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October 10, 2006

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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:** Hospital Outpatient Prospective Payment System and CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program— HCAHPS® Survey, SCIP, and Mortality Proposed Rule

Dear Administrator McClellan,

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for Hospital Outpatient Prospective Payment System and CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program— HCAHPS® Survey, SCIP, and Mortality (Proposed Rule).[1] KCP is an alliance of members of the kidney care community, including renal patient advocates, dialysis care professionals, providers, and suppliers who work together to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2]

Our comments focus on the Ambulatory Surgical Center (ASC) setting and because changes in this area can have important and dramatic effects on patients with kidney failure on dialysis. Specifically, we urge CMS to:

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[1] 71 *Fed. Reg.* 49506 (August 23, 2006).

[2] A list of Kidney Care Partner coalition members is included in Attachment A.

- Expand the covered ASC procedures list to include those procedures related to the maintenance of vascular access for dialysis patients for CY 2007; and

- Ensure that for CY 2008 and beyond the payment structure allows for the performance of vascular access-related procedures in the ASC setting.

I. Dialysis Background: Why vascular access maintenance is important.

Most patients with kidney failure typically receive hemodialysis to replace the blood cleaning functions of their diseased kidneys three-to-four times each week. Each dialysis session lasts for three-to-four hours, depending upon each patient's needs. Through the End Stage Renal Disease (ESRD) program, Medicare covers about 93 percent of the cost of the dialysis patients either as a primary or secondary payer.[3]

The blood cleaning process of dialysis requires an "access" to the patient's bloodstream to carry blood from the patient's body, through the artificial kidney (or dialyzer), and then back to the patient. There are three types of access – arteriovenous (AV) fistulas, synthetic grafts, and catheters. The clinically superior and, therefore, most desirable access for most patients is the AV fistula, which requires the surgical joining of a vein and an artery. The resultant flow of blood from the high pressure in the artery to the lower pressure in the vein, causes expansions along the vein that support the dialysis process. In most cases, the AV fistula is created in a patient's forearm. As CMS recognizes through the Fistula First ESRD quality initiative,[4] AV fistulas are the "gold standard" for establishing access for dialysis. Because fistulas involve the patient's native blood vessels, they last longer and require fewer repairs. This is related to the fact that fistulas have the body's normal defense against infection and normal clotting mechanisms. Therefore, patients with fistulas are less likely to develop either infections that lead to hospitalization or death or clots that require interventional procedures to declotting.

Each type of vascular access requires maintenance to ensure the continued flow of blood to enable the dialysis process. For example, angioplasty allows physicians to "open" a narrowed fistula or graft by cannulating the access at the point of the stenosis. After cannulation, an initial angiogram is performed. Next, a guidewire is inserted. The angioplasty balloon is inserted and dilatation is affected using a syringe. A recent study found that interventional nephrologists performed this procedure with a 96.58 percent success rate with a median procedure time of 33 minutes.[5] Given current technology, this and similar maintenance procedures can safely be performed with minimal blood loss and few complications.

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[3]MedPAC, "Report to the Congress" 109 (March 2006).

[4]See www.cms.hhs.gov/ESRDQualityImprovementInit/04_FistulaFirstBreakthrough.asp# TopOfPage).

[5]Gerald A. Beathard, Terry Litchfeld, & Physician Operations Forum of RMS Lifeline, Inc., "Effectiveness and Safety of Dialysis Vascular Access Procedures Performed by Interventional Nephrologists" 66 *Kidney International* 1622-32 (2004).

II. CMS should expand the covered procedures list to include procedures related to the maintenance of vascular access for dialysis patients for CY 2007,specifically CPT code 35475.

Because of the critical relationship between the access to the bloodstream and the ability to keep patients alive through hemodialysis, these procedures are of great importance to the KCP member organizations. Because of the inconvenience to the patients and the higher costs to the Medicare program of performing dialysis vascular access procedures in hospital settings, KCP members urge CMS to expand the list of procedures that can be performed in the ASC setting to include code 35475.

While we are pleased that the Proposed Rule includes *venous* angioplasty, we do not understand why other procedures, such as 35475, are excluded from the ASC list. The Proposed Rule only states that other procedures "do not meet current clinical criteria," leaving us to essentially guess why *arterial* angiography was not included on the list. Specific reasons for excluding procedures from the ASC list should be provided.

We also suggest that the continued use of ASC-specific criteria (major blood vessels, etc.) be eliminated in the new payment system and that safety and lack of need for an overnight stay should be the only criteria for determining which procedures are reimbursed in the ASC setting.

Specific to that point, we recommend that CMS develop a process for gathering and evaluating reliable information about the safety of performing outpatient surgical procedures in hospital and ASC settings so the Agency can make informed decisions about the relative safety issues of the two sites of services, rather than just presuming that hospital outpatient departments are inherently "safer" in all cases.

Finally, we want to point out that including 35475 would provide patients with a more efficient, but equally effective, option for ensuring the maintenance of their vascular access. We are pleased that CMS proposes to incorporate three of these codes (35476, 37205, and 37206) into the covered procedures list. However, 35475 procedures should also be adopted so patients can receive the care they need in a less expensive and more accessible setting. There is no clinical reason to suggest that these procedures must be performed in a more expensive setting. Recent studies demonstrate that these procedures can be safely performed in the ASC setting by interventional radiologists or interventional nephrologists.[6] Other studies also support and validate the proposal to include providing these services in the ASC setting.[7] Even though the procedures may involve veins and arteries in the patient's forearm, they result in little blood loss.

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[6] *Id.* at 1626.

[7] GA Beathard, "Percutaneous transvenous angioplasty in the treatment of vascular access stenosis" 42 *Kidney Internat'l* 1390-1397 (1992); GA Beathard, "Percutaneous angioplasty for the treatment of venous stenosis: A nephrologist's view," 8 *Semin. Dial.* 166-170 (1995); GA Beathard GA, SM Settle; & MW Shields MW, "Salvage of the nonfunctioning arteriovenous fistula," 33 *Am J. Kidney Dis.* 910-916 (1999); FA Khan & TM Vesely, "Arterial problems associated with

In addition, incorporating these procedures into the ASC setting will result in important savings to the Medicare program. An independent analyst has indicated that incorporating these codes into the ASC list Medicare would save approximately $1.25 billion over 10 years.[8] In 1999, Dr. Allan Collins and his colleagues found that shifting vascular access-related procedures from the inpatient to the outpatient setting resulted in savings of more than $9,000 per event/procedure. They concluded that:

> significant savings on [vascular access (VA)] procedures for hemodialysis patients can be achieved if an appropriate infrastructure and incentives are provided to encourage this site of care. Creative reimbursement systems for VA should be considered to encourage more cost-effective delivery of uncomplicated VA interventions.[9]

Although Dr. Collin's conclusions were based upon comparisons between inpatient and outpatient settings, KCP believes that based upon CMS reimbursement policy, the ASC setting would provide the lowest cost opportunities for performing these procedures while also ensuring a high level of patient safety. CMS would not only save billions of dollars by incorporating these vascular access codes into the covered procedures list for ASCs, but it would also provide patients with a more efficient and accessible option to ensure that their life-saving access is properly maintained.

III. CMS should ensure for CY 2008 and beyond that the payment structure allows for the performance of vascular access-related procedures to be performed in the ASC setting.

In addition to including vascular access-related codes in the covered procedures list for CY 2007, CMS should also ensure that these procedures may also be performed in the ASC setting in

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dysfunctional hemodialysis grafts: evaluation of patients at high risk for arterial disease," 13 *J. Vasc Interv Radiol.* 1109-1114 (2002); TM Vesely, "Endovascular intervention for the failing vascular access," 9 *Adv Ren Replace Ther.* 99-108 (2002); GA Beathard, "Angioplasty for arteriovenous grafts and fistulae," 22 *Semin Neph.* 202-210 (2002); GA Beathard, P Arnold P, J. Jackson, & T Litchfield T, "Aggressive treatment of early fistula failure," 64 *Kidney Internat'l* 1487-1494 (2003); GA Beathard, "Management of complications of endovascular dialysis access procedures," 16 *Semin Dial.* 309-313 (2003); A Asif, D Merrill, P Briones, *et. al.*, "Hemodialysis vascular access: percutaneous interventions by nephrologists," 17 *Semin Dial.*528-534 (2004); SM Surowiec, AJ Fegley, WJ Tanski WJ, *et. al.*, "Endovascular management of central venous stenoses in the hemodialysis patient: results of percutaneous therapy," 38 *Vasc Endovascular Surg.* 349-354 (2004); LR Sprouse, CJ Lesar, GH Meier *et. al.*, "Percutaneous treatment of symptomatic central venous stenosis," 39 J. Vasc. Surg. 578-582 (2004).

