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Boston Scientific

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September 14, 2007

The Honorable Kerry Weems
Acting 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

SEP 14 2007

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates (CMS-1392-P)

Dear Mr. Kuhn:

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) 2008 Payment Rates (CMS-1392-P, Federal Register, Vol. 72, No. 148, August 2, 2007).

As the world's largest company dedicated to the development, manufacturing, and marketing of less-invasive and innovative therapies, Boston Scientific supplies medical devices provided in hospital outpatient settings in the following medical specialty areas:

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

Executive Summary

Boston Scientific appreciates CMS's efforts to refine and enhance the hospital outpatient prospective payment system to improve the accuracy of payment rates. We have specific recommendations on several elements of the payment system. First, in order to improve payment accuracy, CMS should make certain adjustments to account for the effects of charge compression. Such an adjustment would appropriately recognize advanced technology, the costs of which have historically been underrepresented in claims data. Second, CMS should also proceed cautiously and transparently before making any dramatic shifts to increase packaging and bundling. Third, CMS should develop a consistent device replacement policy across sites of service. Fourth, CMS should reconsider some of the procedures it plans to cover in ambulatory surgical centers (ASCs) in order to ensure patient safety.

Finally, we offer a series of recommendations on specific APC reclassifications and refinements to enhance the clinical homogeneity and resource alignment of APCs. Specifically, we recommend that CMS:

- Create a separate APC for rechargeable neurostimulators,
- Maintain separate IVUS and ICE APCs,
- Create separate APCs for coronary & non-coronary angioplasty using specialty balloons,
- Proceed with caution on the proposal to create a Composite APC for EP Evaluation and Ablation,
- Implement a fully transitioned ASC payment for urethral bulking, and
- Assign uterine fibroid embolization (UFE) to a more appropriate APC.

I. Overall Methodological Payment Issues

A. Proposed Calculation of CCRs

Boston Scientific appreciates CMS's commitment to address issues related to payment rate accuracy. However, problems with the claims data and CMS methods used to set payment rates under OPPS continue to result in inadequate payment rates for many procedures utilizing advanced technologies[1,2]. Payment rate inaccuracies continue under OPPS because the methods to calculate relative payment weights do not recognize or adequately adjust for charge compression, the hospital practice of applying a lower percentage markup to higher cost items and services. The RTI study, commissioned by CMS, confirmed that charge compression introduces a systematic bias into payment rates and recommended short, medium, and long-term interventions to substantially reduce this bias. Specifically, RTI recommended using regression-based estimates to disaggregate the departmental CCR for medical supplies to improve payment rate accuracy.

RTI's recommendations will improve OPPS payment rate accuracy
The RTI study, commissioned by CMS, confirmed that charge compression introduces a systematic bias into payment rates and recommended changes to substantially reduce this bias. RTI recommended six short-term interventions, most importantly the use of regression-based estimates to split the cost-to-charge ratio (CCR) for the "Supplies" cost center into one CCR for "Devices and Implants" and a separate CCR for "Other Supplies."

In the proposed rule, CMS concluded that the OPPS ratesetting methodology is already more specific than RTI's recommendation. However, the use of more cost centers or hospital-specific cost centers does **not** necessarily equate to more accurate ratesetting. Implementation of RTI's recommendations will lead to improvements over the current method because RTI's methodology 1) ensures cost centers are designed to reduce markup variation and 2) uses regression-based estimates to adjust, or disaggregate, existing departmental CCRs. Below is an example of why OPPS currently does not take mark-up variation into consideration because of the current design of the cost centers used in OPPS.

While the OPPS does have two cost centers for medical supplies: [cost center 5500 (Med Supplies Charged to Patient) and cost center 3540 (Prosthetic Devices)], these cost centers are not designed to reduce markup variation and improve payment rate accuracy. First, revenue codes do not always

1 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

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

crosswalk to the appropriate cost center. For example, revenue code 278 (Other implants) currently cross walks to cost center 5500, the cost center representing lower-cost medical supplies, and not cost center 3540, which represents higher-cost medical devices. Second, most hospitals do not even use cost center 3540 at all, but instead use secondary cost center 5500 for both lower-cost supplies and higher-cost devices. Because cost center 5500 is used for both lower-cost supplies and higher-cost devices, the current OPPS ratesetting methodology and design of cost centers does not adequately account for variation in charges.

On the other hand, RTI's recommendation does address variations in mark-ups between lower-cost supplies and higher-cost devices within cost centers. RTI's recommendation also uses the CCRs for these disaggregated cost centers, and not departmental CCRs, for ratesetting. Therefore, unlike OPPS, RTI's recommendation does take into account the mark-up variations between medical supplies and implantable devices and creates a separate CCR for each. Both the proper alignment of cost centers and the use of disaggregated CCRs are necessary for the OPPS to reduce the systematic bias introduced through charge compression.

CMS should take steps to reduce the impact of charge compression for CY 2008
CMS proposed the development of an all-charges model, using both outpatient and inpatient claims, to further evaluate charge compression adjustments which could be used in developing CY 2009 OPPS payment rates. Instead of postponing an adjustment for this known payment accuracy issue for yet another year, we urge CMS to implement RTI's short term recommendation for using regression-based estimates based on inpatient claims to split the CCR for the "Supplies" cost center into two separate CCRs for CY 2008. An adjustment or correction to charge compression has been discussed since 2000, yet the underlying claims data and ratesetting mechanisms continue to be inaccurate. CMS could still continue to evaluate additional refinements that can be implemented in subsequent years.

Applying RTI's regression-based estimates to split, or disaggregate, the CCR for the supplies cost center into two separate CCRs for CY 2008 would be a step in the right direction even if an all-charges model were to be implemented at a later date. As noted in RTI's report, an analysis conducted by Dr. Chris Hogan showed that the disaggregated CCRs for the all-charges model are very similar to the disaggregated CCRs using only inpatient claims. Because there is relatively little difference between the two models, there should be a seamless transition from RTI's disaggregated CCRs to the all-charges model if, at a later date, CMS believes the change is necessary. In the meantime, CMS should implement RTI's recommendation on splitting the supplies cost center into two separate CCRs for CY 2008 as this correction is needed to improve the accuracy of CMS data, reduce the systematic payment rate bias from charge compression, and can be executed in a simple and concise manner using CMS's own data files.

If CMS decides that an all-charges model needs to be developed before implementing RTI's recommendations, we would request that CMS' analysis adequately address concerns from both a IPPS and OPPS perspective to ensure that all possible issues (i.e. all-charges model, MS-DRG interactions, potential HSRV impact, etc.) are analyzed in time for implementation in the inpatient and outpatient proposed rules for 2009.

Recommendations and CMS Actions Requested:

- Implement RTI's recommendation for disaggregating the CCR for devices and implants from the CCR for other supplies to calculate CY 2008 final OPPS payment rates.

- If CMS decides not to implement RTI's recommendations in the OPPS, CMS should perform the necessary analysis to address IPPS and OPPS concerns to ensure an all-charges model is analyzed and implemented in the inpatient and outpatient setting for 2009.

B. Packaging and Composite APCs

CMS has proposed a significant expansion of its policy of packaging items and services that are typically ancillary and supportive of a primary or "independent service". We suggest that CMS take a cautious approach to expanding its policy on packaging to ensure payment accuracy and to avoid unintended consequences which could result in limiting access to care of certain therapies and procedures.

One significant concern with the packaging proposal in this proposed rule is the inclusion of some low-volume, high-cost procedures. In the past, CMS has primarily packaged only high-volume, low-cost ancillary services. In this proposal, CMS makes a significant departure from what has traditionally been packaged, without providing clear information on what criteria it has used. For example, CMS's use of a bypass list follows certain specific criteria that are made transparent to the public, whereas CMS has not made clear the logic or criteria used in the proposed expanded packages beyond a vague notion that some are "independent" and some not. Instead of relying on what appear to be subjective criteria, CMS should develop and communicate clear and objective criteria for identifying which codes might qualify for packaging.

One example of a low-volume procedure that appropriately has not been packaged in the past is intravascular ultrasound (IVUS), a diagnostic imaging service using capital equipment and single-use devices to guide therapeutic decision-making and improve proper stent placement. IVUS is currently used in about 1.0 – 6.5 percent of coronary and peripheral stenting procedures, yet CMS has proposed to package IVUS into an APC with codes that are almost always performed without IVUS technology.

Packaging services that are infrequently used in combination with the "independent service" creates several problems:

(1) Technology and capital costs for the low-volume, high-cost procedures are inappropriately allocated to an APC dominated by services that almost never incur the cost of the specialty technology.

(2) Appropriate payment for the low-volume, high-cost procedure is eliminated and threatens the economic viability of performing such procedures.

(3) Specifically for device-dependent procedures or procedures utilizing both single-use devices and specialized capital equipment designed exclusively for use with that unique device, bundling the costs of the packaged procedure will improperly allocate costs and payment to hospitals that perform the primary procedure, regardless whether they purchase the device and specialized capital equipment or not. Such a disparity would reward hospitals who do not invest in the technology.

Instead of giving providers flexibility in making the most cost-effective decisions, packaging may result in Medicare beneficiaries being denied access to this important technology. In the case of IVUS, quite simply, the elimination of separate APC payment for IVUS will disincentivize providers from using a valuable diagnostic tool that could improve clinical outcomes and decrease adverse events.

Packaging should be reserved for higher-volume, lower-cost minor and ancillary services that are frequently performed with the independent service. Additionally, device-dependent procedures or procedures utilizing both single-use devices and capital equipment designed exclusively for use with that unique service should **not** be packaged, as in a technology like IVUS.

We are also concerned about the future accuracy of OPPS rates if CMS implements the proposed expanded packaging. Experience has shown that hospitals are less concerned with reporting packaged

services than separately payable services and the accuracy of coding and cost data decreases when the link between coding and payment is removed. In 2003, CMS discontinued C-codes that had been established to report pass-through devices. However, CMS soon found that the 2003 claims used to set OPPS payment rates had packaged costs much lower than actual device costs. CMS attributed these coding and reporting inaccuracies, in part, to variable hospital billing practices. For 2005, to improve the specificity of claims data, CMS reestablished the C-code requirement. As CMS proceeds with packaging, it must recognize the impact of inadequate reporting of packaged services and associated costs on future ratesetting.

While packaging is a fundamental part of any prospective payment system and has been a part of OPPS since its inception, when substantially expanding the scope of packaging, CMS should describe and make transparent the process used to identify codes that qualify for packaging. In addition, stakeholders should be given ample time to understand, replicate, and analyze the implications of CMS's methodology in order to provide comments to the agency on its packaging proposal. While we know that CMS used its existing ratesetting process of isolating single procedure claims and, when possible, converting multiple procedure claims into pseudo-single claims. However, several details about the proposed packaging process are not known. For example, what percentage of charges for dependent services were retained and allocated to an "independent" procedure, which independent procedures received packaged charges, and whether the allocation is even appropriate. The lack of transparency, combined with the late arrival of a clean OPPS claims data set to allow public evaluation and analysis, makes it difficult to determine how well charges are retained and translated once packaged into an "independent" procedure.

Because so many packaged codes are being proposed at once with limited time for stakeholder review and to ensure appropriate payment for valuable clinical interventions are not lost, we propose that CMS apply the following packaging principles and process improvements before expanding its policy on packaging. If CMS does apply these principles and process improvements for CY 2008, we would ask that CMS implement a final rule with comment period to ensure adequate public review and scrutiny of the finalized list of packaged procedures.

Packaging Principles

- Packaging should be reserved for higher-volume, lower-cost minor and ancillary services that are frequently performed with the independent service.
- Low-volume procedures performed only occasionally in conjunction with the independent service should **not** be packaged.
- Device-dependent procedures or procedures utilizing both single-use devices and capital equipment designed exclusively for use with that unique service should **not** be packaged.
- Add-on codes that are infrequently performed with its independent service should **not** be packaged.
- Exceptions to the packaging policy should be permitted in cases where appropriately justified by concerns that packaging could unreasonably impede access to valuable technologies.

Process Improvements

- Ensure that appropriate program instructions are disseminated to providers to ensure proper coding and charge data submission for packaged codes and that a back-end claims processing logic or edits is developed to ensure that only "correctly" coded claims are used in future ratesetting process.

- Develop and communicate clear and transparent criteria for identifying which codes qualify for packaging.

CMS also proposed bundling separate "independent services" commonly performed in the same hospital outpatient encounter into Composite APCs. We again suggest that CMS proceed with caution regarding the application of this methodology. Any development of Composite APCs should be accompanied by a clear, transparent process for identifying and calculating future Composite APCs and include a comment period to gain transparency and shape a more accurate methodology. It is important that Composite APCs are designed in a manner that sufficiently accounts for the resources associated with performing the common combinations of services.

Ensuring the accuracy of claims data and the OPPS ratesetting mechanism is paramount. For this reason, we request that CMS ensure that the methodological issues discussed above be evaluated and accounted for before implementation.

Recommendations and CMS Actions Requested:

- Apply the principles listed above, including a public comment period, in the development of a more clear and transparent packaging methodology.

- Develop a clear, transparent process, including a public comment period, for the identification and development of future Composite APCs.

C. Proposed Payment When Devices are Replaced with Partial Credit to the Hospital

BSC supports the goal of accurate payment for services provided and recognizes the need for payment offsets for devices replaced without cost or where a credit is furnished to the hospital for a replaced device. However, we believe the proposal will potentially increase hospitals' administrative burdens, and may adversely impact identification efforts to track patterns of device failure.

We applaud CMS for acknowledging these concerns in the FY 2008 IPPS final rule, and encourage CMS to establish consistent device replacement policies in both inpatient and outpatient settings. We believe this will help CMS achieve accurate payments while minimizing the potential disruption to manufacturer quality systems and hospital administrative systems.

We encourage CMS to take steps to achieve accurate payment by ensuring that only claims containing the full costs of the device are included in ratesetting.

CMS' proposal introduces several administrative issues that could affect device returns.

1. At the time of device explant, it will be difficult for the hospital or physician to know if the device will be replaced with full credit, partial credit or no credit. Often, manufacturer analysis to

determine credit eligibility and credit amount takes six to eight weeks from time of explant. This makes it difficult for hospitals to know whether to use the new HCPCS modifier at the time of explant. In the 2008 IPPS final rule, CMS acknowledged the administrative burdens and delays associated with determining whether a device should receive a credit.

2. In the 2008 IPPS final rule, CMS agreed and changed the threshold from 20% to 50%. Having a different threshold for hospitals to administer in the outpatient setting versus the inpatient setting will also cause tremendous confusion.

Potential Unintended Consequences

The proposed OPPS process may drive unintended consequences. As CMS stated in its proposal, manufacturers encourage the return of all devices upon explant. However, in many cases, hospitals use their discretion on whether to return the device to the manufacturer. In fact, our recent experience indicates that 50-70% of explanted devices are not returned despite our encouragement to do so. We agree with CMS that hospitals strive to ensure that quality care is being delivered to their patients. Rather than by lack of concern, we believe devices are not always returned because it can be unclear if devices fail to function properly or reach their life expectancy.

When the device functionality is in doubt, the potential for a credit on the replaced device can only be determined by the manufacturer. We are concerned that the increased administrative burden of the proposed OPPS rule and six to eight week timeframe for determination of credit amount may be enough to discourage device return in those marginal cases. Any reduction in the number of devices returned to the manufacturer reduces the ability to identify and track patterns of device failures, and weakens industry efforts to improve product quality.

Impact of Residual Cost of Partial Credits on Payment Accuracy

CMS's current ratesetting method is not affected by claims that have token charges and the FB modifier. The methodology excludes these claims for which the hospital has received the replacement device at no charge or with full credit. We appreciate CMS' efforts in removing these claims containing token charges and believe this process improves the accuracy device intensive procedures.

In the proposed process for devices replaced with partial credit, CMS has recognized that some hospitals may adjust their charges so that only the residual costs are included after the partial credit is applied. If these claims are included in ratesetting, the reduced charges will artificially depress rates over time.

We encourage CMS to exclude these claims as they did with full credit replacement devices. This can be easily accomplished by excluding claims with the new HCPCS modifier created by CMS to identify claims containing partial credits that meet the threshold for a payment reduction. Removing these claims will provide more accurate hospital payments by ensuring that only claims containing the full costs of the device are included in ratesetting.

Recommendations and CMS Actions Requested:

- Provide clear direction on the use of the new HCPCS modifier to ensure hospitals understand they have the option to 1) submit device replacement claims without using the modifier and submit an adjustment later if necessary or 2) hold the claims until the credit amount is determined.

- Apply a consistent policy across payment systems and set the credit threshold to 50% as finalized in the IPPS rule for FY 2008.

- Remove claims from ratesetting calculations which have the new HCPCS modifier created by CMS to identify claims containing partial credits that meet the threshold for a payment reduction.

D. Procedures Added to the Ambulatory Surgical Center (ASC) List as of 2008

Boston Scientific applauds CMS's ongoing efforts to reform the ASC payment system, and we appreciate the attention given to public comments regarding the safety, quality and payment for ASC procedures. However, we continue to have concerns about some of the procedures added to Medicare's ASC Covered Procedures List for 2008 and we offer the following recommendations to enhance safety and quality:

1. Remove Percutaneous Transluminal Angioplasty (PTA), Atherectomy and Transvenous Electrode Procedures from the Approved List

While we continue to support patients and physicians having the flexibility to determine the appropriate site of care, we also believe that in some cases CMS must exercise caution in providing this flexibility, particularly for procedures that could have catastrophic outcomes if the appropriate emergent care equipment and training are not available in the site where care is delivered. Specifically, Boston Scientific urges CMS to remove the PTA, atherectomy and tranvenous electrode procedures from the list of procedures approved in the ASC (Complete list shown in recommendations).

Boston Scientific requests that these procedures be removed from the list of allowed procedures in the ASC because: 1) they are characterized by one of more of the exclusion criteria established by CMS; and 2) CMS has previously stated that some of these procedures are not safe for ASCs.

These Procedures Involve Major Blood Vessels – A Criterion for Not Allowing a Procedure in ASCs

In the 2008 ASC Payment Policy Final Rule, CMS declined to adopt a modified version of the definition of major blood vessels derived from the textbook by Seeley, Stephens and Tate entitled, "Essentials of Anatomy & Physiology", 6th Edition.[3] Notwithstanding that decision, the fact remains that the PTA, atherectomy and transvenous electrode procedures listed above all involve major blood vessels. And, while the following procedures generally all have excellent safety profiles when performed in hospitals, any procedures involving major blood vessels have elevated risk of complications. The following details the vessels and their potential complications.

