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VIA HAND DELIVERY

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Attention: CMS–1506–P

Dear Dr. McClellan:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"The Hospital Outpatient Prospective Payment System[OPPS] and CY 2007 Payment Rates ..."* 71 Fed. Reg. 49506 (August 23, 2006). The AAMC represents approximately 400 major teaching hospitals and health systems; all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our comments focus on the following areas: the proposal to link the inpatient quality reporting requirements to the OPPS payment update; the proposed changes to the evaluation and management codes that hospitals use to report clinic and emergency department visits and critical care services; the proposal to reduce the ambulatory payment classification (APC) payment for procedures involving replacement of a defective device; the outlier payment policy; payment for acquisition and handling costs of separately payable drugs and biologicals; and new technology APCs.

QUALITY REPORTING UNDER THE OPPS

The AAMC is a founding member of the Hospital Quality Alliance (HQA) which has, among its many purposes, fostering accountability among the nation's hospitals for the care provided to patients. The AAMC has been, and continues to be, a proponent of measuring quality and providing incentives for the improvement of care. However, we

are not in support of the proposed outpatient payment update program and the linkage between the inpatient and outpatient programs.

The National Quality Forum has served as a consensus organization that endorses measures for public accountability and quality improvement. The measures endorsed by NQF cover many settings in the healthcare continuum. A significant amount of research, testing and resources are used to ensure that appropriate and valid measures are approved for specific conditions and care settings.

It is inappropriate to assume that the measures used in the inpatient setting can serve as a proxy for measuring the quality of care in the outpatient setting. This is completely contrary to the performance measurement philosophy subscribed to by the NQF and its membership. One cannot assume that the care processes in the outpatient setting are the same as the inpatient setting and that the only difference between the two is the level of acuity. As currently articulated in the proposed rule, measures do not currently exist for the outpatient setting. Therefore, we believe quality reporting requirement for the outpatient payment update program should be postponed until proper measures are developed through the established NQF process.

The HQA has played the primary role in selecting measures that are publicly reported on the Hospital Compare website. As a result, it has been the case that the measures required for the inpatient payment update have been selected from those measures approved for reporting. We believe that the HQA and the Ambulatory Quality Alliance (AQA), when appropriate, should be the organizations that select the measures to be publicly reported. CMS can then utilize those measures for the appropriate inpatient and or outpatient payment update programs.

Another reason these payment systems should not be linked at this time is that while most hospitals have complied with the inpatient quality reporting requirement and will receive a full inpatient payment update in fiscal year 2007, there are still many technical issues that remain that can put hospital updates at risk. This is the second year that hospitals' data have been required to pass validation screens in order for the hospital to receive their updates. However, it is recognized that this process needs to be improved. Given that the system still needs improvements, it is unreasonable to put hospitals at risk for losing not only their inpatient update but their outpatient update as well.

EVALUATION AND MANAGEMEN (E/M) CODING AND GUIDELINES

Background

Since the implementation of the OPPS, hospitals have been reporting five resource-based coding levels for clinic visits and five coding levels for emergency department visits using CPT E/M codes. The least and most resource intensive codes are combined resulting in three APC payment levels.

Because the CPT E/M codes are designed to reflect the activities of physicians, they do not adequately describe the range and mix of services provided by hospitals during these encounters. Thus, CMS has instructed hospitals to use their own internal guidelines – based on hospital resource use – to determine which CPT level code to report. As a result, there is no consistency in the coding methodology used by various hospitals.

To address concerns that the use of E/M codes with different reporting rules and meanings would violate Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) requirements, CMS recommended in its November 1, 2002 OPPS final rule that an independent expert panel charged with the task of recommending to CMS definitions and guidelines for clinic and emergency E/M codes be convened. The final rule also specified that CMS would not create new codes to replace existing CPT E/M codes for reporting hospitals visits until national guidelines have been developed.

In January 2003, the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) formed an independent expert panel charged with the task of developing E/M coding guidelines. In June 2003, the panel submitted a set of guidelines to CMS.

After making some modifications to the independent expert panel's recommendations, CMS contracted a study to test the guidelines. According to CMS, the contractor's findings indicated that the AHA/AHIMA model did not establish a relationship between the distribution of current hospital reporting of visits using CPT E/M codes that are assigned according to each hospital's internal guidelines and the distribution of code levels under the panel's guidelines. CMS did not adopt the recommendations, but stated that the AHA/AHIMA model should serve as a starting point for national guidelines development.

Proposed Rule

Although the November 1, 2002 OPPS final rule, specified that CMS would not create new codes to replace existing CPT E/M codes for reporting hospital visits until national guidelines have been developed, the Agency is proposing for CY 2007 to create new Health Care Procedure Coding System (HCPCS) level II G codes for hospital clinic visits, emergency department (ED) visits and critical care services. Specifically, CMS would create five G codes to replace the current CPT codes currently used to report clinic visits, five G codes for emergency departments that are open 24 hours (Type A emergency departments), five G codes for emergency departments that satisfy other requirements, but are not open 24 hours (Type B emergency departments), and two G codes to replace the two current CPT codes used to report critical care services. Because Type B emergency departments do not meet the CPT definition of emergency departments, CMS has been instructing hospitals to report services furnished in these

departments using CPT clinic visit E/M codes rather than the emergency department visit codes used by Type A emergency departments.

For clinic and emergency department visit services, CMS proposes that payment be made at five payment levels instead of the current three levels of payment, based on the assignment of the codes to the five clinic visit APCs and the five emergency department visit APCs. Both clinic visit codes and Type B emergency department visit codes would be mapped to the corresponding clinic visit APC payment level, while Type A emergency department visit codes would be mapped to the appropriate emergency department visit APC payment level.

CMS's rationale for creating a separate set of codes for visits to emergency departments that are not open 24 hours is that the codes would help CMS collect and analyze hospital resource costs of visits to Type B EDs. The Agency proposes to continue to pay for Type B ED visits based on clinic visit APCs until it collects and analyzes the data.

The proposed rule would give hospitals the option to continue to use their own internal guidelines to determine the visit levels to be reported with the new G codes or to adjust their guidelines to reflect the new codes and policies.

Comments

The AAMC urges CMS to rescind the proposal to implement new G codes for hospital clinic and emergency department visits before the adoption of national code definitions and national guidelines. The proposal would impose an administrative burden on hospitals for several reasons. First, since G codes are not recognized by other payers, hospitals would need to use two sets of codes to report clinic and emergency department visits: G codes for Medicare and CPT codes for non-Medicare payers. Second, since the G codes are temporary, hospitals would likely need to change their coding processes twice, once with the implementation of G codes and again when national guidelines have been developed. Furthermore, without a standardized methodology to determine the visit levels to be reported with the new G codes, there will continue to be considerable variability in the levels of service and a lack of stability in terms of coding and payment policy. Finally, the proposal to pay E/M visits at five rather than three levels introduces a degree of specificity that would make it very difficult for hospitals to precisely determine the level payment a particular intervention should be assigned to.

In addition, we urge CMS to consider paying for services provided at satellite emergency departments at the Type A emergency department payment rate. Satellite EDs are facilities that are located at a different location than the main campus and, although they are not open 24 hours, they satisfy other emergency department requirements. Because they are an extension of the main campus, they are likely to treat patients that are similar clinically and in terms of resource use to those treated in the emergency department located on the main campus. Therefore, these facilities enhance beneficiary access. We

are concerned that providing payment at the clinic level until such time as CMS gathers sufficient data to determine costs of Type B emergency departments could hurt satellite emergency departments and hinder access to care.

DEVICE-DEPENDENT APCs

The rule proposes that both the APC payment and beneficiary copayment be reduced for selected "device-dependent" procedures that involve replacing a defective implanted device with a new device that was provided to the hospital at no cost or the hospital received full credit for the removed device. The payment reduction would be based on an estimate of the device cost.

CMS provided no information as to how many procedures involve defective device replacement, so it is not possible to know the magnitude of the problem or the impact of this proposal. However, on its face, it seems reasonable that payment for defective devices that are replaced should be taken out of the APC payment rate when the device has been replaced at no cost to the hospital. However, the methodology used to calculate the amount of the APC reduction raises two concerns.

First, even though the hospital may incur no cost for the device that replaces the defective device, the hospital often still incurs administrative costs related to processing the "no charge" status of the device. For example, the hospital needs to record the "no charge" status of the device when it is received; it needs to instruct the finance and patient accounting departments to charge differently for the device/procedure; and the hospital must report to Medicare that the procedure involves the replacement of a defective. Consequently, if CMS does not take into consideration the administrative costs related to the replacement of a defective device, even when the hospital incurs no cost for the device, reducing the APC payment by an amount that equals the full device cost would lead to payment that is lower than the total cost incurred.

Second, reducing the APC payment by the full device cost may result in further underpayment if the replacement device is an upgrade from the device that is removed from the patient. In these cases, hospitals generally must pay the difference between the upgraded device and the replaced device.

