression.

Device Type (from least to highest cost)	No. of Hospitals	Percentage Markup (Mean)
Pacemaker Lead	111	266
ICD Lead	69	221
Pacemaker Pulse Generator	111	221
ICD Pulse Generator	60	142

[2] Premier Healthcare Informatics, Perspective Comparative Database for January 1 through December 31, 2004.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.[3] The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average markup. Significantly, the researcher also showed that cases with very high device and supply charges led to a stronger impact on the device and supply CCR.

CMS recently announced that it has awarded a one-year contract to RTI International to examine the methods for improving the accuracy of construction of the costs used to develop the weights for inpatient hospital stays, recognizing that hospitals tend to mark up high-costs items less than low-cost items. Estimated costs under the OPPS methodology reflect similar problems associated with charge compression. Therefore, St. Jude Medical recommends that CMS makes adjustments to the final CY 2007 OPPS rates to account for this distortion. At a minimum, CMS should implement a payment floor so that the device-related rates do not decrease below their CY 2006 level. In addition, we ask CMS to study this issue further to determine an appropriate adjustment to correct for the distortion caused by charge compression in the OPPS, for implementation in CY 2008 or sooner.

Utilizing External Data

The APC Panel (February 2005) recommended that "...CMS proceed with caution in using existing data on devices submitted with C-codes to set reimbursement rates and that CMS consider using external data in setting rates, especially for those devices with particularly high costs." In 2006, the panel again recommended that CMS use readily available external data to validate costs determined by its claims data. Yet, CMS is proposing to base the payment rates for CY 2007 for device-dependent APCs on median costs calculated using claims with appropriate device codes and no token device charges, without adjustments to the median costs to moderate any decreases in medians from the CY 2006 to CY 2007. With proposed changes in OPPS packaging of two codes for electrophysiologic evaluation of ICDs (discussed below), CMS believes that no special policies are needed to establish payment rates that correctly reflect the relative costs of device-dependent procedures to other procedures paid under OPPS. While we believe that these steps will result in medians that more accurately reflect the costs of providing device-related procedures, the use of correctly coded claims that have no token charges will not address the effect of charge compression on high-cost devices or the reliance on a small number of single- and "pseudo"-single procedure claims to set medians.

The table below shows a historical comparison of median costs (single procedure claims, C-code claims only, and external data) for APC 0108 (ICD System Implant) for CY 2003

3 C. Hogan, Direct Research LLC., March 2006. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data.

through CY 2007. Even using only claims containing device codes to set the medians in CY 2003, CY 2004 and CY 2007, the medians were substantially less than the median acquisition cost of the ICD.

	APC Median Cost Single Procedure Claims	**APC Median Cost C-Code Claims Only**	**Median External Acquisition Cost Data Device Only** [5]
2003	**$12,101.97** [1] *(January 1, 2001-July 1, 2001)* **40%** less than C-coded claims **48%** less than external device acquisition costs	**$20,205.562** *(April 1, 2001-March 31, 2002)*	**$23,120*** *(January 1, 2001-December 31, 2001)* *Represents mean cost – median unavailable
2004	**$11,821.34** [2] *(April 1, 2002-December 31, 2002)* **55%** less than C-coded claims **58%** less than external device acquisition costs	**$26,092.912** *(April 1, 2002-December 31, 2002)*	**$28,313** *(January 1, 2002-December 31, 2002)*
2005	**$11,854.81**[2] *(January – September 2003)* **53%** less than external device acquisition costs	**Not Available**	**$25,198** *(January 1, 2003-December 31, 2003)*
2006	**$18,165.78**[3] *(January 1, 2004– December 31, 2004)* **27%** less than external device acquisition costs	**Not Available**	**$24,824** *(January 1, 2004-December 31, 2004)*
2007	**$22,362.68** [4] **5%** less than C-coded non-token / good edit claims **23%** less than external device acquisition costs	**$22,887.64**[4] *(Non-token, good edit claims)*	**$24,515** *(January 1, 2005-December 31, 2005)*

[1] CMS Proposed Rule: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System Year 2003 Payment Rates; Median Costs for Hospital Outpatient Services, August 9, 2002
[2] CMS Data Presented to APC Advisory Panel, February 2004
[3] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule. Federal Register July 25, 2005, page 42715
[4] CMS Proposed Rule: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System Year 2007 Payment Rates; CY 2007 Proposed Median Costs for Device-Dependent APCs, Table 18, August 23, 2006
[5] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases

Until charge compression and other data issues are addressed, we do not believe that the median cost data will result in rates that uniformly reflect hospitals' cost of providing outpatient services. For CY 2007, we encourage CMS to use external data to adjust medians for the device-dependent APCs when it appears that the adjustment is needed to ensure access to care.

Mandatory Reporting of C-Codes

St. Jude Medical continues to support the mandatory reporting of C-codes and the use of device code edits. We believe that requiring hospitals to report applicable C-codes and charges for all devices that are used to perform procedures where such codes exist will increase the accuracy of the claim data used to set OPPS payment rates. Because edits may not be appropriate in all instances, CMS must make it clear to providers that the absence of an edit does not relieve them of their responsibility to report the appropriate device category C-code whenever a procedure is performed that involves the use of a device described by one of the device category C-codes.

Proposed Payment Policy When Devices are Replaced Without Cost or Where Credit for a Replaced Device is Furnished to the Hospital

CMS is proposing to reduce payment to a limited number of APCs when it determines that the device is replaced without cost to the provider or when the provider receives full credit for the cost of a replaced device. The amount of the reduction to the APC payment rate would be calculated in the same manner as the offset amount that would be applied if the implanted device assigned to the APC had pass-through status. St. Jude Medical believes that reducing the APC payment by the offset amount (in general, the portion of the APC payment intended to cover the device) is appropriate in those cases where the full cost of the device is not incurred. However, we believe that the amount of the adjustment is not appropriate when applied to a case of credit for a replacement device where there is a residual cost because the patient required a more advanced, and consequently more expensive, device.

In such cases, we believe that CMS should reduce the amount of the offset to ensure that providers are not held financially responsible for the residual amount, which may be significant, especially considering that upgrades may occur in as many as 25 percent of cases. The reduced offset amount would result in a more equitable adjustment to hospitals and ensure that beneficiaries have access to appropriate therapy. We believe that this approach is in keeping with CMS' objective of removing the cost of devices from the APC payment for which the hospital incurred no cost.

St. Jude Medical recommends that CMS retains the current FB modifier (Item furnished without cost to provider, supplier or practitioner) to identify cases where the full cost of the device is not incurred. A new modifier should be created to identify those cases in which the replacement device is a more expensive device than the device being removed. This new modifier would identify cases for which an appropriate adjustment is necessary that recognizes the residual costs of an upgraded device and would serve to identify those claims that contain reduced charges so that, in the future, CMS can assess the impact of these claims on median costs.

Until claims data are available on the median device costs in upgrade cases, we urge CMS to meet with stakeholders to determine an appropriate adjustment to the APC in those cases where a hospital implants an upgraded device, while receiving a credit from the manufacturer for the original device.

Impact of Upgrades on the Median Costs

In setting the CY 2007 median cost for device-dependent APC, CMS included only claims that contained appropriate device codes for which charges were in excess of $1.00 (nontoken charge device claims). As expected, this methodology resulted in medians that were in some cases significantly higher than medians using all single procedure bills.

In as many as 25 percent of cases, manufacturers offer credit for a device being replaced if the patient requires an upgrade in therapy. In these instances, the hospital incurs a residual cost due to the implantation of a more expensive device. Hospitals' charging practice would generally reflect the residual cost of the device rather than the usual charge for the upgraded device. Including claims in the medians used for APC payment rate setting for procedures that contain reduced charges could underrepresent the cost of the complete procedure, including the cost of the device. To account for this issue, St. Jude Medical requests that CMS excludes claims with charges representing these residual costs from the medians used for APC payment rate setting, as it has done for claims containing token charges.

Packaging Costs of CPT Codes 93640 and 93641 into ICD Device and Lead Procedures

CMS is proposing to package the cost of CPT 93640 (Electrophysiological evaluation of single- or dual-chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation [induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination] at time of initial implant or replacement) and 93641 (Electrophysiological evaluation of single- or dual-chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation [induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination] at time of initial implant or replacement; with testing of single- or dual-chamber pacing cardioverter defibrillator) with procedure codes that describe the insertion of ICD generator, which are assigned to APCs 0107 (Insertion/Replacement of Cardioverter-Defibrillator Pulse Generator) and 0108 (Insertion/Replacement of Cardioverter-Defibrillator System), or insertion of ICD leads assigned to APCs 0106 (Insertion/ Replacement/Repair of Pacemaker and/or Electrodes) and 0418 (Insertion of Left Ventricular Pacing Electrode).

In the proposed rule, CMS correctly states that CPT codes 93640 and 93641 are always performed during an operative procedure for ICD initial implantation or replacement or with implantation, revision or replacement of ICD leads, and, therefore, it would be appropriate

to package them into the surgical procedure assigned to APCs 0107, 0108 and 0106. However, packaging the cost of CPT codes 93640 and 93641 with procedures assigned to APC 0418 (Insertion of Left Ventricular Pacing Electrode), as proposed, would not be appropriate, as insertion of these pacing leads does not require electrophysiologic testing as described by CPT codes 93640 and 93641.

The proposed CY 2007 payment rate for APC 0418 including the packaging of CPT 93640 and 93641 is $16,489, a 64 percent increase over the CY 2006 payment rate. If CMS removes the costs for CPT 93640 and 93641 from the medians calculated using claims that contain appropriate device codes and nontoken charge device claims, the median cost for APC 0418 would be approximately $9,700, which appears to more accurately capture the costs of the left-ventricular lead procedures (CPT codes 33224 and 33225) assigned to this APC. Therefore, we believe that the use of claims that meet the device edits and do not contain token charges for devices are the appropriate claims to be used to set the median costs for CPT codes 33224 and 33225.