The iliac, femoral and popliteal arteries are main sources of blood supply to and from the upper and lower legs, and a perforation could result in hemorrhage, amputation or even death.[4,5,6,7] Transvenous electrode procedures involve the placement of electrical leads directly into the heart, which is obviously a major blood vessel. Transvenous leads are inserted through either the subclavian or jugular veins and advanced through the superior vena cava into the chambers of the heart. Left ventricle leads are also passed through the coronary sinus into the coronary veins of the left ventricle.

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[3] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.

[4] Young N, *et al.* Complications with outpatient angiography and interventional procedures. *Cardiovasc InterventRadiol.* 2002; 25:123-126.

[5] Waugh JR, Sacharias N. Arteriographic complications in the DSA era. *Radiology.* 1992; 182:243-246.

[6] Krankenberg H, et al. Percutaneous Transluminal Angioplasty of Infrapopliteal Arteries in Patients with Intermittent Claudication: Acute and One-Year Results. *Catheter Cardiovasc Interv.* 2005; 64:12–17.

[7] Gray BH, *et al.* Complex Endovascular Treatment for Critical Limb Ischemia in Poor Surgical Candidates: A Pilot Study. *J Endovasc Ther.* 2002; 9:599-604.

Any procedure that involves insertion, repositioning, replacement or removal of electrical leads directly into the heart involves risk of complications that would require capabilities that are not present in the ASC setting. Some of these complications may include: cardiac perforation, coronary venous dissection, hemothorax, peripheral embolus, cerebrovascular accident (CVA)/stroke, myocardial infarction (MI), or pericardial tamponade. Please refer to the ICD Registry, developed by the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) and required by CMS for reimbursement, to better evaluate the rate of occurrence of these complications.

PTA of the Iliac, Femoral and Popliteal Arteries is Commonly Associated with the Need for Systemic Thrombolytic Therapy – A Criterion for Not Allowing a Procedure in ASCs

In its 2008 ASC Payment Policy Final Rule, CMS states, "we are making it explicit that the final criteria used to evaluate the safety of procedures for performance in ASCs...include the criterion that covered surgical procedures may not be of a type where systemic thrombolytic therapy would commonly be required."[8]

Although CMS did not define "commonly required," in one study of 181 lesions in 166 vessels, 55% of lesions were either occluded or stenosed and occluded.[9] This suggests to Boston Scientific that these procedures "commonly" require thrombolytic therapy.

In addition, when physicians perform peripheral vascular procedures such as PTA, they often do not know the nature of the lesion or blockage before they begin the procedure. Lesions that appear to be stenoses on ultrasound can actually be total occlusions when viewed using angiography. These total occlusions typically require thrombolytic therapy. Additionally, during peripheral interventions it is possible to dislodge plaque or blood clots resulting in total occlusions. This event can also result in the need for systemic thrombolytic therapy. Therefore, CMS should err on the side of caution and exclude all PTA procedures with the exception of hemodialysis access PTAs (G0392 and G0393), which have unique clinical characteristics, from the ASC.

CMS has Previously Stated that Some of the Procedures on the Approved List for 2008 are "Potentially Too Unsafe" to Perform in ASCs

In its 2007 Final Rule for outpatient hospital payment, in the section addressing 2007 ASC payment policy (CMS-1506-FC, Section XVII, Policies Affecting Ambulatory Surgical Centers (ASCs) for CY 2007), CMS stated, "We also believe it is most clinically appropriate to not finalize our proposal to add CPT code 35476 to the ASC list.[10] Although CPT code 35476 is used to report venous rather than arterial procedures, it is appropriately used to report many different procedures, some of which may involve major veins and that are potentially too unsafe for performance in ASCs."[11]

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[8] Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 410 and 416 Medicare Program; Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008; Final Rule. Federal Register. Vol. 72, No. 148. Thursday, August 2, 2007. Page 42481.

[9] Akopian G and Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg*. 2006;44:115-8.

[10] Current Procedural Terminology (CPT) ©2006 American Medical Association. All rights reserved.

[11] Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 410, 416 *et al.* Medicare Program—Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule. Federal Register. Vol. 71, No. 226. Friday, November 24, 2006. Page 68168.

Since CMS's statement in November 2006, we are unaware of any changes in the clinical characteristics of venous or other PTA procedures that would justify a reversal of CMS's position on what is "clinically appropriate." Nonetheless, CMS added not only 35476, but also 35473 and 35474 to the list of procedures approved for ASCs in 2008.

Another procedure identified as inappropriate because it posed a significant safety risk, or is expected to require an overnight stay in Table 2 of the 2008 ASC Final Rule, was the transvenous extraction of cardioverter-defibrillator electrodes (CPT code 33244). Despite this, two codes (33234 and 33235, describing the tranvenous removal of pacemaker electrodes) are currently on the list of approved procedures although they have similar risks to 33244. Boston Scientific requests that these procedures also be removed from the allowed procedures list because CMS has deemed these procedures unsafe for ASCs.

2. Implement Consistent and Enforceable Safety and Quality Standards and Reporting Mechanisms across All ASCs and States / Oversight Authorities

Boston Scientific applauds CMS's decision to implement quality measures effective January 1, 2009 and its publication of the proposed revised Conditions for Coverage (CfCs) for ASCs. However, we remain concerned that the measures proposed in the CfC proposed rule will not adequately or consistently protect patients' safety when treated in ASCs. We will expand on these comments in a separate letter addressing the CfC Proposed Rule.

In this letter, we urge CMS to implement enforceable safety standards and safety reporting mechanisms and that CMS seek to achieve as much consistency as possible in the way states and oversight authorities monitor compliance and address grievances.

In a recent Open Door forum regarding the final ASC Payment Policy for 2008, CMS indicated in response to a question that the mechanisms to monitor safety and adverse events occurring in ASCs and their related outcomes are not currently in place.[12] As a result, CMS has no way to know whether a procedure is inappropriate for performance in an ASC or whether an adverse event occurring in an ASC could have been avoided or better managed had the procedure been performed in a hospital.

Based on our review of the CfC Proposed Rule and the discussion in the 2008 ASC Final Rule, Boston Scientific remains concerned that after implementing new CfCs and quality measures, CMS would still have no way of knowing that a procedure is inappropriate for performance in an ASC.

We acknowledge that the proposed CfCs go farther than the current conditions for coverage in addressing many safety standards. However, by leaving the implementation method to individual ASCs and by continuing to leave enforcement and oversight to individual states with no strong guidance as to methodology or minimum acceptable standards, CMS is unintentionally creating a situation where beneficiaries' rights are being protected to differing degrees and the level of safety available to them will vary by the ASC and the state in which they are treated.

At a minimum, the following standards should be consistently implemented by all ASCs and enforced by all states / oversight authorities:

- *Staff should be trained and experienced in supervising operative settings*
- *Immediate transfer to hospitals must be available*
  The current Medicare Conditions for Coverage (CfCs) for ASCs state that all ASCs must have procedures for the immediate transfer of patients needing hospitalization after an ASC procedure

[12] CMS Open Door Forum on 2008 ASC Payment Policy, Tuesday, July 31, 2007.

and that "such situations should not be infrequent."[13],[14] However, "infrequent" is not defined in the CfCs, and the availability of transport services does not eliminate the risks of infection, dissection and perforation associated moving patients who have undergone procedures in ASCs, particularly those that are catheter-based. Because CMS does not have a consistent method to track transfer rates, CMS (nor patients and physicians) cannot confirm whether a given ASC's rate of complications requiring transfer is infrequent or not.

- *Patients' level of surgical risk should consistently be evaluated and documented*
  Although the proposed CfCs do expand the responsibilities of ASCs in terms of risk evaluation and documentation, CMS is again proposing to leave the level and method of implementing risk assessment and the degree of documentation undertaken to individual ASCs. Again, the inconsistencies that will occur could negatively impact beneficiaries' right to consistent and dependable care regardless of what ASC or state they are treated in.

3. Enhance Opportunities for Consistent Collection of Dependable, Actionable Quality Data

As mentioned earlier, Boston Scientific welcomes the news that CMS would implement quality measures for ASCs for 2009. While CMS discusses quality measures and data collection in the 2008 ASC final rule, CMS does not fully describe what measures will be developed, how data collection will be implemented or how the data will be analyzed and acted upon. Until such measures are in place, CMS cannot fully insure that the well-being of Medicare beneficiaries treated in ASCs is appropriately protected.

Further, given the significant interest CMS and all stakeholders have in gaining insights to the quality of care associated with contemporary clinical practice, it is essential that clinical process and outcomes information be captured to inform decision-making. Some examples include:

- The reporting of specific clinical process information such as surgical infection prevention (SIP) via prophylactic antibiotic administration.[15] Hospitals are currently required to report this information. It would seem that data collection efforts should be consistent across sites of service;
- The utilization of proper medications at admission and whether the patient was evaluated for anesthesia risk; and
- The reporting of the number of cases requiring transfer to hospitals due to complications.

To help achieve this informed decision making we suggest that CMS should consider modeling the ASC quality reporting standards on the Ambulatory Care Quality Alliance (AQA) and the Hospital Quality Alliance (HQA) efforts for hospitals. Another possible starting point for ASC measures is the Surgical Care Improvement Project (SCIP).

[13] 42 CFR §416.41.
[14] DHHS, Centers for Medicare and Medicaid Services. State Operations Manual, Appendix L: Guidance to Surveyors: Ambulatory Surgical Services (Rev. 1, 05-21-04).
[15] *Ibid.*

Recommendations and CMS Requested Actions:

1. **Remove Percutaneous Transluminal Angioplasty (PTA) and Transvenous Electrode Procedures from the Approved List Based on CMS's Established Exclusion Criteria and Previously-Articulated Concerns about Safety (See below for a complete list of procedures to be removed)**

Code	Description
35473	Transluminal balloon angioplasty, percutaneous; iliac
35474	Transluminal balloon angioplasty, percutaneous; femoral-popliteal
35476	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
35492	Transluminal peripheral atherectomy, percutaneous; iliac
33206	Insertion or replacement of permanent pacemaker with transvenous electrode; atrial
33207	Ventricular
33208	Insertion or replacement of permanent pacemaker with transvenous electrodes; atrial and ventricular
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33215	Repositioning of previously implanted transvenous pacemaker or pacing cardioverter defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter defibrillator
33217	Insertion of a transvenous electrode; dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter defibrillator
33218	Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter defibrillator
33220	Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber pacing cardioverter defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of generator
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)
33226	Repositioning of a previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of generator)
33234	Removal of transvenous pacemaker electrode(s); single-lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33249	**(Physician billing only)** Insertion or repositioning of electrode lead(s), for single or dual chamber pacing cardioverter defibrillator and insertion of pulse generator
G0299	**(Medicare hospital outpatient billing only)** Insertion or repositioning of electrode lead for single chamber pacing cardioverter defibrillator and insertion of pulse generator
G0300	**(Medicare hospital outpatient billing only)** Insertion or repositioning of electrode lead(s) for dual chamber pacing cardioverter defibrillator and insertion of pulse generator

2. **Implement Consistent and Enforceable Safety and Quality Standards and Reporting Mechanisms across All ASCs and States / Oversight Authorities**

3. **Enhance Opportunities for Consistent Collection of Dependable, Actionable Quality Data**

II. Specific APC Reclassifications, Assignments & Modifications

A. Implantation of Spinal Neurostimulators (APC 0222)

Boston Scientific recommends that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

CMS's proposal to pay rechargeable and non-rechargeable neurostimulator procedures at the same rate would create financial incentives that may force physicians to limit or reverse adoption of clinically beneficial rechargeable neurostimulators. This would result in economically inefficient use of health resources and avoidable surgical procedures for battery replacement and associated risks for Medicare beneficiaries.

The creation of separate APCs for rechargeable and non-rechargeable neurostimulator procedures would pay both procedures more appropriately by avoiding overpayments for non-rechargeable neurostimulators and significant underpayments for rechargeable devices. A new, separate, rechargeable APC would enable hospitals to continue offering this therapy to Medicare beneficiaries and other chronic intractable pain patients while producing substantial cost-savings to the Medicare program.

Boston Scientific and other manufacturers of neurostimulators met with CMS in February 2007 and September 2007 to express our concerns with Medicare's future payment rates for procedures that use these devices and provide recommendations on how CMS could develop separate APCs that would assure more appropriate payments for rechargeable neurostimulators. We are particularly concerned that the proposed 2008 payment rates to hospitals for outpatient procedures using rechargeable neurostimulators would create unintended barriers to access for Medicare beneficiaries, as well as have chilling effects on adoption of this beneficial technology.

Hospitals may be unable to offer rechargeable neurostimulator technology to Medicare beneficiaries at the proposed rate ($12,314), which is significantly less than both the actual device costs and the current hospital payments with the new technology pass through payment in effect. We understand that CMS intends the transitional pass-through payment to be a temporary payment mechanism to facilitate adoption of new technologies over a 2-3 year period of time. Additionally, we understand that the usual practice is to package the costs of these new technologies into the predecessor APC(s) after the pass-through payment expires. However, packaging the primary cost driver for these alternative treatments into the same APC would result in highly inadequate payment levels in this case. Since rechargeable neurostimulators represent a small minority of procedures in APC 0222, this would remain a persistent problem in future years if CMS were to move forward with this proposal.

For Medicare beneficiaries, we are very concerned that hospitals may revert to implanting non-rechargeable neurostimulators with much shorter battery lives (2-4 years). Such a response would ultimately result in Medicare paying for thousands of additional, avoidable battery replacement procedures. It would also place beneficiaries at greater risk of complications due to these additional procedures that could be averted through the use of rechargeable neurostimulators. Alternatively, hospitals may decide to force physicians to discontinue offering rechargeable – or even any – neurostimulation therapy, to all patients to avoid discrimination based on ability to pay despite the procedure's proven clinical and cost-effectiveness.[16]

[16] Taylor RS, et al. The cost-effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. J Pain Symptom Management 2004;27:37-78

Clinical Value of Rechargeable Neurostimulators.
Rechargeable neurostimulators represent a major advancement in spinal cord stimulation for chronic intractable pain. Older, non-rechargeable neurostimulator technologies are limited by the need for frequent repeat surgical procedures for battery replacement (every 2 – 4 years). They are also limited by the need for reduced power settings or turning the system "off" for part of the day in order to prolong battery life- both of which compromise the patient's pain management.

Rechargeable neurostimulators are designed to enable high-power neurostimulation settings, dramatically extending battery life when compared to non-rechargeable neurostimulators and reducing the frequency of device replacement procedures. About 25% to 30% of all neurostimulators implanted each year are replacements of depleted, non-rechargeable batteries, or about 1,500 avoidable procedures per year on Medicare patients. Not only would the use of rechargeable neurostimulators prevent these unnecessary surgeries, but it would lead to reductions in complications from fewer surgeries and reductions in related follow-up costs.

CMS's Analysis of OPPS 2006 Claims Data Demonstrate Substantial Cost Differences
CMS's own analysis of APC 0222 claims data as shown in Table 35 of the preamble reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While this spread of median costs in APC 0222 does not create a two times rule violation, the $6,481 difference in median costs represents a substantial and burdensome variance in resource utilization for hospitals. We believe that this clear, substantial, absolute difference in median costs merit separating rechargeable and non-rechargeable neurostimulators into distinct APCs.

Boston Scientific OPPS Claims Data Analysis
We performed an analysis of Medicare 2006 OPPS claims data for rechargeable and non-rechargeable neurostimulator procedures. We focused our analysis on single procedure claims within APC 0222. We excluded claims with token charges, those that did not meet the device edits, and those that were billed with modifier "FB". In our 2006 OPPS Limited Dataset data file, we found considerably fewer claims than CMS reported in Table 35 of the proposed rule. We found 257 (13% of the total, median cost $18,305) single procedure rechargeable claims and 1,715 (median cost $11,369) single procedure non-rechargeable claims in APC 0222. We found similar and substantial differences in total procedure costs.

Our analysis shows that rechargeable neurostimulators represent a very small percentage (13%, n=253/1,973) of the procedures assigned to APC 0222 and therefore, they exert a small influence on the APC median cost. Despite the beneficial impact of the pass-through payment policy that enabled hospital adoption for patients who would benefit from rechargeable neurostimulators, other types of non-rechargeable devices represent a large majority (87%, n=1,711) of the cases assigned to this APC. Most of these (61%, n=1,199) involve non-rechargeable peripheral nerve stimulators implanted outside the spinal cord – including sacral nerve stimulators for overactive bladder and gastric stimulators for gastroparesis – with the remainder (26%, n=512) involving non-rechargeable spinal cord stimulators.

Overall, this analysis supports the conclusion that rechargeable neurostimulators would make a persistently small and inadequate impact on median costs of APC 0222 in future years if CMS were to move forward with this proposal, especially if the proposed payment policy limits patient access and utilization of this beneficial technology.

Private Cost Date Shows Striking Differences
External device cost data from the IMS Hospital Supply Index (01/01/06 – 12/31/06) shows an even larger difference in device costs between rechargeable ($17,980) and non-rechargeable ($11,721) neurostimulators. Based on CMS's estimated device portion of the APC (83.29%), CMS's device costs

would be $15,066 for rechargeable and $9,668 for non-rechargeable, both of which are lower than the device costs reported in the IMS Hospital Supply Index. It appears that the total procedure costs that CMS computed from its claims data are underestimated and likely due to charge compression.

Two-Times Rule

The two-times rule was intended to be one criterion that CMS should use to evaluate reassigning procedures into other APCs or creating new APCs. However, it was not meant to be a minimum criterion that must be met. CMS has established precedent when other procedures within an APC were not two times as costly as the highest cost procedure in the APC.

Specifically, in 2007, CMS created a new APC (APC 0293) for implanting a keratoprosthesis (CPT 65770, artificial cornea) after its transitional pass-through payment had expired at the end of 2005 after finding costs were "significantly higher than the median costs of other procedures assigned to APC 0244, although there was no 2 times violation." In this case, the median cost of 65770 was $3,177 while the lowest median cost of other procedures in the same APC was $1,931 – a difference of only $1,246 or, 65%. CMS concluded that there was likely to be a "persistent small contribution to the median cost" and that an APC reassignment was merited "in order to pay more appropriately for the procedure and related device."[17] [18]

In another example, CMS reassigned percutaneous diskectomy procedures (CPT 62287) from APC 0220 to the higher paying APC 0221 after the pass-through payment for C2614 (probe, percutaneous diskectomy) expired at the end of 2004.[19] The median costs of 62287 were $1,919 and represented less than one percent of the single procedure volume in APC 0220, thus exerting little influence on the median cost of the APC at $1,013.[20] [21] CMS stated that the resource costs for CPT 62287 may be more appropriate for APC 0221, and assigned the code the more appropriate APC 0221. Finally, the dollar bandwidths within each New Technology APC also demonstrate significantly smaller cost differences ranging from $10 to $500. The highest New Technology APC includes procedures ranging from $9,500 to $10,000 in costs. A $500 variation in costs would place a technology in the next lowest APC.