In light of these concerns, we urge CMS to reduce the APC payment amount for devices that are replaced at no cost to the hospital by a percentage that is lower than the percentage associated with the full cost of the defective device. In addition, for upgraded devices, we urge CMS to apply a smaller offset amount to the APC associated with the upgraded device than the offset applied to an APC associated with a device that is replaced at no cost to the hospital.

CMS is proposing that hospitals use a modifier to identify those devices that have been replaced without cost to the hospital or where full credit was given by the manufacturer.

The Agency recognizes that the "the current FB modifier may not be appropriate in cases in which the replacement device is a more expensive device than the device being removed and may need to be changed to expand its use for all potential APC payment adjustment scenarios." (71 Fed. Reg. at 49577). It is unclear whether CMS proposes to continue using the FB modifier or whether another modifier would be required for the purpose of identifying devices that have been replaced without cost to the hospital or where full credit was given by the manufacturer. We urge CMS to clarify how the modifier would be used in order to identify devices that are more expensive than the removed device.

OUTLIER PAYMENTS

Outlier payments are an important component of the OPPS, because they provide some financial cushion when hospitals provide high cost services. In 2006, CMS reduced the percentage of the total outlier payments from two percent of total expenditures to one percent. For 2007, CMS is proposing to continue to allocate one percent of total payments for outlier payments.

A hospital receives an outlier payment for a service if the hospital's cost for that service exceeds 1.75 times the APC payment rate and the cost exceeds the APC payment rate plus a fixed dollar threshold of $1,175. CMS proposes to increase the fixed-dollar threshold by $575 (from $1,250 to $1,825), while keeping the multiplier threshold at its current level of 1.75. CMS states that the increase in the outlier threshold is the result of applying a new methodology for calculating the cost-to-charge ratios (CCR) as well as targeting the outlier pool to account for one percent of total payments. According to CMS changes to outlier payments are estimated to result in a 0.25 percent loss in total payments for hospitals.

As we have noted in the past, major teaching hospitals tend to treat a larger proportion of complex and costly cases, thereby relying more heavily on outlier payments. For instance, data from CY 2004 and CY 2005 show that outlier payments as a percent of total payments are greater for major teaching hospitals (3.0 percent and 3.2 percent respectively) than for non-teaching (1.8 percent and 1.5 percent respectively) and other teaching (1.7 percent and 1.8 percent respectively).[1] Furthermore, according to CMS's analyses published in the November 10, 2005 final rule, non-teaching and minor teaching hospitals were estimated to experience a slight positive impact due to the outlier pool reduction (0.2 percent), while major teaching hospitals were estimated to see a 0.7 percent decrease in total payments in CY 2006.[2]

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[1] See Table 16 (CY 2004 OPPS final rule) and Table 42 (CY 2005 OPPS final rule) in 68 Fed. Reg. at 63475 (Nov. 7, 2003), and 69 Fed. Reg. at 65857 (Nov. 15, 2004), respectively.

[2] See Table 40 in 70 Fed. Reg. at 68725 (Nov.10,2005).

In the proposed rule, CMS did not include any analyses that would specifically show the impact of the revised CCR calculation on outlier payments and has provided no data to support the proposed reduction or its impact on various classes of hospitals. Even more important, unlike the inpatient proposed rule, the OPPS rule contains no information about whether historical outlier payments were more or less than the outlier pool. We believe these data must be made available to allow providers to make meaningful comments as to whether increasing the outlier threshold is appropriate.

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Relying on hospital cost reports and outpatient claims data to estimate costs, CMS is proposing to pay for separately payable drugs and biologicals at the average sales price (ASP) plus five percent. This constitutes a one percent payment reduction from the payment rate hospitals receive in 2006. It also is lower than the physician office setting payment rate of ASP plus six percent.

We appreciate CMS's request for comments on hospitals' overhead costs associated with these drugs (71 Fed. Reg. at 49585). We believe that both the current and proposed payment rates may be too low for certain drugs and biologicals with very high overhead and handling costs. According to CMS's analyses, paying hospitals at ASP plus five percent would cover both the acquisition and the handling costs for drugs and biologicals. We have heard from several of our hospitals, however, that some of their acquisition and handling costs exceed even the current payment rate of ASP plus six percent.

There may be two potential explanations that can account for the discrepancy between the payment that CMS believes would cover the acquisition and handling costs of certain separately payable drugs and biologicals and what would constitute sufficient payment to cover their costs.

First, there is the issue of "charge compression." Studies have shown that hospitals usually use a lower markup for high cost items than they do for lower cost items. CMS however, applies one department level cost-to-charge ratio to all services reflected in that department. Because this methodology does not take into account hospitals' variability in setting charges, it invariably results in what is referred to as "charge compression", which is the under-estimation of costs associated with low markup services and over-estimation of costs associated with high-markup items.[3] Recognizing the likelihood of this phenomenon on the inpatient side, CMS has awarded a one-year study to RTI International to study methods of improving the accuracy of the adjustment of charges to costs for inpatient services. Since hospitals use the same practice on the outpatient side, it is likely that outpatient services are also affected by the charge compression. Thus, the more expensive the drug or biological, and the lower the markup, the more likely that its

[3] Note: This issue also applies to device-related APCs.

cost derived from the application of a department level cost-to-charge ratio is underestimated.

Second, in its June 2005 Report to the Congress, the Medicare Payment Advisory Commission (MedPAC) found that drug handling costs are not negligible and vary greatly depending upon the type of drug involved. The report further noted that some classes of hospitals, including teaching hospitals, provide many services that include separately payable drugs and biologicals and a payment system based on acquisition costs could have redistributive effects among facilities.[4] We are concerned that CMS uses a methodology based on averages that may mask the high handling costs of certain drugs and biologicals.

We urge CMS to clarify in the final rule the methodology used to arrive at the ASP plus five percent payment proposal. The proposed rule does not fully explain how the claims data analyses were translated into the ASP methodology. The preamble discussion merely states that "using mean unit cost [from the CY 2005 hospital claims data] . . . would be equivalent to basing their payment rates, on average, at ASP + 5 percent." (71 Fed. Reg. at 49585). Given that the ASP methodology is drug-specific, it is unclear what "crosswalk" CMS used to connect the claims data and the ASP data. We urge CMS to provide further explanation of its methodology in the final rule. We further respectfully request that CMS provide information as to what variables from the claims data the Agency is using to arrive at the proposed payment rates, how many hospitals are included in the data analysis, and the trimming procedures utilized.

In light of these concerns, and until such time as these data have been provided and hospitals have had the opportunity to review and comment on the methodology used to determine payment rates for drugs and biologicals, we urge CMS to continue paying for separately payable drugs and biologicals at ASP plus six percent.

NEW TECHNOLOGY APCs

CMS is proposing to move certain procedures from "new technology APCs" to clinical APCs in less than two years. A number of these procedures will experience payment reductions due to these new assignments. Although it is the purview of CMS to move services from new technology APCs to clinical APCs in less than two years, we are concerned that the data that CMS obtains in the first two years after services are approved may not be accurate because diffusion of new technologies can be slow and hospitals need time to update their charge masters to appropriately reflect charges that reflect the actual costs of the new services. We ask CMS to consider maintaining procedures in the new technology APC categories for a minimum of two years before assigning them to a clinical APC.

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[4] See MedPAC's June 2005 Report to the Congress: *Issues in a modernized Medicare program*, page 140.

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Teaching hospital's outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the mission of teaching hospitals. Medicare outpatient payments are critical for teaching hospitals to continue their missions in the outpatient setting, including serving important access roles for outpatient services that range from clinic and emergency room visits to technically-advanced innovations. We would be pleased to work with CMS as it continues to refine and improve this important Medicare payment system.

If you have questions concerning these comments, please contact Diana Mayes, at dmayes@aamc.org, or 202-828-0498 or Karen Fisher at kfisher@aamc.org, or 202-862-6140.

Sincerely,

Darrell G. Kirch

Darrell G. Kirch, M.D.

cc: Robert Dickler, AAMC
Karen Fisher, AAMC
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October 10, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
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Department of Health and Human Services
Room 445-G
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200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Calendar Year (CY) 2007 Update to the Ambulatory Surgical Center Payment System (CMS-1506-P, Section XVII)

Dear Dr. McClellan:

Boston Scientific Corporation (Boston Scientific) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed CY 2007 Update to the Ambulatory Surgical Center Payment System (CMS-1506-P, Federal Register, Vol. 71, No. 163, August 23, 2006).

As the world's largest company dedicated to developing, manufacturing, and marketing of less-invasive therapies, Boston Scientific supplies medical devices and technologies to the following medical specialty areas:

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

Executive Summary

Boston Scientific's comments are categorized into two major sections. The first addresses broad, systemic issues centered on definitions and exclusion criteria, patient safety and quality measures, while the second section proposes recommendations relating to specific procedures. The issues and our recommendations are outlined below.