[8]Judy Xanthopoulos, "Analysis of Section 101: Modification of Physician Surgical Reimbursement for Dialysis Access Procedures to Align Incentives for Cost and Quality" (2005). Available upon request.

[9]Allan J. Collins, James Ebben, Shu Chen, & Jennie Z. Ma, "Cost-Effectiveness in Inpatient and Outpatient Vascular Access Services" Minneapolis Medical Research Foundation, University of Minnesota, Twin Cities, University of Tennessee, Memphis (1999). Presentation available upon request.

CY 2008 and beyond. As CMS shifts toward the MedPAC recommendation of allowing payments to ASCs for any surgical procedure,[10] except those that are explicitly excluded, we urge the Agency to allow the vascular access-related codes to be reimbursed as well.

How the vascular access procedures fare under the new payment system for 2008 is also of critical importance. To the extent that the rates for vascular access procedures are reduced, that would likely result in more procedures being done in the more extensive hospital setting, increasing the amount of money paid by both Medicare beneficiaries and the government. Also, in the case, there should be a longer transition period than the current one year phase-in.

IV. Conclusion

KCP supports the incorporation of codes 35476 (venous angioplasty) and 37205 and 37206 (stent placement) into the covered procedures list. We appreciate the. opportunity to work with CMS to ensure that vascular access-related procedures that can be safely and effectively performed in the ASC, such as 35475 (arterial angioplasty) are incorporated into the reforms proposed. We would welcome the opportunity to discuss these procedures with you in detail. Please do not hesitate to contact Kathy Lester at (202) 457-6562 if you have comments or questions.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

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[10] 71 *Fed. Reg.* at 49636.

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

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October 9, 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. 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 Rule to the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List; and the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Administrator McClellan:

US Vascular Access Holdings, LLC (USVA), a division of Fresenius Medical Care North America, is pleased to submit these comments to the above referenced Proposed Rule that was published in the *Federal Register* on August 23, 2006. Specifically, USVA urges CMS to include CPT code 35475 (Transluminal Balloon Angioplasty, brachiocephalic trunk or branches, each vessel) in the list of ASC eligible services effective January 1, 2007, and also in the ASC approved list subject to the revised payment system, effective January 1, 2008.

I. Background

In its November 2004 proposed rule, CMS recommended additions and deletions to the list of services appropriate to the Ambulatory Surgical Center (ASC) setting, and added CPT codes 35475 (arterial angioplasty) and 35476 (venous angioplasty) to the list. The Final Rule, published on May 4, 2005, removed both CPT codes 35475 and 35476 from the list stating the Agency had received "a single comment" opposing the additions of CPT codes 35475 and 35476 on the basis of a concern about "major vessel" involvement. CMS determined that "angioplasty codes are more appropriately limited to the hospital outpatient and inpatient settings at this time." In response to the Final Rule, CMS received a number additional comments objecting to the exclusion of 35476 and 35475, emphasizing the importance of these procedures in maintaining vascular access for patients on hemodialysis. Commenters included nephrologists, interventional nephrologists, vascular surgery centers, ASC trade organizations, the Society of Interventional Radiology, the Renal Physicians Association and the National Kidney Foundation.

In its recent 2007 Update to the Ambulatory Surgical Center Covered Procedure List, the Proposed Rule once again includes 35476, but excludes 35475, arterial angioplasty, citing that this procedure "did not meet required clinical criteria." CMS further clarified the exclusion of 35475 by listing this procedure as requiring an overnight stay. For reasons clarified in this correspondence, we urge CMS to reconsider this exclusion of CPT code 35475 from both the 2007 update and the revised ASC payment system, effective January 1, 2008.

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II. Long Definitions of Arterial Angioplasty Procedures

CMS lists thirteen CPT codes for arterial angioplasty procedures, all with a short description of "repair arterial blockage." The CPT long definitions of these procedures and the settings which CMS believes are most appropriate are as follows:

Approved for ASC in 2008

35473 Transluminal balloon angioplasty, percutaneous; iliac
35474 Transluminal balloon angioplasty, percutaneous; femoral-popliteal

Requires an Overnight Stay

35458 Transluminal balloon angioplasty, open; brachiocephalic trunk or branches, each vessel
35470 Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk or branches, each vessel
35471 Transluminal balloon angioplasty, percutaneous; renal or visceral artery
35472 Transluminal balloon angioplasty, percutaneous; aortic
* 35475 Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel (procedure at issue in this comment)

Excluded from ASC because 80% are performed on inpatient basis

35459 Transluminal balloon angioplasty, open; tibioperoneal trunk and branches

Inpatient Only

35450 Transluminal balloon angioplasty, open; renal or other visceral artery
35452 Transluminal balloon angioplasty, open; aortic
35456 Transluminal balloon angioplasty, open; femoral-popliteal
35454 Transluminal balloon angioplasty, open; iliac

III. Current Situation With Regard to Vascular Access in Hemodialysis

The optimal treatment of patients receiving hemodialysis is dependent on access to their bloodstream, which is necessary for the conduct of the dialysis procedure, or on their "vascular access." In the US, hemodialysis vascular access failures, procedures and complications account for greater than 20% of hospitalizations for hemodialysis patients, resulting in over $1 billion per year in government expenditures.[1] The superiority of arteriovenous (AV) fistulas over AV grafts has been shown to significantly improve patency rates, lower complication and infection rates and lower mortality rates.[2] In view of these statistics, the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-DOQI) guidelines for vascular access recommend an aggressive approach to the creation of AV fisulas.[3]

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[1] Ilizler T, Himmelfarb J, Trials and trade-offs in hemodialysis vascular access monitoring. *Nephrology Dialysis Transplantation* 2006

[2] Beathard G, Interventionalist's Role in Identifying Candidates for Secondary Fistulas. *Seminars in Dialysis* – Vol 17, No 3 (May – June) 2004 pp.233-236

[3] National Kidney Foundation: NKF-K/DOQI clinical practice guidelines for vascular access guideline

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The guidelines propose that primary AV fistulas should be created in at least 50% of all new patients requiring hemodialysis, with a long-range goal of maintaining fistulas in 40% of eligible patients who remain on dialysis. In support of this goal, CMS is leading a national effort to increase the use of fistulas by creating, funding and overseeing the Fistula First quality initiative bringing together a project team that is working with major stakeholders, including dialysis providers, primary care physicians, nephrologists, vascular access surgeons, interventional radiologists/nephrologists, professional societies and patient advocacy groups. [4]

Because of the significance of vascular access to hemodialysis patients, interventional nephrologists commonly perform a variety of vascular access procedures, including angioplasty for venous stenosis, treatment of thrombsed vascular access (declotting), salvage of undeveloped AV fistulas, management of tunneled dialysis catheters and other related procedures. Transluminal balloon angioplasty of peripheral veins and arteries in the arm (35475, 35476) are common procedures to maintain the patency of AV fistulas for hemodialysis access. "Percutaneous balloon angioplasty has become a standard treatment for the management of arteriovenous dialysis access (graft and fistula) stenosis." [5]

IV. CMS Should Include CPT Code 35475 in the 2007 Update and the Revised ASC Payment System, Effective January 1, 2008

Determination of Procedures Requiring an Overnight Stay

The longstanding criterion for determining which procedures are appropriate for inclusion on the ASC list has been that the procedures do not require an extended recovery time. Under §416.65(b)(ii) CMS has historically considered procedures that require more than four hours of recovery time to be inappropriately performed in the ASC setting. More recently CMS has revised this assessment and has published the following guideline: "We are proposing to exclude from payment of an ASC facility fee any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure."