Hospital Incentives and Bundling

We understand the goal of CMS to provide incentives to hospitals for improving efficiency and that the use of broader payment bundles may help accomplish this goal in many cases. While we agree in concept with the policy goal of improving hospital efficiency, we do not believe it is appropriate to bundle payments for services when the differences in clinical benefits and absolute costs are so significant ($6,481) that the resulting payment levels would compromise patient access to the most appropriate technology while increasing overall costs to the Medicare program. Procedures using rechargeable neurostimulators have very different patient outcomes (fewer repeat procedures due to battery depletion) than non-rechargeable systems, leading to long term cost savings in the Medicare program for patients requiring high-power stimulation settings.

CMS has solicited comments on how this situation differs from other scenarios under OPPS where relatively general HCPCS codes describe procedures that may use a variety of devices with different costs, and payment is packaged. While we agree with the policy goal of comparable treatment across OPPS payment categories, we respectfully submit that this situation differs from other scenarios in several important respects. In many instances where CMS has packaged different devices into a

[17] http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1506fc.pdf
[18] http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/CMS1506FC_HCPCS_Code.zip
[19] http://www.cms.hhs.gov/hospitaloutpatientpps/downloads/cms-1427-fc.zip
[20] http://www.cms.hhs.gov/hospitaloutpatientpps/downloads/cms-1427-fc_hcpcsmedians.zip
[21] http://www.cms.hhs.gov/hospitaloutpatientpps/downloads/cms-1427-fc_apcmedians.zip

procedure, they represent subordinate, supportive or optional components of the procedure that are ancillary to overall procedure costs.

In contrast, rechargeable and non-rechargeable neurostimulators represent alternative treatment options that drive around 90% of total costs for this highly device-intensive service. We are unaware of other APCs where the magnitude of the cost difference among packaged services is as substantial as proposed for neurostimulators. We are very concerned that packaging these technologies would significantly affect hospital acquisition behavior and hinder beneficiary access to rechargeable neurostimulators due to the large financial losses that would accrue. Finally, there are important clinical differences between rechargeable and non-rechargeable neurostimulators that relate to the CMS policy goal of encouraging efficiency. Unlike many other services, rechargeable neurostimulators increase economic efficiency by eliminating the need for frequent replacement surgeries. However, the proposed policy would provide strong disincentives to offer this option and thereby discourage efficient resource utilization. Creating a new APC for rechargeable neurostimulators would neutralize these incentives and appropriately encourage efficient use of hospital resources.

Economic Value of Rechargeable Neurostimulators and Impacts to the Medicare Program
Boston Scientific worked with a leading expert in cost-effectiveness analysis and medical technology assessment (Dr. John Hornberger) and a leading clinician researcher in pain management and neurostimulation (Dr. Krishna Kumar) to assess the long-term cost consequences of rechargeable versus non-rechargeable spinal cord stimulation using decision-analytic modeling techniques.[22] The results showed that the use of rechargeable neurostimulators may save approximately $120,000 over a patient's lifetime compared to non-rechargeable neurostimulators and result in more than three fewer procedures per patient for battery replacement. More details about this study can be found in Appendix A.

We also modified the model and analysis to examine the budgetary impact of adopting rechargeable systems in the Medicare program for beneficiaries age 65 and older.[23] For this analysis, we used 2006 Medicare payment rates for procedures and services including estimated new technology payments that were approved for rechargeable systems in 2006. We also used actual Medicare annual neurostimulator implant volumes from Medicare 2004 claims data, a 15% annual procedure growth rate, and a 50% estimate of rechargeable neurostimulator market penetration in 2006 from the Millennium Research Group.

The results show that Medicare may save $78 million and avoid over 4,200 repeat procedures over 5 years. The additional upfront costs of rechargeable procedures are likely offset after about 2.5 years. Higher rechargeable adoption rate assumptions result in even greater cost savings. These significant cost savings occur despite incremental new technology payments for rechargeable devices. It should also be noted that these findings significantly underestimate the actual cost savings to Medicare because approximately 50% of Medicare beneficiaries who receive neurostimulators for chronic pain qualify for Medicare benefits based on disability rather than age. Details of this analysis can be found in Appendix B.

The analysis described above incorporates total cost savings (in 2006 dollars) to the Medicare program including neurostimulator implant costs (physician and facility), complication costs, and ongoing costs for other related services during the follow-up period. To put it more simply, at the current Medicare cost of $20,497 (2007 hospital outpatient and physicians payment rates) per non-rechargeable neurostimulator implant, Medicare saves $33,619 per rechargeable neurostimulator implanted (typical 65 year old

[22] Hornberger J, Verhulst E, Clark M, Hernandez J. Long-term cost consequences of a rechargeable spinal cord stimulation (SCS) unit for chronic pain. Presented at the International Spine Intervention Society Annual Meeting, June 13-14, 2006.

[23] Clark M, Hernandez J, Verhulst E, Hornberger J. Budgetary impact of rechargeable spinal cord stimulation (SCS) adoption in the Medicare Program. Presented at the North American Neuromodulation Society Annual Meeting, December 7 – 10, 2006.

Medicare chronic pain patient). The value of rechargeable neurostimulators, considering only procedural implant cost savings due to fewer repeat procedures for battery replacement and ignoring other follow-up cost savings, is 164% more than the initial procedure cost of a non-rechargeable implant procedure. The Medicare payment level that would be set to appropriately recognize device and facility costs of rechargeable neurostimulator implant procedures in a separate APC would be significantly less than the value realized by Medicare. Table I below illustrates this point.

Table I – Value of Rechargeable Neurostimulators to the Medicare Program

Permanent Neurostimulator Implant Procedure	Medicare 2007 Payment Rates – Non-Rechargeable
Hospital Outpatient	
Percutaneous Leads (2)	APC 0040 = $3,477 * 2 = $6,954
Neurostimulator Generator	APC 0222 = $11,164
Programming	APC 0692 = $119
Physician	
Percutaneous Leads (2)	CPT 63650 = $396 * 1.5 = $594
Neurostimulator Generator	CPT 63685 = $461
Programming	CPT 95972 = $75
Total Initial Procedure Costs	$20,497
Total Lifetime Non-Rechargeable Procedures per Patient	5.65
Total Lifetime Rechargeable Procedures per Patient	2.14
Total Procedures Avoided per Patient	3.51
Total $ Saved per Patient	3.51 * $20,497 = $77,944
Medicare Savings per Rechargeable Device Implanted	$77,944 / 2.14 = $33,619

G-codes or C-codes

CMS needs to create a technical pathway to assign rechargeable neurostimulator procedures to the new APC. Boston Scientific and other manufacturers recommended creating G-codes to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator or making the APC assignment based on utilization of existing C-codes. The existing CPT code does not distinguish between the two different devices and there needs to be a way to drive to the appropriate APC using HCPCS codes. One way to accomplish this is through the creation of G-codes. CMS has often done this to distinguish among different devices used or implanted during a procedure. CMS has stated that it prefers to avoid creating G-codes because it places a burdensome administrative process on hospitals. We have consulted with hospitals about this issue and found that they are familiar with this type of coding change and that appropriate payment outweighs any concern about administrative burden in using G-codes. These hospitals already use G-codes routinely for other procedures such as coronary stents and defibrillators and when G-codes are necessary for appropriate payment, this administrative process is not burdensome. However, another option may be to use the existing device C-code (C1820) for rechargeable neurostimulators to assign procedures to a new APC. It is our understanding that CMS has the technical capability to base the APC assignment on the device C-code and we offer this as an alternative for CMS consideration.

External, Non-Implantable Prosthetics, Orthotics, and DME

CMS states in the proposed rule that non-implantable prosthetics, orthotics, and DME are not packaged into the APC weights because hospitals are instructed to bill separately for these items and are paid under the DEMPOS fee schedule. Revenue codes 274 (non-implantable PO) and 290 (non-implantable DME)

are explicitly excluded from the list of packaged revenue codes and hospitals are instructed about this policy in the Medicare claims processing manual.

However, there are certain device c-codes that identify non-implantable PO/DME that overlap with separately billable HCPCS codes. It is unclear whether the costs associated with these c-codes are included in the APC, or whether hospitals should bill other HCPCS codes on the DMEPOS fee schedule. For example, should hospitals bill L8681 (neurostimulator patient programmer) and L8689 (neurostimulator recharger) and be paid separately when they implant a rechargeable neurostimulator? These two codes were assigned a status indicator "A"(Not paid under OPPS. Paid by fiscal intermediaries under a fee schedule or payment system other than OPPS) in Addendum B of the proposed rule.

Recommendations and CMS Requested Actions:

- Create a separate APC for rechargeable neurostimulator implant procedures to recognize the full device and facility costs associated with these procedures.
- Maintain APC 0222 for implantation of non-rechargeable neurostimulators.
- Clarify CMS's intention that hospitals should bill separately for external, non-implantable prosthetics

B. Maintain Separate Payment for Intravascular Ultrasound (IVUS) & Intravascular ECG (ICE) Through Defined Criteria for Packaging Intraoperative Procedures

As discussed above, we think CMS should develop and propose specific criteria before proceeding with packaging. If CMS does decide to proceed, we urge CMS to consider the principles outlined above, which we believe will improve payment accuracy for the relevant procedures (both packaged and unpackaged). Below are specific comments on IVUS and ICE procedures.

IVUS and ICE have extremely low claims volumes
While CMS has said that a non-therapeutic procedure performed in conjunction with any procedure is defined as "integral," we believe that an important measure of whether a procedure is truly integral to a procedure is the percentage of times it is used in conjunction with related procedures. Low volume procedures have minimal impact on median costs when packaged with primary procedures – especially those that are spread across multiple APCs.

IVUS is typically either paired with diagnostic catheterization or stent procedures. An analysis of 2006 OPPS claims data (See Table II below) demonstrates that IVUS (CPT codes 92978 & 92979 for coronary IVUS, 37250 & 37251 for peripheral IVUS) and ICE (CPT 93662) is used less than 1-6.5% of the time in its related diagnostic or intervention. These are de minimis volumes.

Table II IVUS, ICE Percent of Primary Procedure APCs- Multiple Claims

IVUS Coronary			
APC	Total APC Claims Flagged Multiple	Total IVUS Claims 92978, 92979	% IVUS of APC
80	275,769	4,254	1.54%
104	4,020	201	6.49%
656	21,609	1,417	6.56%
Total	301,398	5,872	1.95%
IVUS Peripheral			
APC	Total APC Claims Flagged Multiple	Total IVUS Claims 37250, 37251	% IVUS of APC
229	430,028	553	1.29%
280	124,333	377	0.30%
668	20,681	912	1.98%
Total	575,042	1,842	0.32%
ICE			
APC	Total APC Claims Flagged Multiple	Total ICE Claims 93662	% IVUS of APC
85	41,586	60	0.144%
Total	41,586	60	0.144%

Significant Capital Equipment Investment with IVUS and ICE

CMS has suggested that its proposal to create APC groups "reflect a modest degree of packaging" and that the packaging should include capital-related costs (pg 42649) that would reflect total resource use. IVUS and ICE require the purchase of capital equipment in the $150,000-$200,000 range, which represents a significant investment by the hospitals investing in these technologies. By packaging these costs, those hospitals that purchase the capital equipment will be reimbursed the same amount for the primary procedure as hospitals that do not purchase the equipment. Such a move would create a disparity that rewards hospitals who do not invest in the technology.

IVUS and ICE costs are substantially higher than most proposed intraoperative procedures to be packaged and a limit should be established to maintain separate payment

Table III below shows the median costs associated with IVUS and ICE (taken from CMS's 2005 OPPS median costs, the most recent data available) which are dramatically higher than all but two of the services proposed for bundling, the bundling of these procedures would be anything but "modest."

Table III - CY2007 True Median Costs for Intraoperative HCPCS Codes Proposed for Packaging (Table 12 from Proposed Rule)

HCPCS Code	Short Descriptor	CY2007 SI	CY2007 APC	CY2007 "True" Median Cost	Proposed CY2008 SI
93621	Electrophysiology evaluation	T	85	1470.83	N
93622	Electrophysiology evaluation	T	85	2142.6	N
93609	Map tachycardia, add-on	T	87	1508.63	N
93613	Electrophys map 3d, add-on	T	87	1234.98	N
93623	Stimulation, pacing heart	T	87	925.91	N
93631	Heart pacing, mapping	T	87	NA	N
58110	Bx done w/colposcopy add-on	T	188	NA	N
95955	EEG during surgery	S	213	295.81	N
95829	Surgery electrocorticogram	S	214	211.48	N
95999	Neurological procedure	S	215	42.85	N

95920	Intraop nerve test add-on	S	216	[illegible]	N
67299	Eye surgery procedure	T	235	1165.29	N
73530	X-ray exam of hip	X	261	121.86	N
74300	X-ray bile ducts/pancreas	X	263	95.91	N
74301	X-rays at surgery add-on	X	263	61.03	N
75898	Follow-up angiography	X	263	137.08	N
20975	Electrical bone stimulation	X	340	3320.88	N
G0268	Removal of impacted wax md	X	340	37.24	N
92547	Supplemental electrical test	X	363	51.67	N
96020	Functional brain mapping	X	373	NA	N
78020	Thyroid met uptake	S	399	83.24	N
78478	Heart wall motion add-on	S	399	93.37	N
78480	Heart function add-on	S	399	90.75	N
78496	Heart first pass add-on1	S	399	113.28	N
37250	**Iv us first vessel add-on**	**S**	**416**	2046.24	**N**
37251	**Iv us each add vessel add-on**	**S**	**416**	1914.46	**N**
92979	**Intravasc us, heart add-on**	**S**	**416**	832.45	**N**
93572	Heart flow reserve measure	S	416	NA	N
31620	Endobronchial us add-on	S	670	282.7	N
92978	**Intravasc us, heart add-on**	**S**	**670**	1977.19	**N**
93571	Heart flow reserve measure	S	670	1662.87	N
93662	**Intracardiac ecg (ice)**	**S**	**670**	1296.77	**N**
93320	Doppler echo exam, heart	S	697	103.03	N
93321	Doppler echo exam, heart	S	697	74.74	N
93640	Evaluation heart device	N	n/a	NA	N
93641	Electrophysiology evaluation	N	n/a	NA	N
0126T	Chd risk imt study	N	n/a	NA	Q
0173T	Iop monit io pressure	N	n/a	NA	N
G0275	Renal angio, cardiac cath	N	n/a	NA	N
G0278	Iliac art angio,cardiac cath	N	n/a	NA	N

IVUS median costs continue to be significantly influenced by device costs. As can be seen in the table above the median cost of IVUS is $1,977. Based on current ASPs, about 42% ($840) of 92978's median cost reflects catheter and guidewire costs. CMS recognized APC 0670 as device-dependent in 2006 because there are significant device resources in this APC. CMS should continue to recognize device-intensive procedures and not reverse course on this important principle by incorporating these costs into multiple APCs.

Clinical Value of IVUS in Treating Coronary Artery Disease (CAD)

While IVUS is used in a very limited number of situations, it plays an important role in the treatment of CAD.

IVUS helps physicians correctly assess a lesion's significance to determine its plaque composition. It also helps provide good clinical results by helping to make sure that the stent is "in the right place." Correct stent placement may have important clinical implications. As the attached article (Appendix C) notes, "the use of IVUS to ensure excellent stent apposition and stent expansion should be considered during implantation of drug-eluting stents (DES).[24] IVUS may play a role in achieving better clinical results as discussed in a second article on predictors of subacute stent thrombosis where IVUS was used during the intervention.[25] Another study, entitled Can Routine Ultrasound Influence Stent Expansion

[24] R. Torguson and R. Waksman, Clinical Perspective: The Importance of IVUS Guidance during Contemporary Percutaneous Coronary Intervention With Drug-eluting Stents for the Prevention of Stent Thromosis; Presented at CRT, 2007

[25] Edward Cheneau etc al, Predictors of Subacute Stent Thrombosis Results of a Systematic Intravascular Ultrasound Study; Circulation Vol. 108 No. 1, July 2003

(CRUISE), demonstrates the importance of using IVUS when 88% of PCI subacute thrombosis incidence occurs without IVUS. Also, CRUISE data suggests that IVUS guidance of stent placement may result in a more effective stent expansion which generally improves clinical outcomes.[26]

Packaging IVUS May Discourage Use
Given the clinical role of IVUS it is important to maintain an environment which facilitates its use. While the choices physicians make to address a person's health condition are driven by the clinical need, it must be recognized that eliminating separate payment for IVUS and ICE (with their associated high median costs) may contribute to a hospital atmosphere that discourages use of this important tool.

IVUS can Facilitate more Effective Use of Medicare's Resources
IVUS can also serve to more effectively utilize healthcare resources. As stated on page 42650, CMS wishes to "achieve better health outcomes for Medicare beneficiaries at a lower cost." Clearly, IVUS can help the clinician be more discerning about the need for the deployment of these stents and can reduce Medicare spending on costly interventions.

Due to IVUS and ICE low volumes, high median cost, ability to improve an intervention's clinical outcomes through avoiding reinterventions and adverse advents, we feel that keeping APC 0670 and 0416 separate is advantageous to beneficiaries and CMS.

Recommendations and CMS Requested Actions:

- Preserve coronary IVUS (CPTs 92978, 92979) and non-coronary (peripheral) IVUS (CPT 37250, 37251) procedures as separately payable, non-packaged services.
- Keep ICE (CPT 93662) procedures as separately payable, non-packaged service.
- Maintain current APCs 0670 and 0416

C. APC Assignment for Coronary and Non-Coronary Angioplasty and Atherectomy

In 2008, CMS is proposing to eliminate APC 0081 (Noncoronary Angioplasty or Atherectomy) and to reassign these procedures to one of two new APCs: APC 0082 (Coronary or Noncoronary Atherectomy) and APC 0083 (Coronary or Noncoronary Angioplasty and Percutaneous Valvuloplasty).