I. Systemic Issues: Refining and Expanding Clinical Exclusion Criteria, Patient Safety Standards, and Quality Reporting Systems

After reviewing CMS' proposed additions to the ASC coverage list for 2007, we ask that CMS amend the current clinical exclusion criteria definitions, create effective and consistent patient safety standards, and put in place clinical quality reporting systems as part of the overall ASC payment system for CY 2007.

II. Procedure-Specific Issues

Because of concerns about patient safety, we urge CMS to remove CPT codes 37205, 37206 and 35476 from the CY 2007 list of ASC Covered Procedures.[1] We also ask that CMS reassign CPT codes 58563 and 58353 to ASC Payment Group 9 effective 1/1/2007, consistent with its proposed reassignment of CPT code 58565.

Discussion of Rationales for Requests

I. Systemic Issues: Refining and Expanding Procedural Exclusion Criteria, Patient Safety Standards, and Quality Reporting Systems

1. **Adopt a modified version of the definition of "Major Blood Vessel" provided in Essentials of Anatomy & Physiology, 6th Edition**[2] (Please refer to Appendix A for our proposed definition of "Major Blood Vessel").

   Section 416.65(b)(3) of the CFR limits covered ASC procedures to those that do not involve major blood vessels or extensive blood loss. Boston Scientific agrees with this regulation. However, the current regulatory language does not provide detailed definitions of either "Major Blood Vessel" or "Extensive Blood Loss," which we believe are necessary as prerequisites for CMS adding any additional procedures to the ASC list. The lack of clarity serves to create confusion, make compliance difficult, and generate opportunities for procedures to either be inappropriately added to or excluded from the ASC Covered Procedures List. We strongly encourage CMS to establish regulatory definitions of "major blood vessel" and "extensive blood loss."

   Defining Major Blood Vessel
   To develop a suggested definition of "Major Blood Vessel," Boston Scientific conducted research in peer-reviewed literature to determine whether a standard definition exists. The most comprehensive list of major blood vessels found in our research is provided by Seeley, Stephens and Tate in their medical textbook, Essentials of Anatomy & Physiology, 6th Edition.[3] This list includes not only the heart and the aorta, but also includes vessels providing primary blood supply to major limbs and organs including the legs and the kidneys.[4]

   We urge CMS to adopt a modified version of the definition of major blood vessels provided in Essentials of Anatomy & Physiology, 6th Edition, a text that is used in many medical schools throughout the United States, as its standard for determining whether a procedure should be added to the ASC list. CMS could, for example, modify the Seeley, Stephens, and Tate definition by allowing exceptions for those procedures are already being performed in the ASC.

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[1] *Current Procedural Terminology (CPT)* is copyright 2006 American Medical Association. All rights reserved.
[2] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.
[3] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.
[4] *Ibid.*

By adopting a modified version of the Seeley definition, CMS will not affect any of the procedures currently covered in the ASC, but it will take an important step towards insuring the safety and wellbeing of Medicare beneficiaries as the list is expanded.

2. **Adopt the American College of Surgeons' Definition of "Extensive Blood Loss".[5]**

Boston Scientific proposes that CMS adopts the American College of Surgeons' definition of extensive blood loss, which is the loss of ≥15% of total blood volume during the routine performance of the procedure (excluding any peri-procedural complications).[6] The loss of <15% of total blood volume typically results in no change in vital signs, and fluid resuscitation is not usually necessary.

3. **Establish Consistent Standards for Patient Safety Across Sites of Care Before Expanding the List of Procedures Covered in the ASC.**

Medicare's interest in both safety and quality is reflected in recent initiatives for both inpatient and outpatient care.[7] Unfortunately, despite suggestions from MedPAC and the Office of the Inspector General (OIG) to implement quality standards for ASCs, Medicare has not proposed safety and quality standards for ASCs that are consistent with those in hospitals.[8,9]

For example, hospitals are required to have experienced nurses or physicians supervising operating rooms; ASCs are not. Although Medicare requires hospitals to document history and physical examination for every patient prior to surgery, there is no similar requirement for ASCs.[10]

Based on these important gaps and inconsistencies in oversight and safety standards, we urge CMS to standardize safety requirements across all sites of service before moving additional procedures to the ASC setting.

4. **Establish Site-Relevant Clinical Quality Reporting Standards and a Method for Attributing Adverse Events to the Originating Site of Care**

Given the significant interest CMS and all stakeholders have in gaining insights to clinical outcomes associated with contemporary clinical practice, it is essential that clinical outcomes information be captured to inform decision-making. Unfortunately, the patchwork of quality reporting "systems" are not as comprehensive for ASCs compared to hospitals, skilled nursing facilities, and other settings.

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[5] American College of Surgeons' Advanced Trauma Life Support (ATLS) as defined at http://en.wikipedia.org/wiki/Hemorrhage .
[6] American College of Surgeons' Advanced Trauma Life Support (ATLS) as defined at http://en.wikipedia.org/wiki/Hemorrhage .
[7] http://www.cms.hhs.gov/HospitalQualityInits/ .
[8] MedPAC. March 2005 Report to Congress. Page 154.
[9] DHHS, Office of Inspector General. Quality Oversight of Ambulatory Surgical Centers. February, 2002.
[10] http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalStarterSet200512.pdf .

From a quality perspective, hospitals must report specific information related to surgical infection prevention (SIP), including prophylactic antibiotic administration, that ASCs are not required to report (for a full list of the hospital quality measures required by Medicare, please refer to Appendix B).[11]

In addition, state licensing requirements and accreditation standards are extremely variable. In a report by the American Hospital Association (AHA), only 43 of 50 states even require ASCs to be licensed whereas all states require hospitals to be licensed.[12]

The AHA report also suggests that "states' ability to oversee ASCs on behalf of Medicare is eroding because of the growth in ASCs and states' limited resources. Of state-surveyed ASCs, one-third (872) had not undergone a recertification survey in over five years."[13] According to the OIG, "CMS gives little oversight to ASC surveys and accreditation, and CMS does not make findings readily available to the public as it does for hospitals and other types of providers."[14] Few states have restrictions on the procedures that can be performed in ASCs, and few states regulate infection control practices or equipment requirements.[15]

According to the AHA, state and Medicare standards for monitoring the quality of care delivered in ASCs are not as stringent as those for hospitals.[16] In addition, inconsistent regulation and reporting standards by states provide no clear pathway to understanding the outcomes in this site of service. Therefore, Medicare cannot track complications arising from ASC cases. Moreover, there is currently no way to assess the safety of procedures in ASCs and to tie infections and complications stemming from procedures performed in ASCs back to the ASC, rather than attributing them to the hospital that ultimately treats the complications.

II. Procedure-Specific Issues

1. Remove CPT Codes 37205, 37206, and 35476 from the list of ASC Covered Procedures.[17]

For CY 2007, CMS is proposing to add 14 additional procedures to the ASC Covered Procedures List including the following peripheral vascular procedures:

- *37205 - Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel*
- *37206 - Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel*
- *35476 - Transluminal balloon angioplasty, percutaneous; venous*

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[11] *Ibid.*
[12] *Ibid.*
[13] *Ibid.*
[14] *Ibid.*
[15] *Ibid.*
[16] American Hospital Association. The Migration of Care to Non-hospital Settings: Have Regulatory Structures Kept Pace with Changes in Care Delivery? *TrendWatch*. July, 2006.
[17] *Current Procedural Terminology (CPT)* © 2006 American Medical Association. All rights reserved.

As manufacturers of medical devices, Boston Scientific is interested in expanding access to services that use our products. However, our first and foremost concern is the safe and effective delivery of health care services. The three CPT codes listed above (37205, 37206 and 35476) do not meet the clinical inclusion criteria established by Medicare. First, they do not meet the definition of major blood vessel identified above. And, second, they involve more than 90 minutes of physician time. Finally, the procedures may trigger complications, requiring emergent hospital care.

These Procedures Fail to Meet the "Major Vessel" definition Identified Above
These procedures all involve major blood vessels per the definition of "major blood vessel" put forth by Seeley, Stephens, and Tate in their medical textbook, Essentials of Anatomy & Physiology.[18] Transluminal balloon angioplasty, venous, and transcatheter placement of intravascular stents involve dilatation of major blood vessels including:

- The superficial femoral artery and the femoral popliteal artery (maintaining blood supply above and below the knee)
- The iliac vessels (main source of blood supply to the legs)
- The renal arteries (main source of blood supply to the kidneys).
- Veins of the abdomen and pelvis, the lower limbs, and the hepatic portal system

These Procedures Involve More than 90 Minutes of Physician Time
According to CMS data file 2007NPRM_PTF on the total physician time associated with procedures, these procedures require the following amounts of time:

- 37205: 98 minutes
- 37206: 90 minutes (please note that this procedure is only performed in conjunction with 37205. Therefore, this procedure actually extends the time associated with 37205 by 90 minutes for each additional vessel stented).
- 35476: 145 minutes

These times represent physician service time, and all well exceed the 90 minute cutoff mandated Section 416.65 of the CFR. Because CMS is not proposing coverage criteria changes for January 1, 2007 implementation, these procedures should be excluded from the covered services list since they exceed the maximum allowable length of time under current rules.