Patients undergoing a CPT code 35475 procedure do <u>not</u> fall within this category. It seems inconsistent, therefore, for CMS to cover two angioplasty procedures performed on diseased native iliac and femerol-popliteal arteries in the lower extremities in the ASC setting (35473, 35474), but determine that angioplasty of the anastomosis of a healthier but stenotic arterial portion of an AV fistula in an upper extremity would require an overnight stay and therefore be excluded from the list of covered procedures in the ASC setting.

Safety of Angioplasty Procedures

We contend that there are no greater significant safety concerns with CPT code 35475 (arterial angioplasty) procedures than with 35476 (venous angioplasty) procedures. We base this conclusion on the following:

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[4] www.cms.hhs.gov/ESRDQualityImproveInit/04_FistulaFirstBreakthrough.asp#TopOfPage

[5] Asif A, Merrill, D, Briones P, et al Inflow stenosis in arteriovenous fistulas and grafts: A multicenter, prospective study. *Kidney International*, Vol 67 (2005), pp. 1986-1992

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- CPT code 35475 is a procedure involving a peripheral blood vessel, not a "major vessel."
- This procedure is an inherently different procedure when performed on a vascular access of the upper extremity (where most AV fistulas are located) than it is in diseased vessels of the lower extremities.
- In angiography of an AV fistula, the physician accesses the anastamosis of a vein and an artery, and generally does not directly access the native arterial vessel alone, which is typical in angioplasty of vessels in the lower extremities.
- The vessels that are dilated during AV fistula angioplasty are inherently healthy, but have been affected by the anatomic vascular shunt. The lesions in an AV fistula are predominately due to fibrous hyperplasia as opposed to destructive artherosclerotic vessel disease. The risk of complication from a procedure performed on a healthy anastomosis of vein and artery with some degree of fibrous hyperplasia is far less than angioplasty of a native vessel in the lower extremity, which is likely to be diseased and artherosclerotic.
- CPT code 35475 is an approved procedure in the extension of practice and hospital outpatient settings.
- Most patients are discharged to home or to the dialysis clinic for treatment following percutaneous angioplasty of their AV fistula. There is no expectation that this procedure would require extensive post-procedure observation.

In addition, frequently the arterial angioplasty procedure of an AV fistula is performed in concert with venous angioplasty and possibly a thrombectomy. Decisions regarding which procedures are indicated are made by the interventional provider at the time the case is underway, and are not made in advance of fistula studies. Based upon radiological findings, the physician determines whether an arterial lesion at the anastomotic site requires dilatation. A requirement to perform angioplasty of the arterial lesions in AV fistulas in a separate setting from where the venous portion of the AV fistula is corrected will unnecessarily increase the cost of care and will inconvenience dialysis beneficiaries, as it would require them to undergo two separate procedures in perhaps two separate locations to fully resolve their vascular access problem.

Finally, the creation of the AV fistula is a covered procedure in the ASC setting (CPT code 36819), which furthers the goals of CMS's Fistula First quality initiative[6] to promote use of fistulas in larger percentage of dialysis patients. Non-approval of safe procedures to maintain the patency of the fistula in the same setting is inconsistent with these goals.

V. Conclusion

We applaud the Agency's decision to approve CPT code 35476 (venous angioplasty) in its 2007 Update to the Ambulatory Surgical Center Covered Procedure List. This is appropriate and will serve to benefit patients receiving chronic hemodialysis who rely on this procedure to maintain patency of their vascular access, which in turn allows them to maintain life via hemodialysis. However, the decision not to also include 35475 (arterial angioplasty) as a covered procedure in the ASC setting is inconsistent with decisions to approve procedures that, by their nature, carry a higher degree of risk (35473, 35474) and with the goals of a CMS ESRD quality initiative to promote use of AV fistulas in dialysis patients.

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[6] www.cms.hhs.gov/ESRDQualityImproveInit/04_FistulaFirstBreakthrough.asp#TopOfPage

Fresenius Medical Care

We strongly urge CMS to include CPT code 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel) specific to vascular access for hemodialysis as a covered procedure in the ASC setting effective January 1, 2007, and also in the ASC approved list subject to the revised payment system, effective January 1, 2008.

Fresenius Medical Care North America and US Vascular Holdings look forward to working with CMS to ensure that hemodialysis vascular access-related procedures that can safely and effectively be performed in the ASC are incorporated into the proposed reforms. Please do not hesitate to contact Kathleen Smith at 202-296-8632 if you have any comments or questions.

Sincerely,

Cathleen O'Keefe

Cathleen O'Keefe, RN, JD
Vice President - Regulatory and Government Affairs
Products and Hospital Group
Fresenius Medical Care North America

Esther R. Scherb
Direct Line: (202) 637-2266
esther.scherb@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: (202) 637-2200 Fax: (202) 637-2201
www.lw.com

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LATHAM & WATKINS LLP

File No. 039841.0002

October 10, 2006

VIA HAND DELIVERY

Mark B. 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, D.C. 20201

Re: **Comments on CMS-1506-P; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (High-Energy Extracorporeal Shock Wave Therapy; *"Other New Technology Services"*)**

Dear Dr. McClellan:

On behalf of SANUWAVE, Inc. ("SANUWAVE"), a leader in the provision of High-Energy Extracorporeal Shock Wave ("High-Energy ESW") equipment for the treatment of chronic plantar fasciitis and lateral epicondylitis, we are pleased to present comments on the assignment of High-Energy ESW to a clinical ambulatory payment classification ("APC"). In its proposed changes to the Hospital Outpatient Prospective Payment System ("OPPS") for calendar year ("CY") 2007, the Centers for Medicare and Medicaid Services ("CMS") reassigned the ESW procedures to APC 0050, representing Level II musculoskeletal procedure.[1] SANUWAVE continues to believe—as it has expressed in its prior comment letters—that the true costs of the clinical resources associated with these High-Energy ESW have not been fully recognized under the OPPS. Until, however, the Medicare claims data for hospital outpatient departments becomes more robust, the Company agrees that for CY 2007, the reassignments as currently proposed are appropriate.

SANUWAVE's Ossatron® is a Class III device that employs High-Energy ESW technology for the noninvasive surgical treatment of chronic plantar fasciitis and lateral epicondylitis.[2] Following approvals by the Food and Drug Administration ("FDA") for these indications, beginning January 1, 2005, CMS recognized payment for the procedures in the

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1 71 Fed. Reg. § 49505, 49556 (Aug. 23, 2006).

2 SANUWAVE acquired the orthopedic High-Energy ESW assets of HealthTronics, Inc., the prior owner of the OssaTron® technology, on August 2, 2005.

hospital outpatient department under New Technology APC 1547, with a payment rate of $850. It appears that CMS's assignment was based on the misapprehension that the costs and resources involved in performing a diagnostic colonoscopy were the appropriate proxy for the costs and resources used for these surgical procedures. For CY 2006, CMS retained the procedures within New Technology APC 1547. The agency for CY 2006 also reiterated its decision to rely on Medicare data for other procedures.

For CY 2005, the only year for which Medicare data for the two procedures is now available, there were two HCPCS codes assigned—C9720 (High-Energy ESW treatment for lateral epicondylitis) and C9721 (High-Energy ESW treatment for plantar fasciitis). The Medicare claims data for 2005 became the basis for a proposed reassignment to a clinical APC for CY 2007. SANUWAVE is concerned that because the 2005 Medicare payment levels ($850) fell far short of the costs of hospital resources to provide these High-Energy ESW procedures, hospitals were not always able to offer the procedures to Medicare beneficiaries and, in turn, the claims data was not fully representative of the costs of the procedures.