While packaging the costs of intraoperative electrophysiologic testing of the ICD into procedures associated with APCs 0107, 0108, and 0106 yields many more single bills on which to set median costs, it does not improve the accuracy of the median costs acquired from the claims data.

Pass-Through Payments for Devices

CMS proposes to continue to make payment under the pass-through provisions for category C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system) for CY 2007. We support implementation of this proposal in the final rule.

Conclusion

We appreciate the opportunity to comment on the CY 2007 Proposed Rule and welcome the opportunity to work with CMS to ensure that the costs of medical technologies are reflected appropriately in the OPPS rates.

Please contact Susan Walker, Senior Director, Health Policy and Reimbursement, at (651) 481-7638 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Sincerely,

Angela Craig

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AdvaMed
Advanced Medical Technology Association

October 10, 2006

Via Electronic Mail and Hand Delivery

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List (CMS-1506-P)

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Proposed Hospital Outpatient Prospective Payment System and 2007 Payment Rates and 2007 Update to the Ambulatory Surgical Center Covered Procedures List (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505). AdvaMed is the world's largest association representing manufacturers that 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. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the proposed 2007 Hospital Outpatient Prospective Payment System

(OPPS) and 2007 Ambulatory Surgical Center (ASC) rules. While we are pleased with some of the proposed changes we remain concerned with other proposals. Our comments will address our concerns and support for provisions within each of the rules.

Part I. Proposed Updates Affecting OPPS Payments for CY 2007

AdvaMed appreciates the opportunity to provide you with comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed 2007 updates to the OPPS payments for Calendar Year 2007. Our comments will address several issues raised in the 2007 update including:

- Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
- Device-Dependent APCs—Use of a Payment Floor in CY 2007
- Charge Compression and APC Relative Weights
- New Technology APCs
- Proposed Movement of Procedures from New Technology APCs to Clinical APCs
- Proposed APC-Specific Policies
- Device –Dependent APCs
- Proposed Brachytherapy Source Payment Changes
- Proposed Payment for Blood and Blood Products
- Drug Administration

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

Data Used to Determine APC Rates-- AdvaMed appreciates the significant effort on the part of CMS to stabilize variation in APC payment rates for CY 2007. AdvaMed continues to advocate for the use of external data to validate rates given that the latest available median outpatient claims data is two years old and the Medicare cost reports are older and often inadequate to capture accurate median costs.

Use of Single and Multiple Procedure Claims. AdvaMed commends CMS on their decision to bypass specific codes that do not have significant packaged costs in order to use more data from multiple procedure claims. CMS's new single and "pseudo" single procedure claims rate-setting methodology has yielded data that, on initial analysis, appears to more accurately capture the costs of procedures. We recommend that CMS continue to refine these methodologies to improve the accuracy of estimates for the costs of devices included in multiple procedure claims.

Use of Correctly Coded Claims. AdvaMed is pleased with the CMS decision to use only correctly coded claims that include the appropriate C-code for all device-related APCs in setting payment rates. Use of this methodology results in

payment rates that more appropriately reflect the costs associated with these procedures.

AdvaMed continues to support the mandatory reporting of all C-codes and related incentives to encourage hospitals to remain vigilant in reporting the costs of performing device-related services. Furthermore, we urge CMS to continue educating hospitals on the importance of accurate coding for devices and other technologies. Accurate reporting of device and technology charges will ensure that these items are more appropriately reflected in future payment rates for outpatient services.

Utilizing External Data. AdvaMed continues to have concerns regarding the accuracy of the data used to set rates. Medicare claims and cost report data lag behind advances in technology. This is particularly an issue for high-cost devices. AdvaMed recommends that:

- CMS adopt the 2005 and 2006 Advisory Panel on Ambulatory Payment Classification (APC) recommendations that the agency use external data in setting rates, where the claims data may not accurately reflect device costs
- CMS use external data to validate rates where existing claims data is inadequate and/or outdated
- CMS make adjustments that more accurately represent the cost of performing device and technology-related services, including the incorporation of external data provided by manufacturers and other stakeholders into median cost calculations

B. Device-Dependent APCs—Use of a Payment Floor in CY 2007

AdvaMed appreciates the efforts that CMS has made to improve the rate calculations for some device-related APCs in 2007. In calendar years 2004, 2005, and 2006 CMS implemented a floor to limit the reductions in payment for device dependent APCs whose medians were experiencing significant and unexplained reductions. CMS has not proposed to include a payment floor for CY 2007. We are concerned that the continued reductions in the reimbursement for device dependent APCs will prevent hospitals from covering their costs, translating into significant losses for hospitals that perform these procedures, and leading to access problems for beneficiaries. CMS should continue to use payment floors to avoid future decreases that prevent reimbursement levels from adequately reflecting the costs of the devices and other resources required to perform these procedures.

Cumulative decreases in payment over several years for some APCs have significantly reduced the payment for various procedures. The table below illustrates the continued payment reductions that have been imposed on several device-related procedures since 2002.

APC/Description	2002	2003	2004	2005	*2006*	2007	*Change*
0039 – Implantation of Neurostimulator (Neurostimulator)	$15,489	$11,876 -23.3%	$12,832 8%	$12,532 -2.3%	$11,602 -8%	$10,829 -6.7%	-30%
0222-Implantation of Neurological Device	$15,400	$11,877 -22.9%	$12,669 6.6%	$12,372 -2.3%	$11,455 -7.4%	$10,964 -4.3%	-28.8%
0315, Level II Implantation of Neurostimulator	N/A	N/A	N/A	$20,078	$18,950 -5.6%	$14,500 -23.4%	-27.8%

Improvements are still needed to ensure accuracy in the overall payment for device dependent procedures. **Until CMS has addressed lags in claims and cost data used to calculate the payment rates, AdvaMed urges CMS to set a floor on the 2007 device-related APC rates at no less than 100 percent of the 2006 rates plus the market basket update for all device-related APCs.** Although this change will not alleviate the reductions many devices have experienced over the past several years, it will provide a greater level of continuity.

C. Charge Compression and APC Relative Weights

Under OPPS, payment rates for procedures are based on estimated costs, calculated using Medicare claims and Medicare Hospital Cost Reports. The cost estimation methodology for the CY 2007 OPPS rates relies on CY 2005 hospital claims and FY 2004 or earlier cost reports. Due to the lags in data, recent advances in medical technology are, by definition, omitted from the two data sources. The longer the data lags, the more likely that new technology costs will not be fully reflected in the hospital cost reports and claims data, resulting in inaccurate estimated costs.

Further, studies have found that hospitals typically have a smaller mark-up for higher-cost items compared to other items and services. By using a single cost-to-charge ratio (CCR) for varied items and services in a single hospital department the methodology systematically under-estimates the costs associated with low mark-up items, over-estimates the costs associated with high mark-up items, and does not recognize the variability among hospitals in setting charges. This "charge compression" problem may be particularly problematic when the charge for a device accounts for a high percentage of the total charges associated with an APC.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.[1] The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the researcher also showed that cases with very high device and supply charges significantly impacted the device and supply CCR.

CMS recently announced that it has awarded a one-year contract to RTI International to examine the methods for improving the accuracy of construction of the costs used to develop the weights for inpatient hospitals stays, recognizing that hospitals tend to mark-up high costs items less than low-cost items. Estimated costs under the OPPS methodology reflect similar problems associated with charge compression. Therefore, AdvaMed recommends that CMS:

- make adjustments to the final 2007 OPPS rates to account for charge compression
- implement a payment floor such that the device-related rates do not decrease below their 2006 level
- study methodologies to account for charge compression so as to appropriately adjust payment rates under the OPPS

D. New Technology APCs

AdvaMed recommends that CMS examine the criteria and process for moving procedures from New Technology APCs to clinical APCs and consider measures that would prevent excessive reductions in payment-- including moving procedures to different APCs, utilizing external data for rate-setting purposes, and/or allowing procedures to maintain their New Technology APC designation for a period of time sufficient for the collection of adequate data to substantiate movement to an appropriate clinical APC. **AdvaMed supports the APC Panel's August 2006 recommendation which asks CMS to retain codes that have been assigned to New Technology APCs for at least 2 years until sufficient claims data is collected.**

Inappropriate reductions, which exist under the current system, may not only affect access to new services, but have the potential to negatively affect emerging technology. Therefore, AdvaMed continues to urge CMS to not rely solely on claims data, especially given the potential for errors.

If accurate rates are to be established it is critical that hospitals be educated on the importance of correctly reporting procedures which incorporate a device. AdvaMed also recommends that CMS study the process used by hospitals to report the costs of procedures that are part of New Technology APCs. We are concerned that hospitals may

[1] C. Hogan, Direct Research LLC., March 2006. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data. By accounting for charge compression, Medicare payments will more appropriately reflect use of devices and advanced medical technologies.

only be reporting the device costs instead of reporting all of the costs associated with the New Technology procedures. These reporting errors could explain the reductions in median costs when procedures move from New Technology APCs to Clinical APCs and may also explain why technologies are placed into incorrect clinical APCs.

E. Proposed Movement of Procedures from New Technology APCs to Clinical APCs

AdvaMed would like to comment on two procedures that are proposed to move from New Technology APCs to clinical APCs in 2007:

Ablation, bone tumor(s) -- CMS has proposed to move HCPCS 20982 (Ablation, bone tumor(s) (e.g., Osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomographic guidance) from New Technology APC 1557 with a payment rate of $1,850 to clinical APC 0050 with a payment rate of $1,542. Unlike other tumor ablation procedures in APC 0050, HCPCS 20982 includes imaging guidance which adds additional costs to the procedure. Additionally, the payment for APC 0050 does not cover the CMS median costs for HCPCS 20982.[2] Therefore, AdvaMed recommends that CMS move HCPCS 20982 to APC 0051, a clinical APC with greater resource use similarity.