These Procedures May Trigger Complications Necessitating Emergent Hospital Care
In our review of the literature on peripheral vascular procedures, we obtained key insights to the importance of consistent safety standards across treatment settings. While infrequent, there can be complications associated with peripheral vascular procedures including infection, dissection, amputation and even death.

Both angioplasty and transcatheter intravascular stent placement are generally safe. However stent placement procedures are associated with adverse events that can place a patient at risk for dissection, amputation, infection and even death. These complications, which primarily stem

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

from the need for femoral puncture to gain access to the target vessel(s), are usually relatively easily managed in hospitals. If such complications arise in a physician office or ASC setting, the patient would be required to be transported to a hospital for further management while maintaining open femoral access. Maintaining an open femoral puncture during transport raises the risk of dissection or infection.

In a recent study of 112 interventions in 97 patients, 9 (8%) outpatient procedures resulted in admission, including one patient with a major puncture site hematoma requiring blood transfusion and two patients with minor hematomas at the puncture site.[19] In another study of 197 interventional procedures, 177 of which were balloon dilatations, there were 68 complications (35%), including five patients (2.5%) who had significant problems requiring admission and active therapy.[20] Waugh and Sacharias described a significant complication rate of 3.6% among patients undergoing peripheral interventional procedures (63% of which were balloon angioplasty procedures).[21]

Occlusion is also commonly found in, or may be a complication of, peripheral vascular interventions including venous PTA and transcatheter placement of intravascular stents. In one study of 181 lesions in 166 vessels, 55% of lesions were either occluded or stenosed and occluded.[22] In another study of 23 patients with critical limb ischemia, patients typically presented with combined stenoses and occlusions in 15 (60%) limbs, stenoses alone in 4 (16%), and occlusions alone in 6 (24%).[23]

Occlusion is often managed with inpatient lytic therapy. Because lytic therapy is administered on an inpatient basis typically via intra-arterial catheters, it would necessitate transfer with an open catheter site from an ASC or physician office to a hospital. Movement associated with transfer could result in dissection/perforation. Moreover, transfer involves movement of the patient in non-sterile environments, increasing the risk of infection.

In sum, these procedures should be excluded from the ASC Covered Procedures List because they do not meet Medicare's criteria for coverage and in some situations may result in adverse events.

2. Reassign Endometrial Ablation Procedures to ASC Payment Group 9 effective 1/1/07.[24]

We are pleased that CMS continues to make refinements to its ASC payment system for 2007 despite the impending 2008 ASC payment system changes. Based on the merits of CMS'

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[19] Akopian G and Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg.* 2006;44:115-8.
[20] Young N, *et al.* Complications with outpatient angiography and interventional procedures. *Cardiovasc Intervent Radiol.* 2002; 25:123-126.
[21] Waugh JR, Sacharias N. Arteriographic complications in the DSA era. *Radiology.* 1992; 182:243-246.
[22] 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.
[23] 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.
[24] *Current Procedural Terminology (CPT)* © 2006 American Medical Association. All rights reserved.

proposed 2007 change in payment category for CPT code 58565, we are requesting a similar reassignment for CPT codes 58563 and 58353, the descriptors of which are shown below:

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

Endometrial ablation is a minimally invasive, less costly alternative to hysterectomy for women suffering from abnormal or excessive uterine bleeding. The procedure is well tolerated by patients, easily learned by physicians and ideally suited for ASCs.

In its proposal, CMS stated the following on CPT code 58565 *(Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants)*:

> "After further review, we are convinced that the procedure described by CPT code 58565 is significantly more resource-intensive than the other procedures in ASC payment group 4 and, therefore, we are proposing to reassign it to ASC payment group 9 for CY 2007."

Hysteroscopic tubal occlusion (CPT code 58565) is a less invasive gynecologic procedure which uses a single-use, transcervical device to achieve fallopian tube occlusion. We strongly support CMS' proposed reclassification, as this would better match the resources of procedure to a more comparable payment category. For the same reasons, we also request that CPT codes 58563 and 58353 be reassigned to payment group 9.[25]

58563 and 58353 are Similar to 58565

Endometrial ablation procedures described by CPT codes 58563 & 58353 use transcervical, single-use devices and are similar in resource intensity to 58565. In terms of anesthesia requirements, all three procedures can be done safely in ASCs under monitored anesthesia care (MAC) or total intravenous anesthesia (TIVA). All three procedures are done primarily by gynecologists. According to 2005 Medicare PSPSF data, the percent of total procedures performed by OB-GYNs were: 58353 – 97%, 58353 – 97% and 58565 – 95%.

In addition, the 2005 Medicare outpatient hospital median cost data are very similar in terms of resource intensity, as outlined below.

CPT Code	2005 OPPS Median Cost
58565	$2,247.70
58563	$2,106.50
58353	$1,982.60

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

Reassigning Codes 58563 and 58353 Provides More Adequate and Stable Payment
By reassigning 58563 and 58353 to ASC Payment Group 9 effective 1/1/07, CMS would make it financially feasible to perform these procedures in the lower cost ASC setting. Under the current payment scenario, the Group 4 rate of $630 does not even cover the disposable device cost, making the procedure cost-prohibitive and forcing more cases to the higher cost hospital setting.

Using current OPPS payment estimates for 58563 and 58353, the fully-implemented 2009 proposed ASC rate of $1,312 would be very close to the current ASC Group 9 payment of $1,339. The reassignment of these codes in 2007 would foster a smoother transition to the new payment system for these procedures, compared with the highly varied rates that would be effective without reassignment. The 3-year proposed payment outlook for endometrial ablation procedures would be:

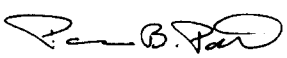
CPT code[26]	2007	2008	2009
58563	$1,339	$1,326	$1,312
58353	$1,339	$1,236	$1,132

We believe our request to reclassify CPT codes 58353 and 58563 to ASC Group 9, effective 1/107, is warranted and consistent with CMS' proposed reassignment for CPT code 58565.

****

Thank you for the opportunity to comment on the 2007 proposed changes to the ASC payment system. 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: Herb Kuhn, Center for Medicare Management
Tom Gustafson, Center for Medicare Management
Elizabeth Richter, Hospital & Ambulatory Policy Group
Jim Hart, Hospital & Ambulatory Policy Group
Joan Sanow, Hospital & Ambulatory Policy Group
Scott Reid, Boston Scientific Corporation

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

Appendix A: Proposed Definition of "Major Blood Vessel"[27]

According to Seeley, Stephens and Tate in their well-known medical textbook, Essentials of Anatomy & Physiology, 6th Edition, the following vessels are considered "major blood vessels." Please note that because procedures involving some of the vessels defined as "major" in the textbook are already performed safely in ASCs, Boston Scientific proposes omitting these vessels from the definition:

- Heart
- Divisions and Branches of the Aorta
  - Ascending aorta
  - Aortic arch
  - Descending aorta (thoracic and abdominal aorta)
- Arteries of the Shoulder and Upper Limb
  - Right and left subclavian arteries
  - Axillary arteries
- Arteries of the Head and Neck
  - Common, external and internal carotid arteries
  - Vertebral arteries
- Major Branches of the Abdominal Aorta
  - Celiac trunk
  - Superior and inferior mesenteric arteries
  - Renal arteries (supplier of blood to kidneys)
  - Gonadal arteries
  - Common iliac arteries (at L_5 level; sole supply of blood to legs)
- Arteries of the Pelvis and Lower Limb
  - Right or left common iliac artery
  - Femoral artery
  - Anterior and Posterior tibial artery
- Veins Entering the Right Atrium
  - Coronary sinus veins
  - Superior and inferior vena cava
- Veins of the Head and Neck
  - External and internal jugular veins
  - Vertebral vein
- Veins of Abdomen and Pelvis
  - Hepatic, renal and gonadal veins
  - Right and left common iliac veins
- Veins of Lower Limb
  - Anterior and posterior tibial veins
- Hepatic Portal System
  - Hepatic portal vein
  - Mesenteric veins
  - Gastric veins
  - Cystic vein

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

Appendix B: Medicare Hospital Quality Measures[28]

The Hospital Quality Alliance (HQA) Ten Measure "Starter Set"