SANUWAVE recognizes that generally, a procedure is kept in the New Technology APC to which it is initially assigned until CMS has collected sufficient data to move the procedure to a clinically appropriate APC.[3] In the proposed CY 2007 rule, CMS indicates that it has adequate data to support the assignment of the procedures to a clinical APC. For CY 2007, the median costs of procedures currently classified under clinical APC 0050 are not dissimilar to the median Medicare costs available to CMS for HCPCS codes C9720 and C9721. Although the Company believes that the true costs of the resources associated with these procedures are not fully reflected in the 2005 Medicare claims data for the reasons stated above, SANUWAVE is encouraged that the reclassification to clinical APC 0050 more appropriately reflects costs and clinical resources than APC 1547. SANUWAVE therefore recommends that CMS adopt its proposal but that the agency continue to track and evaluate claims data and revisit the classification when additional Medicare claims data and other information becomes available.

We note at this juncture that beginning CY 2006, the agency also recognized the new CPT codes assigned to the procedures—28890 (High-Energy ESW, requiring anesthesia, involving plantar fascia) and 0102T (High-Energy ESW, requiring anesthesia, involving lateral humeral epicondyle).[4] In addition to its proposal to reassign these two procedures to APC 0050, CMS also has proposed to reassign procedures under Category III CPT code 0101T (High-Energy ESW involving musculoskeletal system, not otherwise specified) to APC 0050. We are unclear as to the basis for this decision. The code describes a variety of unspecified procedures for which there is no 2005 Medicare hospital outpatient claims data. Nor, to our knowledge, has there been a new technology application submitted to CMS to identify the nature of the procedures, including the various indications that may be associated with these procedures, and their costs. As such, placement in the current new technology APC or reassignment to a clinical

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[3] *See* 66 Fed. Reg. 59856, 59897 (Nov. 30, 2001).

[4] The change in the codes is another reason why continued evaluation of claims data is important. When Medicare claims data becomes available for 2006, hospitals' ability to timely transition their chargemasters and claims reporting would be significant factors in evaluating such data information.

APC is premature. SANUWAVE believes that these APC assignments severely underestimate costs of certain very resource-intensive High-Energy ESW procedures and result in barriers to patient access. Given the lack of supporting Medicare claims data or procedure-specific cost data, CMS should not assign Category III code 0101T to APC 0050 or to any inappropriately low-priced new technology APC.

* * * * *

Thank you for your consideration of these comments. Should you need additional information, please do not hesitate to contact me at 202-637-2266.

Sincerely,

Esther R. Scherb
of LATHAM & WATKINS LLP

cc: SANUWAVE, Inc.
Stuart Kurlander, Latham & Watkins LLP

1666

US Oncology

October 9, 2006

HAND DELIVERED

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

Re: **CMS-1506-P**

Dear Dr. McClellan:

US Oncology[1] would like to thank you for the opportunity to comment on Proposed Rule CMS-1506-P, "Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule" (the "Proposed Rule") published in the *Federal Register* on August 23, 2006.[2]

As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

CMS should accept the Ambulatory Payment Classification (APC) Panel's recommendation to maintain payment for non-pass-through drugs at Average Sales Price (ASP) plus 6% in 2007

CMS proposes to reduce payment for drugs without pass-through status to ASP + 5%. US Oncology urges CMS to rescind this proposal and accept instead the APC Panel's

[1] US Oncology, headquartered in Houston, Texas, is one of the nation's largest cancer treatment and research networks. US Oncology provides extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced treatments and technologies, build integrated community-based cancer care centers, improve their therapeutic drug management programs and participate in many of the new cancer-related clinical research studies. US Oncology is affiliated with 977 physicians operating in 392 locations, including 90 radiation oncology facilities in 34 states. US Oncology also provides a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting and analysis.

[2] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

recommendation to maintain reimbursement for all separately payable drugs under the hospital outpatient prospective payment system (HOPPS) – pass-through and non-pass-through alike – at the reimbursement rate set under the Physician Fee Schedule, which is ASP + 6%.

Further, we encourage CMS to adopt our recommendations to clarify certain aspects of the proposed definition of *bona fide* service fees that are to be excluded from the ASP calculation and to treat prompt pay discounts extended to wholesalers as fees that also should be excluded. We hope too that CMS will respond favorably to our request that they work cooperatively with us, other stakeholders and Congress to develop operationally manageable processes for reducing the lag between the reporting of ASP and reimbursement based on the reported numbers. These ASP recommendations are discussed in more detail in the comments US Oncology filed on CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B," published in the *Federal Register* on August 22, 2006.[3] Consistent with the intent of the MMA, the revisions to ASP we propose will make that reimbursement metric more representative of prices available to providers in the marketplace.

US Oncology has long been committed to maintaining beneficiary access to new, innovative cancer therapies in community-based setting. We are cognizant of the financial difficulties facing practices in the US Oncology network under an ASP + 6% reimbursement system and are convinced hospital-based infusion centers will be even more hard-pressed if reimbursement for separately payable drugs is reduced to ASP + 5%. Because many cancer drugs currently viewed as the standard of care are not available to hospitals, physicians or any other retail class of trade at discounted prices and because wholesaler prompt pay discounts are not routinely passed on to their hospital or physician customers, without the changes we are advocating, we fear beneficiary access will be severely compromised.

Medicare's current payment rate for separately payable drugs does not adequately reimburse hospitals for their drug acquisition costs, much less their pharmacy services costs. The APC Panel heard testimony at its August 26, 2006 meeting that the current Medicare HOPPS payment rate of ASP + 6% fails to cover the cost of over 50% of the separately payable drugs on many hospital formularies. A recent survey conducted by the Association of Community Cancer Centers (ACCC) confirms the APC Panel testimony. The ACCC survey indicates the proposed Medicare payments of ASP + 5% will not be sufficient to cover the cost of five of the eight common oncology therapies considered in the survey.[4] The majority of survey respondents predicted their costs

[3] 71 *Fed. Reg.* 48982 (Aug. 22, 2006).

[4] ACCC's Survey on Hospital Outpatient Department Drug Reimbursement Levels is available at http://www.accc-cancer.org/media/media_hopdsurvey06.asp. The majority of survey respondents indicated that the proposed CY 2007 reimbursement will be insufficient to cover the acquisition and pharmacy-related overhead costs for the following drugs: Neulasta (pegfilgrastim); Taxotere (docetaxel); Velcade (bortezomib); Eloxatin (oxaliplatin); and Aranesp (darbepoetin). Approximately 37 to 42 percent of survey respondents indicated that the proposed that the proposed CY 2007 reimbursement will be insufficient to

700 13th Street NW, Suite 525, Washington, DC 20005 Tel: 202-638-3833 Fax: 202-638-7677

would be greater than the proposed 2007 Medicare payment rate by more than $100 per cancer therapy.

The proposed reduction to ASP + 5% will make what is already a difficult financial situation for many hospitals even worse. Some hospitals, particularly those in rural areas where costs typically run higher or those that serve as safety net providers, simply will not be able to continue offering outpatient chemotherapy services under the Proposed Rule. Others may have to limit the availability of certain more innovative and costly cancer treatments on their formularies. Still others may be forced to offer certain therapies only on an inpatient basis.[5] This particular "solution" to cost pressures that could develop as a result of the drug reimbursement rates proposed for 2007 will not only deprive patients of care in the most clinically appropriate, patient-friendly setting but also increase costs to the healthcare system as a whole.

In testimony to the House Ways and Means Subcommittee on Health on July 13, 2006, Mark Miller, Executive Director of the MedPAC, stated that many oncology practices have stopped treating Medicare beneficiaries since the change to an ASP-based reimbursement methodology.[6] As a result, the number of Medicare beneficiaries transferred to hospital outpatient departments increased in 2005.[7] These patients and their families could be left with no or limited service option in their communities if the proposed drug reimbursement cuts force hospitals to trim standard-of-care therapies from their formularies or shutter their outpatient infusion centers. CMS should be sensitive to this access concern and increase the payment rate for non-pass-through drugs to ASP + 6% under the Proposed Rule.

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cover the acquisition and pharmacy-related overhead costs for the following drugs: Herceptin (trastuzumab); Rituxan (rituximab); and Avastin (bevacizumab).