For a variety of reasons detailed below, Boston Scientific recommends that CMS reconfigure its proposal as it relates to certain coronary and non-coronary angioplasty (PTCA/PTA) procedures that utilize specialty balloons. Specifically, our request is as follows:

1. Establish a G code for use by hospitals to differentiate coronary and non-coronary PTCA/PTA procedures using specialty balloons from those utilizing standard, non-specialty balloons. For purposes of these comments, Boston Scientific defines "specialty balloons" as balloons which can be used for other than inflation/deflation (i.e., cutting balloons, cold therapy balloons). To operationalize the definition, we suggest that specialty balloons be defined as those which have a median reported cost of more than $800 based on hospital claims for the PTCA/PTA balloon C-code, C1725 (Catheter, transluminal angioplasty, non-laser). Our rationale for establishing an $800 threshold is that non-specialty balloons cost approximately $200-$400, and we are assuming that a specialty balloon would cost at least two times the highest non-specialty balloon.

[26] Peter Fitzgerald et er al, Final Results of the Can Routine Ultrasound Influence Stent Expansion (Cruise) Study; Circulation, Vol. 102 No. 5, August 2000

2. Establish an additional APC for coronary and non-coronary angioplasty procedures using specialty balloons and assign the newly-created G-code to this APC.

3. Base CY08 payment for the new APC on the median costs associated with procedures performed using specialty balloons, as indicated on claims by the reporting of C1725 where the median reported cost is more than $800.

G-code Use Not Burdensome to Hospitals
CMS has stated it prefers to avoid creating G-codes because it places a burdensome administrative process on hospitals. We have consulted with hospitals about this issue and found that they are familiar with this type of coding change and that appropriate payment outweighs any concern about administrative burden in using G-codes. These hospitals already use G-codes routinely for other procedures such as coronary stents and defibrillators and when G-codes are necessary for appropriate payment, this administrative process is not burdensome.

Proposed Payment Does Not Cover Procedure Costs When Specialty Balloons are Utilized
While we understand the approach of creating separate APCs for atherectomy and angioplasty based on median costs, the split fails to recognize the differences in the median costs associated with the use of specialty balloons in PTCA/PTA procedures. To demonstrate the costs of specialty balloon procedures, we analyzed 2006 Medicare single claims data to better understand the costs associated with performing a PTCA/PTA procedure using a specialized balloon.

We began our analysis by reviewing single claims data for all occurrences of codes for coronary and non-coronary angioplasty procedures (CPT codes[27] 35470-35476, 92982 and 92984). We then divided those occurrences into the groups that can be seen below in the column entitled "APC claims and subsets." Our findings, summarized in Table IV below, indicate that the weighted median costs for PTCA/PTA procedures involving a specialty balloon (as indicated by the reporting of C1725 with a cost greater than $800) are approximately 55% higher than costs for all PTCA/PTA procedures in APC 83 (regardless of balloon selection) and 54% higher than costs for all procedures in the same APC.

Table IV. Average and Median Standardized Costs: PTCA/PTA with Specialized Balloon (APC 0083)

APC Occurrences and subsets	Number of Occur-rences	2008 Proposed Payment	2006 Weighted Average Cost	2006 Weighted Median Cost
Occurrences of all codes in APC 0083	118,716	$2,934	$3,671	$2,864
Occurrences of all PTCA/PTA codes in APC 0083	34,275	$2,934	$3,602	$2,852
Occurrences of PTCA/PTA codes in APC 0083 with any C-code	33,622	$2,934	$3,611	$2,858
Occurrences of PTCA/PTA codes in APC 0083 with no C-Code	653	$2,934	$3,155	$2,602
Occurrences of PTCA/PTA codes in APC	28,074	$2,934	$3,256	$2,659

[27] Current Procedural Terminology (CPT) ©2006 American Medical Association. All rights reserved.

0083 with C1725 reported with associated costs ≤$800				
Occurrences of PTCA/PTA codes in APC 0083 with C1725 reported with associated costs >$800 (Assumed to represent specialty balloon use)	**4,947**	**$2,934**	**$5,527**	**$4,411**

While we recognize that CMS uses a "2 times" criterion as one means of determining when costs merit another assignment of a procedure to another APC, as noted earlier in comments regarding rechargeable neurostimulators, it is not intended to be a required criterion that must be met before a new APC can be established. Earlier in this document, we have noted several examples where CMS created new APCs even when the associated costs did not meet the 2 times rule.

Based on Boston Scientific's analysis, the code occurrences for PTCA/PTA procedures using specialty balloons represent only 4% of all code occurrences assigned to APC 0083 and only 14% of all reported PTCA/PTA procedures. Moreover, when we looked at the impact to APC 0083 of removing claims with C1725 that have associated costs of greater than $800, the median costs for APC decrease only slightly, from $2,797 to $2,621 (less than 7%). In other words, creation of a new APC for PTCA/PTA using specialty balloons would have a *de minimis* impact, as shown below in Table V.

Table V - Average and Median Standardized Costs: Impact to APC 0083 of Removing Claims where Specialty Balloons are Reported

APC Claims Impact	Number of Claims	2008 Proposed Payment	2006 Mean Claim Cost	2006 Median Claim Cost
Total claims in APC 0083	33,073	$2,934	$3,628	$2,797
Total claims in APC 0083 with C1725 reported with associated costs >$800	4,902	$2,934	$5,577	$4,376
Total claims in APC 0083 after claims with C1725 reported with associated costs >$800 are removed	28,171	$2,934	$3,289	$2,621

At the same time, ensuring adequate payment for PTCA/PTA procedures using specialty balloons would preserve an important clinical option for physicians and Medicare beneficiaries, as demonstrated by the clinical data described below.

Clinical Data Support Appropriate Use of Specialized Balloon Catheters in PTCA/PTA

Although the majority of coronary and non-coronary angioplasty procedures are performed using non-specialized balloon catheters, there are certain procedures where a specialized balloon may be more desirable. An important example of a specialized PTA balloon catheter that may have important clinical benefits but is also associated with higher costs is the PolarCath™ Peripheral Dilatation System.

The PolarCath System utilizes nitrous oxide inside the balloon during peripheral angioplasty to apply extreme cold to the target lesion and is indicated to dilate stenosis in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of Polytetrafluoroethylene (PTFE) access grafts or native arteriovenous dialysis fistulae. The

PolarCath Peripheral Dilatation system is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents.[28]

Approximately 1 percent of Americans age 50 and older are affected by critical limb ischemia (CLI). People with diabetes mellitus are at particularly high risk.[29,30] Within one year of being diagnosed with CLI, approximately 25 to 30 percent of diabetic patients have a major above- or below-the-knee amputation.[4,31] There are surgical options for limb salvage, such as lower extremity bypass surgery, however endovascular treatments are also utilized. PTA alone, using a standard balloon catheter, is associated with a high frequency of dissection, significant recoil, and high restenosis rates.[32,33]

PolarCath Clinical Data Encouraging

In a recent prospective, multi-center study of angioplasty using a PolarCath balloon (sometimes referred to as cryoplasty) for patients with CLI (Rutherford class 4-6, Fontaine Stage III or IV) plus either stenotic or occlusive lesion(s) obstructing the infrapopliteal arteries with greater than or equal to 50 percent, PolarCath was shown to have a technical success rate of 97 percent, and 93 percent of patients remained free from major amputation at 180 days.[34] At 365 days, 85 percent of patients remained free from major amputation.[35] The Below The Knee (BTK) Chill study concluded that:

- Acute outcomes have been enhanced by low dissection and stent;
- CryoPlasty has provided durable outcomes that have potentially prevented or delayed bypass surgery and amputation; and
- CryoPlasty yielded a high rate of limb salvage at one year and offered a valuable option in the treatment strategy for with CLI.[36]

Findings from other articles support performing angioplasty using a PolarCath balloon. Laird *et al.*, in a discussion of long-term follow-up results from a multi-center study of patients treated with cryoplasty who were then followed for an average of 2 years post-treatment, found that "cryoplasty is a durable therapy, with relatively low long-term restenosis rates compared to other endovascular treatment approaches."[37] Samson RH, *et al.* concluded that "[angioplasty using a PolarCath balloon] appears to be a viable endovascular therapeutic option to achieve longer term patency without compromising options for future interventions. The lack of early occlusions may be due to a low rate of spiral dissection that may be a particular benefit of this form of angioplasty."[38] Finally, Sean Lyden, in a review of a single-center series and a multicenter registry, concluded that "Cryoplasty appears to improve patency over conventional angioplasty and to reduce the need for bailout stenting in femoropopliteal stenoses and occlusions, 10 cm in length. Cryoplasty appears to be promising to treat critical limb ischemia in patients

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[28] Boston Scientific Corporation. PolarCath™ Peripheral Dilatation System Directions for Use.

[29] Hiatt WR. Medical treatment of peripheral arterial disease and claudication. *N Engl J Med.* 2001; 344:1608-1621.

[30] Jaff MR, Biamino G. An overview of critical limb ischemia: today's therapeutic advances are changing the way we evaluate and treat this common and often fatal disorder. *Endovasc Today.* 2004;3(2):44-48.

[31] Wolfe JH, Wyatt MG. Critical and subcritical ischaemia. *Eur J Vasc Endovasc Surg.* 1997;13(6):578-582

[32] Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicenter, randomized controlled trial. *Lancet.* 2005;366(9501):1925-1934.

[33] Kandarpa K, Becker GJ, Hunink MGM, et al. Transcatheter interventions for the treatment of peripheral atherosclerotic lesions: Part I. *J Vasc Interv Radiol.* 2001;12(6):683-695.

[34] Das T. Below The Knee Chill 180-Day Outcomes. Presented at Vascular Interventional Advances (VIVA) 2006 Conference, September 26-29, 2006. Las Vegas, NV.

[35] Das T. Below The Knee Chill 365-Day Outcomes. Presented at American College of Cardiology (ACC) 2007 Annual Scientific Session. March 24-27, 2007. New Orleans, LA.

[36] Ibid.

[37] Laird JR, *et al.* Cryoplasty for the Treatment of Femoropopliteal Arterial Disease: Extended Follow-Up Results. *J Endovasc Ther.* 2006;13(Suppl II): II-52–II-59.

[38] Samson RH, *et al.* CryoPlasty Therapy of the Superficial Femoral and Popliteal Arteries: A Single Center Experience. *Vascular and Endovascular Surgery.* 2007; 40(6): 446-450.

with tibial disease."[39]

These findings illustrate why it is critical for CMS to create a pathway for appropriate payment to allow physicians who feel that using a PolarCath balloon to perform a PTA procedure is in the best interest of their patients to do so without placing a financial burden on their practices or their institutions. By creating a distinct APC for PTA/PTCA using a specialty balloon, CMS will provide this pathway.

Recommendations and CMS Requested Actions:

1. Establish a G code for use by hospitals to differentiate coronary and non-coronary angioplasty procedures using specialty balloons from those utilizing standard, non-specialty balloons. The G-code could read as follows:
    - GXXXX: Transluminal balloon angioplasty, percutaneous; specialty balloon

2. Establish an additional APC for coronary and non-coronary angioplasty procedures using specialty balloons and assign the newly-created G-code to this APC. The APC could read as follows:
    - APCXXXX, Coronary and non-coronary angioplasty, specialty balloon

3. Base CY08 payment for the new APC on the median costs associated with procedures performed using specialty balloons, as indicated on claims by the reporting of C1725 where the median reported cost is more than $800.

D. Proposed Composite APC for Cardiac Electrophysiologic Evaluation and Ablation

Boston Scientific appreciates CMS efforts in proposing to create composite APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), by bundling payment for five cardiac electrophysiologic CPT codes (CPTs 93619, 93620, 93650, 93651, 93652) as members of the category of intraoperative services that were previously assigned to APCs 0085 and 0087. We also see potential merit in the proposal to individually pay for procedures that do not meet the criteria for payment under the composite APC by reconfiguring APCs 0084, 0085, and 0086.

Boston Scientific believes the proposed bundling approach can be an efficient and effective way to optimize the use of available hospital outpatient claims data to establish more appropriate payment rates for the composite service and represent the resources associated with performing the common combinations of these services that are clinically typical. While this initial attempt to create composite APCs appears to achieve the goals of simplification and more accurate recognition of procedural costs, we are wary of expanding this mechanism too quickly. Further scrutiny of this method and its long term impact is warranted before the mechanism is employed in a broader manner. Monitoring and reporting the impact of the initial two examples is a logical next step before other additional Composite APCs are contemplated.

[39] Lyden, SP. Indications and Results with Cryoplasty in the Treatment of Infrainguinal Arterial Occlusive Disease. *Vascular*. 2006; 14(5): 290-296.

Recommendations and CMS Requested Actions

- Proceed with caution on the proposal to create a composite APC for EP Evaluation and Ablation
- Monitor, report, and discuss the impact of the initial two proposed Composite APCs prior to any broader application of this mechanism.

E. Urethral Bulking – Device Payments Disappear Under Proposed OPPS/ASC Approach.

Boston Scientific appreciates CMS efforts to recognize the resources used in device-intensive procedures under the new ASC payment system. However, we are concerned some payments may be inadequate for some procedures that do not qualify as "device-intensive" but now currently receive DMEPOS fee schedule payments.

One such procedure of particular concern to us is CPT code 51715 - *Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck.*

CPT code 51715 is currently billed and paid in conjunction with either of the following two HCPCS codes under the existing ASC system:

> L8603 - INJECTABLE BULKING AGENT, COLLAGEN IMPLANT, URINARY TRACT, 2.5 ML SYRINGE, INCLUDES SHIPPING AND NECESSARY SUPPLIES
>
> L8606 - INJECTABLE BULKING AGENT, SYNTHETIC IMPLANT, URINARY TRACT, 1 ML SYRINGE, INCLUDES SHIPPING AND NECESSARY SUPPLIES

These codes are currently billed and paid based on the number of syringes utilized in the procedure.

CMS has determined that under the new ASC system, there should be no separate payment for such Level II HCPCS device codes as they are not separately payable and are considered to be packaged under the OPPS. CMS has further determined that there should only be separate recognition of their costs if they meet the CMS definition of device-intensive.

However, by applying the four-year transition to the existing payment for the primary procedure code alone (CPT code 51715 in this instance) and blending its 2007 ASC payment with this code's proposed 2008 OPPS payment, CMS is entirely ignoring the existing device payments, which essentially disappear and will take until 2011 to be recognized in any meaningful way under this approach.

The solution appears to be fairly straightforward. CMS should exempt CPT code 51715 from the four-year transition and immediately adopt the "fully implemented" ASC payment rate of $1,250.26 for this service to provide a more appropriate transition and recognition of the procedure's device costs. There is a clear precedent for this, as CMS has exempted transitions for any procedures newly approved for ASC payment in 2008 and beyond, given that there is no relevant payment within the current ASC system upon which to base the transition. We believe that the immediate loss of the current ASC reimbursement associated with the loss of billing Level II HCPCS codes associated with CPT code 51715 makes this an analogous case deserving the same remedy.

In the preamble to the CY 2008 ASC final rule (p.42492 of 8/2/07 Federal Register) CMS stated: *"our final policy of a 4-year transition to phase in the revised ASC payment system should mitigate the potential disruption in care that could be associated with significant increases or decreases in payments for specific surgical procedures under the revised payment system."* While we agree with this statement

and the four-year transition in general, we believe that its application has had an unintended consequence for this subset of ASC procedures (specifically for CPT code 51715) and needs to be adjusted for CY 2008.

Recommendation and CMS Requested Action:

- Exempt CPT code 51715 from the four-year transition policy associated with the implementation of the new ASC payment system, thereby establishing 2008 ASC payment for urethral bulking at 65% of the OPPS payment rate.

F. Appropriate APC Assignment for Uterine Fibroid Embolization

In follow-up to a comment we made to last year's proposed rule, Boston Scientific is again requesting reconsideration of the current APC assignment of CPT 37210 - *Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure*. We continue to believe that the current assignment to APC 0202 - (*Level X Female Reproductive Procedure*) is inappropriate based on the lack of clinical and resource homogeneity between the UFE procedure and the other procedures assigned to that APC.

We note that the APC Advisory Panel, at their most recent meeting, recommended reclassifying CPT code 37210 to APC 0229 or APC 0667. Given the relatively unique nature of the UFE procedure, we believe that the optimal solution would be to assign the procedure to its own APC.

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.

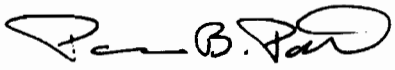
Recommendation and CMS Requested Action:

- Reassign CPT code 37210 to a more appropriate APC either by creating a new APC to accommodate this relatively unique procedure or by adopting the recent reassignment recommendation of the APC Advisory Panel.

****

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,



Parashar Patel
Vice President, Health Economics & Reimbursement
Boston Scientific Corporation

cc: Carol Bazell, MD, Hospital & Ambulatory Policy Group
Terry Kay, Hospital & Ambulatory Policy Group
Herb Kuhn, Deputy Administrator
Scott Reid, Boston Scientific Corporation
Elizabeth Richter, Center for Medicare Management
Joan Sanow, Hospital & Ambulatory Policy Group
Don Thompson, Center for Medicare Management

Appendix A

Presented at the International Spine Intervention Society Annual Meeting, June 13 – 15, 2006

Poster Presentation

Long-term Cost Consequences of a Rechargeable Spinal Cord Stimulation (SCS) Unit for Chronic Pain

John Homberger[1,2,3] Eric Verhulst[1] Mary Ann Clark[4] John Hernandez[4]

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[2]Department of Veterans Affairs, Palo Alto, CA
[3]Department of Medicine, Stanford University School of Medicine, Stanford, CA
[4]Advanced Bionics, A Boston Scientific Company, Valencia, CA

BACKGROUND

- Many published studies have concluded that SCS is a cost-effective therapy for managing chronic intractable pain.
- No data exist comparing the long-term costs associated with non-rechargeable SCS (NRC-SCS) versus newer, higher cost, rechargeable SCS (RC-SCS) systems.
- Rechargeable SCS adoption may be influenced by payers' willingness to pay for the added cost of these RC-SCSs.
- Cost-savings gained through reductions in replacement procedures due to reduced battery life will provide valuable evidence for payer decision-making.

OBJECTIVES

- Using decision-analytic modeling techniques, assess whether patients receiving RC-SCSs (for chronic pain due to FBSS) have lower lifetime costs than patients with NRC-SCSs.
- Determine the magnitude of the economic impact.
- Perform sensitivity analyses to determine key model variables that most affect costs.