Nonmyocardial Positron Emission Tomography (PET) and PET/Computed Tomography (CT) Scans-- AdvaMed is concerned with CMS's decision to move PET/CT scans from new technology APC 1514 to new APC 0308. The proposed change does not distinguish between this technology and PET scans. PET/CT scans have emerged as one of the most important technologies used to manage cancer patients. Patients benefit from PET/CT scans through earlier diagnosis, more accurate staging, precise treatment planning, and improved monitoring of therapy. The enhanced images generated by these scans allow physicians to pinpoint tumor position and detect cancer cells often well before they are readily visible.

In 2004, PET/CT was a new technology with no established codes. This technology was granted three separate HCPCS codes by the American Medical Association (AMA) and in March 2005, CMS assigned these codes to New Technology APC 1514. In the 2007 proposed rule, CMS states there is adequate claims data for HCPCS codes 78814, 78815, and 78816 to move from the New Technology APC 1514 (New Technology- Level XIV, $1,200-$1,300) to a "clinically appropriate" APC (proposed APC 0308, $865.30). Moving the procedures to APC 0308 would decrease payment by 30 percent, far below the costs of providing this service.

PET/CT is an enhanced technology that is not comparable to PET or CT scans alone. CMS is required to place HCPCS codes in APCs that are similar clinically, as well as on the basis of resource use. CMS does not appear to have a sufficient amount of accurate

[2] CMS has assigned HCPCS 20982 a 2007 median cost of $1897.59-- based on claims data for January 1, 2005 through December 31, 2005.

claims data to justify movement of these new technologies into an existing clinical APC. In August 2006, the APC Panel recommended that CMS maintain HCPCS codes 78814, 78815 and 78816 in New Technology APC 1514 for CY 2007. AdvaMed agrees with the Panel's recommendation and urges CMS to adopt it in the final rule. Maintaining the PET/CT codes in their existing New Technology category will ensure that they are appropriately reimbursed.

F. Proposed APC-Specific Policies

AdvaMed would like to comment on several procedures that are proposed to move from their current clinical APC to lower paying clinical APCs in 2007:

Percutaneous Renal Cryoablation of Renal Tumor (HCPCS 0135T) -- AdvaMed is pleased that CMS has proposed to adopt the APC Panel recommendation to move Percutaneous Renal Cryoablation of Renal Tumor (HCPCS 0135T) from APC 163 to APC 423 for CY 2007. However, AdvaMed continues to be concerned with the movement of procedures from their existing clinical APCs to lower paying clinical APCs based on inadequate data. While HCPCS 0135T is now grouped with clinically similar percutaneous ablation procedures the rate is not based on timely data and does not adequately reflect the costs incurred by hospitals to perform the renal cryoablation procedure (including the cost of the cryoprobes used in conjunction with the procedure). AdvaMed recommends that CMS review and adjust the payment rate for HCPCS 0135T. We realize the difficulty in pricing new procedures because of the lack of timely and accurate hospital claims and cost report data. In such cases using all available data, including external data in making a determination to move procedures from one clinical APC to another is particularly important.

MRgFUS (HCPCS 0071T and 0072T)-- After reviewing the proposed rule regarding changes to the OPPS payment rates for calendar year 2007 and the APC assignment for the MRgFUS procedure, we are requesting that CMS reconsider the APC assignment of HCPCS codes 0071T and 0072T from APCs 0195 and 0202 respectively to APC 0127 for 2007. Current estimated costs for the MRgFUS procedure are significantly higher than the payment rates for APCs 0195 and 0202. We recommend that CMS place these codes in APC 0127 due to the clinical and cost similarities between MRgFUS and the Stereotactic Radiosurgery (SRS) procedure. Both procedures require treatment planning, continuous monitoring during treatment, use of imaging technology, and a significant amount of time to perform the procedure.

Insertion of Mesh or Other Prosthesis (HCPCS 57567) -- AdvaMed urges CMS to move HCPCS code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site),* to APC 0202 (Level X Female Reproductive Procedures). HCPCS code 57267 is a resource intensive gynecologic procedure requiring the use of a device. CMS has assigned similar gynecology codes to APC 0202, such as endometrial cryoablation (HCPCS code 58356) and hysteroscopic tubal occlusion (HCPCS code 58565).

While CMS analyzed claims for HCPCS code 57267, to better ascertain the costs of this add-on procedure, the analysis inappropriately grouped claims with the C-code for hernia repair (C1781) rather than with the C-codes used to report mesh devices used in pelvic floor reconstruction procedures (C1762 and C1763). When the appropriate C-codes are used, the median costs (after applying the multiple procedure reduction) are closer to APC 0202 (HCPCS 57267 is always performed as an add-on code, and would always be subject to the multiple procedure reduction).

GI Procedures with Stents (APC 0384) -- The payment rate for APC 0384 (GI Procedures with Stents) is proposed to be reduced by 13 percent-- from an APC 2006 rate of $1,601 to $1,395 in 2007. AdvaMed is concerned that the proposed payment rate reduction for APC 0384 may reflect changes in the application of C-code screens rather than actual reductions in costs. In particular three HCPCS codes 43219, 43268 and 43269, accounting for over 90 percent of the single procedures claims, do not require C-code reporting. CMS's application of a C-code screen to all procedures in APC 0384 (including 43219, 43268 and 43269), resulted in a 2006 APC payment rate that better reflected costs. We urge CMS to apply a C-code screen again this year to ensure that device costs are adequately reflected in the payment rate.

G. Device –Dependent APCs

AdvaMed would like to comment on the issues discussed in section IV(A)(4) of the proposed OPPS rule regarding proposed payment policies when devices are replaced without cost or where credit for a replaced device is furnished to the hospital.

Payment for Replaced Devices-- For services furnished on or after January 1, 2007, CMS proposes to reduce the hospital payment and beneficiary co-payment for select APCs in cases where a replacement device is provided at no cost or with full credit for the cost of the replaced device. AdvaMed agrees that neither the Medicare program nor the Medicare beneficiary should be required to pay for devices provided to the hospital at no cost.

However, in proposing to uniformly reduce the amount of the APC payment rates by the amount of the pass through offset, CMS fails to recognize that a patient's current medical condition and diagnosis at the time of replacement may require the implant of a more advanced or different type of device, which often may be, more expensive. AdvaMed recommends that CMS should reduce the offset amount to ensure that the hospital is not held financially responsible for these residual costs.

As mentioned, depending on a patient's diagnosis, upgrades may even result in the need for a different type of technology and the purchase of an additional device (or devices) as a patient's disease progresses and their device indications change. In the case of "same device type" upgrades, a reduced offset percentage would result in more accurate payments to the hospital and ensure that beneficiaries have access to devices that are

appropriate to treat their current medical condition. Cases involving "different device type" upgrades should be exempt from any reduction. Both approaches are in keeping with the principle behind the CMS proposal. AdvaMed is willing to work with CMS and other stakeholders to identify a reduced percentage offset that is appropriate for these cases.

CMS proposes to utilize the presence of the –FB modifier to trigger the offset adjustment to the APC payment rate. Because the current -FB modifier ("Item furnished without cost to provider, supplier or practitioner") as currently defined is not appropriate to identify the cases involving same device type upgrades, AdvaMed recommends that CMS create an additional modifier to facilitate the application of the reduced offset amount. The creation of this new modifier would allow for the appropriate adjustment to the hospital payment rate for the residual costs of an upgraded device and identify those claims to ensure appropriate rate setting in future years.

Impact of Residual Costs of Upgrades on Median Costs for APCs 0107 and 0108--

Currently, when a device is furnished without cost to the hospital, CMS instructs hospitals to charge less than $1.01. In the development of the proposed rates, CMS went to great lengths to exclude claims with these token charges to ensure that only claims that contain the full costs of devices were used in 2007 rate setting. As a result, the median costs for some APCs were significantly increased. We applaud CMS for implementing this change to improve the accuracy of the data used to develop the payments.

As described above, there are circumstances where the hospital may receive only a partial credit for a replacement device. In these instances, the hospital incurs residual costs and bills the difference between its usual charge for the replaced device and its usual charge for the upgraded replacement device. These residual costs, although not insignificant to the hospital, would result in charges that are well below the full cost of a device, which may, in turn, result in depressed median values that would under-represent the cost of the complete procedure. To account for this issue, Advamed believes it is important that CMS exclude claims with charges representing these residual costs from the median used for APC payment rate setting.

An analysis of the median costs for APCs 0107 and 0108 shows that the median costs are increased when claims carrying residual charges were removed from the data set (see chart below).

2007 Proposed Rule File (CY 2005 Claims)				
	From CMS Proposed Rule - the final single-procedure claim medians after device edit.		N of single proc claims FOR APC	Single proc median FOR APC
APC	Table 18 single proc FOR APC	Table 18 Median Cost FOR APC	Claims excluding residual device charges that are less than or equal to $6,000	
	2007	2007	2007	2007
0107	481	$ 17,245	440	$ 18,205
0108	2577	$ 22,887	2440	$ 23,153

Registry Data-- AdvaMed supports evidence-based medicine and the use of sound evidence to support medical practice. As we have stated in comments to CMS in response to the agency's "coverage with evidence development" (CED) guidance document, data collected to improve quality of care and outcomes may provide decision-makers with information on the impact of new technologies and procedures on the Medicare population. Notwithstanding, in matters related to data gathering, we urge CMS to take a "minimum necessary" approach. It is important to consider the significant costs incurred in data gathering. Conducting a "value of information" analysis in consultation with all stakeholders will help to address whether the additional burden and costs of data collection (including the costs incurred by individual hospitals, physicians, and other health care professionals) are warranted. AdvaMed strongly believes that any data collection should occur only to resolve explicit and well-defined appropriateness matters or research questions, and that the questions that need resolution should shape the specific type and manner of data that is collected. Such specificity will create the "stopping rules" for data collection.