Performance Measures	Measure Description – for additional information including inclusions and exclusions click on the Performance Measure
AMI - Aspirin at Arrival	Acute myocardial infarction (AMI) patients without aspirin contraindications who received aspirin within 24 hours before or after hospital arrival.
AMI - Aspirin Prescribed at Discharge	Acute myocardial infarction (AMI) patients without aspirin contraindications who are prescribed aspirin at hospital discharge.
AMI – ACEI or ARB for LVSD	Acute myocardial infarction (AMI) patients with left ventricular systolic dysfunction (LVSD) and without angiotensin converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) contraindications who are prescribed either an ACEI or ARB at hospital discharge.*
AMI - Beta Blocker at Arrival	Acute myocardial infarction (AMI) patients without beta blocker contraindications who received a beta blocker within 24 hours after hospital arrival.
AMI - Beta Blocker at Discharge	Acute myocardial infarction (AMI) patients without beta blocker contraindications who are prescribed a beta blocker at hospital discharge.
HF-LVF Assessment	Heart failure patients with documentation in the hospital record that left ventricular function (LVF) were assessed before arrival, during hospitalization, or planned for after discharge.
HF-ACEI or ARB for LVSD	Heart failure patients with left ventricular systolic dysfunction (LVSD) and without angiotensin converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) contraindications who are prescribed either an ACEI or ARB at hospital discharge.*
PNE-Initial Antibiotic Timing	Pneumonia patients who receive their first dose of antibiotics within 4 hours after arrival at the hospital.
PNE-Pneumococcal Vaccination	Pneumonia patients age 65 and older who were screened for pneumococcal vaccine status and were administered the vaccine prior to discharge, if indicated.
PNE-Oxygenation Assessment	Pneumonia patients who had an assessment of arterial oxygenation by arterial blood gas measurement or pulse oximetry within 24 hours prior to or after arrival at the hospital.

*Measure revised to incorporate ARBs, per **joint agreement** of the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) issued on November 15, 2004. Page last updated November 22, 2005

[28] http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalStarterSet200512.pdf .

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Joint Commission
on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

October 10, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
CMS-1506-P
CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System (OPPS) and Fiscal Year 2007 Rates; Promoting Effective Use of Healthcare Information Technology (HIT); Healthcare Information Transparency Initiative, and; Reporting Hospital Quality Data for FY2008 Inpatient Prospective Payment System (IPPS) and Annual Update Program

The Joint Commission on Accreditation of Healthcare Organizations welcomes the opportunity to comment on the outpatient quality reporting, hospital inpatient quality reporting, and healthcare information technology (HIT) issues contained within the Outpatient Prospective Payment System (OPPS) proposed rule released August 23, 2006. Established in 1951, the Joint Commission is an independent, not-for-profit organization that evaluates and accredits nearly 15,000 healthcare organizations in the U.S. These include hospitals, laboratories, ambulatory care and office-based surgery facilities, and assisted living, behavioral healthcare, home care, hospice, and long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission accreditation decisions and findings for Medicare and licensure purposes across all of the Joint Commission's accreditation programs.

The Joint Commission is a recognized and award winning international leader with a long proven ability to identify, test and specify standardized performance measures. We engage in cutting edge performance measurement research and development activities, and have established successful, ongoing, collaborative relationships with key performance

measurement entities. Furthermore, the Joint Commission presides over a growing, national, comparative performance measurement database that can inform internal healthcare organization quality improvement activities, external accountability efforts, and pay for performance (P4P) programs.

Hospital Quality Data: Reporting Quality Data Under the OPPS (Section XX)

- Overall, the Joint Commission agrees that the absence of hospital outpatient quality measures for Medicare beneficiaries creates an "issue of payment equity." Indeed, improved quality reporting for all healthcare services, regardless of setting, should be a top priority for CMS. Increasingly, evidence supports the use of value-based purchasing mechanisms to promote higher quality and more efficient healthcare services.
- Section XX of the proposed rule, contains statements that the Joint Commission find confusing and, at times, conflicting. This made it difficult for us to determine the specific outpatient reporting requirements hospitals must undertake to receive the full conversion factor update[1]. After discussions with other stakeholders, the Joint Commission determined that there could be two distinct interpretations: (1) hospital outpatient departments must report the IPPS measures for outpatient discharges, to prevent a 2.0 percent reduction in their FY2007 OPPS conversion factor update, or; (2) hospitals that report all the IPPS measures for inpatient discharges will automatically receive the full FY2007 OPPS conversion factor update. Because the Joint Commission is not clear on CMS' intent, our comments will address both of these interpretations.

Joint Commission Comments: Option One - CMS Requires Outpatient Departments to Report

Any way you interpret Section XX of the proposed rule, it is certain that CMS will initiate a Reporting Hospital Quality Data for Annual Payment Update under the OPPS (OPPS RHQDAPU) effective January 1, 2007. However, under the first interpretation, hospitals that are required to participate in the IPPS RHQDAPU will need to report these same 21 IPPS measures under the OPPS RHQDAPU for their outpatient discharges, in order to receive the full FY2007 OPPS conversion factor update. If this is the correct interpretation,

[1] The conversion factor update is a combination of a market basket increase, as well as budget neutrality and outlier threshold adjustments.

the Joint Commission strongly encourages CMS to develop a mechanism to test the use of the inpatient measures for services that are delivered in outpatient settings. The Joint Commission believes that the introduction of measures to the outpatient arena, which were developed for inpatient services, should not be undertaken without sufficient reliability and validity testing. The authority under section 1833(t)(2)(E) of the Social Security Act to make "adjustments as determined to be necessary to ensure equitable payments" is not a sufficient argument to implement such a burdensome, untested mandate. Hospital outpatient departments will not be able to prepare for, and participate in, this reporting requirement in such a short period of time. Additionally, the Joint Commission is concerned that the diversion of resources needed for the proposed OPPS reporting might negatively affect the ability of hospitals to report all the HQA-approved IPPS measures, possibly negating the improvement potential of both.

As an organization that has worked on quality measures for decades, the Joint Commission strongly cautions CMS on the assumption that the use of inpatient measures "reasonably represent the quality of care provided to hospital outpatients." How accountabilities might map from the inpatient to the outpatient setting in the context of measurement is, at best, unknown without specific empiric testing. A specific example of this inpatient/outpatient incompatibility involves the acute myocardial infarction (AMI) population in the inpatient setting, which is identified by an ICD-9-CM principal discharge diagnosis of AMI. In this proposed rule, it is noted that the seven inpatient AMI measures will likely serve as reasonable proxies for the quality of patients presenting to the hospital outpatient department, with chest pain related to a myocardial infarction, who commonly receive care along the continuum. Currently these measures have never been tested to ensure that the population in the outpatient setting can be reliably identified using the same methodology and the specified ICD-9-CM codes, which do not include codes for chest pain. Furthermore, it is unclear how the inpatient measure exclusions applicable to all measures, would be applied in the outpatient setting.

The Joint Commission believes that a substantial amount of research and field input, similar to what was necessary for the development of the IPPS measure set, should be expended on any measures that will be applied to the outpatient arena. Anything less rigorous would most likely impede quality improvement efforts in the provider community, not

enhance them. Furthermore, CMS should seek to consolidate the various silos of measures into a single set that promotes patient-centeredness, episodes of care, the continuum of care, and disease management. There also needs to be a national measurement framework for establishing the priorities for outpatient measures. And, before the implementation of these outpatient measures, that CMS proposes would happen in 2009, some testing, dry run or pilot expansion process should be pursued previous to public reporting of the findings.

Joint Commission Comments: Option Two – IPPS Reporting Alters OPPS Payment

If it is the intent of CMS to simply use the evidence of IPPS reporting to influence the OPPS conversion factor update for FY2007 and FY2008, then the Joint Commission supports the extra incentive for hospital quality reporting. As noted in the proposed rule, not all hospitals are currently participating in the IPPS reporting system, and have had their IPPS payment updates reduced accordingly. It is imperative that all hospitals participate in this avenue for accountability and quality improvement. Thus, basing a portion of OPPS payment on whether hospitals report their IPPS measures is warranted.

Health Information Technology (HIT): Promoting Effective Use of HIT (Section XXI)

- CMS is seeking comment on their statutory authority to promote the adoption and use of HIT, possibly through hospital conditions of participation (CoPs).

Joint Commission Comments:

The Joint Commission commends CMS for utilizing this proposed rule as a vehicle to energize the public dialogue about HIT. CMS' leadership is crucial if we are to bring information technology into the healthcare industry in an efficient and effective manner. The creation of a comprehensive HIT infrastructure is integrally linked to healthcare quality and patient safety improvement efforts, and is critically associated with their success. Within this framework, an important role for quality oversight and quality improvement organizations, such as the Joint Commission, is to develop information management standards, to apply these standards, and to use these standards to promote the adoption of proper HIT systems. In accordance with its mission to improve patient safety and quality among the nation's healthcare organizations, the Joint Commission supports the evolution of an HIT

infrastructure where performance measurement becomes a natural derivative of the care delivery process. It is only under these circumstances that measurement requirements can continue to evolve without creating undue burden on healthcare organizations.