METHODS

- Perspective: US Centers for Medicare and Medicaid Services
- Study Design: Cost analysis using a decision analytic model
- Model Structure: State-transition model – annual cycle length
- Base case: Literature review for model parameters; Medicare cost data (indirect costs excluded); age-dependent mortality - National Center for Health Statistics
- One-way sensitivity analyses conducted

MODEL STRUCTURE

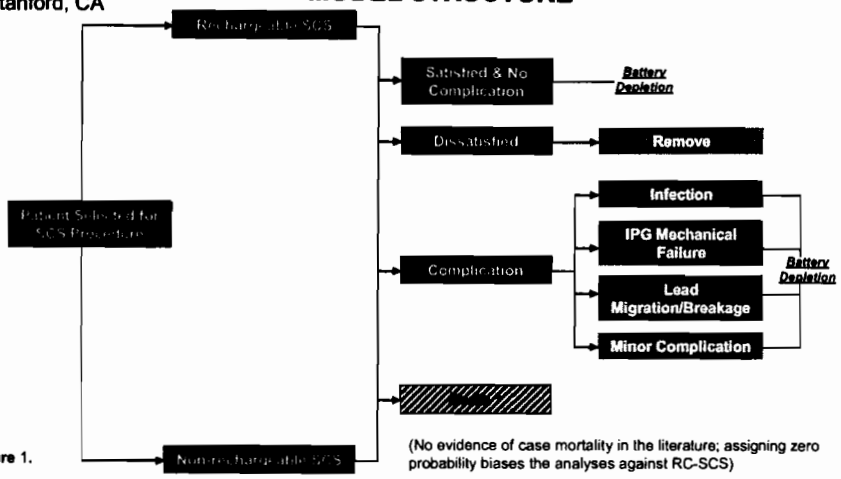


Figure 1.

(No evidence of case mortality in the literature; assigning zero probability biases the analyses against RC-SCS)

** Allows for death from other causes*

BASE CASE DATA ASSUMPTIONS

Parameter	Basecase Estimate	Data Source
Patient Demographics:		
Mean Age at First Implantation, Years	46	Mekhail 2004
Proportion Female	69%	Mekhail 2004
Procedural Complications:	34.3%	Turner 2004
Infection	4.5%	Turner 2004, Cameron 2004, Bell 1997
IPG Removal or Replacement	11.0%	Turner 2004
Lead Repositioning	14.0%	Bell 1997
Lead Replacement	7.3%	Bell 1997
IPG Removal, Given Mechanical Failure	1.2%	Mekhail 2004
Battery Life:		
Rechargeable	23.3 yrs.	Assumption
Non-rechargeable	5.3 yrs.	Published manufacturer data
Reimplanting Device After Battery Depletion:	100%	Expert opinion
Costs:		
Initial Procedure	$26,005 (NRC) $35,109 (RC)	Centers for Medicare and Medicaid Services (CMS) 2006
Replace Lead	$7,338	CMS 2006
Reposition Lead	$3,421	CMS 2006
Remove IPG w/o Replacement	$8,286	CMS 2006
Replace IPG	$11,932 (NRC) $21,036 (RC)	CMS 2006
Infection	$27,378 (NRC) $36,482 (RC)	CMS 2006
Minor Complications	$350	Assumption
Annual Cost With SCS	$5,989	CMS 2006; Bell 199, Mekhail 2004
Annual Cost After SCS Removal	$34,366	CMS 2006; Bell 1997, Mekhail 2004
Policy Variables:		
Fixed Annual Discount Rate	3%	Lipscomb 1996
Time Horizon, Years	70	Assumption (lifetime)

Table 1.

ANNUAL FOLLOW-UP COSTS AND RESOURCE USE

		With SCS Implanted	
Type of Service	**Unit Cost**	**# Units**	**Total Cost**
Office Visit	$51	9.1	$462
ER Visit	$192	0.4	$67
Medical Hospitalization	$4,248	0.7	$2,974
Nerve Blocks	$306	2.5	$765
Surgery	$8,689	0	$0
MRI	$472	0.1	$47
CT	$294	0.3	$74
Rx			$1,250
Rehab			$350
TOTAL Annual Cost			***$5,989***

Table 2.

BASE CASE – AVERAGE OUTCOMES PER PATIENT (OVER LIFETIME)

Outcomes	**Non-Rechargeable (NRC)**	**Rechargeable (RC)**	**Difference (RC-NRC)**
Median Battery Life (years)	5.3	23.3*	18
Life Expectancy	34.2	34.2	0
Total SCS Procedures	5.11	1.82	-3.3
SCS Implant Costs	$90,637	$48,509	-$42,128
Complication Costs	$18,179	$17,032	-$1,147
Removal Costs for Dissatisfaction	$231	$92	-$139
Follow-up Costs	$249,889	$173,264	-$76,625
Total Lifetime Costs per Patient	**$358,937**	**$238,890**	**-$120,046**

Table 3.

CUMULATIVE COSTS PER PATIENT

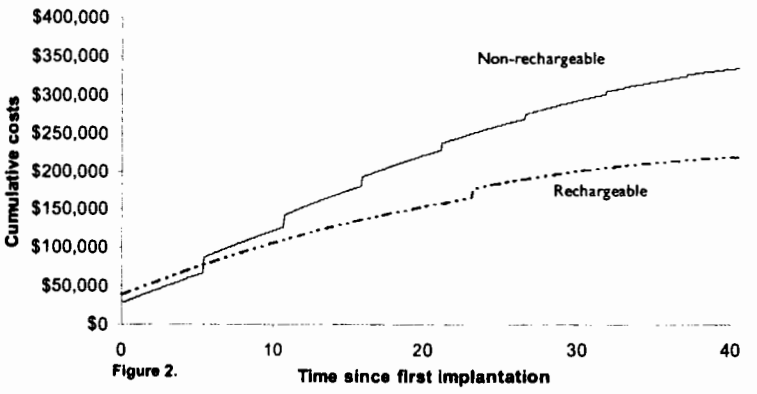


Figure 2.

Assuming median battery life = 23.3 years.

Although RC-SCS is initially more expensive than NRC-SCS, RC-SCS may pay for itself at the time a second implant is needed (e.g., 5.3 years in the base case).

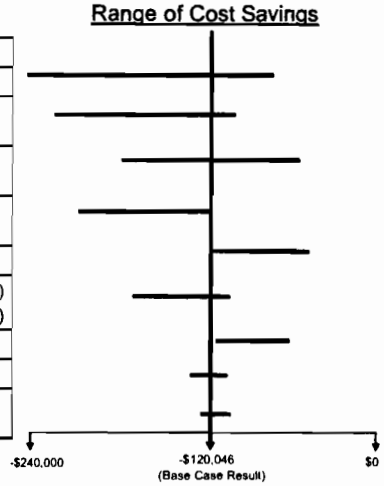
RC-SCS IS COST-SAVING FOR ALL ONE-WAY SENSITIVITY ANALYSES

Most Sensitive Variables

Model Variable	**Input Range**
Discount Rate	0% - 5%
Annual $ After SCS Removal	$29,211 - $68,732
Mean Age at 1st Implant	30 – 60yrs
P Battery Replacement	85% - 100%
Time Horizon	20 – 70yrs
Initial Procedure Cost	$22,104-$52,010(N) $29,843-$70,218(R)
P Dissatisfied	0.01% - 20%
Complication Rate	25.7% - 42.9%
Annual Cost with SCS	$5,091 - $11,978

Figure 3.

Range of Cost Savings



SUMMARY

- This economic model projects that the use of RC-SCS for chronic pain may save about $120,000 over a patient's lifetime compared to NRC-SCS.
- The use of RC-SCS may result in more than 3 fewer procedures for battery replacement over a patient's lifetime.
- Most of the cost savings are due to reduced SCS implant costs for battery depletion and follow-up costs.
- Cost savings occur despite the added upfront costs of about $9,000 for RC-SCS.
- RC-SCS was found to be cost-saving in all one-way sensitivity analyses.
  - Range of lifetime savings: -$67,000 to -$234,000
- Effect of average battery life
  - Under base case, median battery life was 4.5-fold longer with RC-SCS (assumption) than with NRC-SCS. Lifetime cost-savings: $120,046
  - If lower to 2-fold longer with RC-SCS, then RC-SCS still cost-saving, but savings falls to $64,581.

CONCLUSIONS

- RC-SCS should reduce the number of reimplantation procedures due to battery depletion as well as reduce the number of complications associated with reimplantation procedures.
- Although the initial cost of RC-SCS is significantly higher than NRC-SCS, these costs are likely offset at the time of reimplantation with NRC, resulting in cost savings to payers and the health system.

Appendix B

Presented at the North American Neuromodulation Society Annual Meeting, December 7 - 10, 2006

Poster Presentation

Budgetary Impact of Rechargeable Spinal Cord Stimulation (SCS) Adoption in the Medicare Program

Mary Ann Clark [1] John Hernandez [1] Eric Verhulst [2] John Hornberger [2,3,4]

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[4] Department of Medicine, Stanford University School of Medicine, Stanford, CA

BACKGROUND

Additional procedures and associated risks due to non-rechargeable spinal cord stimulation (N-SCS) battery depletion are costly to the Medicare Program. Rechargeable SCS (R-SCS) are expected to dramatically extend battery life and result in lower costs due to reductions in unnecessary procedures. The Centers for Medicare and Medicaid Services (CMS) determined that R-SCS represents a "substantial clinical improvement" over N-SCS. In 2006, CMS significantly increased Medicare facility payments for R-SCS in all sites of service by approximately $9,000. The purpose of this research is to project the budget impact of the adoption of R-SCS for Medicare chronic pain patients.

METHODS

- Perspective: US Centers for Medicare and Medicaid Services
- Study Design: Budget impact analysis using a decision analytic model.
- Model Structure: State-transition model – annual cycle length
- Base case: Literature review for model parameters; Medicare cost data (indirect costs excluded); Medicare SCS demographic data; age-dependent mortality data – National Center for Health Statistics
- Budget Impact Analysis: Medicare SCS volume and annual growth data; 50% R-SCS adoption rate assumed
- One-way sensitivity analyses conducted

Table 1 - Basecase Data Assumptions

Parameter	Basecase Estimate	Data Source
Patient demographics:		
Mean age at first implantation, years	65	Centers for Medicare and Medicaid Services (CMS) 2004
Proportion female	57%	CMS 2004
Procedural Complications:	34.3%	Turner 2004
Infection	4.5%	Turner 2004, Cameron 2004, Bell 1997
IPG removal or replacement	11.0%	Turner 2004
Lead repositioning	14.0%	Bell 1997
Lead replacement	7.3%	Bell 1997
IPG removal, given mechanical failure	1.2%	Mekhail 2004
Costs:		
Initial Procedure	$26,005 (NRC) $35,109 (RC)	CMS 2006
Replace Lead	$7,338	CMS 2006
Reposition Lead	$3,421	CMS 2006
Remove IPG w/o replacement	$8,286	CMS 2006
Replace IPG	$11,932 (NRC) $21,036 (RC)	CMS 2006
Infection	$27,378 (NRC) $36,482 (RC)	CMS 2006
Minor complications	$350	Assumption
Annual cost with SCS	$5,989	CMS 2006; Bell 1997, Mekhail 2004
Annual cost after SCS removal	$34,366	CMS 2006; Bell 1997, Mekhail 2004
Battery Life:		
Rechargeable	10 yrs.	Assumption
Non-Rechargeable	2.2 yrs.	VanBuyten 2003
Reimplanting device after battery depletion:	100%	Expert opinion
Policy variables:		
Fixed annual discount rate	3%	Lipscomb 1996
Time horizon, years	70	Assumption (lifetime)
Budget Impact Parameters:		
# Medicare SCS patients	4,560	Medicare 2004 claims data
Annual Medicare SCS patient growth rate	15%	Assumption
Rechargeable SCS adoption rate	50%	Millennium Research Group estimate

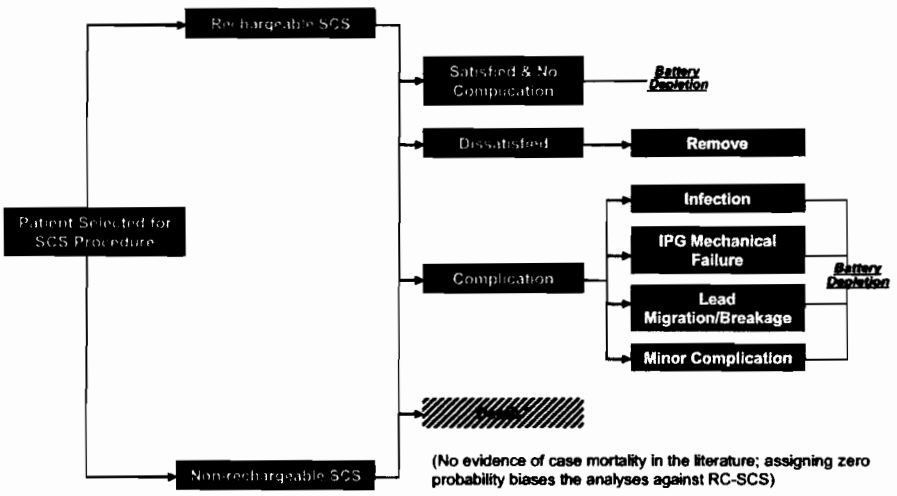


Figure 1 - Model Structure

RESULTS

Table 2 – Lifetime Impacts Per Medicare SCS Patient

Outcomes	Non-Rechargeable (NRC)	Rechargeable (RC)	Difference (RC-NRC)
Mean Battery Life (years)	2.2	10*	7.8
Life Expectancy	18.1	18.1	0
Total SCS Procedures	5.59	2.11	-3.5
SCS Implant Costs	$117,520	$60,708	-$56,812
Complication Costs	$13,267	$10,692	-$2,575
Removal Costs for Dissatisfaction	$300	$115	-$185
Follow-up Costs	$195,110	$117,690	-$77,420
Total Lifetime Costs per Medicare SCS patient	$326,197	$189,205	-$136,992

* Assumption

Figure 2
5-Year Medicare Cumulative Cost Savings with Rechargeable SCS Adoption

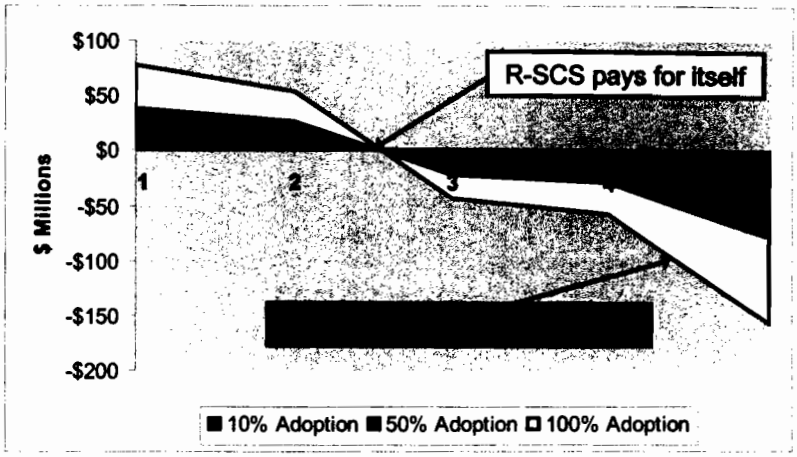
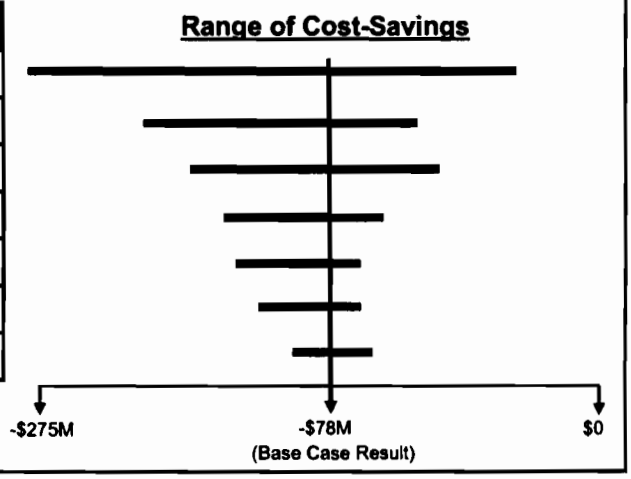


Figure 3 – Sensitivity Analysis Results

Model Variable	Input Range
Battery Life NRC	1 - 5 years
Annual $ with SCS	$2,994 - $11,978
Annual $ SCS removed	$8,592 - $68,732
Annual Discount Rate	0% - 5%
P Dissatisfied	0.01% - 20%
Complication Rate	25.7% - 42.9%
Annual Patient Growth	5% - 25%



SUMMARY

- This budget impact model projects that given a 50% adoption rate of R-SCS, the Medicare Program will save approximately $78 million over 5 years.
  - If R-SCS fully replaces N-SCS, the projected 5-year savings is over $156M.
- Added up-front costs of R-SCS are offset after about 2.5 years.
- The use of R-SCS by Medicare patients may result in 3.5 fewer procedures for battery replacement over a patient's lifetime.
- Most of the cost savings are due to reduced SCS implant costs for battery depletion and follow-up costs.
- R-SCS was found to provide budgetary cost savings over 5 years in all one-way sensitivity analyses
  - Budgetary cost savings were most sensitive to changes in non-rechargeable battery life – ranging from $2M (5 year battery life) to $274M (1 year battery life) in cost savings over 5 years.

CONCLUSIONS

- Increasing adoption of R-SCS in the Medicare Program could lead to budgetary cost savings of as much as $156M over 5 years.
  - Cost savings are due to reductions in the number of repeat procedures from battery failure and their related complications
- Significant cost savings are projected despite incremental pass-through and new technology add-on payments for R-SCS of about $9,000 per Medicare SCS patient.

★721

The Importance of IVUS Guidance during Contemporary Percutaneous Coronary Intervention With Drug-Eluting Stents for the Prevention of Stent Thrombosis

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Background: Drug eluting stents (DES) proven to reduce restenosis in both the pivotal randomized trials and post approval registries. The incidence of stent thrombosis is increasing as the use of DES becomes more liberal. We aim to identify angiographic and procedural predictors of stent thrombosis from an unrestricted population of lesions receiving DES.
Methods: From a total of 5066 lesions treated since April 2003 we identified 62 which presented within 1 year of initial stent implantation with stent thrombosis. Logistic regression analysis was conducted to determine the angiographic and procedural correlates of stent thrombosis. All the univariate predictors of stent thrombosis that were statistically significant were used in a stepwise multivariate Cox regression model with an entry of 0.05 and a stay of 0.2.
Results: Compared with lesions without stent thrombosis, patients with stent thrombosis had a higher frequency of being in the LAD, proximal segment of artery, receive a Cypher stent, not undergo IVUS guided PCI, received smaller stents, and start off with larger lesion diameter stenoses. Univariate analysis detected correlates of stent thrombosis, including lesions in the LAD, proximal segment of the artery, the lack of IVUS guided angioplasty, and stent diameter ($p \leq 0.05$). Multivariate analysis, however, detected only the lack of IVUS guided angioplasty as an independent predictor of stent thrombosis within 1 year. (Table)
Conclusion: The use of IVUS to ensure excellent stent apposition and stent expansion should be considered during implantation of DES in attempt to prevent stent thrombosis.