Moreover, in CMS's revised CED guidance document, CMS states as a principle governing the application of CED that it "will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices."[3] Furthermore, CMS states that it "will not assume the NIH's role in fostering, managing, or prioritizing clinical trials."[4] We agree with the agency's recognition of the separate and distinct roles and mandates of CMS, FDA, and NIH. We urge the agency to use this approach in both Medicare coverage and payment contexts as CMS considers its role in fostering data collection efforts.

Finally, we note that CMS's statements in the OPPS proposed rule imply that registry data will contribute to the "development of high quality, evidence-based clinical practice guidelines for the care of patients who may receive device-intensive procedures." We agree that, when structured appropriately, registry data may yield hypothesis-generating information that can be used to direct and focus additional research efforts. However, in general, studies need to be performed and yield additional evidence before clinical

[3] Guidance for the Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006, at 9.
[4] *Id.*

guidelines can be developed and formalized. Although registry data may help identify issues related to certain procedures such as the impact of the product on certain sub-populations, clinical practice guidelines should generally be based on more conclusive evidence than the observational data that registries provide.

H. Proposed Brachytherapy Source Payment Changes

CMS should continue the current OPPS payment method for brachytherapy devices provided to Medicare patients in the hospital outpatient setting in 2007. The Medicare Modernization Act required a GAO study, giving CMS and the public 2 full years to analyze the GAO report and make recommendations on payment methods for brachytherapy devices. That GAO study was not published until July 25, 2006 and there has been no reasonable opportunity to assess and incorporate the GAO findings in CMS' proposal. Additionally, an inadequate number of claims exist to determine appropriate payment for many brachytherapy devices. Therefore, the underlying data is not a reliable basis for setting fixed payment levels for brachytherapy devices. AdvaMed encourages CMS to adopt the August 2006 recommendations of the APC Panel and the Practicing Physicians Advisory Council that CMS continue paying for brachytherapy services in 2007 using the cost to charge ratio method. Continuing the current method for CY 2007 will ensure more accurate payments that support high quality care for Medicare patients needing these services.

I. Proposed Payment for Blood and Blood Products

AdvaMed continues to be concerned that low outpatient payments for blood and blood products will continue to challenge hospitals' abilities to assure the availability of safe blood products-- compromising patient safety. Our member companies research, develop and manufacture a broad range of innovative technologies for the collection, testing, safety assurance, processing, storage, and transfusion of blood.

We commend CMS for its efforts, in recent years, to address methodological issues related to the development of APC rates for blood and blood products. Overall, these efforts have resulted in more appropriate APC rates for these products. However, we are concerned that even with these improvements the APC rates continue to be well below actual hospital acquisition costs. We urge CMS to carefully review the blood and blood product APCs and make adjustments to them, particularly focusing on the most commonly used blood products such as leukocyte-reduced red blood cells (APC 0954), that ensure access to the safest possible blood products by Medicare beneficiaries. We also urge CMS to adopt the APC Panel recommendation to reconsider the methodology it uses to develop payment rates for blood and blood products to more accurately reflect the true costs of blood and blood products to hospitals using external and other data.

J. Drug Administration

AdvaMed strongly supports the CMS proposal to create six new drug administration APCs and to provide separate payment for additional hours of drug administration services so as to adequately reimburse hospitals for the staff, supplies, and overhead associated with these services. Currently, payment for second and subsequent hours of drug administration services is packaged into payment for the first hour. We urge CMS to retain these proposed changes in the final rule. Further, we recommend that CMS revise its methods for reimbursing hospitals for hydration and therapeutic infusions administered during the same visit. Under OPPS, both hydration and therapeutic infusions share the same codes. As a result, when a hospital administers both a one-hour hydration infusion and a one-hour therapeutic infusion, the hospital is paid for the first hour of one infusion (under APC 440 *Level VI Drug Administration* with a proposed payment rate of $112.94) and a reduced payment rate for the subsequent hour of the other infusion (under APC 437 *Level II Drug Administration* with a proposed payment rate of $25.49). We recommend that CMS adopt a mechanism to allow for full payment for the first hour of both hydration and therapeutic infusions, similar to the approach used under the physician fee schedule.

Part II: Proposed Policies Affecting Ambulatory Surgical Centers (ASCs) for CY 2007

AdvaMed appreciates the opportunity to provide you with comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed 2007 updates to the list of ASC covered procedures. Our comments will address several issues raised in the 2007 update including:

- Proposed additions for 2007
- Payment determination and group assignment
- Payment for New Technology Intraocular Lenses (NTIOLS)

A. Response to Interim Final Rule Comments

The current list of ASC covered procedures includes services that are: commonly performed on an inpatient basis but may be safely performed in an ASC, are not commonly performed in a physicians' office, require a dedicated operating room or surgery suite and a post-operative recovery room or short-term convalescent room, and are not otherwise excluded from Medicare coverage. Specific ASC standards also require that these procedures not exceed 90 minutes operating or 4 hours recovery/convalescent time, require only local or regional anesthesia (not exceeding 90 minutes), not result in extensive blood loss or prolonged invasion of body cavities that involve major blood vessels, and not be emergency or generally life-threatening. CMS will continue to apply these standards to the 2007 updates.

Procedures Proposed for Addition to the ASC List-- CMS has proposed to add 14 surgical procedures to the ASC list for 2007. These procedures are required to meet existing CMS safety criteria and are performed in an inpatient department more than 20 percent of the time and/or in a physician's office less than 50 percent of the time.

Implantation of Peripheral Stents (CPT codes 37205 and 37206)-- AdvaMed is concerned that several of the proposed additions to the 2007 list of ASC approved procedures cannot be safely performed in that setting. Of particular concern are procedures related to the implantation of peripheral stents, CPT codes 37205 and 37206. These procedures involve major blood vessels— specifically femoral arteries of the pelvic and lower limbs. Pursuant to 42 C.F.R. section 416.65(b)(3(iii) of the ASC standards, procedures that directly involve major blood vessels may not be performed in an ASC. The surgical procedures used in conjunction with CPT codes 37205 and 37206 directly involve major blood vessels/arteries and therefore do not meet the criteria for inclusion on the list of ASC approved procedures. Therefore, to ensure that these services are performed in the appropriate setting, AdvaMed requests that CPT codes 37205 and 37206 not be added to the list of ASC covered procedures for 2007.[5]

Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (CPT code 57267)-- AdvaMed recommends that CMS add CPT 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach to the list of ASC approved procedures for 2007. This code is equivalent in intent and function to CPT 49568 – Implantation of mesh or other prosthesis for incisional or ventral hernia repair. CPT code 49568 crosswalks to Payment Group 7. Because of the similarities between the codes we ask that CMS add CPT 57267 to the approved ASC list and assign it to payment Group 7.

Procedures Involving Medical Devices and Other Technologies for which the Costs Are Not Captured by the Payment Group Rate-- The ASC covered procedure list includes procedures that involve the utilization or implantation of medical devices or other technologies for which the cost may exceed the payment group rate, thereby discouraging ASCs from making these procedures available. These payment issues not only impede the transition of procedures associated with devices or other technologies to the ASC setting, but may also limit patient access to needed procedures. Because of this trend, AdvaMed has previously recommended that CMS move procedures from lower to higher payment groups, allow separate payment for medical devices or other technologies, and delay inclusion of certain CPT codes on the covered procedure list. AdvaMed is pleased that in this proposed rule, CMS has adopted several of the recommendations we made in response to the May 2005 Interim Final ASC Rule. However, we remain concerned with CMS's decision to not include several items discussed in detail below.

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[5] It is interesting to note that while CMS has proposed to add CPT code 37206 to the list of ASC approved procedures in 2007 that same procedure is not covered in the ASC setting effective 2008.

Separate Payment for Medical Devices or Other Technologies. In our comments on the 2005 Interim Final ASC rule AdvaMed asked CMS to consider allowing medical devices or other technologies to be reimbursed separately in order to adequately cover device costs. The 2007 ASC update rule adopts some of our recommendations regarding payment for these services, including moving HCPCS codes 36475 and 36476 to higher payment groups. However, we are still concerned that CMS has not adequately addressed payment for supply costs, specifically probes and catheters, not covered by the new payment group assignments.

In our 2005 comments AdvaMed recommended that radiofrequency ablation of venous reflux procedures (RFA)(CPT codes 36475 and 36476) be removed from the list of covered procedures due to insufficient data and because the procedures use considerably more facility resources than other procedures assigned to payment group 3. In response to our comments CMS is proposing to keep the procedures on the list, citing their appropriateness for performance in an ASC, while reassigning them to payment group 9 effective January 2007. AdvaMed is pleased with the CMS proposal to move these procedure codes from payment group 3 to payment group 9 for calendar year 2007.[6]

The 2007 ASC update proposes moving HCPCS code 19298, placement of breast radiotherapy tube/catheters, from payment group 1 to payment group 9. AdvaMed commends CMS for making this change which will more appropriately cover some of the facility costs for this procedure. Moving this code to payment group 9 will reduce the gap in payment between the ASC and hospital outpatient departments for this procedure and allow patients to receive the treatment in both settings. While reassignment to a higher payment group represents a positive change, AdvaMed remains concerned with the reimbursement of supply costs associated with this procedure. In the proposed rule, CMS states that the cost of the implant catheters used with this procedure cannot be paid separately because their cost is packaged into the procedure costs. AdvaMed recommends that CMS consider an add-on payment to cover the cost of these supplies.

Reassignment of Procedures to Higher Payment Groups. AdvaMed also asked CMS to move HCPCS 57288 (repair bladder defect) from payment group 5 ($717) to payment group 9 ($1,339). Under the hospital outpatient prospective payment system ("OPPS"), HCPCS 57288 is assigned to APC 202 with a payment of $2,639. In the ASC setting, payment group 5 does not adequately cover the device costs associated with this procedure or the facility costs. CMS has proposed to keep this code in payment group 5 for 2007. AdvaMed renews its request that HCPCS code 57288 be reassigned to payment group 9 in order to cover the associated device and facility costs.

[6] While the text is correct, Addendum AA mistakenly lists the code in payment group 8.