The Joint Commission further suggests that interoperability, which enables authorized users to capture, share, and report information from any system, is essential for improving healthcare and reducing medical errors, as well as for encouraging consumer choice and portability. The impetus for interoperability and the foundation of a national healthcare information network should be built on the six quality aims set forth in the Institute of Medicine's, "*Quality Chasm*" report (i.e., healthcare should be safe, beneficial, patient centered, timely, cost efficient, and equitable.) For HIT systems to be truly interoperable, the context and connotation of the data must be identical as it moves between networks. Achieving this universal definition will require a common set of policies, procedures and standards for data collection and documentation. Although a variety of systems presently exist, they do not use standardized data – making comparisons of data between these systems, nearly impossible. A set of public, non-proprietary standards would define the performance expectations, structures and processes that must be in place.

Any HIT implementation effort, a certification process must be in place for quality assurance purposes. A third party, independent certification process should be used to promote evidence-based standards and policies, monitor compliance to the standards; and update/add standards in the future. Any certification process should involve an ongoing-self assessment program. The certification process should also include an educational component to support the regional networks' performance improvement activities.

In this section, CMS also suggests that linking HIT standards with hospital conditions of participation (CoPs) may be a mechanism to promote HIT adoption. The Joint Commission is supportive of systematic mechanisms that promote the interoperability of HIT systems, and acknowledge that the development of a CoP is one possible approach. We believe, however, that the Medicare hospitals CoPs should undergo a comprehensive update that reflects the use of HIT to promote safe quality healthcare. Under this approach, the Joint Commission and CMS can partner to ensure that the cultural changes, necessary to achieve the widespread redesign of care delivery that must accompany HIT adoption, are implemented by our nation's hospitals. As we have noted in previous correspondence, the Joint

Commission strongly believes that the Medicare hospital CoPs need to be revised in their entirety to reflect how inpatient care is actually delivered. The Joint Commission recognizes the political expediency of using a piece-meal approach that "carves out" particular CoPs for revision. Unfortunately, such a method only increases the fragmentation in the delivery system and undermines a more over-arching focus on increasing the quality and safety of patient care in our nation's hospitals.

Transparency of Healthcare Information (Section XXII)

- CMS is seeking comment on their "transparency initiative" efforts to provide more comprehensive information on quality and costs to the public.

Joint Commission Comments:

The Joint Commission agrees that the healthcare consumer is best served by readily available quality and price/cost information. We support any approach that would serve this objective, but we believe that significant groundwork is needed before CMS undertakes any initiative to advance the transparency of quality and pricing data. Specifically, we believe the Secretary of DHHS must develop or adopt a standardized, consumer-friendly taxonomy with easily understandable definitions and sufficient explanatory information to make it useful to the average consumer. Additionally, such information must be captured within a system that ensures all providers report this data in a consistent manner.

FY2008 IPPS RHQDAPU: Additional Quality Measures and Procedures for Hospital Reporting of Quality Date for the FY2008 IPPS Payment Update (Section XXIII)

- This section CMS is proposing the implementation of HCAHPS, SCIP and 30-day mortality measures, part of the final set of quality measures required by the *Deficit Reduction Act of 2005*, and detailed in the April 25, 2006 IPPS proposed rule.

Joint Commission Comments:

The Joint Commission has been an integral participant in the Hospital Quality Alliance (HQA), in the development and assessment of the HCAHPS, Surgical Care Improvement Project (SCIP), and the 30-day mortality measures discussed in this section. Because of this, the Joint Commission would like to use this opportunity to focus on processes to ensure the validity and reliability of inpatient quality data. Earlier in the year, the Joint Commission provided comments to CMS on a specific statement within the IPPS proposed rule asserting that CMS was "to develop an infrastructure that would facilitate the efficient transmission and storage of data." In our comments, we informed CMS that this "is a confusing mandate, because clarification is needed as to where this database would reside (e.g., CMS, AHRQ, QIOs, private vendors, etc.), and who has oversight and is responsible for the infrastructure." The Joint Commission hopes CMS would consult with healthcare stakeholders before determining where the quality data is housed.

CMS also suggested in the proposed IPPS rule that data can be transmitted to the QIO Clinical Warehouse by performance measurement system vendors. While this is true – and essentially represents the current method by which Hospital Compare data are derived - CMS does not have any contractual relationship with performance measurement system vendors. Rather, only the Joint Commission has such contractual relationships in place and the majority of the data currently being transmitted through the QNet Exchange is derived from Joint Commission-listed vendors. The integrity of data being transmitted to the QIO data warehouse is an essential element for success. Because the proposed quality reporting and value-based purchasing process is entirely dependent on a third party, vendor without having a formal relationship with that party, we suggest CMS create a private-sector mechanism to leverage the reporting benefit the Joint Commission is providing through its vendors, especially respecting attention to the quality of the data. For many years, the Joint Commission has had in place specific requirements for these performance measurement system vendors against which they are evaluated annually in order to be deemed a "listed system". The Joint Commission also verifies and validates whether the vendors have successfully embedded the standardized performance measures in accord with specific technical requirements, and maintains an ongoing oversight process for the systems.

WOODCREST HEALTHCARE, INC.

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October 3, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-p or CMS-4125-P
PO Box 8011
Baltimore, MD 21244-1850

RE: Comments to CMS-P Partial Hospitalization Program (PHP)

Woodcrest Healthcare, Inc. was certified by Medicare July, 1997 as a Community Mental Health Center and has continued to provide all core services incumbent upon us, including PHP since that time in Natchitoches, La. We have gone through medical review, cost report audits and have maintained our certification through all. When OPPS was implemented and went from a cost based program to fee for service, we asked CMS to utilize the mandated cost reports that we are required to file on an annual basis and give PHP a fair daily rate that would allow us to continue to providing quality service to the mentally ill population we are serving. CMHC'S do not have the resources that a hospital based program has in being able to allocate costs for the time employees are in the outpatient department along with other variable costs directly related to the PHP while in operation. CMHC employees, rents, benefits, electricity, etc are borne by the facility regardless of what time the PHP is operable. We have four core services to provide not just PHP. Our staff is hired for 8 hours a day and not just for the time the PHP is operating thus we believe any reduction to current daily rate for PHP is totally unwarranted. We have adjusted our operations and programs to match the daily rate of PHP to the point that any further cuts will jeopardize the quality of service. We have not received any transitional outlier payments for the past three years, operating only on the daily rate. The professional staff we employ and clients we serve attest to the need for PHP.

COMMENT 1- DECREASE IN PARTIAL HOSPITAL PAYMENTS BY 15% WHILE PARTIAL COSTS INCREASED SUBSTANTIALLY.

Insurance rates across the state have risen from 50%-200%. Nursing Salaries have increased by 10-15%. Cost of food, rent, and gas have all increased this past year.

The proposed wage indexes in Louisiana have been lowered post hurricane instead of adjusted upward. This results in a much lower payment rate for Natchitoches. Wages have increased substantially.

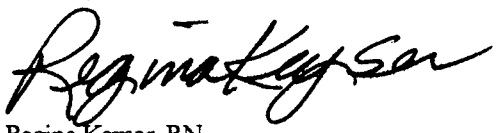
COMMENT 2- PAYMENT FOR PARTIAL HOSPITALIZATION VERSUS OUTPATIENT

The payment for Partial Hospitalization Services includes a full program, inclusive of Nursing Staff, Psychiatrists, PHD prepared LPC counselors, and Medical Technicians. All therapies provided are included in the one daily rate for APC 033.

The rates for PHP should be adequately set to reimburse providers appropriately for the setting and level of care. PHP should be reimbursed, at a minimum, the average payment rates set for Psychiatric Outpatient Services.

I am asking you not to cut the rate 15% for CMHC 2007.

Sincerely,



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Seton Medical Center

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October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

To Whom It May Concern:

Re: PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient psychiatric services

Seton Medical Center provides outpatient psychiatric services in Daly City, CA.

We are a long-standing provider of Partial Hospitalization services. The initial shock of CMS-1506-P and another 15% rate reduction for CY2007 was an overwhelming blow. The very existence of this service will be threatened for the future if our facility must absorb this extreme revenue reduction again. It is very difficult to convince providers to continue programs year after year on a break-even basis at best.

A $37.64/day reduction in the daily rate will be impossible to absorb. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited in the services they can provide.

We are a member of the Association of Ambulatory Behavioral Healthcare. Our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1506-P pp. 99-105 describes the CMS methodology of rate calculations for PHP each year since 2000. A close review indicates that CMS arbitrarily applies its' own bias assumptions and methodology on a different basis every year from CY2003 through CY2006. Only the methodology from CY2006 and CY2007 are the same and there is no calculation of a methodology. It is nothing more than an arbitrary decision by CMS.

2. We quote CMS on p. 105 to say "To calculate the CY2007 APC PHP per diem cost, we reduced $245.65 (the CY2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 15 percent, which resulted in a combined median per diem cost of $208.80."