Table:

Univariate Logistic Regression			
	Odds Ratio	95% Confidence Interval	P value
LAD Lesion	1.82	1.10-3.01	0.019
Proximal Lesion	1.66	1.00-2.76	0.050
Cypher Stent	1.67	0.93-2.99	0.086
Lack of IVUS	2.23	1.35-3.69	0.002
Type C	1.22	0.68-2.19	0.507
Pre Dilatation	1.49	0.90-2.13	0.121
Post Dilatation	1.21	0.69-2.13	0.504
Stent Diameter	0.43	0.22-0.87	0.019
Pre Diameter Stenosis	9.27	0.66-130.15	0.099
Multivariate Logistic Regression			
Cypher Stent	1.86	0.98-3.52	0.056
Lack of IVUS	2.41	1.39-4.18	0.002
LAD	1.65	0.95-2.85	0.076
Pre Diameter Stenosis	14.43	0.68-308.48	0.088

Federation of
American
Hospitals™

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September 14, 2007

Charles N. Kahn III
President

VIA HAND DELIVERY

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Washington, DC 20201

Re: CMS-1392-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates: Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (Vol. 72, No. 148), August 2, 2007

Dear Mr. Weems:

This letter presents the comments and recommendations of the Federation of American Hospitals ("FAH") to certain aspects of the Hospital Outpatient Prospective Payment System ("OPPS") and calendar year ("CY") 2008 payment rates which were published by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on August 2, 2007 (the "proposed rule").

The Federation of American Hospitals is the national representative of investor owned or operated community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay acute, rehabilitation, psychiatric, cancer, and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. The FAH greatly appreciates the opportunity to comment on CMS' proposed rule regarding the outpatient prospective payment system updates for CY 2008.

I. Proposed Updates Affecting OPPS Payments

- **"OPPS: Packaged Services", 42648 – 42690**

"We are considering the possibility of greater bundling of payment for major hospital outpatient services, which could result in establishing OPPS payment for episodes of care... We are currently considering the complex policy issues related to the possible development and implementation of a bundled payment policy for

hospital outpatient services that involves significant services provided over a period of time which could be paid through an episode-based payment methodology, but we consider this possible approach to be a long-term policy objective. We encourage public comments regarding the specific hospital outpatient services, clinical and financial issues, ratesetting methodologies, and operational challenges we should consider in our exploratory work in this area."

FAH supports the principles of a prospective payment system where some services are packaged into the payment rates of other services. FAH also supports some level of encounter or episode-based payments such as those described by the proposed composite APC methodology for prostate brachytherapy and cardiac electrophysiologic services and those recommended by FAH in these comments. However, we caution CMS against establishing a single composite APC payment for significant services provided over a period of time. FAH is concerned about the potential negative impact to recurring therapeutic services for Medicare beneficiaries. FAH believes it would be difficult to set appropriate rates for recurring therapeutic services such as chemotherapy, infusion therapy, cardiac rehab, and wound care. FAH believes this could be especially problematic when these services vary in volume, intensity, and complexity based on the specific patient. We urge CMS to explore and implement encounter-based payment relative to single hospital encounters only.

"In the case of much of the care furnished in the HOPD, we believe that it is appropriate to view a complete service as potentially being reported by a combination of two or more HCPCS codes, rather than a single code, and to establish payment policy that supports this view... Specifically, as our initial substantial step toward creating larger payment groups for hospital outpatient care, we are proposing to package payment for items and services in the seven categories listed below into the payment for the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories are the HCPCS codes that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support...

Specifically, we are proposing to package the payment for HCPCS codes describing the dependent items and services in the following seven categories into the payment for the independent services with which they are furnished:

- *Guidance services*
- *Image processing services*
- *Intraoperative services*
- *Imaging supervision and interpretation services*
- *Diagnostic radiopharmaceuticals*
- *Contrast media and*
- *Observation services."*

The FAH supports the principles of a prospective payment system and commends CMS' efforts in continuing to analyze hospital claims data in an effort to develop more appropriate payment rates for hospitals especially through the use of multiple procedure claims. FAH supports CMS' view of a complete service as potentially being reported by a combination of two or more HCPCS codes for some services. However, FAH encourages CMS to carefully evaluate the overall impact of packaging on all hospitals.

FAH supports the packaging of contrast materials. FAH agrees with CMS that these products are always used as a dependent service and are appropriately packaged into the independent procedure performed. Additionally, FAH supports the packaging of the lists of "guidance" procedures, "image processing" procedures, and "intraoperative" procedures shown in tables 8, 10, and 12 respectively. FAH agrees that all of the HCPCS codes listed in these tables are dependent procedures which can be appropriately packaged or conditionally packaged into the independent procedure. FAH recommends CMS finalize these 4 proposals.

FAH supports the packaging of diagnostic radiopharmaceuticals whose median day costs are at or below $200. FAH urges CMS to continue to pay separately for diagnostic radiopharmaceuticals whose median day costs exceed $200. In addition, FAH recommends CMS establish edits for nuclear medicine procedures requiring the presence of revenue code 343 or 344 to ensure the diagnostic and therapeutic radiopharmaceuticals are always separately reported.

While FAH supports packaging in general, we urge CMS to significantly modify its proposal to package all of the radiology supervision and interpretation (S&I) services. The radiology S&I codes are always reported in conjunction with a surgical code. FAH believes it is appropriate to consider the combination of the surgical and radiology S&I code together to represent the service and to establish a single APC for the service. However, many of the surgical codes have already been packaged by CMS, which already achieves this methodology. FAH believes it is inappropriate to package and/or conditionally package both codes.

FAH recommends CMS package only the 33 radiologic S&I codes where the surgical code is separately paid. FAH urges CMS to retain separate payment of the 93 radiology S&I codes where the surgical code is packaged. FAH believes packaging of these 93 services could create inadequate payment for services in many scenarios. For example in the proposed rule, CMS indicates that Myelography CPT code 72265 is reported with lumbar CT CPT code 72132 sixty-two percent (62%) of the time. This means myelography is reported by itself or with other services 38% of the time. FAH reviewed the excel file made available by CMS which shows the medians by HCPCS and noted that CPT code 72265 was only reported by itself 43 times in CY2006 but was reported with something other than lumbar CT over 12,400 times. FAH does not have the detail claims data to determine what other combination of services were commonly performed with the myelography. We are concerned that these are likely various combinations such that the cost of the myelography would not be reflected in their APC rates.

As an alternative to packaging, FAH recommends CMS review claims data for the 93 radiological S&I codes to identify high volume combinations of services and evaluate these combinations for composite APC payment. For example in the proposed rule, CMS indicates that Myelography CPT code 72265 is reported with lumbar CT CPT code 72132 sixty-two percent (62%) of the time. While FAH believes it would be inappropriate to conditionally package CPT code 72265, FAH supports establishment of a composite APC payment for the combination of the Myelography and lumbar CT together. Using a composite APC in this manner would allow appropriate payment for Myelography alone, CT alone, and the combined service. FAH believes CMS may overpay lumbar CT when performed alone if the myelography is packaged especially since almost half of the lumbar CT claims did not include myelography. FAH also believes the hospital will be significantly underpaid when Myelography is performed without lumbar CT but in addition to another OPPS service such as an ED visit or other radiological service.

FAH is opposed to the packaging of all observation services. CMS has proposed multiple packaging and composite APC payment methodologies for CY2008. FAH urges CMS to delay any changes relative to observation payment until CMS can further evaluate encounter based payment methodology. FAH believes establishing encounter based payment that specifically includes observation in the composite APC rates would be a more effective packaging methodology. FAH urges CMS to retain the current observation payment methodology until further research and consideration of composite APCs can be performed. FAH recommends CMS analyze the types of services provided in combination with observation and consider developing composite APCs for those combined services.

> *"We believe that we could use the data from many more multiple procedure claims by creating APCs for payment of those services defined as frequently occurring common combinations of HCPCS codes for component services that we see in correctly coded multiple procedure claims.*
>
> *Our examination of data for multiple procedure claims identified two specific sets of services that we believe are good candidates for payment based on the naturally occurring common combinations of component codes that we see on the multiple procedure claims. These are low dose rate (LDR) prostate brachytherapy and cardiac electrophysiologic evaluation and ablation services...*
>
> *We look forward to public comments on the concept of composite APCs in general and, specifically, the two new proposed encounter-based composite APCs for CY 2008, and we hope to involve the public and the APC Panel in the creation of additional composite APCs. Our goal would be to use the many naturally occurring multiple procedure claims that cannot currently be incorporated under the existing APC structure, regardless of whether the naturally occurring pattern of multiple procedure claims prevents the development of single bills."*

As noted throughout these comments, FAH supports the composite APC methodology and would like to see it further considered for other service combinations. FAH approves of both composite APCs proposed by CMS and urges CMS to finalize these composite APCs. FAH commends CMS for its continued efforts to utilize multiple APC claims and to establish appropriate payment for complex hospital services. However, FAH believes that composite APCs differ significantly from conditional packaging methodology and therefore FAH urges CMS to assign a status indicator other than Q to services subject to composite APC methodology.

- **"OPPS: Partial Hospitalization", 42690 – 42693**

The legislative intent of the partial hospitalization benefit was to provide Medicare beneficiaries with an alternative to inpatient psychiatric care that would allow patients to move more quickly out of the hospital to a less intensive, "step-down" program or that would prevent the need for hospitalization. Before the advent of this benefit, Medicare's mental health benefit structure was limited to inpatient psychiatric hospital care or outpatient, office-based visits. The partial hospitalization benefit created an important intermediary service between outpatient, office-based visits and inpatient psychiatric care.

A. Significant Partial Hospitalization Payment Reduction

The partial hospitalization payment rate, which declined by more than 12% in 2006, was further reduced by another 5% in 2007. CMS is proposing to again reduce the partial hospitalization rate by an additional 24% in CY08. For many FAH members, the cost of providing partial hospitalization services exceeds the current payment rate.

The impact has been that partial hospitalization programs (PHP) that have been the most clinically intensive have struggled to continue to operate these types of programs as payment rates have dramatically declined. For the first time, CMS has clearly documented in the proposed outpatient PPS rule that PHPs that offer the most structured, clinically intensive programs have substantially higher median costs than other PHP programs. The CMS analysis clearly shows the need to focus on the PHPs that are meeting the highest acuity needs of Medicare patients and find ways to make sure that these programs can continue to meet this critical need. Restoring the partial hospitalization rate would ensure Medicare beneficiaries continuing access to this essential level of care.

B. PHP Congressional Intent

As authorized by Congress, Medicare beneficiaries eligible for PHP are individuals who would require inpatient psychiatric care in the absence of partial hospitalization. Moreover, CMS in subsequent interpretive guidelines and program memoranda have stated that partial hospitalization programs are designed to treat patients who exhibit severe or disabling conditions related to an acute psychiatric condition or an exacerbation of a severe and persistent mental disorder. CMS also has stated that partial

hospitalization may occur in lieu of either admission to an inpatient hospital or a continued inpatient hospitalization. Clearly, the intent was to provide a highly structured, clinically intensive PHP for patients who either were stepping down from hospital care or were using PHP as a diversion from hospital care.

As the new Medicare inpatient psychiatric prospective payment system (IPPPS) reaches full implementation (with major incentives to shorten the length of inpatient stays), the importance of partial hospital services for step-down and diversion from inpatient services becomes more important to the successful functioning of the total system. Medicare's transition to 100% IPPPS rates will be complete for cost-reporting periods beginning in 2008.

C. Intensive Provider PHP Settings Penalized.

CMS data shows that PHP programs providing four or more units of service per day (in other words, programs that are highly intensive) have a substantially higher median cost than the overall median cost per day.

Hospital-based programs (in which 66% of their days have four or more units of service) have a median cost of $218 vs. $186 for their overall median costs. It should also be noted that although two-thirds of the days offered by hospital-based PHPs have four or more units of service, this understates the degree to which hospital-based programs are structured around four or more units of services. On some days in these programs, a patient may only get three services (due to leaving early for illness or other reasons). This number also does not take into account patients that would be transitioning out of the program. However, these programs' cost structures are based on a model of care that is prepared to deliver – and in most cases do deliver – four or more units of service per day.

Community mental health centers (in which 36% of their days have four or more units of service) have a median cost of $191 vs. $178 for their overall median costs.

D. Adequate PHP Payment.

To meet the original congressional intent of the PHP program (highly structured, clinically intensive), and CMS's directives, it is imperative to provide the necessary financial incentives to providers to offer the appropriate number of units of services per day to meet the clinical needs of the patient. Currently, the most structured, clinically intensive programs, which generally provide four or more services per day, are penalized with lower payment rates than their median costs.

The PHPs that have been meeting the needs of the most "acute" Medicare patients should not be penalized for meeting this critical need, but in fact should receive the necessary payments to allow these programs to continue to offer this highly intensive model of care.

To achieve this objective, there must be an upward adjustment to the payment level for PHP from the proposed rate. The proposed rate reduction of 24% (resulting in a per diem

of $178) is woefully inadequate and would continue to place a growing burden on those programs that are providing the most structured, clinically intensive programming, which will likely result in fewer of these programs being offered in the future. This would undermine Congressional intent and CMS expectations.

In fact, the proposed $178 per diem would be a massive cut -- $40 per-day less than the median per diem of the highly intensive hospital-based PHPs that offer four or more services on a daily basis.

We would propose that the rate remain at least at the $233 per day level to ensure that the highly structured, clinically-intensive PHPs are able to continue to offer these types of programs, which reduce hospitalizations, and Medicare inpatient expenditures.

E. Equivalent Remapping of CMHC Revenue Codes.

Although CMS conducted an analysis on the mapping of revenue codes in hospital-based programs, CMS continues to use the overall cost-to-charge ratio for CMHCs. It is our view that if CMS collected the partial hospitalization cost-to-charge ratio in CMHCs (vs. the overall cost-to-charge ratio), the median costs would increase in CMHC PHPs. That is because PHPs are the highest-cost service provided by the CMHC. Therefore, using the overall cost-to-charge ratio has the effect of diluting the imputed cost of PHP services offered in CMHCs.

F. Stabilization of APC Payment Rates.

The group psychotherapy APC has declined by 17% in 2007 and is proposed to be reduced further by close to 3% in 2008. Many Medicare beneficiaries can be cared for in less-intensive outpatient programs than PHPs. Unless the group psychotherapy APC rate and other psychiatric APCs cover the costs of delivering these services, this could lead to higher utilization of more costly outpatient services, like PHP, or could result in hospitalization that could otherwise be avoided.

G. Include CMHC Data in the *Healthcare Cost Report Information System* (HCRIS).

The inclusion of CMHC cost report data in the HCRIS file would provide full transparency for industry review and analysis. The HCRIS file currently only includes the following cost report data:

- Hospital Cost Report (CMS-2552-96) for 06/30/07
- Skilled Nursing Facility Cost Report (CMS-2540-96) for 06/30/07
- Renal (CMS-265-94) for 06/30/07
- Hospice (CMS-1984-99) for 06/30/07
- Home Health Agency (CMS-1728-94) for 06/30/07

Currently, interested parties can only obtain hard copies of the CMHC 2088-92 cost report reports via Freedom of Information (FOI) requests from the fiscal intermediary.

RECOMMENDATIONS

The FAH offers the following recommendations:

1. Retain the partial hospitalization rate at least at the current $233 per day level to ensure that the highly structured, clinically-intensive PHPs are able to continue to meet the needs of Medicare beneficiaries who have the most acute psychiatric needs and are either stepping down from hospitalization or trying to avoid hospitalization.

2. Conduct an analysis to look at cost to charge ratios directly related to PHP within CMHCs (vs. overall cost-to-charge ratios) as done for hospital-based PHPs.

3. Analyze the group psychotherapy APC to better understand the reasons for the decline in the APC rate over the last few years.

4. Begin to include CMHC data from the CMS-2088-92 cost reports in the *Healthcare Cost Report Information System* (HCRIS). The inclusion of this data would provide full transparency for industry review and analysis.

- **"OPPS: Wage Index", 42693 – 42695**

"In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually. In accordance with our established policy, we are proposing to use the final FY 2008 final version of these wage indices to determine the wage adjustments for the OPPS payment rate and co-payment standardized amount that would be published in our final rule with comment period for CY 2008."

The FAH commends CMS for its proposal to extend the IPPS wage indices to OPPS as in previous years. This simplifies the payment process for providers.

"OPPS: Rural SCH Payments", p. 42698

FAH strongly supports CMS's proposal to continue the 7.1 percent payment increase for rural SCHs and to include brachytherapy sources in the group of services eligible for that adjustment. As the sole hospital provider in the rural communities they serve, SCHs are indispensable in ensuring that seniors in rural areas have full and equal access to the outpatient health care they need. CMS's prior analysis clearly established the cost difference for rural SCHs and the appropriateness of the 7.1 percent payment adjustment it proposes to continue. FAH urges CMS to finalize this proposal for 2008.

- **"OPPS: Outlier Payments", 42698 – 42699**

"In order to ensure that estimated CY 2008 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,000 fixed-dollar threshold."

For CY 2008, CMS has proposed to set the projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS. FAH supports limiting the aggregate outlier payments to 1.0 percent of aggregate total payments under OPPS. FAH commends CMS for the proposed increase in the outlier threshold to keep the outlier payment percentage to 1% or less of the estimated total payments.

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

- **"IVIG Preadministration-Related Services", 42705**

"For CY 2008, we are proposing to continue to provide separate payment for IVIG preadministration-related services through the assignment of HCPCS code G0332 to a clinical APC. This service has been assigned to a New Technology APC under the OPPS for 2 full years. As noted previously, under the OPPS, we retain services within New Technology APC groups where they are assigned according to our estimates of their costs until we gather sufficient claims data to enable us to assign the services to clinically appropriate APCs based on hospital resource costs as calculated from claims. According to our analysis of the hospital outpatient claims data, we believe we have adequate claims data from CY 2006 upon which to determine the median cost of performing IVIG preadministration-related services and to reassign HCPCS code G0332 to an appropriate clinical APC for CY 2008."