AdvaMed appreciates CMS' efforts to reclassify procedures to other payment groups when appropriate. Toward that end, we urge CMS to reassign the following endometrial ablation procedures (CPT codes 58563 & 58353) from ASC Group 4 to ASC Group 9, effective January 1, 2007.

- *58563 - Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)* and
- *58353 - Endometrial ablation, thermal, without hysteroscopic guidance*

For 2007, CMS has proposed to reclassify CPT code 58565 (hysteroscopic tubal occlusion) to payment group 9, citing the fact that the procedure is significantly more resource-intensive other procedures in ASC payment group 4. Endometrial ablation is a procedure similar to hysteroscopic tubal occlusion, with similar OPPS median costs. Given the similarity of these procedures, we strongly urge CMS to assign CPT codes 58563 and 58353 to ASC payment group 9 for 2007.

The 2007 ASC update proposes moving HCPCS code 61885 (Implant neuroelectrode) from payment group 2 ($446) to payment group 9 ($1,339) and 64573 (Insertion/redo neurostim 1 array), from payment group 1 ($333) to payment group 9 ($1,339). The current ASC payments for these procedures represent less than 20 percent of the proposed 2007 hospital outpatient department costs. Moving these procedures into payment group 9 will more appropriately cover some facility costs and will reduce the gap in payment between the ASC and hospital outpatient departments for these procedures. While reassignment to the higher payment group represents a positive change, AdvaMed remains concerned with the reimbursement of supply costs associated with these procedures. In the proposed rule, CMS states that the cost of the implantable neuroelectrodes and neurostimulators used with these procedures cannot be paid separately because it is packaged into the procedure costs. The supplies associated with these procedures represent a significant potion of the total procedure cost. For this reason, AdvaMed recommends that CMS consider an add-on payment to cover the cost of the supplies used in conjunction with CPT codes 61885 and 64573.

B. NTIOL

Since the inception of the ASC payment process there had been a system for reimbursing Intra Ocular Lenses (IOLs) supplied concurrent with or following cataract surgery. In 1999 CMS began making an additional payment adjustment of $50 for lenses that it determined were New Technology Intraocular Lenses (NTIOLs). These lenses receive NTIOL status, lasting 5 years, following completion of an application process and satisfaction of CMS criteria. In the current ASC update rule, CMS is proposing to significantly change the NTIOL process by making several modifications to the process for notifying the public regarding NTIOLs and revising the content of an NTIOL request.

CMS has historically received and reviewed applications for NTIOLs throughout the year. AdvaMed supports CMS's proposal to fully integrate the NTIOL-related notifications into the annual notice and comment rulemaking for updating the ASC payment rates . In addition, AdvaMed also agrees that requiring additional information in the NTIOL application will allow CMS's medical advisors to complete a more comprehensive evaluation of new NTIOLs, ensuring appropriate payment adjustments.

The NTIOL submission requirements have always been published in the Code of Federal Regulations at § 416.195(a). AdvaMed is concerned by the proposal to post information regarding the revised NTIOL application criteria on the CMS website only. While we support CMS's goal of making the information available as soon as possible and the desire to provide ease of access, AdvaMed recommends that any information concerning NTIOLs also be made available for public review and comment.

Part III. Quality Measures Under the OPPS

AdvaMed appreciates the opportunity to provide you with comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed 2007 changes to the OPPS system regarding quality measures. Our comments will address several issues raised in the 2007 proposal including:

- Hospital Quality Data
- Health Information Technology
- Transparency of health care information

A. Hospital Quality Data

CMS proposes to implement an outpatient prospective payment system (OPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program effective for payments beginning in January 2007. CMS proposes to reduce the OPPS conversion factor update in CY 2007 by 2.0 percentage points if a hospital does not meet requirements for the full FY 2007 inpatient PPS payment update. Thus, CMS will base outpatient payments on hospitals' reporting of quality measures for inpatient care. CMS describes the CY 2007 OPPS proposal as the initial phase of a broader, long-term effort by Medicare to develop quality measures for the care provided to patients in hospital outpatient departments.

While AdvaMed supports steps to improve the quality of hospital care, we are concerned about the specific OPPS proposal that CMS has put forward and the seeming lack of statutory authority to do so. In the proposed rule's preamble, CMS notes that the IPPS quality measures rest on detailed and explicit statutory authorizations. Social Security Act sections 1886(b)(3)(B)(viii)(I)-(VII) states that hospitals are required to submit inpatient quality data to the HHS Secretary and that the Secretary is required to use this data in the computation of IPPS rates. CMS is proposing to apply these same

requirements to OPPS, even though the statutory provisions applicable to OPPS provide no such authority. The agency purports to base its OPPS proposal on very general statutory language concerning "equitable payments," or, as a potential alternative, on equally general language concerning "controlling unnecessary increases in the volume" of services. Neither of these provisions authorizes CMS to apply prescriptive data reporting requirements and conversion factor adjustments to OPPS.

Improvement in the quality of care provided in hospital outpatient departments represents a significant policy goal. Achieving this goal will be particularly challenging given the quality of the information reported on hospitals' claims data (missing codes, multiple procedures on a single claim, etc.) and will require the broad support of stakeholders . Also, a successful value-based purchasing program must include a robust risk adjustment mechanism, and too little attention has been paid to this issue to date. All of the efforts underway toward identifying quality measures will be wasted if the result is to create a disincentive for physicians to treat the most complicated and/or noncompliant cases. AdvaMed would welcome the opportunity to work with CMS, Congress, and other stakeholders to foster thoughtful steps for measuring and improving the quality of hospital outpatient care.

CMS requested comments on ideal measures and value-based purchasing. AdvaMed believes that both quality and cost of care measures, in all settings, should conform to standards of clinically appropriate care as established by peer-reviewed literature or professional consensus. Furthermore, we believe that financial incentives to encourage providers to meet standards based on quality measures are appropriate. Financial incentives should provide for flexibility in meeting the unique needs of individual patients and not encourage providers to avoid the most difficult cases. Examples of costs of care measures that meet these standards are those that accurately calculate the savings from reductions in: medical errors, surgical complications, preventable hospitalizations, inappropriate use of emergency rooms, unnecessary and harmful services, and duplicative procedures.

AdvaMed strongly believes that costs of care measures should not be used to compare the "efficiency" of providers who do not deliver the same quality of care.

AdvaMed believes that quality measures should be flexible enough to allow access to new, improved technology and devices, and should be reviewed and updated periodically to reflect new benchmarks and standards of care. Furthermore, quality measures should not specify a particular brand or model of device and when all providers satisfy a particular measure, it should be removed to reduce the burden of reporting.

If CMS were to adopt a quality measure that assesses whether or not a provider uses a particular medical device or technology, it should allow exceptions. Providers who use a different new device or technology should be excluded from measurement on this indicator, by exclusion from both the numerator and denominator for the measure, or required to report this use through a separate measure. As use of new devices or

technologies often begins in a particular locality, CMS should allow for variation in measures across the country to capture this variability. If CMS does not recognize use of new devices or technologies when evaluating providers, it runs the risk of freezing medical treatment in place, even after it has become outdated. Medical innovation and successful patient outcomes would be inhibited by such limits.

A value-based purchasing program is based on measures of efficiency, which consider both quality and cost of care over an appropriate time period, such as an episode of care. AdvaMed agrees with the Institute of Medicine (IOM) criteria that measures of quality of care should focus on effectiveness, safety, patient-centeredness and timeliness. We believe that the two other IOM criteria – efficiency and equity – can only be determined for a high level of quality. We also believe that efficiency measures must be based on robust measures of the patient's outcome of care.

The measures and the incentive structure in a value-based purchasing program should address the potential conflict between appropriate treatment and less cost. AdvaMed does not support a value-based purchasing program based on efficiency measures that ultimately encourage the provision of low cost care. For this reason, AdvaMed opposes using process measures to assess quality in the context of efficiency and supports using patient outcome measures instead. Reliance on process measures of quality when assessing efficiency could inhibit access to new technologies. Incentives should be aligned such that physicians and other providers are encouraged to deliver high quality care with patient access to advanced medical technologies. In addition, physicians who participate in clinical trials should not have the data from those trials included in their ratings. This would allow for the development of new procedures and other innovations.

As development of additional measures and revision of existing measures occurs, we urge CMS to consider appropriate episodes of care for assessment of quality, cost and equity. For example, some Medicare patients are very active and have life expectancies that may challenge some of the older device designs. When comparing the value of treatment with a new device versus an older device, CMS must consider the long-term benefits and costs. A one-year period would be insufficient to assess the benefits to patients of many new technologies.

AdvaMed supports an open process to develop quality and cost of care measures. The goals of this process should include routinely updated performance measures based on appropriate evidence, effectively related to desired outcomes, and derived through a fully transparent process involving all relevant stakeholders. We encourage CMS to collaborate with consensus-building organizations that allow input from all stakeholders, including manufacturers of medical technology and patients who benefit from this technology, and guarantee transparency when developing, selecting and updating performance measures.

B. Health Information Technology

AdvaMed supports widespread, rapid adoption of health information technology (HIT) throughout the health care system, including universal adoption of electronic health records. We believe that any value-based purchasing system should include incentives for adoption and use of HIT. In addition, we support removal of barriers to the dissemination of resources (financial, equipment or otherwise) to physicians to allow for the use and adoption of interoperable HIT.

AdvaMed supports incentives to reward new modes of providing services that result in quality improvement or cost reduction at the same or improved level of quality for patient care, such as remote patient monitoring, computer-assisted surgery, imaging, telemedicine, and virtual physician visits.

C. Transparency of Health Care Information

AdvaMed supports dissemination of accurate information on the value of health care services. We urge CMS to use caution when releasing such information to ensure that the care being measured is appropriate, that all costs and benefits are included, and that the episode of care examined spans the full period over which benefits and costs accrue.