3. CMS-1506-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00 in the last paragraph of p. 105. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas over the past two years. A daily per diem of $208.27 cannot be justified with these expenses.

4. CMS identified the Median cost of group therapy at $66.40. Our program offers 4 group services per day at a minimum. This summarizes to a median cost of $265.60. A per diem of $208.27 cannot be justified with these expenses.

5. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in your state. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $166.62 ($208.27 x .80). A daily per diem of $208.27 cannot be justified with this situation.

6. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally tow years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

That being said:

7. Patients already have too few options for psychiatric care. Outpatient care is their best option. Outpatient services are a much less expensive alternative to hospital inpatient care or emergency departments. Rather than spending Medicare dollars on Outpatient services, Medicare will, most assuredly, spend more dollars on patients who use inpatient hospital units or emergency centers because -

8. Patients who need psychiatric care will go where ever they have to go to get care. Why would CMS **not** support the less costly outpatient option? It is a fiscally responsible decision.

Based on the above issues, Seton Medical Center asks that CMS:

- **Not implement** the PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient psychiatric services, until CMS examines the data and researches the numerous problems identified.

- **Consider a consistent methodology** that can stabilize the PHP per diem rate and avoid the drastic year-to-year fluctuations that threaten the very existence of the program services for this targeted, severely mentally ill population.

- **Allow energy, time and resources** to develop a reasonable payment methodology by working with provider and community organizations who would welcome the opportunity to work with CMS to develop a payment rate that is fair, consistent and predictable.

Thank you for your consideration of our comments. We look forward to your response. We are hopeful that we will be able to continue to treat the mentally ill and elderly in the most economically responsible way and at the lowest level of care possible.

Sincerely,

Jill Giles, RN, MFT

Jill Giles, RN, MFT
Manager, Seton Outpatient Mental Health

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Daly City, CA 94015

650-991-6470 - phone
650-994-6719 - fax

MAYO CLINIC

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4500 San Pablo Road
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904-953-2000

October 1, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: **CMS-1506-P** Proposed Changes to the Hospital Outpatient PPS and 2007 Payment Rates
New CPT Code Percutaneous Intradiscal Electrothermal Annuloplasty to be Classified into APC 51

Dear Dr. McClellan:

Thank you for this opportunity to comment on the Proposed 2007 Medicare Hospital Outpatient Prospective Payment System (OPPS) rule. I am an interventional neuroradiologist at the Mayo Clinic in Jacksonville, Florida and I am writing to recommend that CMS place the new CPT procedure codes for intradiscal electrothermal annuloplasty into APC 51 Level III Musculoskeletal Procedures. Earlier this year, I sponsored an application to the American Medical Association (AMA) for the creation of new CPT codes for percutaneous intradiscal electrothermal annuloplasty (also known as IDET). I understand that the AMA CPT Editorial Panel viewed this application favorably and new CPT codes will be established and effective January 1, 2007.

Therefore, it is important for CMS to recognize the new CPT codes in the final 2007 OPPS rule and assign these procedures to the appropriate clinical APC with reasonable payment based on the hospital resources involved. Based on the costs for the equipment and necessary supplies, I am writing today to recommend that the new CPT codes be placed in APC 51 with a proposed payment rate of $2,539. Such an assignment will ensure appropriate reimbursement for this important surgical procedure.

IDET is a surgical procedure for the treatment of chronic discogenic low back pain. It is indicated for coagulation and decompression of disc material to treat patients with annular disruption of contained herniated disc. When performing IDET, a physician inserts a catheter with a two inch thermal resistive coil into the posterior annual wall of the disc. The catheter then delivers electrothermal heat to the intervertebral disc for about 20 minutes. The total operative room time is about 1.5 hours. I also wish to point out that in at least 50% of cases, we use a second thermal catheter, and the catheter alone costs over $1,000.

APC 51, Level III Musculoskeletal Procedures, is an appropriate placement for IDET both in terms of clinical activities performed and resources required. This APC includes several procedures that

involve similar resources and also covers conditions of the spine. Moreover, it reimburses hospitals at a rate that reflects the hospital's surgical resources required for this procedure.[1]

I believe that this assignment will establish an accurate reimbursement rate for hospitals that perform IDET and will ensure that hospitals can offer this procedure to Medicare patients without encountering adverse financial pressure.

Thank you very much for considering these comments to the proposed rule. If you have any questions, I would be happy to further discuss the IDET procedure with you. Please feel free to contact me at the telephone number above.

Very truly yours,

Douglas Fenton, M.D.

[1] In 2006, IDET was described by 0062T and assigned to APC 50 with a payment rate of $1,542.47. CMS data published in the proposed 2007 rule notes that the median hospital cost for 0062T procedures was over $2,000 and the mean cost is about $2,230. We believe that IDET, which is one of several procedures billed under CPT 0062T, may actually have resources higher than reflected in CMS's cost data. For example, we expect that hospitals costs for IDET are closer to $3,500 to $4,000.

RMS Lifeline Inc.

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October 10, 2006

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

Re: CMS-1506-P - Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates

Dear Administrator McClellan:

RMS Lifeline is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments about the proposed updates to the Ambulatory Surgery Center Covered Procedures List. RMS Lifeline provides management services to twenty-six (26) outpatient vascular access centers across the United States, specifically designed and operated to care for the vascular access needs of End-Stage Renal Disease (ESRD) patients. These access procedures are performed by highly trained interventional nephrologists and vascular surgeons who also treat ESRD patients within their local communities. We are on the leading edge of advances in imaging-guided, minimally-invasive medicine. Procedures performed by interventional nephrologists -- through small catheters and other devices under radiological imaging -- are often less costly and significantly less invasive than alternative surgical therapies.

In addition, the outpatient vascular access centers that we manage have consistently outperformed traditional benchmarks along two key criteria: patient satisfaction and clinical success/safety. Historically, the patient satisfaction scores of centers that we manage have averaged 91%, while maintaining a 97% clinical success rate and a average complication rate of 2.2%, and 2005 complication rate of only 1.7%. I have included these results with this letter as additional documentation. These patient satisfaction rates show that patients prefer the prompt, quality healthcare services they receive in a dedicated vascular access center over the cumbersome and lengthy process of being worked into a hospital surgical schedule.

Based upon our clinical experience, we would like to make the following two points pertaining to the CY 2007 proposal. We will be commenting on the CY 2008 Revised ASC Payment System under separate cover.

Three Hawthorn Parkway, Suite 410 Vernon Hills, IL 60061 phone 847-388-2001 fax 847-388-2020

- There is ample scientific literature (attached) that supports and validates your proposal to add CPT code **35476** (transluminal balloon angioplasty, percutaneous; venous).
- There is also a body of scientific literature (attached) demonstrating that CPT code **35475** (transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel). Can safely be performed in an ambulatory surgery setting. We believe CMS should reconsider adding it to the list of ASC-approved procedures.

Procedures Proposed for Addition to the CY2007 ASC List

CMS' decision to include CPT code 35476 (transluminal balloon angioplasty, percutaneous, venous) on the ASC-approved list provides the agency the opportunity to help ensure appropriate access and promote safe, high-quality outcomes for, end-stage renal disease (ESRD) patients. Moreover, this addition is consistent with Secretary Leavitt's 2007 agenda of ASC reform, and fits into the overall objectives of CMS' Fistula First initiative.

CMS' *Fistula First* initiative was introduced in 2004 to encourage greater use of fistulae. Despite this initiative, the use of fistulae remains low. The inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Suggested Additions Not Accepted

We respectfully urge CMS to reconsider adding CPT code 35475 (transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel) to the list as well, given the overwhelming clinical evidence, as seen below and in Appendix A, that demonstrates the safety of performing this procedure in an outpatient setting. In addition to demonstrated safety, the concerns expressed in CMS-1506-P (that CPT code 35475 "may either result in greater than 4 hours of recovery time or result in excessive blood loss, etc.") are actually refuted by clinical evidence.

The addition of CPT code 35475 is consistent with the recommendation made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. That report suggest that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list. If using MedPAC recommendations as a guide, this code should be included as we have provided evidence of their safety and proven that overnight stays are not required. RMS Lifeline average documented recovery time for CPT code 35475 is 1 hour, which is recorded in our data system for each patient.

Safety Evidence/Support

- Of 16,319 RMS Lifeline patients[1] who had angioplasty procedures performed, 97.8% of all procedures were clinically successful
- Of these 16,319 patients, there is a low complication rate of 2.2% (353 procedures).
- A total complication rate of 2.2 % is well below the established threshold of 5% for safe practice established by the reporting standards of the Society for Interventional Radiology.
- Of the 353 complications, the overwhelming majority (328) were categorized as minor complications and only 25 (0.2% of total angioplasties) were deemed major complications.
- The average recovery time is 1 hour.