[5] Although a baseline study of 2004 Medicare claims data coupled with a Web-based convenience survey of Medicare beneficiaries in early 2005 conducted by the Duke Clinical Research Institute for the Global Access Project (*The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?*, Kevin A Schulman *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Sept. 15, 2006)) found no statistically significant differences in time to treatment or site of treatment for Medicare beneficiaries with cancer before the MMA and in the first year (2004) of the MMA's implementation, it did note some apparent dislocations in access in rural areas and among Medicare beneficiaries without supplemental insurance, including an increase in inpatient treatment. The report recommended interpreting these findings with caution, however, because these beneficiary subgroups were too small to permit the covariate adjustments needed to determine whether the findings reflected baseline differences between the pre-MMA and post-MMA cohorts. To obtain a copy of this study, please contact Gail McGrath, President, NPAF, at 202-347-8009.

[6] Medicare Part B Drugs and Oncology: *Testimony Before the Subcommittee on Health Committee on Ways and Means U.S. House of Representatives* (July 13, 2006) (Statement of Mark E. Miller, PhD, Executive Director, Medicare Payment Advisory Commission).

[7] *Id.*

700 13th Street NW, Suite 525, Washington, DC 20005 Tel: 202-638-3833 Fax: 202-638-7677

New Technology APCs

CMS Should Assign PET/CT to APC 1514 for 2007 and 2008

CMS proposed to move PET/CT from a new technology APC (APC 1514) to a clinical APC (APC 308) for 2007. US Oncology strongly urges CMS to rescind this proposal and accept the recommendation of its APC Panel and keep PET/CT scans in APC 1514.

The proposed OPPS payment amount of $862.29 represents a drastic payment cut of over 31%. PET/CT is a critically important part of the treatment plan for many cancer patients. As numerous studies have shown, PET/CT yields numerous clinical and patient benefits because of the short scan times (less patient movement) and the ability to see both a metabolic and anatomical image set acquired in the same setting. We are concerned that at the proposed reimbursement rate Medicare beneficiaries will not have access to PET/CT scans which largely have replaced PET as the standard of care.

The cost of performing PET/CT is underestimated in the OPPS fee schedule because the capital equipment cost is spread out over all procedures in the revenue center. We note that hospitals allocate the costs of expensive capital equipment over all procedures with costs attributable to a specific revenue center. In the case of PET/CT, the cost of a $2 million PET/CT scanner is allocated over all procedures in the diagnostic radiology (or nuclear medicine) revenue center. The hospital "cost" of providing a PET/CT scan is underestimated because the cost of the scanner is spread out over all radiologic services. In essence, hospital cost reporting results in the cost of non-PET/CT services being overestimated and the cost of PET/CT underestimated.

Furthermore, we suspect the claims data being used to set the payment rates under the Proposed Rule are flawed because we understand many hospitals have not yet updated their chargemasters to separate charges for PET and PET/CT and more accurately reflect the cost of the newer technology. We recommend that PET/CT remain in the new technology APC (1514) for a minimum of two years to allow hospitals time to establish PET/CT-specific charges that more accurately reflect the costs associated with the services. On a number of occasions, CMS has mitigated significant decreases in reimbursement by transitioning payment reductions over several years to allow providers to take steps to minimize the effect of reduced reimbursement on their ability to provide care to Medicare beneficiaries. In fact, CMS is doing precisely that with regard to transitioning in physician fee schedule payments under the new practice expense methodology from 2007 to 2010.

Lastly, we note that if CMS would blend its own external data (from the refined direct cost inputs used to establish practice expense RVUs under the PFS) with OPPS claims data to establish a payment rate for PET/CT, the payment rate would be significantly higher than the payment rate in the Proposed Rule and the 2007 OPPS Proposed Rule. Such a result lends additional support to placing PET/CT in APC 1514.

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700 13th Street NW, Suite 525, Washington, DC 20005 Tel: 202-638-3833 Fax: 202-638-7677

In closing and on behalf of US Oncology and our nationwide network of cancer care specialists, thank you for this opportunity to provide our comments on Proposed Rule CMS-1506-P. As you know, we are grateful for the opportunity to engage in substantive discussions and practice site visits with CMS officials, and we continue to stand ready should you have any questions about the issues, concerns, suggestions and data analyses discussed above.

Sincerely,

Dan Cohen
Senior Vice President
Government Relations & Public Policy

700 13th Street NW, Suite 525, Washington, DC 20005 Tel: 202-638-3833 Fax: 202-638-7677

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October 9, 2006

BY HAND DELIVERY

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

Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule) – Pass-Through Drugs and Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

Dear Administrator McClellan:

Biogen Idec is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2007 payment rates, published in the Federal Register on August 23, 2006 (the "Proposed Rule").1 Biogen Idec is an international biotechnology company that creates new standards of care in oncology, neurology, and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare.

In these comments, we address provisions of the Proposed Rule that relate to two of our therapies, Tysabri® (natalizumab) and Zevalin® (ibritumomab tiuxetan). Biogen Idec also is a member of the Biotechnology Industry Organization (BIO), and we support those comments as well. In particular, we support the comments submitted by BIO regarding the proposed changes to reimbursement for radiopharmaceuticals. As we will discuss more thoroughly below, we are concerned that CMS' proposed reimbursement methodology for radiopharmaceuticals in general and Zevalin® in particular would limit Medicare beneficiaries' access to important therapies. Consequently, we support BIO's position of continuing the current reimbursement methodology for at least another year. This position is also supported by the Council on Radionuclides and Radiopharmaceuticals (CORAR), of which we are a member and whose comments we also support.

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1 71 Fed. Reg. 49506 (August 23, 2006).

In addition, as outlined in BIO's comments, we believe that CMS' proposal to reimburse drugs and biologicals without pass-through status at average sales price (ASP) plus 5 percent will produce rates that are inadequate to cover all of the costs of acquiring and preparing critical therapies. Until CMS finds an appropriate mechanism to reimburse hospitals for their substantial pharmacy service costs and better understands and adjusts for charge compression, we believe CMS should reimburse hospitals for drugs and biologicals at least as much as they are reimbursed in a physician office. Moreover, CMS should eliminate the bundling threshold and pay separately for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting. Both these recommendations were made by the Advisory Panel on Ambulatory Payment Classification (APC) Groups,2 and we urge CMS to implement them in the final rule.

I. Pass-Through Status for Tysabri® (natalizumab) (Pass-Through Drugs)

Biogen Idec appreciates CMS' proposal to retain Tysabri® (natalizumab) on the list of drugs and biologicals with pass-through status.3 This decision will help protect Medicare beneficiaries' access to Tysabri® by setting a more appropriate payment rate for this innovative therapy. CMS notes in the Proposed Rule that the payment rates in Addenda A and B are based on the pricing data from the April 1, 2006 Part B drug pricing files.4 The agency also proposes to adjust the amounts shown in Addenda A and B in the final rule and on a quarterly basis during 2007 if later average sales price (ASP) submissions or more recent wholesale acquisition costs (WACs) or average wholesale prices (AWPs) indicate that adjustments are necessary.5 We support this proposal, and we ask CMS to ensure that the final rule reflects the current WAC for Tysabri®. The rate published in the July 2006 update to Addendum B and in the October update to the ASP file – $7.72, or 106 percent of the current WAC – is correct.6

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2 Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip; October 2006 ASP Pricing File, http://www.cms.hhs.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/oct06asp_hcpcs.zip.

3 71 Fed. Reg. at 49582.