AdvaMed urges CMS to consider the time-frame over which quality and costs are assessed. If an episode of care encompasses too-short of a time frame, costs and quality may be inaccurately determined. For example, use of an implant for total joint replacement may have to be assessed over the lifetime of the patient, or implant, which may extend over a period considerably longer than one year.

AdvaMed applauds CMS's efforts to increase the quality of care provided to Medicare beneficiaries. We believe that hospital reporting on the expanded set of quality measures is appropriate. Furthermore, we concur that CMS should develop a comprehensive plan for a hospital value-based purchasing program with input from the public and for increasing transparency of health care information. Our overarching concern is that information on costs of care not be reported, or used as a basis for payment, without consideration of the quality of care provided. Low cost, low quality care is not our goal. We strive to provide patients access to advanced medical technology to improve their health.

Conclusion

AdvaMed greatly appreciates the opportunity to comment on the 2007 OPPS, ASC Update, and OPPS quality measure 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 our 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., Associate Vice President, Payment and Policy, at 202/434-7218, if we can be of further assistance.

Sincerely,

Ann-Marie Lynch
Executive Vice President,
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cc: Leslie Norwalk
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October 10, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates (CMS-1506-P)

Dear Dr. McClellan:

Boston Scientific Corporation (Boston Scientific) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year (CY) 2007 Payment Rates (CMS-1506-P, Federal Register, Vol. 71, No. 163, August 23, 2006).

As the world's largest company dedicated to developing, manufacturing, and marketing of less-invasive therapies, Boston Scientific supplies medical devices and technologies to the following medical specialty areas, many of which provide beneficiary care in the hospital outpatient department setting:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation.

Executive Summary

These comments address broad methodological issues relative to hospital outpatient ratesetting, including the need to appropriately recognize advanced technology, the costs of which have historically been under-represented in the claims data due to the well-known dynamic of "charge compression." We are concerned that CMS' proposal to pay hospitals the full APC rate minus the device offset portion for procedures in which recalled devices are replaced does not accurately account for the partial costs hospitals sometimes incur for some types of recalls. We also offer suggestions for CMS to establish more accurate payment rates for APCs which have a predominate share of multiple procedure claims. Finally, we offer a series of recommendations on APC assignments, reclassifications and device edits that enhance the clinical homogeneity and resource alignment of the APCs in question.

I. Overall Methodological Payment Issues

A. Apply Charge Compression Finding to OPPS

Boston Scientific appreciates CMS' commitment to address issues related to payment for advanced medical technologies under OPPS. However, problems with the claims data and the methods used by CMS to set payment rates continue to result in inadequate payment for a number of procedures utilizing advanced technologies. Payment rates are inadequate for many device-related procedures because the methods CMS uses to calculate relative payment weights do not recognize or adequately adjust for "charge compression" (the tendency of hospitals to "mark up" low cost services and items at a higher rate than more expensive services and items), which particularly affects high-cost implantable devices. [1] Studies sponsored by MedPAC [2], the GAO[2], AdvaMed[3], as well as Boston Scientific's Cardiac Rhythm Management division (formerly Guidant)[4] have clearly confirmed the existence of charge compression and its negative impact on payment rates for implantable cardioverter defibrillator procedures and other advanced technologies such as cochlear implants.

Boston Scientific commends CMS for undertaking the charge compression study as stated in its August 18, 2006 inpatient prospective payment system (IPPS) final rule. Charge compression has a greater impact in the OPPS setting because devices comprise a larger percentage of the payment rate in the outpatient setting than in an inpatient setting. Therefore, we encourage CMS to incorporate and apply the IPPS study findings to the CY 2008 OPPS rule. Boston Scientific will continue to work with CMS and stakeholders to find solutions for improving accuracy in rate-setting methodologies.

B. Improving Accuracy of Payment Rates by Using More Multiple Procedure Claims

Boston Scientific commends CMS for bypassing specific codes without significant packaged costs in order to use more data from multiple procedure claims as a step to ensure appropriate payment. However, even though CMS' single and "pseudo" single procedure claims methodology yields more information that can be used to determine relative weights, we believe that the exclusion of large shares of multiple procedure claims continues to be problematic.

An example of this problem is seen with APC 0082 (*Coronary Atherectomy)*, which is comprised of the following two CPT codes:

- CPT code 92995 - *Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; single vessel* and
- CPT code 92996 - *Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; each additional vessel.*

In CMS' Excel file posted on the CMS website entitled "Median Costs for Hospital Outpatient Services, by HCPCS code", only 9.7%, or 19 of the 195 claims for APC 0082 met the "pseudo" or single claims definition. CMS considers 100 single procedure claims as the baseline for creating bypass codes to ensure that observed costs and charges were sufficiently representative of packaging that might occur in

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[1] GAO Highlights from GAO-04-772. "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services". (http://www.gao.gov/highlights/d04772high.pdf)

[2] GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf

[3] The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003

[4] Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003

multiple claims.[5] Starting with a relatively small volume, 195 claims, and eliminating over 90% of the claims clearly indicates a need for an improved or different methodology to provide more reliable and stable cost estimates.

Bypass codes used for creating pseudo single claims found on Table 1 (Page 49517) of the proposed rule[6] are not typically associated with coronary atherectomy procedures, so these procedures do not benefit from increased use of pseudo single claims.

Boston Scientific analyzed 2005 claims data for APC 0082 to determine the extent to which mean and median costs vary across all claims submitted compared to the 18 claims CMS used for CPT code 92995 to set the APC rate. We first determined how many claims had the required c-codes and then compared the results to the CMS single claims by HCPCS code data. We also examined claims without c-codes to determine if there is a cost difference compared to claims with c-codes. The table below shows the results of our analysis compared to CMS single claims data.

Boston Scientific Internal Analysis of APC 0082

APC 0082 — 92995 Coronary Atherectomy					
CMS Single Claims Data (Median Costs for Hospital Outpatient Services, by HCPCS code)					
	N Claims	**Mean Cost**	**Median Cost**	**Minimum Cost**	**Maximum Cost**
CMS Single Claims Data	18	$4,127.12	$3,481.59	$532.66	$15,324.96
Boston Scientific Analysis					
Total Claims (Note CMS had 177)	171	$10,533.15	$8,936.52	$1,623.11	$38,060.84
With C-code (C1714 or C1724)	142	$11,064.09	$9,597.73	$1,623.11	$38,060.84
Without C-code	29	$7,933.40	$6,590.50	$2,293.17	$23,186.81

From our analysis, we concluded the following:

- C-coded claims represent 83% of total claims, but most of these claims were not used in ratesetting.
- C-coded claims had the highest mean and median costs.
- Even among claims with no c-code, the median cost in our analysis is 89% higher than the median derived from CMS' analysis of single claims data.

CMS should not use only single claims to estimate costs for APCs like APC 0082 where the number of single use claims is low and are not representative of overall claims data. Instead, CMS should identify certain common billing combinations of coronary atherectomy with other procedures and incorporate these more common billing scenarios that better reflect the resources of these procedures into ratesetting.

A Similar Shortage of Single Procedure Claims for APC 0653

Another example of the issues associated with excluding multiple procedure claims is APC 0653, (*Vascular Reconstruction/Fistula Repair with Device*). In this case, CMS data shows that only 2.4% (656 claims) of the 27,131 claims for this APC met the "Pseudo" or Single Claims definition, indicating that the procedures in this APC are rarely performed alone. By only considering "single" claims in an APC with a high percentage of multiple procedure claims, CMS may be overlooking important cost information contained within multiple procedure claims.

[5]Federal Register, Page 49515

[6]Federal Register/Vol. 71, No 163, August 23, 2006, Medicare: Hospital Outpatient Prospective Payment System and CY2007 Payment Rates; Proposed Rule, Pages 49517-49527

As with APC 0082, Boston Scientific analyzed 2005 OPPS claims data for APC 0653. We found that CPT code 36870, the most commonly reported CPT code in APC 0653, is associated with a significant discrepancy in the level of c-code reporting and the median costs associated with single versus multiple procedure claims. Only 40% of single procedure claims are reported with a c-code, and the median costs are less than 50% of the median costs associated with multiple procedure claims.

APC 0653	36870 Thrombectomy, percutaneous, AV Fistula					
CMS Single Claims Data (Median Costs for Hospital Outpatient Services, by HCPCS code)						
	N Total Claims	**N Single Claims**	**Mean Cost**	**Median Cost**	**Minimum Cost**	**Maximum Cost**
CMS Single Claims Data for APC 653 (% with c-codes Reported)	27,131	656 (n/a)	$2,191.32	$1,942.96	$294.49	$11,754.25
Boston Scientific Analysis						
Total Single Claims for 36870 (% with c-codes Reported)	n/a	251 (40%)	$2,147.28	$1,901.37	$24.10	$9,387.98
Total Multiple Claims for 36870 (% with c-codes Reported)	17,335 (81%)	n/a	$5,239.92	$4,164.03	$33.45	$117,566.95
Total Other CPT Coded Claims in APC 653 (Single)	n/a	509	$2,372.13	$2,225.32	$368.12	$9,349.41
Total Other CPT Coded Claims in APC 653 (Multiple)	25,470	n/a	$4,615.96	$4,030.94	$41.84	$34,182.58

Based on our analysis of APC 0653 (particularly CPT code 36870), we conclude that single claims represent a minority of claims and under-represent the device use of procedures in this device-dependent APC. Also, multiple procedure claims appear to more consistently incorporate device related costs.

Suggested Alternative Methodology for Managing Multiple Procedure Claims

CMS has made significant progress toward recognizing a larger number of claims in its ratesetting methodology, and we appreciate their efforts. Still, we believe that for certain APCs in which single procedures claims are relatively rare, CMS should develop methods of better incorporating multiple procedure claims when estimating costs. CMS has already set standards for capturing device costs with the implementation of device edits; now the Agency should take one additional step and include more claims for "multiple procedure-dependent" APCs that have small volume or shares of single procedure claims.