FAH urges CMS to finalize its proposal to continue separate payment for IVIG preadministration-related services. However, FAH urges CMS to maintain HCPCS code G0332 in the current New Technology APC group for CY2008. At this time CMS only has one year of data available for HCPCS code G0332 and the CMS 1392P Median File by HCPCS spreadsheet shows a large fluctuation in charge amounts ($1.93 - $699.24) reported by hospitals in CY 2006. Because both the HCPCS code and the instructions to charge separately for this service were new in CY 2006, FAH believes hospitals may have initially encountered some difficulties and confusion when establishing charges for this new service. This appears to be supported by the large variability in the 2006 claims data. While there is a large volume of claims for this service, FAH urges CMS to retain this important service in the New Technology APC group at the existing payment rate for another year until more stable claims data is available.

- **"Implantation of Cardioverter-Defibrillators", 42714 – 42715**

"We believe that the differences between the median costs for the two Level II HCPCS codes assigned to each APC (that is, G0297 and G0298 for APC 0107 and G0299 and G0300 for APC 0108) do not currently support differential APC assignments for single and dual chamber ICD insertion procedures. The required device coding would allow us to continue to follow the different costs over time by examining subsets of ICD implantation procedure claims based on the type of device reported on the claims. Moreover, we are sensitive to the benefits of minimizing the reporting burden on hospitals. Therefore, for CY 2008 we are proposing to delete the Level II HCPCS codes for ICD insertion procedures and require hospitals to bill the appropriate CPT codes, along with the applicable device C-codes, for payment under the OPPS."

FAH supports CMS' elimination of the HCPCS level II codes for ICD implantation. It is an administrative burden for hospitals to follow coding rules for Medicare patients that are inconsistent with CPT coding guidelines; therefore FAH supports eliminating level II HCPCS codes when level I CPT codes are available. FAH urges CMS to finalize this proposal and to consistently use national codes and national coding rules as the basis for OPPS payments.

FAH is concerned, however, about the potential negative impact to hospitals when the more expensive dual chamber device is used for Medicare beneficiaries. There have been several instances when procedural payment rates do not accurately reflect resources expended due to significant variability in the costs of different device types used in the procedure. In the past CMS has developed level II HCPCS codes for certain of these types of procedures to allow more appropriate payment based on the specific type of device used. While the current ICD implantation HCPCS codes are one example of this methodology, another example is the level II HCPCS codes G0290 and G0291 for implantation of drug-eluting stents.

While FAH appreciates the more appropriate payment rates allowed by the additional HCPCS codes, the administrative burden to follow special Medicare coding rules limits this benefit. FAH urges CMS to analyze the use of composite APCs for these types of device dependent procedures where the device costs can vary significantly based on the type of device used. FAH believes composite APCs could be established based on the device procedure CPT code and the specific level II HCPCS code for the device. Since CMS already requires separate reporting of device level II HCPCS codes for device dependent procedures, this should not require any additional administrative burden to hospitals. FAH believes setting a composite procedural payment rate based on the combination of the device HCPCS code and implantation procedure CPT code will allow coding to remain consistent across all payers and still allow CMS to set specific device related payment rates for certain procedures.

FAH urges CMS to establish composite APC rates for ICD implantation and coronary stenting using this methodology. FAH also recommends CMS consider this methodology for other device dependent procedures having significant variability in the costs of different device types used in the procedure, such as keratoprosthesis (CPT code 65770).

- **"Implantation of Spinal Neurostimulators", 47215 -47216**

"Review of our CY 2007 claims data for APC 0222 shows that the costs of the associated neurostimulator implantation procedures are higher when the rechargeable neurostimulator is implanted rather than the traditional nonrechargeable neurostimulator...In addition, to pay differentially would require us to establish one or more Level II HCPCS codes for reporting under the OPPS, because the three CPT codes for which device category code C1820 is currently an allowed device do not differentiate among the device implantation procedures based on the specific device used...

Therefore, for CY 2008 we are proposing to package the costs of rechargeable neurostimulators into the payment for the CPT codes that describe the services furnished. Our proposed median cost for APC 0222 is $12,161.64, upon which the CY 2008 payment rate for APC 0222 would be based."

FAH supports CMS' decision to not implement new level II HCPCS to differentiate between implantation of rechargeable or non-rechargeable neurostimulator, since it is an administrative burden for hospitals to follow coding rules for Medicare patients that are inconsistent with CPT coding guidelines. However, FAH is concerned about the significant variation in the costs of the two devices.

As discussed above in relation to ICD implantation and coronary stenting, FAH urges CMS to develop a composite APC based on the reported implantation procedure CPT code and the specific device HCPCS code. FAH believes using a composite APC approach will allow CMS to set appropriate payment rates based on the implantation procedure and the specific type of implant used (rechargeable vs. non-rechargeable). This methodology should allow CMS to pay less when a lower cost device is implanted while still allowing higher reimbursement when the more expensive device is implanted. This methodology would have the same benefit as differentiating the implantation procedures using level II HCPCS codes without requiring the administrative burden of different coding rules for the implantation procedure.

FAH urges CMS to consistently use national codes and national coding rules and adopt payment methodology such as composite APCs to handle payment variation when needed. If CMS is concerned about the potential volume of composite APC codes, FAH suggests implementing composite APC codes in cost bands similar to those used for new technology. Composite APCs could be established in $50 increments up to $500, $100 increments up to $1000, and $500 increments for those over $1000.

- **"Blood Transfusions", 42717 – 42718**

"Therefore, for CY 2008 we are proposing to maintain our current payment policy, which bases payment for transfusion on the costs of all transfusion services furnished on a single date of service and which examines hospital claims to ensure that payment is provided for only one unit of CPT code 36430 on a date of service."

FAH supports CMS' decision to maintain current transfusion payment policy. The March 2001 issue of AMA *CPT Assistant* indicates that the CPT coding rules for CPT code 36430 are to report the CPT code once per transfusion regardless of the number of units administered. It is an administrative burden for hospitals to follow coding rules for Medicare patients that are inconsistent with CPT coding guidelines. FAH urges CMS to finalize this proposal and to consistently use national codes and national coding rules as the basis for OPPS payments.

III. Proposed OPPS Payment for Devices

- "OPPS: Device-Dependent APCs", 42719 – 42727

"In summary, we are proposing to create a HCPCS modifier to be reported on a procedure code in Table 38 below if a device listed in Table 39 below is replaced with partial credit from the manufacturer that is greater than or equal to 20 percent of the cost of the replacement device and to reduce the payment for the procedure by 50 percent of the amount of the estimated packaged cost of the device being replaced when the modifier is reported with a procedure code that is assigned to an APC in Table 38."

FAH understands CMS' objective to reduce device-dependent procedure payments when the device has been provided at a reduced cost by the manufacturer. However, hospitals will assume a substantial administrative burden to identify these devices that receive a discount or credit, especially when the credit is determined at a much later date. In addition, the proposed rule is unclear what "cost" should be considered when applying the threshold and who will be responsible for making this determination.

Hospitals frequently receive volume discounts and manufacturer rebates that may not be known at the time a procedure is performed. In these instances, the savings are applied to the cost report and end up reflected in the departmental CCR used by CMS to establish future payment rates. Hospital staff may not have either the usual device cost or the amount of credit for the device at the time of the procedure to calculate the "cost" of the device and determine whether the credit is more or less than a threshold amount.

In addition, FAH believes a payment reduction of 50% of the APC payment relative to the device is excessive in relation to a credit of only 20-40% of the device. Because procedural APCs have payment rates established based on an average cost for the procedure, which may not reimburse hospitals the full cost of the actual procedure performed and device used, FAH believes it is inappropriate to reduce the payment by

50% of the average device portion when the hospital receives a credit of only 20%. FAH opposes implementation of this reduction for a device discount as low as 20%.

FAH urges CMS to delay implementation of this proposal until CMS can specifically define what hospitals should use as the device "cost" and how to handle delayed credits. If CMS implements a reduction based on partial credit for a device, FAH urges CMS to only apply the reduction to devices with credits of at least 50% of the device cost.

IV. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

- "OPPS: Pass-Through Drugs", 42730 – 42731

"Given our CY 2008 proposal to provide payment for nonpass-through separately payable drugs and biologicals at ASP+5 percent as described further in section V.B.3 of this proposed rule, we believe it would be most consistent with the statute to provide payment for drugs and biologicals with pass-through status that are not part of the Part B drug CAP at a rate of ASP+6 percent, ... we are proposing for CY 2008 to pay for pass-through drugs and biologicals that are not part of the Part B drug CAP at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2008."

Physician reimbursement for CY2008 will be maintained at ASP+6% for the identical drug products if administered in a physician's office. If payment for nonpass-through drugs and biologicals is lowered under OPPS to ASP+5%, this contradicts CMS' goal, "to get rid of inadvertent incentives that favor one setting over another". The FAH believes that the changes to drug reimbursement proposed by CMS (from ASP+6% to ASP+5%) could have a detrimental effect on the ability of hospital outpatient departments and ambulatory clinics to provide the level of patient care needed by Medicare beneficiaries. The FAH strongly urges CMS to continue ASP+6% reimbursement for all separately paid drugs and biologicals under OPPS, similar to the physician office schedule in CY2008.

- "OPPS: Packaging Drugs and Biologicals", 42732 – 42733

"Based on the calculations described above, we are proposing a packaging threshold for CY 2008 of $60... While we are not proposing for CY 2008 to change this established approach to establishing the general packaging threshold for drugs, biologicals, and radiopharmaceuticals, in view of our proposed packaging approach for the CY 2008 OPPS as outlined in section II.A.4. of this proposed rule and our desire to move the OPPS toward a more encounter-based and episode-based payment in the future, we will consider expanded packaging of payment for drugs, biologicals, and radiopharmaceuticals for a future OPPS update."

FAH supports the use of a packaging threshold for drugs and does not support the separate payment of all drugs. FAH believes that paying separately for all HCPCS-coded drugs would be inconsistent with OPPS packaging principles and could increase

hospitals' administrative burden. FAH is also concerned about the potential negative impact to payments for other services if all HCPCS coded drugs are paid separately since the impact to the total OPPS payments must be budget neutral. FAH commends CMS for continuing to raise the drug packaging threshold, which is consistent with the principles of a prospective payment system.

- "OPPS: Specified Covered Outpatient Drugs", 42733 – 42736

"We believe that our payment rates for drug acquisition costs and pharmacy overhead should be determined based on the costs reflected in our claims data, as these costs reflect both acquisition costs and overhead costs. We also believe that establishing additional payment for pharmacy overhead beyond our proposed payment rates based on claims data would distort the relative relationship of costs across HOPD services, which is the basis of the OPPS.

...we are proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an uncoded revenue code line on the claim beginning in CY 2008...

With regard to our current proposal for CY 2008 to have hospitals report a charge for the drug and a charge for pharmacy overhead via an uncoded revenue code line, we believe our current approach is consistent with Medicare regulations. So long as hospitals provide the same total charge to all payers, it would be acceptable to report that charge as a line item for one payer and two (or more) line items for another payer."

The FAH is strongly opposed to the separate reporting of drug overhead and/or handling charges. CMS has proposed to require hospitals to report the drug charge(s) (with correct HCPCS code(s) and billing units) and also separately report the associated pharmacy overhead and handling charges on an uncoded revenue code line. As recognized by CMS in the NPRM for calendar year 2006 and by MedPAC in its June 2005 report to Congress, pharmacy overhead and handling costs are not separately billed by the vast majority of hospitals. They are typically captured as part of the markup or charge algorithm for the drugs the hospital provides. In addition, the vast majority of hospitals do not have sophisticated cost accounting systems that would permit the determination of pharmacy overhead and handling costs for each billable drug.

FAH urges CMS to continue to recognize and pay or package (as appropriate based on the drug packaging threshold) a single drug product charge representing both pharmacy acquisition cost as well as the pharmacy overhead and handling cost.

The proposed requirement to separately report charges for pharmacy overhead and handling raises several concerns as outlined below:

- Inadequate Cost Accounting Systems: Hospitals do not have cost accounting systems that are sufficiently sophisticated to identify and track the overhead/ handling costs for each drug product. Hospitals would be required to manually identify and remove the pharmacy overhead and handling costs currently included in each drug line item's charge. FAH believes it would be extremely difficult to identify what portion of the markup or charge algorithm would be solely for the drug product and what portion would be attributable to the pharmacy overhead and handling costs.

- High Volume Burden: The volume of drug items that will require modification to reduce each current drug charge to reflect only the drug product itself would place a tremendous administrative burden on hospitals. The pharmacy chargemaster for most hospitals contains several thousand line items. Hospitals will also have to determine how to establish new charges for pharmacy overhead and handling as well as develop extensive training programs to educate all impacted areas of the hospital since drugs are dispensed and administered all over the hospital. This proposal also requires continuous maintenance by hospitals to ensure that the new handling charges are appropriately updated to reflect changes in pharmacy handling and overhead costs due to use of new products and/or techniques for preparing and handling drugs.

- Complex Drug Reporting: Hospitals already struggle to report the correct HCPCS code and units of service for drugs based on the dose administered to the patient as described by the HCPCS code rather than a quantity based on the way the drug is packaged, dispensed, or administered. Drug administration CPT codes also require complex decisions to identify initial, concurrent, and sequential drug administration services. Requiring hospitals to separately report a charge for pharmacy overhead/ handling adds an additional level of complexity to an already complex system. CMS has indicated its intent to package the pharmacy overhead/ handling charges into the associated procedures instead of the drug products beginning with CY2010. This will only work reasonably well if hospitals can accurately and efficiently identify and remove their pharmacy overhead and handling costs. There is also an issue if hospitals report the new drug overhead/ handling charges separately without restructuring their existing drug charges to remove the drug handling costs already included in the drug charges.

- Increased Hospital Costs without Payment: CMS has not proposed separate reporting of pharmacy overhead/ handling charges in order to pay separately for these services. CMS is proposing to package these costs into the service provided such as the drug administration. This proposal imposes substantially increased burden and cost on hospitals with no commensurate financial benefit. In the 2008 OPPS proposed rule, CMS repeatedly stresses a desire to package payment for more services to encourage hospitals to provide the most efficient and cost effective care. Establishing and maintaining separate charges for pharmacy overhead and handling charges is neither efficient nor cost effective for hospitals. Neither does it promote cost effective or efficient use of drug products. Because the pharmacy handling and overhead has always been a part of the drug charge and payment, CMS should continue to establish payment for separately payable drug services at a rate which includes both acquisition

cost and overhead. If CMS has proposed this change with the intent to increase packaging, a better and less burdensome strategy could be implemented through a higher packaging threshold for drugs and biologicals.

- Continued Inability to Determine Actual Drug Acquisition Costs: Even if the administratively burdensome process of billing for pharmacy overhead and handling charges is adopted by CMS, FAH is convinced that CMS will still be unable to determine actual drug acquisition costs at the individual drug level. CMS will likely still apply an average Pharmacy department CCR, which includes both drug acquisition and pharmacy overhead and handling, to billed drug charges to determine drug acquisition costs. While CCRs can adequately determine costs in total (for a total hospital department, such as Pharmacy), CCRs were never intended to determine cost at the service level, such as average drug acquisition cost for individual drugs. If CMS requires hospitals to unbundle the charges for pharmacy overhead and handling from the pharmacy products while still applying a pharmacy department CCR that averages all costs (including overhead and handling), the result will be even less likely to represent the average acquisition cost of drugs.

- Impact on Other Payers: Medicare providers must have a consistent charge structure in order to prepare the Medicare cost report. The proposal by CMS to require hospitals to begin billing the pharmacy overhead and handling charge as a separate line item charge may present billing and payment concerns for all other payers. Many payers reimburse hospitals for high cost drugs based on special carve outs or drug charges, which currently include pharmacy overhead and handling costs. The proposal to remove the pharmacy overhead and handling costs from the drug charges could negatively impact the hospitals' payment from these third party payers.

  While CMS has indicated that hospitals can report the separate charges for the drug and the pharmacy handling and overhead to Medicare and report a combined charge to third party payers, this approach is problematic. Most hospital systems are not sophisticated enough to automatically combine or split these charges based on payer preference, so this would have to be done manually. Additionally, since hospital patients frequently require more than one drug in an outpatient encounter, it may be impossible to identify any correlation between each of the drug charges reported and the pharmacy handling charges reported to be able to combine the charges for other payers. By proposing to require hospitals to bill a handling charge when the industry practice has been to bill a combined charge, CMS is adding administrative burden and additional costs without any recognizable benefit to the program or hospital payment.

To reiterate, FAH is strongly opposed to the separate reporting of handling costs. We believe this would be administratively burdensome and would, in fact, create significant new costs to identify, remove and separately report pharmacy overhead charges. In addition, FAH believes this proposal runs counter to typical hospital charging practices. Traditionally, hospitals have only separately charged for items and services directly responsible for care of the patient. Charging separately for overhead, handling fees, administrative costs, etc. is a fundamental departure from generally accepted charging

practice as these are considered embedded costs that are best captured as part of the markup or charge algorithm for the services, items or procedures the hospital provides. Over the last two years CMS has affirmed that hospitals include their overhead and handling charges into the costs of their drugs, and has even instructed providers to be sure that this was the practice for radiopharmaceuticals.

Since CMS and MedPAC recognize that drug handling costs are already included in the hospitals' charge for drugs and the pharmacy overhead and handling cost is already reflected in the Pharmacy department on the Medicare cost report, FAH urges CMS to continue to use ASP data and hospital claims data to achieve a reasonable estimate of pharmacy acquisition costs and the pharmacy overhead and handling costs.

- "OPPS: Nonpass-Through Coded Drugs, Biologicals, and Radiopharmaceuticals without Claims Data", 42741 – 42743

"We are proposing to allow hospitals to submit claims by reporting any HCPCS code for a Part B drug that is covered under the OPPS, regardless of the unit determination in the HCPCS code descriptor, beginning in CY 2008. Stakeholders have told us that this policy would reduce the administrative burden associated with our current requirement that hospitals report drugs using only the HCPCS codes with the lowest increments in their code descriptors. Whenever possible, we seek to reduce hospitals' administrative burden in submitting claims for payment under the OPPS, and we appreciate the APC Panel's recommendation in this area."

The FAH appreciates CMS' recognition of the administrative burden caused by the current requirement for hospitals to report only the HCPCS code for a drug with the lowest dosage in the description. We commend CMS for the proposal to allow hospitals to report any HCPCS code for a Part B covered drug and urge CMS to finalize this proposal for CY2008. FAH supports the payment setting methodology proposed for these previously unrecognized HCPCS codes.

- ''OPPS: Payment for Therapeutic Radiopharmaceuticals'', 42738 - 42741

"...we believe that setting CY 2008 prospective payment rates based on CY 2006 hospital claims data as described above serves as an acceptable combined proxy for average hospital acquisition costs and radiopharmaceutical handling.