4 Id. at 49581.

5 Id.

6 July 2006 Addendum B Update, http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&itemID=CMS1183849.

II. Payment for Radiopharmaceuticals (OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals)

Biogen Idec is deeply concerned that, if implemented, the Proposed Rule would produce devastating cuts to reimbursement for certain radiopharmaceuticals, including therapeutic radiopharmaceuticals such as Zevalin®, and would set rates far below these therapies' acquisition costs. In 2006, CMS correctly recognized that "rapid reductions could adversely affect beneficiary access to services utilizing radiopharmaceuticals."7 To protect access to these therapies, CMS strove to maintain consistency, whenever possible, between the 2005 and 2006 rates.8 We agree with this approach, and we are deeply concerned that CMS is not pursuing this same goal for 2007. CMS proposes to establish rates for all radiopharmaceuticals in 2007 using mean costs derived from calendar year 2005 claims data.9 The agency proposes to apply hospital-specific departmental cost-to-charge ratios (CCRs) to derive these costs from hospital charges.10

Under this proposal, payment for Y-90 Zevalin® would drop to $12,130.20, a 42 percent reduction from the 2005 level of $20,948.25, and 38 percent less than the average purchase price reported by the Government Accountability Office in 2005.11 In addition, the payment for In-111 Zevalin would drop from $2,419.78 in 2005 to $1,344.34 in 2007, a 44 percent reduction. Furthermore, the reassignment of Current Procedural Terminology (CPT) code 79403 to a clinical APC from a New Technology APC results in a 43 percent reduction in payment for administration of Y-90 Zevalin®.12 A similar reassignment of CPT code 78804 from a New Technology APC results in a 53 percent reduction in payment for the administration of In-111 Zevalin and the necessary scans. The combination of these various payment reductions raises serious concerns about whether Medicare's reimbursement in 2007 will be adequate to protect access to this therapy.

The Zevalin therapeutic regimen is indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphomas (NHL), including patients with rituximab-refractory follicular NHL. The risk of NHL increases steadily with age; the median age of

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7 70 Fed. Reg. 68515, 68653 (November 10, 2005).
8 Id.
9 71 Fed. Reg. at 49587.
10 Id.
11 GAO, Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting, GAO-05-733R, July 14, 2005, at 6.
12 71 Fed. Reg. at 49556.

patients with NHL at diagnosis is 66.5 years13. Clinical data have shown that Zevalin is a safe and effective treatment option in elderly patients. Integrated analyses of 4 multicenter clinical trials were performed to evaluate the safety and efficacy of the Zevalin therapeutic regimen in older patients14. The authors concluded that Zevalin is efficacious in patients age 60 years of age and older, achieving response rates and remissions comparable to the younger patients. Additionally, based on the safety profile, the regimen is a suitable treatment alternative for older patients who may not tolerate chemotherapy.

Zevalin® offers these patients new hope and a shorter treatment regimen, but it also requires additional work to prepare. Unlike other treatments that require months of chemotherapy, the Zevalin® therapeutic regimen is administered over seven to nine days in two separate steps:

(1) On day 1, a predose of rituximab 250 mg/m^2 is followed by an imaging dose of In-111 ibritumomab tiuxetan 5 mCi. At 48 to 72 hours after administration of the imaging dose, whole-body gamma images are performed to evaluate the biodistribution of In-111. Additional imaging studies may be performed at other time points if ambiguities arise.

(2) On day 7, 8 or 9, a therapeutic dose of Y-90 ibritumomab tiuxetan 0.3 or 0.4 mCi/kg (maximum total dose of 32 mCi) is administered. A predose of rituximab 250 mg/m^2 is also given 4 hours before the therapeutic dose to improve the biodistribution of the radioimmunconjugate.

To prepare each dose, the hospital must follow specific instructions, including storing Zevalin® at two to eight degrees Celsius, transporting the isotopes in a five-pound lead unit-dose container, and handling the radioisotopes inside a laminar flow hood.

As outlined above, CMS' proposed rates simply are too low to allow hospitals to offer Zevalin®. If CMS moves forward with this methodology, it could effectively end access to this therapy for Medicare beneficiaries. Additionally, drastic year-to-year changes in reimbursement are destabilizing for hospitals and

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13 Ries LAG, Eisner MP, Kosary CL, et al, eds. SEER Cancer Statistics Review, 1975–2000. National Cancer Institute. 2003. Available at: http://seer.cancer.gov/csr/1975_2000. Accessed January 13, 2005.

14 Schilder RJ, Emmanouilides C, Vo K, et al. Yttrium 90 ibritumomab tiuxetan (Zevalin) is safe and effective in older patients with relapsed or refractory NHL. Poster presented at: The American Society of Clinical Oncology 41st Annual Meeting; May 13-17, 2005; Orlando, FL; #6562.

for manufacturers and could limit future investment in providing and developing new, innovative therapies.

Not only would this proposal produce a drastic cut in reimbursement for 2007, it would impede CMS' efforts to gather more accurate data for rate-setting in future years. CMS needs to have a stable payment methodology in place for at least two years to gather accurate and consistent data. This proposal is the fifth change in payment methodology for Zevalin® in six years. The payment methodologies for all radiopharmaceuticals have experienced similar fluctuations. Because the payment methodology has changed so frequently, CMS has not been able to accurately capture costs for Zevalin®, including the costs of acquisition, preparing, handling, and disposing of this therapy.

In the final rule for 2006, CMS made an important step toward improving the accuracy of the data on which it bases OPPS rates. The agency responded to comments that hospitals had not been reporting their acquisition and overhead costs for radiopharmaceuticals uniformly and accurately by clarifying that "it is appropriate for hospitals to set charges for these agents in 2006 based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients."15 We are hopeful that hospitals have followed this guidance to set appropriate charges perhaps as soon as 2006.

Unfortunately, instead of continuing the 2006 methodology to collect more accurate data, CMS proposes to use calendar year 2005 data to set the rates for 2007. The 2005 data do not capture any of the changes that hospitals implemented as a result of the guidance CMS provided last year, and the rates set using these data will not include the considerable costs of preparing radiopharmaceuticals for administration. As the Medicare Payment Advisory Commission (MedPAC) reported in June 2005, those costs are significant and not uniformly reported in hospitals' charge data. The MedPAC report found that an adjustment to the OPPS rates for pharmacy handling costs was warranted for all drugs.16 Due to additional safety and quality assurance requirements, radiopharmaceuticals require the most resources of all drugs to prepare.17 MedPAC also reported that most hospitals do not develop charges for hospital pharmacy handling costs and do not have precise information about those costs,18

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15 70 Fed. Reg. at 68654.

16 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 142.

17 Id. at 145-146.

18 Id. at 140.

indicating that these costs were not accurately reflected in hospitals' charges in 2005. Although CMS asserts that these costs are included in the 2005 charge data used to create the proposed rates,19 the MedPAC report clearly demonstrates that hospitals did not uniformly report charges for these services in 2005. Using data from 2005 therefore would not produce rates for 2007 that include the substantial costs of preparing, handling, and disposing of radiopharmaceuticals in addition to the acquisition costs of these therapies.

CMS also proposes to use hospital-specific departmental CCRs instead of the hospital-specific overall CCRs it used in 2006.20 By using a departmental CCR, CMS might fail to capture any changes in hospitals charges made since it issued its guidance last year. We recommend that CMS continue to use the overall CCR until it determines whether hospitals have been able to update their charges to include all costs associated with providing therapeutic radiopharmaceuticals. This also will add stability and consistency to the system.

In the final rule for 2006, CMS concluded that reimbursing radiopharmaceuticals based on a hospital's charge reduced to cost using the hospital's overall cost-to-charge ratio would be the "best available proxy for average acquisition costs of the radiopharmaceuticals along with their handling costs."21 In the Proposed Rule, CMS again acknowledges that this methodology is an acceptable proxy for these costs.22 Additionally, the Advisory Panel on Ambulatory Payment Classification (APC) Groups recommends that CMS continue to use the current payment methodology for radiopharmaceuticals in 2007, and we urge CMS to follow this recommendation.23 Instead of implementing yet another destabilizing change to reimbursement for radiopharmaceuticals, we recommend that CMS continue to use the current CCR methodology for at least one year to allow the agency to collect accurate charge data, while ensuring beneficiary access to these therapies. At that time, CMS should evaluate the quality of the data and determine whether to continue to use this methodology for another year, develop an alternative payment methodology in 2008 using the 2006 data, or develop a different reimbursement formula.

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19 71 Fed. Reg. at 49587.

20 Id.

21 70 Fed. Reg. at 68654.

22 71 Fed. Reg. at 49587.