Recommendations and CMS Requested Action:

- Develop standards and methods to include additional multiple procedure claims in estimating costs. As part of this effort, we recommend that CMS convene a group of hospital billing experts to develop a system that provides for better recognition of the total procedure costs, and to establish combinations of procedures that frequently appear together in claims so that the costs of such combination billing scenarios can be incorporated into cost estimates.

- Ensure pseudo single-procedure claim methodology accurately reflects both procedural and associated device costs by developing metrics for linking the procedure with the corresponding c-code(s) as established by the device edit list and not using claims where c-codes are not reported.

C. Appropriate Payment for Procedures Involving Recalled Devices

Boston Scientific supports CMS' goal of accurate payment for services provided. To that end, we ask that CMS have a system that can manage and accurately account for no-cost, partial-cost, and full-cost devices. Boston Scientific recognizes the concept of a reduced payment when a device is replaced without cost to the hospital, or with full credit for the removed device which is charged then credited through the hospital's accounting system. However, the methodology and process requires further consideration and work before implementing any program of this type. In many specific cases, hospitals do bear a fraction of device costs; the appropriate billing and payment framework must recognize the complexity of tracking costs for no-cost and partial-cost devices, as well as how to appropriately pay for them. Additionally, Boston Scientific is concerned about the process by which CMS will identify no-cost and reduced-cost devices, and how that process will affect claims data moving forward.

CMS should have a detailed understanding of manufacturers' warranty practices before making any policy changes because not all devices are replaced without charge under a recall. A policy that does not accurately recognize and account for manufacturers' warranty practices could potentially result in a hospital being dramatically underpaid for the service. For example, a device's cost may be prorated based on the remaining service life as compared to its projected longevity. Additionally, as CMS states, many devices are upgraded at this time and there is often a cost for both hospital and patient for the upgrade in device type. It is important to note that each recall is a unique situation; depending upon the circumstances involved, hospitals may find themselves paying a portion of the costs of a device but not receiving appropriate payment from CMS if the proposal is implemented in its current form.

Any process CMS creates should be easy for hospitals to follow and implement. Keeping track of credits and applying them to the proper claims forms can be administratively difficult for hospitals to track at the individual claims level. Adding complexity to this process could increase confusion and potential errors for both CMS and hospitals. Once a simple process is created, payment rates should also be commensurate with the level of payment for the device.

We are in agreement with CMS' goal to pay accurately for services provided; as such, Boston Scientific asks that CMS find an appropriate method to manage and correctly account for no-cost, partial-cost, and full-cost devices for both hospital payment policy and for claims data. If such a system cannot be implemented in time for the January 1, 2007 OPPS implementation date, Boston Scientific respectfully requests that CMS delay this proposal until CMS fully understands the manufacturers' warranty programs so that any system and process for tracking information is clear, and it ensures appropriate payment mechanisms for hospitals. Because much of this information is confidential, we would be willing to meet with CMS to further discuss this topic.

Using Registries for Tracking Device Issues

Manufacturers currently follow device issues by tracking model and serial number in the MAUDE database. Boston Scientific supports enhancing the current system in place to track such issues rather than implementing a new registry.

Additionally, while registries have merit, they are limited in their usefulness to identify potential individual device issues. Instead, a technology with daily monitoring of device parameters and information that will identify individuals with specificity and timeliness is advantageous; these remote monitoring technologies from device manufacturers provide better information to both physicians and patients. Boston Scientific recommends that to the extent that CMS is able, they encourage device manufacturers to continue to build or expand upon these active, daily monitoring capabilities.

II. Specific APC Reclassifications, Assignments & Modifications

A. Proposed APC Assignment for Defibrillator Lead Procedures

Boston Scientific recommends that CPT codes 33218 (*Repair of Defibrillator Lead*) and 33220 (*Repositioning of Defibrillator Lead*) should be mapped to APC 0105 instead of 0106. These procedures are not device-dependent and therefore should not map to a device-dependent APC. Additionally, the median cost with CPT codes 33220 and 33218 is much lower than the other procedures in APC 0106; however, they are closer to the median cost of APC 0105.

Also, BSC suggests that CMS remove the word, "Repair" from APC 0106, as it would better describe the procedures, and update the description of APC 0105 as: "Revision/Removal/Repair of Pacemakers, AICD, and/or Electrodes".

Recommendations and CMS Requested Action:

- Reassign CPT codes 33218 and 33220 to APC 0105 from APC 0106
- Remove "Repair" from descriptor of APC 0106
- Update descriptor of APC 0105 to reflect procedure reassignments

B. Appropriate APC Grouping of CPT code 57267

Boston Scientific thanks CMS for addressing the issue we raised in our March 2006 APC Panel Presentation on CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site).* We indicated that APC 0154 (*Hernia/Hydrocele Procedures*) was not a clinically appropriate APC for 57267 from both a clinical and resource use perspective. The code was implemented in 2005 and is an add-on code. As such, it is never billed as a stand alone procedure and is subject to the multiple procedure discounting rules resulting in payment of 50% of the applicable APC rate.

The panel agreed on the clinical inappropriateness of the APC assignment, and CMS has proposed to reassign 57267 to APC 195 (*Level IX Female Reproductive Procedures*) in 2007. While we agree that a move to the Female Reproductive Procedure APC series is a better option in terms of clinical fit, the payment differential in the APC chosen is insignificant relative to the current rate. The proposed 2007 rate of $885 ($1,769.04 * 50%) for APC 0195 does little to improve the inadequate payment for these procedures.

APC 0202 Used for Gynecology Device Dependent Procedures
We believe assigning 57267 to APC 0202 (*Level X Female Reproductive Procedures)* with a proposed 2007 payment of $1,319.52 ($2,639.04 * 50%) would better reflect the device-intensive nature of this gynecology procedure.

CMS has grouped other device-intensive gynecology codes to APC 0202. In the November 15, 2004 OPPS Final Rule, CMS assigned CPT code 58356 (*endometrial cryoablation*) to APC 0202, stating that this procedure is "*more clinically compatible with APC 0202, which contains other resource intensive gynecologic services that also use a device...APC 0202 is a device-dependent APC and, therefore, a more appropriate placement for a procedure that uses a device.*"

CPT code 57267 is also a resource intensive gynecologic procedure requiring the use of a device, which suggests it should also be grouped in APC 0202.

Incorrect Device Code used in CMS Data Analysis
In the proposed rule, CMS conducted a data analysis to identify the median cost of 57267, and determined that the proposed payment of $885 was adequate. We appreciate CMS taking this additional step, but

note that the inclusion criteria in CMS' analysis were incorrect. CMS looked at claims billed with both CPT code 57267 and C1781-Mesh (implantable), but the devices mapped to C1781 are for hernia repair mesh devices (Transmittal A-01-41 from March 22, 2001), not for mesh devices used in pelvic floor repair procedures.

The two c-codes describing mesh devices used in pelvic floor graft augmentation procedures would be correctly billed under:

- C1762- Connective Tissue, human
- C1763- Connective Tissue, non-human

OPPS Data Shows Significantly Higher Median Costs
Because 57267 is an add-on CPT code and can never be billed alone, single coded claims are an inappropriate measure of median costs. CPT code 57267 is mostly billed with the following cystocele and rectocele CPT codes:

- 57240 - Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
- 57250 - Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
- 57260 - Combined anteroposterior colporrhaphy;
- 57265 - Combined anteroposterior colporrhaphy; with enterocele repair

As a result, a correctly coded claim for a pelvic floor repair procedure with graft augmentation would include one cystocele/rectocele CPT code (from list above), CPT code 57267 and either C1762 or C1763, examining claims data showing those coding combinations is the only accurate way to measure costs for the add-on procedure. (The c-codes are needed to accurately reflect the device burden of correctly coded claims.)

We conducted a 2005 OPPS claims data analysis using the parameters outlined above to demonstrate the true median cost for correctly coded pelvic floor repair procedures with graft insertion. Because cystocele/rectocele procedures can also be done without graft augmentation, we compared those procedures without graft insertion with those correctly coded claims that did. The table below details our results:

Procedure	Median Claim Cost		Dollar Difference	Percent Difference
	Without 57267 and either C1762 or C1763	With 57267 and either C1762 or C1763		
57240 - Cystocele repair	$2,914	$3,860	$946	32%
57250 - Rectocele repair	$2,370	$3,756	$1,386	59%
57260 - Combined A&P repair	$2,969	$4,182	$1,213	41%
57265 - Combined A&P repair w/enterocele	$3,200	$4,665	$1,465	46%
		Average Difference	**$1,254**	**45%**

The average median claim cost for correctly coded cystocele/rectocele repair with graft insertion claims is $1,254 or 45% higher than for those same procedures performed without the graft insertion procedure. The proposed 2007 payment of $885 ($1,769.04 * 50%) falls well short of adequately covering the median costs for correctly coded claims. We believe our analysis demonstrates both the inadequacy of CMS' proposed payment and the device-intensive nature of 57267.

Recommendations and CMS Requested Action:

- Assign CPT code 57267 to APC 0202.
- Use only C1762 and C1763 as required device edits for 57267 claims to establish proper ratesetting.

C. Proposed Payment for APC 0384 (*GI Procedures with Stents*)

Boston Scientific manufactures and markets many of the stents used in GI stenting procedures, and has fully participated in the policy and payment debates surrounding appropriate payments for GI stenting since this APC was introduced.