Clinical Efficacy Evidence/Support

- Of 16,319 patients who had angioplasty procedures performed, 15,982 patient encounters (98.0%) were considered "successful" as defined by the Society of Interventional Radiology standard (having <30% stenosis remaining post procedure).
- Only 180 (1.1%) procedures were deemed unsuccessful, and 157 (0.9%) were aborted.

Patient Satisfaction

Patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting.

- All patients in this series were queried using the Ware Patient Satisfaction survey tool.
- Of the 40% who responded, 88% of the respondents rated their experience at these centers as either very good or excellent.

Lastly, the American Society of Interventional Nephrology (otherwise referred to as ASDIN), the society which represents over 95 % of the interventional nephrologists in the United States as well as many radiologists who specialize in interventional procedures for dialysis accesses, supports the addition of these codes on the ASC approved list stating "these procedures have been safely performed in the outpatient setting."

We sincerely hope that CMS will give consideration to our comments and will incorporate our suggestions into the Final Rule. Please feel free to contact Terry Litchfield at 847-388-2038 if you have any questions regarding these comments as we look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to treatment in the appropriate sites of service.

Sincerely.

Gerald Beathard, MD
VP, Provider Development
RMS Lifeline, Inc.

Richard Nee
VP and General Manager
RMS Lifeline, Inc.

[1] RMS Lifeline outpatient vascular access center angioplasty outcomes data from managed vascular access centers from October 1, 2002 to May 5, 2005

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October 10th, 2006

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

Re: CMS-1506-P - Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System

Dear Administrator McClellan:

DaVita is a leading kidney care provider serving patients with high-quality specialized prevention and treatment services, spanning 41 states and the District of Columbia[1]. The DaVita network includes more than 1,250 outpatient facilities as well as provides acute dialysis to inpatients units in over 750 hospitals. We are pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the CMS Medicare Administrative Contractors (MAC) transitional plan.

DaVita understands CMS' goals and commitment regarding the restructuring of the Medicare contracting system, and recognizes the potential for improving the efficiency and effectiveness of program services. There are, however serious concerns about the transition process, especially the operational burden it will place on providers. CMS has not proposed specific transitional requirements addressing how new, potentially inexperienced MACs will achieve and fulfill their new obligations, in particular for processing specialized claims for services provided to vulnerable populations such as those with End Stage Renal Disease.

MAC Transitions

DaVita is concerned about the assignment, transition and operational aspects of the new MAC plan, particularly in light of its untested, complicated, and potentially unpredictable nature. We question whether a full assessment of the cost, time and effort that the proposed plan will impose on providers has been made, and therefore respectfully request that CMS give greater consideration to the burden this new plan is likely to place on providers. This is especially true for MACs that are not familiar with ESRD claims, as ESRD claims and populations are unique. The complexity of these claims requires familiarity and experience with the dialysis sector. As such, we are concerned that newly appointed MACs may not have the expertise or familiarity needed to process claims in an appropriate and efficient manner. Lack of preparedness and training, may cause increased inefficiencies leading to increased appeals, increased CMS inquiries and lack of continuity to beneficiaries. Like

[1] The DaVita patient population includes over 100,000 patients who have been diagnosed with End-Stage Renal Disease (ESRD), a group representing approximately one-quarter of all Americans with ESRD and approximately one-third of all Americans receiving dialysis services. DaVita's nationwide network is staffed by over 28,000 teammates and more than 1,000 medical directors.

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CMS, DaVita is committed to ensuring patients receive high-quality care without disruption of services during these transitions.

CMS is expecting contracting reform to generate significant trust fund and administrative savings ($900 million by 2010)[2]. Beyond 2011, CMS projects administrative savings that will exceed $100 million annually. However the agency must balance the urgency of achieving operational and program savings with the need to manage the operational risks of disrupted services to beneficiaries and providers. DaVita has the following suggestions for addressing these issues:

- CMS should maintain maximum flexibility in order to ensure continuity during the MAC transitional phase (October 1, 2005 through October 1, 2011). The NPRM states, ".....during this period, any existing intermediary and carrier contracts could be maintained until replaced by a MAC contract" (71 Fed. Reg. at 49661).
- Accordingly, CMS should allow large chain providers to maintain relationships with existing FIs until the MAC transition is complete, or the latest date possible. A slower transition would balance the need and urgency of achieving operational and programmatic savings with the need to manage operational risk of service disruption to providers and suppliers, which could ultimately harm beneficiaries.
- Like CMS, providers also incur significant expenses when a Medicare contractor leaves the program and another takes on its work. CMS itself estimates contracting reform will exceed the $58.8 million that MMA set aside for its implementation due to anticipated transitional costs and activities. Providers also experience direct and indirect cost such as, ensuring IT compatibility, teammate training, relationship building, and outgoing contractor finalization.
- As with DaVita, many providers are highly dependent on Medicare cash flows, as 80% of ESRD patients are funded by the program. It is conceivable there could be transition issues with moving to a new, inexperienced MAC, which could result in significant payment delays to providers leading to cash flow problems, and potential negative operational impacts. Providers would likely be forced to borrow money to fully maintain operations, thus incurring significant borrowing costs. For example, it would cost DaVita approximately $825K/ month in borrowing costs if there was a 30-day delay in claims payments.
- Allowing all parties involved in contracting reform (providers, contractors and CMS) flexibility during the transitional phases will not only minimize disruption of Medicare claims processing and operations, it will aid CMS in completing transitional activities within the projected time frame in the most cost effective and efficient manner, which will in turn enable the program to actualize the projected savings..

Large Chain Providers

DaVita supports CMS' proposed language allowing large chain providers to apply for single MAC status, but questions why this MAC has to be "assigned" to the provider; and if single status is assigned, why assignment must be based on the provider's home office. Per the proposed regulation, "As a general rule, Medicare providers and suppliers will be assigned to the MAC that is contracted to administer the types of services billed by the provider or supplier in the geographic locale in which the provider or supplier is physically located or furnishes health care services" (71 Fed. Reg. at 49662). DaVita has the following suggestions for addressing these issues:

- It is unclear from the preamble and regulation text if a "legal entity", defined as "any corporation, limited liability company, or partnership that is majority-owned by a parent company or one of its subsidiaries", will continue to be allowed to bill under a single FI (MAC) status. DaVita requests that CMS clarify in

[2]2005, Secretary Michael O. Leavitt, Department of Health and Human Services: Report to Congress: Medicare Contracting Reform: A Blueprint for a Better Medicare

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the final rule that companies with more than one legal entity, and currently assigned to a single FI, are allowed to continue to bill as a single FI. This will help to ensure operational efficiency and reduce the administrative billing expenses incurred by the Medicare program and by providers. In addition, we ask that CMS include language that allows legal entities to apply for single MAC status, and thereby be recognized as individual distinct large chain providers.

- When requested by a large chain provider, CMS should grant exceptions to assignment in the provider's home office. Allowing providers this flexibility would ensure maximum efficiency, continuity of service, and familiarity of ESRD claims, as well as minimal disruption and economic impact to the Medicare program,. Such flexibility will also support the implementation of the MACs which is clearly in the compelling interest of the Medicare program, and would meet the general requirement provided the MAC was located in a state in which the provider furnished health care services.

Assignments of Providers and Suppliers to MACs

The regulation negates the ability of providers and suppliers to request reassignment but gives CMS full authority to reassign MACs if deemed in the "best interest of the program." We believe CMS should clarify what is meant by the "best interest of the program" and at a minimum, should establish a clear notification and transition process for notifying providers of potential reassignments deemed necessary by the Agency. In addition, as with existing requirements, a full explanation by the Secretary, for the reasons for determining that the intermediary change would result in a more efficient and effective administration of services.

Designation of National or Regional MACS

We respectfully propose that a "one-size fits all" approach is not likely to work with large chain providers. This is an especially important concern in light of the specialized nature of Medicare's ESRD program, which includes complex coverage and payment issues, and is unlike most other Part A and Part B benefits. Section 1816 of the Act was amended in 1977 to allow for the Secretary to designate regional or national intermediaries (RHHIs) to process claims for home health services. CMS expanded the RHHIs scope to also include hospice provider communities, due to their service to a very specialized population and unique claims needs. DaVita believes that CMS made the correct decision by recognizing these specialized services and populations; and as such, requests that:

- CMS also provide ESRD providers with the option of having claims handled by multi-state, regional MACs. We believe allowing this option of consolidated regional billing by large chains is within the discretion of the Secretary under section ***911 of Pub. L. 108-73.*** A regional structure for ESRD providers would allow for greater efficiency and consistency across larger jurisdictions, by capturing most of the chain-based providers within a single jurisdiction.

We continue to look forward to our ongoing collaboration with CMS in the near future.

Sincerely,

Dennis Kogod,
Group President, DaVita
DaVita

cc: Kent Thiry, Mayor and CEO, DaVita
Eric Berger, Senior Vice President, DaVita
Cynthia LaMunyon, Director Revenue Operations, DaVita
Stephanie Dyson, Director Public Policy, DaVita