23 Advisory Panel on Ambulatory Payment Classification (APC) Groups, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

Biogen Idec appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at (202) 383-1440 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

Kathleen Weldon

Kathleen Weldon
Vice President, Government Strategy
Biogen Idec

Providence Health & Services

October 10, 2006

Honorable Leslie Norwalk
Interim Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-4125-P

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual payment Update Program – HCAHPS® Survey, SCIP, and Mortality; Proposed Rule

Dear Ms. Norwalk:

On behalf of Providence Health & Services, I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to payment policies under the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates. CMS published these changes as part of its Notice of Proposed Rule Making in the Federal Register on August 23, 2006. Providence Health & Services is a faith-based, non-profit health system that operates acute care hospitals, physician groups, skilled nursing facilities, home health agencies, assisted living, senior housing, PACE programs, and a health plan in Washington State, Oregon, California and Montana.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is pleased to submit the following comments on the "Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update - HCAHPS® Survey, SCIP and Mortality." Today, through separate correspondence, we are

submitting other comments for the non-hospital quality reporting proposals in the above NPRM. In addition, we will submit our comments on the NPRM for the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates in subsequent correspondence.

Hospital Quality Data

CMS proposes to implement an OPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program effective for payments beginning on January 1, 2007. As an initial step, CMS proposes to link the CY 2007 OPPS payment update to hospital reporting of quality measures in effect under the existing inpatient prospective payment system (IPPS) RHQDAPU program. For CY 2007, hospitals would only receive the full update to the conversion factor used to determine CY 2007 OPPS payments if they meet the IPPS RHQDAPU requirements for FY 2007. Hospitals that do not meet the IPPS RHQDAPU requirements for FY 2007 would receive an update to the CY 2007 OPPS conversion factor that is reduced by 2.0 percentage points (i.e., 1.4 percent instead of the full 3.4 percent update.) A reduction applied in one year would not affect a hospital's OPPS update in a subsequent year.

CMS believes that the IPPS RHQDAPU, which involves the collection and submission of performance data and the public reporting of comparative information about hospital performance, will provide strong incentives to encourage hospital accountability in general and quality improvement in particular.

The RHQDAPU program, first implemented in FY 2005, requires hospitals to submit certain quality data in order to receive a full annual payment rate update. The current program uses 10 quality measures; however, beginning in FY 2007 the program will expand to include 21 quality measures. In linking OPPS payment to the IPPS quality measures, CMS asserts that the 21 quality measures in use for FY 2007, though developed for inpatient facilities, reasonably reflect the quality of care provided by hospital outpatient departments.

CMS also discusses the applicability to OPPS of the additional IPPS quality measures proposed for FY 2008. These measures involve a patient survey, additional surgical care measures, and mortality within 30 days of hospital admission. Again, in each case, CMS concludes these measures reasonably reflect care in hospital outpatient departments and indicates its intention to adopt the full set of proposed FY 2008 IPPS quality measures to the CY 2008 OPPS RHQDAPU program. The proposal will be formalized next year in the proposed rule for CY 2008 OPPS payment.

Linking IPPS quality measures to the OPPS is planned as an interim step. CMS intends to begin work, in collaboration with stakeholders, on a set of quality and cost of care measures specific to hospital outpatient departments for implementation at the earliest possible date. Reporting of a more fully developed, outpatient-specific set of quality and cost of care measures may be used for purposes of determining the update as early as CY 2009 following development and announcement of the measures; consideration of comments from the hospital community, patient advocates, and other stakeholders; establishment of the requisite mechanisms for reporting; and initiation of actual reporting of the measures by hospitals.

Comments:

1. Providence Health & Services strongly supports the goal of promoting higher quality health care services. Accordingly, we also support the appropriate application of "value-base purchasing" as a viable strategy to this end.

2. We recognize that there is some correlation between outpatient care and inpatient care for specific diagnoses, particularly the 30-day mortality measure, and desire to see pay for performance systems constructed around episodes of care. We are concerned, however, that the current measures were not developed to focus on such episodes of care, but were developed with a single purpose in mind.

We agree on the need for ambulatory measures; at the same time, we believe that the timeline for outpatient pay for reporting is unrealistically short given that there is currently no structure in place at hospitals to measure and report in the outpatient setting. Quality measurement for outpatient departments is not nearly as advanced as that of the inpatient setting; moreover, there has yet to be trial and testing of even the current inpatient measures. Consequently, we believe it would premature to implement the pay for reporting requirement in CY 2007. Outpatient departments will need sufficient time to establish quality measurement systems distinct from the inpatient setting.

The inpatient payment update provisions provide a strong incentive for hospitals to report inpatient data, and we question whether linking the outpatient payment update to the same data furthers this purpose. Those hospitals that are positioned to report have every incentive to do so, while those hospitals that face a barrier to report now suffer a double penalty for failing to report. At the same time, these inpatient measures may not provide a strong indication of outpatient quality, so increased attention to these measures may diminish attention to outpatient quality issues, proving counter productive in terms of outpatient quality.

Recommendation:
Given the necessity of developing a measurement and reporting structure in the outpatient setting, we recommend that CMS implement the voluntary reporting phase for Outpatient Departments in CY 2007 but do not move forward with pay for reporting until at least CY 2009 when the systems are establishing and tested. By that time the ambulatory quality measures can be incorporated into the set of measures to create a more robust quality reporting system and one that broadly reflects quality across the hospital. This is also consistent with the timeline that was used for development of the inpatient pay for reporting system that is currently in place and will hopefully coincide with a similar system for physicians under the physician fee schedule.

In closing, thank you for the opportunity to review and comment on the proposed Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update hospital outpatient PPS rule for CY 2007. Please contact Steve Brennan, Director, Government Affairs, at (206) 464-4717 or via e-mail at Steve.Brennan@providence.org if you have questions about any of the information submitted in this letter.

Sincerely,

John Koster MD

John Koster, M.D.
President/Chief Executive Officer
Providence Health & Services

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Providence Health & Services

October 10, 2006

Honorable Leslie Norwalk
Interim Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-4125-P

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual payment Update Program – HCAHPS® Survey, SCIP, and Mortality; Proposed Rule

Dear Ms. Norwalk:

On behalf of Providence Health & Services, I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to payment policies under the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates. CMS published these changes as part of its Notice of Proposed Rule Making in the Federal Register on August 23, 2006. Providence Health & Services is a faith-based, non-profit health system that operates acute care hospitals, physician groups, skilled nursing facilities, home health agencies, assisted living, senior housing, PACE programs, and a health plan in Washington State, Oregon, California and Montana.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is pleased to submit the following comments, with two exceptions, on the above notice of proposed rulemaking (NPRM), which was published in the *Federal Register* (Vol. 71, No. 163, pages 49506-49977) on August 23, 2006.

Also today, through separate correspondence, we are submitting our comments on the NPRM for the Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update (Section XXIII – File code CMS-4125-P). In addition, we will submit our comments on the NPRM for the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates in subsequent correspondence.

APC Relative Weights

For 2006, CMS proposes to use the same methodology it has for a number of years to determine the relative APC weights, including creation of "pseudo" single claims from multiple procedure claims. New for 2007, the median cost of each APC is compared to APC 0606, rather than APC 0601, which will no longer exist under the proposed rules.

Despite CMS's continued efforts to improve its claims data processes, the APC weights remain highly volatile. Over 250 APC weights are lower this year, some by 10 or 20%, and a few even more. Well over 300 APC weights increase, many substantially, some by over 30%. None of these changes reflect actual changes in hospital costs for the procedures reported.

The volatility in the APC weights creates tremendous uncertainty for hospitals in planning services and budgeting—processes that are well under way, or complete for 2007 in many cases. Hospitals that "guess wrong" in these processes may find themselves dramatically affected by a substantial change in the APC weights and may discover it is nearly impossible to maintain a service. Thus, the continued volatility jeopardizes the availability of services to Program beneficiaries.

Recommendation:
We again urge CMS to develop a complete, long-term solution to this problem, by re-examining the billing system, and convening a panel to consider additional submittal requirements that could substantially improve the data from which the weights are determined. For the near term, we encourage CMS to implement measures to mitigate the effects of the changes in APC weights under the current system, such as limiting the extent of change in any one year.