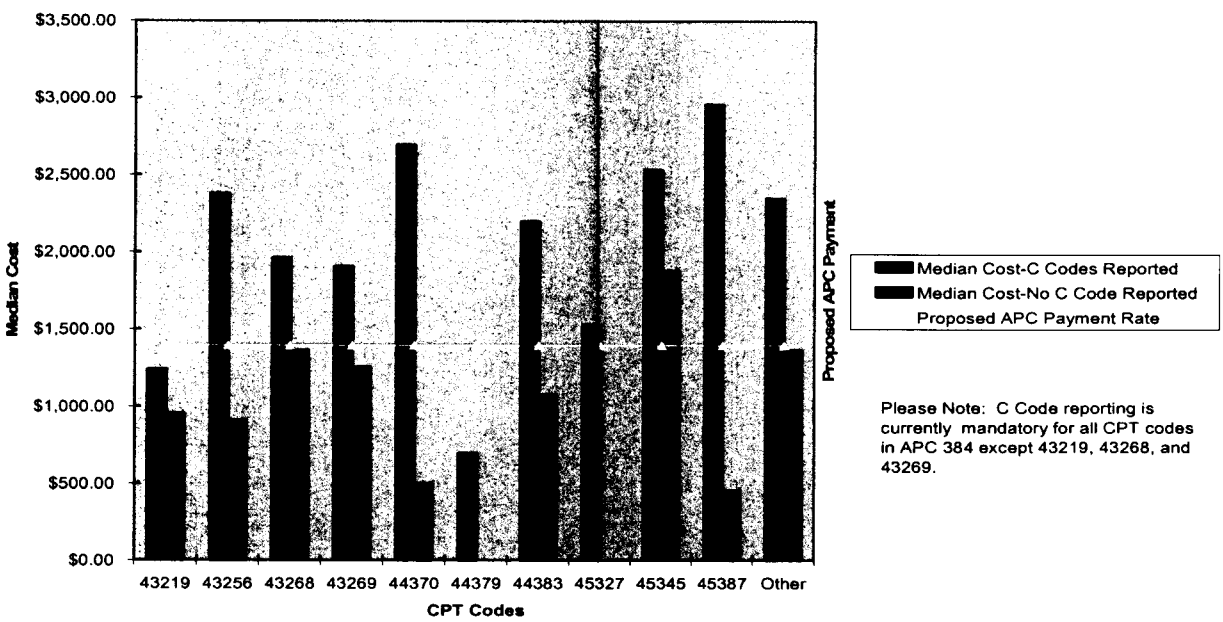
In setting 2006 APC rates, CMS applied device edits (must have c-code, device cost $1 or higher) to the underlying 2004 claims data for all procedures in APC 0384. This step raised the median claims cost of APC 0384 by over $300, from $1,262 to $1,598, which was used to set the 2006 APC rate of $1,601.

While CMS is applying the same device edits in setting its proposed 2007 rates for device-dependent APCs, we believe three of the CPT codes within APC 0384 do not require a c-code in order to be billed and therefore are not being subjected to the edit requirements. These three procedures, which account for over 90% of the claims used in ratesetting, are shown below:

- CPT code 43268 - *Endoscopic retrograde cholangiopancreatography (ERCP); with endoscopic retrograde insertion of tube or stent into bile or pancreatic duct*
- CPT code 43269 - *Endoscopic retrograde cholangiopancreatography (ERCP); with endoscopic retrograde removal of foreign body and/or change of tube or stent*
- CPT code 43219 - *Esophagoscopy, rigid or flexible; with insertion of plastic tube or stent*

The chart below shows our analysis of 2005 OPPS data for APC 0384, with median costs shown for all procedures within the APC, both with and without stent c-codes. The significantly higher median costs from claims that use c-codes can be observed across the full spectrum of procedures in APC 0384, including CPT codes 43268, 43269 and 43219.

APC 384-GI Stenting: Comparison of Claims With and Without Stent C Codes (C2625, C1874, C1875, C1876, C1877, C2617)



Although CMS used a device screen in its 2007 proposal for APC 0384, the median costs were artificially dampened because the three CPT codes (43219, 43268 and 43269) accounting for over 90% of the single procedures claims do not require c-code reporting. It is only because CMS applied the c-code screen to all procedures in APC 0384, including these three procedures shown above, that the 2006 rate for APC 0384 better reflected the device costs. We urge CMS to take the same step this year.

All of the procedures in APC 0384 require the placement of one or more stents. Therefore, hospitals should be using at least one c-code for every Medicare procedure performed. Toward that end, we urge CMS to set its 2007 payment rate for APC 0384 based on median costs calculated using claims for all APC 0384 procedures having appropriate device codes and token charge edits.

This step is consistent with CMS' proposal for other device-dependent APCs, and is consistent with the APC Advisory Panel's August 2005 recommendation that the median costs for APC 0384 be determined using only those claims with c-codes.

Recommendations and CMS Requested Action:

- Apply device edits for all procedures in APC 0384 to ensure that device costs are adequately reflected in APC 0384's payment rate.

D. Appropriate APC Assignment for Uterine Artery Embolization

Boston Scientific is aware that a new Category I CPT code for uterine artery embolization (UAE) will be implemented for services provided on or after January 1, 2007[7]. While the APC assignment for CPT code 37xxx, *Uterine artery embolization*, was not addressed in the proposed rule, we understand that the final rule will include an APC assignment for this new code, and we offer the following information to assist with the APC assignment of CPT 37xxx.

Procedure Description
UAE is a fluoroscopically guided, percutaneous, catheter-based intervention. In a typical UAE procedure, arterial access is gained through the right common femoral artery. The physician uses fluoroscopy to identify the uterine arteries and selectively catheterizes the first uterine artery. Embolic material is injected through the catheter to stop the flow of blood to the uterine fibroid. The particles occlude the blood flow to the fibroids and result in their infarction and shrinkage. Fluoroscopic guidance is used to locate the uterine artery, place the catheter and ensure the embolic material is injected properly. Once the embolization of the first uterine artery is complete the procedure is repeated on the second uterine artery. One or two angiograms are performed immediately after the procedure to confirm a satisfactory endpoint of therapy.

Current Coding for UAE
Providers currently use multiple CPT codes to bill for UAE (see table below). These CPT codes map to APC 0115 (*Cannula/Device Device Procedures),* APC 0297 (*Level III Therapeutic Radiologic Procedures*) and APC 0263, (*Level I Miscellaneous Radiology Procedures*). CPT 37xxx, however, will bundle all procedure components (catheterization, embolization, imaging guidance and angiography) into one CPT code. Therefore, it is important that CPT 37xxx map to an APC that will appropriately reimburse hospitals for all aspects of the UAE procedure, including imaging.

[7] This request on UAE is essentially identical to that contained within a September 27, 2006 letter to Elizabeth Richter from Boston Scientific's Ms. Carole Dembek.

Current Coding & Hospital Outpatient Payment for UAE

Procedure Component	CPT Code	APC	OPPS Status Indicator*	2006 Medicare APC Payment
Selective catheterization of uterine arteries	36247 (billed twice)	NA	N	NA
Transcatheter embolization	37204	0115	T	$2,201
Radiologic guidance for embolization	75894	0297	S	$303
Angiography, pelvic	75898 (billed twice)	0263	X	$202
Total Payment				$2,706

*OPPS Status Indicators:
N = Service is packaged into another APC group (no separate payment), S = Separate payment, T = Multiple procedure discount applies, X = Ancillary service eligible for payment

Clinical Homogeneity
UAE is clinically similar to percutaneous, transcatheter procedures performed under fluoroscopy. The following CPT codes describe procedures that are most similar to UAE:

CPT Code	CPT Descriptor
37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid and vertebral vessel), percutaneous
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (TIPS)
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (TIPS)

Resource Use
Several published studies have reported the cost of UAE from the hospital perspective (see table below). Subramanian and Spies used microcosting and cost-to-charge ratios to determine facility cost of UAE. They reported facility costs of $2,058-$4,951 (mean $3,080) in 1998 dollars. Baker et al also reported hospital costs for UAE using cost-to-charge ratios. This group reported UAE hospital costs of $3,193 (2001 dollars). Finally, Beinfeld and colleagues used a hospital cost accounting system to determine both direct and indirect hospital costs for UAE. Beinfeld reported a mean cost of $8,223 (2000 dollars). Physician costs were not included in any of the studies.

Published Hospital Costs for UAE

Reference	Hospital Cost	Hospital Cost in 2006 Dollars	APC 0229 Median Cost 2006
Baker CM, Winkel CA, Subramanian S, Spies JB. Estimated costs for uterine artery embolization and abdominal myomectomy for uterine leiomyomata: a comparative study at a single institution. J Vasc Interv Radiol. 2002 Dec;13(12):1207-10.	$3,193 (2001 dollars)	$3,781	$3,646
Beinfeld MT, Bosch JL, Gazelle GS. Hospital costs of uterine artery embolization and hysterectomy for uterine fibroid tumors. Acad Radiol. 2002 Nov;9(11):1300-4.	$8,223 (2000 dollars)	$10,361	$3,646
Subramanian S, Spies JB. Uterine artery embolization for leiomyomata: resource use and cost estimation. J Vasc Interv Radiol. 2001 May;12(5):571-4.	$3,080 (1998 dollars)	$3,974	$3,646

An appropriate APC for CPT 37xxx must include procedures that are similar to UAE from both a clinical and resource use perspective. APC 0229 (*Transcatheter Placement of Intravascular Shunts*) appears to meet both of these criteria, as it includes percutaneous, transcatheter procedures such as TIPS and percutaneous transcatheter stent placement, both of which are clinically homogeneous to UAE. APC 0229 is also appropriate for UAE from a resource use perspective. Adjusted for inflation, the UAE hospital costs in the Baker and Subramanian studies are $3,781 and $3,974, respectively, in 2006 dollars. These costs compare favorably with the 2006 median cost of $3,646 for APC 0229.

Recommendation and CMS Requested Action:

- Assign the new UAE code 37xxx to APC 0229 (*Transcatheter Placement of Intravascular Shunts*)

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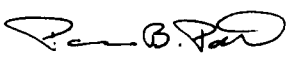
Thank you for the opportunity to comment on the proposed hospital outpatient rule. We urge CMS to consider our recommendations in this comment letter, and welcome the opportunity to discuss our responses to CMS' proposal. Please contact me at (508) 652-7492 or parashar.patel@bsci.com or Scott Reid, Director of Health Policy and Payment, at (202) 637-8021 or reids@bsci.com if you have any questions.

Sincerely,



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