...we are not proposing to collect hospital invoices or otherwise rely on external data in order to establish prospective payment rates for therapeutic radiopharmaceuticals for CY 2008."

FAH commends CMS for its proposal to establish prospective payment rates for separately payable radiopharmaceuticals using costs derived from the CY 2006 claims data, where the costs are determined using a standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges and defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.

V. Proposed Payment for Brachytherapy Sources

- "OPPS: Brachytherapy", 42746 – 42750

"We are proposing a payment methodology for separately paid brachytherapy sources for CY 2008 based upon their median unit costs calculated using CY 2006 claims data."

FAH commends CMS for its proposal to continue separate payment of brachytherapy sources and to establish prospective payment rates for brachytherapy sources using costs derived from the CY 2006 claims data. FAH supports the principles of a prospective payment system and urges CMS to pay services under APC, whenever feasible, rather than through cost based reimbursement.

VI. Proposed OPPS Drug Administration Coding and Payment

- ''OPPS: Drug Administration'', 42750 - 42751

"We continue to ask hospitals to report all CPT drug administration codes, and we expect hospitals to report CPT codes consistently with CPT coding guidelines and applicable instructions."

FAH supports CMS' decision to maintain current drug administration coding policy. It is an administrative burden for hospitals to follow coding rules for Medicare patients that are inconsistent with CPT coding guidelines. FAH urges CMS to finalize this proposal and to consistently use national codes and national coding rules as the basis for OPPS payments.

VII. Proposed Hospital Coding and Payments for Visits, 42751 – 42765

"In summary, for CY 2008, we are proposing that hospitals continue to use the CPT codes to bill for clinic visits and to distinguish between new and established patient visits. For CY 2008, the CPT codes for new and established visits would continue to be payable under the OPPS, but we would reconsider in the future whether there should be a distinction between new and established patient visits as we continue to work on developing national guidelines. For CY 2008, we are proposing to change the status of the consultation codes so that these codes are no longer recognized for payment under the OPPS.

...We hope to receive additional input from stakeholders over the upcoming months to address whether there is a definite contemporary need for national guidelines, given their potential to redistribute payment under the OPPS and the currently reassuring observed patterns of OPPS visit services. While we understand the interest of some hospitals in our moving quickly to promulgate national guidelines that will ensure standardized reporting of outpatient hospital visit levels, we believe that the issues identified both by us and others that may arise are important and require serious consideration prior to the implementation of national guidelines. Because of our

commitment to provide hospitals with 6–12 months notice prior to implementation of national guidelines, we would not implement national guidelines prior to CY 2009. Our goal is to ensure that OPPS national or hospital-specific visit guidelines continue to facilitate consistent and accurate reporting of hospital outpatient visits, in a manner that is resource-based and supportive of appropriate OPPS payments for the efficient and effective provision of visits in hospital outpatient settings."

FAH supports the proposal to eliminate reporting of the consultation codes under OPPS and recommends that CMS finalize this proposal. FAH also supports the elimination of a distinction between new and established visits as described in the existing AMA clinic E/M CPT codes. FAH believes differences in resources should be captured via the level reported and not the code or patient type. Some patients who are established patients at the hospital that are new to the clinic may be as resource intensive as another patient who is new to the hospital and clinic. In addition, this distinction can be administratively burdensome for hospitals to manage. We recommend, however, that CMS not eliminate the use of the CPT codes for new patients until national standards have been developed.

FAH urges CMS to develop national standards in order to promote consistency across the industry, and hopes that the standards developed by CMS are adopted by all payers. Currently, E/M services are the only codes hospitals report that have no national coding guidelines. Some payers do not support facility specific standards and require hospitals to report E/M services based on physician-specific or payer-specific methodologies that may not match either the facility's or CMS' standards. This makes it very difficult for hospitals to apply the same charge across all payers. In addition, hospitals have increased administrative burdens maintaining their own E/M standards for clinics and emergency departments and keeping them current with annual and quarterly OPPS clarifications and updates. FAH urges CMS to produce national standards that will be used by all hospitals, and adopted by all payers.

VIII. Proposed OPPS Payment for Blood and Blood Products

- "OPPS: Blood and Blood Products", 42765 – 42767

"...we are proposing to use the median costs derived from the application of blood cost center CCRs for those hospitals that have blood cost centers or simulated blood cost center CCRs for those hospitals that do not have blood cost centers as the basis for the CY 2008 payments for blood and blood products without further adjustment."

FAH commends CMS for its proposal to establish prospective payment rates for blood products using costs derived from the CY 2006 claims data. FAH supports using claims data to set blood product rates keeping in line with the principles of a prospective based payment system.

IX. Proposed OPPS Payment for Observation Services

- "OPPS: Observation Services", 42768 - 42770

"A. Observation Time
1. Observation time must be documented in the medical record.
2. A beneficiary's time in observation (and hospital billing) begins with the beneficiary's admission to an observation bed.
3. A beneficiary's time in observation (and hospital billing) ends when all clinical or medical interventions have been completed, including follow-up care furnished by hospital staff and physicians that may take place after a physician has ordered the patient be released or admitted as an inpatient."

FAH noticed a discrepancy in the observation start time language in the proposed rule as excerpted above and the language currently in the CMS manuals. According to the Medicare Claims Processing Manual, Chapter 4, Section 290.2.2, Reporting Hours of Observation, "*Observation time begins at the clock time documented in the patient's medical record, which coincides with the time the patient is placed in a bed for the purpose of initiating observation care in accordance with a physician's order.*" The proposed rule lacks any reference to a physician order requirement in regards to the initiation of observation care. FAH requests CMS clarify whether this discrepancy is an oversight by CMS or if CMS is specifically changing the observation requirements to no longer include a physician order in regards to start time.

X. Proposed Procedures That Will Be Paid Only as Inpatient Procedures

- "OPPS: Inpatient Procedures", 42770 – 42771

"...we are proposing to accept the APC Panel's recommendation to remove the 13 procedures from the OPPS inpatient list for CY 2008 and to assign them to clinically appropriate APCs as shown in Table 56."

FAH commends CMS for continuing to evaluate and remove procedures from the inpatient only list that may be safely performed in an outpatient setting. We urge CMS to finalize the proposal to move these 13 procedures to APC payment. However, FAH again urges CMS to eliminate the inpatient only list and rely on physicians to appropriately admit patients who require inpatient stays based on their individual needs.

XI. Proposed Nonrecurring Technical and Policy Changes

- "Wound Care Services", 42772 - 42773

"...for CY 2008 we are proposing that when services reported with CPT codes 97597, 97598, 97602, 97605, and 97606 are performed by a qualified therapist under a certified therapy plan of care, providers should attach an appropriate therapy modifier (that is, GP for physical therapy, GO for occupational therapy, and GN for speech-language pathology) or report their charge under a therapy revenue code (that is, 042X, 043X, or 044X), or both, to receive payment under the MPFS."

FAH supports the proposed change to include the full range of therapy revenue codes to identify wound care services performed by a therapist in order to pay them under the MPFS. FAH recommends CMS finalize this proposal and continue to pay wound care services reported with all other revenue codes under the OPPS.

- "Cardiac Rehabilitation Services", 42773

"For CY 2008, we are proposing to discontinue recognizing the current CPT codes for cardiac rehabilitation services and to establish two new Level II HCPCS codes that we believe are more appropriate for specifically reporting cardiac rehabilitation services under the OPPS. The proposed HCPCS codes are: GXXX1 (Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour)) and GXXX2 (Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)). In contrast with the current CPT codes, we believe the descriptors of these proposed G-codes more specifically reflect the way cardiac rehabilitation services are provided in HOPDs so that reporting would be more straightforward for hospitals and would result in more accurate data for OPPS ratesetting in 2 years."

FAH does not support the addition of level II HCPCS codes in place of level I CPT codes due to the increased administrative burden hospitals experience following the imposition of coding rules for Medicare patients that are inconsistent with CPT coding guidelines. In addition, since the proposed level II HCPCS codes include the terminology "Physician services", FAH does not agree that these HCPCS codes are more appropriate for reporting outpatient hospital services. Hospitals are reporting cardiac rehab services performed by hospital staff, not physicians. The addition of new HCPCS level II codes that allow payment per hour seems inconsistent with CMS' move toward episode based payment. FAH recommends that CMS not finalize this proposal.

- "Bone Marrow and Stem Cell Processing Services", 42773 – 42774

"For CY 2008, we are proposing to continue to assign the historical claims data for HCPCS code G0267 to APC 0110. In addition, we are proposing to discontinue recognizing HCPCS code G0267 for CY 2008, assigning it to status indicator "B," and to recognize the six more specific CPT codes, which we are proposing to also assign to APC 0110 with a status indicator of "S."

FAH supports CMS' decision to recognize the 6 CPT codes for bone marrow and stem cell processing services instead of HCPCS code G0267. It is an administrative burden for hospitals to follow coding rules for Medicare patients that are inconsistent with CPT coding guidelines. FAH urges CMS to finalize this proposal and to consistently use national codes and national coding rules as the basis for OPPS payments.

XII. "Quality Data", 42799 - 42806

In its proposed rule, CMS outlines its plans for implementation of Section 109 of the Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109-432), which mandate a hospital outpatient quality reporting program. The FAH has consistently supported high quality patient care, regardless of the setting, and maintains the goal of building a national quality reporting system that provides standardized, useful information to public and private payors, patients and their families, regulatory and accrediting bodies, and other stakeholders in the health care delivery system.

Through the TRHCA program, hospitals will report on measures of hospital outpatient care in order to receive the full market basket update in CY 2009. Should a hospital fail to report outpatient data, its annual outpatient payment update would be reduced by two (2) percentage points. In the proposed regulation, hospitals would be required to begin reporting on outpatient quality measures in January 2008.

- **Measure Selection**

The CMS is proposing to implement the legislative mandate by starting with reporting on ten (10) quality outpatient measures. In general, the FAH believes that any measures used for quality improvement must be endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA). We appreciate CMS continuing to recognize measures that reflect NQF endorsement and adoption by the HQA. The FAH wishes to point out that the measures included in the proposed rule were only provisionally adopted by the HQA for the outpatient measure reporting program. While HQA gave preliminary approval to the ten proposed measures, the measures still need additional refinement and specification development.

The measures for the outpatient setting should be specific, focused and designed to reflect the care that is delivered and under the control of the hospital outpatient setting. The FAH recommends that ideally, when a measure is chosen that the specifications of that measure be complete, that the measures already have the endorsement of the NQF and that the numerator and denominator be well defined, and that field testing has been conducted.

The ten measures that are being proposed for the initial set of OPPS measures cover a wide variety of services. Some of these services are within the control of the hospital outpatient department, and some more clearly reflect care delivered by other health care providers.

The FAH appreciates the Department's releasing the specifications of the proposed ten measures as early as the specifications became available. The work that was done to develop the specifications was subcontracted to respected organizations with significant experience in the field. However, prior experience has taught us that no matter how well defined the measures are, field testing is essential to ensure proper data collection and to pinpoint areas of misspecifications in the measures. We strongly urge CMS to provide

funding to fully field test all ten measures for the outpatient setting including vendor abstraction tool development, hospital data collection, reporting of results, and CMS validation by the CDAC. We believe that the outpatient measures should be treated no differently than the inpatient measures and that rigorous testing must take place to ensure that operational issues between the outpatient providers and the vendors can be resolved before the pay-for-reporting program is fully implemented.

The FAH agrees with HQA adoption, but wishes to point out that at least one measure is a good example of why field testing is absolutely necessary--the Hemoglobin A1c diabetes Mellitus measure. We recognize that the PQRI #1: Hemoglobin A1c Poor Control in Type I or 2 Diabetes Mellitus, now called OP – 2, is a good measure of a patient's control of blood sugar. This is an important indicator and a good predictor of overall outcome of medical therapy intervention. The measure specification developers have stated that the denominator population for the diabetes measure includes patients who must have had at least one visit in that clinic with a known diagnosis of diabetes before the visit being reviewed. However, when reviewing the specifications published by CMS, this definition is not written clearly. Field testing will indicate whether the lack of clear definition will result in under/over reporting on the measure.

This is also a good example of a measure where alignment is needed across all care delivery systems. For a successful outcome on Hemoglobin A1c, the patient, physician, and outpatient clinic all have to be working together. The outpatient clinic, with the use of this measure, is being held responsible for a number of variables, including patient compliance with recommended protocols, that are not in its complete control. The number of variables, including patient compliance with recommended protocols, make this a challenging outpatient department measure and one that clearly needs to be field tested before being implemented.

With regard to the measures proposed for CY 2010, the FAH strongly recommends that any measures being considered be included only after they are well specified, the NQF endorsement is final and the HQA has recommended the measures. Again, this will ensure that the specifications are complete and understood and that the measure is well-defined. This process would also include field testing of any new measures.

The FAH supports the CMS goal of trying to harmonize the measures across all care settings - inpatient, outpatient and ambulatory. Recognizing that care is delivered in a variety of settings and by a variety of practitioners, the measures used for quality reporting at the federal level should work to align incentives for all practitioners and facilities. This alignment is essential to focusing on patient needs and minimizing the burdens of data collection. While there may be some differences in the specifications for the various settings because of data sources and defined populations and coding requirements, every effort should be made to align as close as possible the measures being collected so that there is equity in the burden and clinical process for all care givers. For example, the current PQRI program requires the addition of CPT codes to the

claim. However, the PQRI program lacks the extensive algorithms, inclusions and exclusions of the inpatient and now hospital-based outpatient programs.

- **Technical Issues Delaying Implementation of Data Collection**

CMS is proposing that data collection on the ten measures begin with services provided in the outpatient setting on or after January 1, 2008. To make this happen, hospitals will have to review the specifications, develop data collection tools for their institutions and train staff on the data collection. The staff engaged in data collection in the hospital inpatient setting generally will not be involved with or able to assist with data collecting in the outpatient setting. The outpatient and inpatient services are generally completely separate entities within a hospital structure. Significant time is required to train and educate staff on the details of the measures and how to collect the necessary data.

In addition, data vendors will need to develop data abstraction tools. They will also need to test the software to implement the outpatient measures. While we appreciate the specifications being released as soon as possible, implementation by January 1, 2008, only 60 days after CMS issues the final rule, will be extremely difficult. FAH hospitals have very specific questions on how to collect certain measures as they work their way through the details, but are very concerned about their ability to meet the deadline. Some of the data will need to be collected from clinical records and some from billing records, but the outpatient setting has not yet developed data abstraction tools. Emergency departments are often separate from the outpatient departments and from the inpatient department. The clinical record keeping and data collection tools for these entities are often different. It is unclear to us at this point if the vendors will be able to accurately collect the data by January 1, 2008 either. The FAH strongly recommends that CMS delay the implementation of the data collection until field testing has been fully completed and until NQF has fully endorsed all the measures.

- **Administrative Requirements**

In the proposed rule CMS defines a process whereby the hospital must register with the Quality Net Exchange and complete the Notice of Participation form no later than November 17, 2007 for the CY 2009 Hospital Outpatients Program Quality Data Reporting Program. The FAH appreciates that the hospital registration will stand and be considered active without the need for annual submissions unless affirmative action is taken to withdraw from the program. This will have a positive effect in reducing the administrative burden on the hospitals. We note that the proposal also states that hospitals not wishing to participate must submit a notice of non-participation.

Since the proposed deadlines for submission of participation forms are different from any other dates related to hospital quality reporting, the FAH strongly recommends that CMS undertake a comprehensive and long-term educational campaign with numerous notices to outpatient providers to ensure that the deadlines are understood.

- **OPPS Clinical Warehouse**

FAH notes that the proposed rule indicates that a data warehouse has not been chosen for the OPPS program. The FAH would encourage CMS to competitively bid the warehouse and ensure that the entity that wins the contract has the ability and resources to handle what will likely be an expanding set of quality data and that CMS provide sufficient funds to ensure that the contractor/subcontractor be prepared to move to broader information collection in an outpatient environment should the episode of care model be implemented in the future. We are concerned about the ability of CMS to integrate the data warehouse for the OPPS program with the current RHQDAPU warehouse. We suggest that CMS hire an outside firm with expertise in this area to map a comprehensive and long-term integration plan.

- **Validation Process**

The proposed rule defines a process for validating data submitted under the outpatient reporting program that is, especially for the 2009 payment update, troubling. The process proposes randomly selecting five (5) cases from each hospital from among the patients receiving services in the first month of the program, January 2008. The cases will be randomly abstracted by a clinical data abstraction center (CDAC). The FAH recommends that random abstraction cover more than one month and would far prefer that a full quarter of data be considered for validation. Limiting abstraction to the first month of a brand new program with many challenges to overcome is impractical and unwise and could result in payment penalties being applied prematurely. On the inpatient side, there was ample time for the institutions to improve their internal processes before a penalty such as a reduction in the payment update was imposed.

The FAH is also concerned about the threshold for reliability. While this process is similar to the inpatient process, the inpatient threshold of 80 percent was achieved over time as entities became more familiar with the data and the data collection process. Implementing this outpatient quality program is not an extension of the inpatient program. Although that program has given all of us valuable insight into what is required, the process in the outpatient setting will be quite different and experience is needed before data confidence is achieved. The FAH recommends that the threshold for the first year be lower than 80 percent and that it gradually rise to 80 percent over several years.

- **Reconsideration Process**

The FAH is pleased that CMS included a reconsideration process from the inception of this new program. The reconsideration process for those hospitals that failed to meet the RHQDAPU program requirements has been very important. We are sure that they will be equally important on the outpatient side. We believe that the reconsideration process should be similar to the one on the inpatient side and should be timely, easily understood and transparent.

- **Ambulatory Surgery Center Quality Reporting**

In the proposed regulation, CMS asks for comments on requiring Ambulatory Surgery Centers (ASCs) to report on quality measures. The FAH believes that quality reporting in all settings is important to overall patient care and would be supportive of a similar program for reporting in the ASC environment and would encourage that movement into the ASC environment be preceded by thorough and complete field testing.

FAH looks forward to continuing to work with CMS to develop measures that accurately reflect the quality of care delivered to patients across all settings with the goal of enhancing patient care delivery.

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FAH appreciates the opportunity to comment and would welcome the opportunity to meet, at your convenience, to discuss our views. If you have any questions or need additional information, please contact me or Steve Speil, Sr. Vice President, Health Finance and Policy, or Jayne Hart Chambers, Sr. Vice President, Strategic Policy & Corporate Secretary to discuss quality data, at 202.624.1500.

Respectfully submitted,