Outlier Payments

CMS proposes to target outlier payments at 1% of total OPPS payments again, and to set both a multiple threshold and a fixed-dollar threshold for outlier payments for any procedure. It proposes to increase the fixed-dollar threshold from $1,250 to $1,875, in order to avoid overpayments that might occur under the proposed new method of calculating cost to charge ratios.

Few hospitals can avail themselves of outlier payments under the current thresholds, and this change further limits the availability of outlier payments. This is problematic in any year, because outlier payments serve to lessen the effect of the lack of coherence between hospitals' actual costs and the relative APC weights discussed above.

In the long term, we believe that the entire outlier system should be reevaluated, which might result in lowering the target for payments further, so that it truly addresses only the most significant cases or limiting the availability of outlier payments to certain facilities.

Recommendation:
It would be particularly helpful to undertake this effort in conjunction with an effort to stabilize the APC weights. For the near term, we recommend reducing the impact of the sudden, sizable increase in the fixed dollar threshold by increasing the target or taking other mitigating steps.

Medication Therapy Management Services

In the proposed rule, CMS rejects the APC Panel's recommendation to create new APCs with nominal payment rates for pharmacist-provided medication management services. CMS states that such services are already included in hospital costs for procedures or are already paid as part of physician services.

On many occasions, however, a medication management visit with a pharmacist can be a cost-effective alternative to a clinic or physician visit that results in delivery of better care to beneficiaries. Examples include: Improving diabetes patients' insulin management and usage, furthering pain and nausea control for patients undergoing chemotherapy, helping patients receiving anti-coagulation therapy manage their medication and diet to enhance outcomes, and improving overall medication management for patients with complex medication regimens—potentially eliminating certain medications or interactions. These services not only improve outcomes, but can reduce overall Program costs.

Recommendation:
This position overlooks the benefits that such services, when separately provided, may have for both the Medicare Program and for Program beneficiaries. We strongly urge that CMS reconsider its position on this issue, based on the recognition that such pharmacist visits are new in the sense that they will be available independent of a physician or clinic procedure and hence, can be mapped to new technology APCs.

Device Dependent APCs

Median Weights. CMS proposes to set median weights for device dependent APCs on two years of claims data, which utilize edits implemented in April and

October, 2005. CMS proposes to eliminate use of any adjustments to weights determined using this methodology, such as linking payment to the payment median for the preceding year.

Despite CMS's good faith effort to ensure the reliability and appropriateness of the claims data for these APCs, it has little experience with this data – only two years – and even less with the edits. We are concerned that these data may well exacerbate the volatility in APC weights mentioned above.

Recommendation:
Accordingly, we urge CMS to continue utilizing the "dampening" measures it has employed in the past to avoid sizable changes in the weights for these important APCS, such as relying on external data or linking a median cost to the prior year's payment median.

Devices Replaced Without Cost or With Credit Given. CMS proposes to reduce the APC payment rate when it learns that a device is replaced during the procedure without cost for replacement or with full credit for the device removed. The amount of the reduction would be calculated in the manner of an offset for a pass-through device.

While this provides a reasonable approach to addressing the recent issues with device recalls, it may result in a reducing the average cost of these procedures, so that it impacts even procedures with devices paid at full cost. The recall and replacement issues may be a temporary concern, and the effects of the "cure" may run well past the time when the problem is solved.

Recommendation:
In light of this concern, we urge CMS to implement steps to ensure that what may be an anomaly does not impact average costs, and create a swing in APC weights, at least until more data is available. One such step might be to exclude claims in which the APC payment is reduced because of a device replacement from future calculations of costs and payments for these APCs, for the time being.

CAHs: Emergency Medical Screening

CMS proposes to permit nurses to perform emergency medical screenings at critical access hospitals, just as they may at acute care facilities (provided that all appropriate requirements are met). We support this change to allow a practice that may be even more important for CAHs than for other facilities, given the limited availability of physician staff. However, the ramifications for payment are not clear, and we encourage CMS to ensure that this change does not adversely impact payment for screening services at CAHs, many of which already face financial difficulties in maintaining their emergency services.

Inpatient-Only List

The list was created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the Hospital outpatient prospective payment system (OPPS). There are numerous problems created by the inpatient list as has been documented in past comments. The biggest continuing problem is that such a list is not binding on physicians. Consequently, since the physician receives payment when a procedure on the inpatient list is performed on an outpatient basis, there is no incentive for the physician to be concerned whether Medicare will pay the hospital for the procedure. This is a particularly troubling issue in teaching hospitals. This fact underscores the reality that it is the physician, not the hospital, who determines whether a procedure will be performed in the outpatient or inpatient setting.

In the past, CMS has responded to such comments by saying that "[it] believes that appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion." From our perspective, it does no good for hospitals or their representative organizations to try to educate physicians as to this situation. When it comes to economic issues, physicians, quite understandably, pay little attention to how hospitals are paid. And the CMS provider education staff does not appear to have made any headway on this matter as well.

Recommendation:
Providence Health & Services continues to urge the elimination of the inpatient list primarily because the list is not binding on physicians.

In closing, thank you for the opportunity to review and comment on the proposed Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update hospital outpatient PPS rule for CY 2007. Please contact Steve Brennan, Director, Government Affairs, at (206) 464-4717 or via e-mail at Steve.Brennan@providence.org if you have questions about any of the material in this letter

Sincerely,

John Koster MD

John Koster, M.D.
President/Chief Executive Officer
Providence Health & Services

ST. FRANCIS MEDICAL TECHNOLOGIES, INC

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October 10, 2006

BY HAND DELIVERY

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

Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates)

Dear Administrator McClellan:

St. Francis Medical Technologies, Inc. ("SFMT") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule related to the calendar year ("CY") 2007 outpatient hospital prospective payment system ("Proposed Rule").[1] SFMT is engaged in the discovery, development and marketing of novel treatments for degenerative spinal disorders worldwide, focusing on minimally invasive technologies to treat degenerative spine problems that help patients quickly regain their mobility. For one of our technologies, the X STOP® Interspinous Process Decompression System ("X STOP "), CMS granted our application for pass-through status effective January 1, 2007, which will provide for reimbursement for the X STOP device.

These comments, however, are directed at the appropriate payment levels under the outpatient prospective payment system ("OPPS") for the procedures used to implant the X STOP, which will be billed in 2007 using the following two new Category III Current Procedural Terminology ("CPT") codes:

1. **0171T** (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level); and
2. **0172T** (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level).

[1] 71 Fed. Reg. 49506 (Aug. 23, 2006).

960 Atlantic Avenue, Suite 102
Alameda, California 94501
510.337.2600
Fax 510.337.2698
info@sfmt.com

For the reasons discussed below, we recommend that the single level implant code (0171T) and the subsequent level(s) implant code (0172T) be assigned to Ambulatory Payment Classification ("APC") 51. Although, as explained below, the level of resources utilized in the second and subsequent level implant procedures is less than those for the single level implant, we believe that APC 51 is appropriate for 0172T because that APC is subject to the multiple procedure reduction which, by definition, would apply to 0172T (since a single level procedure, 0171T, also would be billed for the same outpatient encounter).[2]

BACKGROUND

The X STOP is a new minimally invasive, stand-alone alternative treatment for lumbar spinal stenosis ("LSS"), that received premarket approval by the Food and Drug Administration ("FDA") on November 21, 2005. The X STOP is placed between the spinous processes to limit extension of the symptomatic level(s), yet allows flexion, axial rotation and lateral bending. This provides a potential alternative to conservative and surgical treatments (e.g., lumbar spinal decompression, decompression with laminectomy, and fusion). LSS and the role of the X STOP in treating patients suffering from LSS was described by CMS in the recent inpatient hospital prospective payment system ("IPPS") final rule as follows:

> Lumbar spinal stenosis describes a condition that occurs when the spaces between the bones in the spine become narrowed due to arthritis and other age-related conditions. This narrowing, or stenosis, causes nerves coming from the spinal cord to be compressed, thereby causing symptoms including pain, numbness and weakness. It particularly causes symptoms when the spine is in extension, as occurs when a patient stands fully upright or leans back. The X STOP device is inserted between the spinous processes of adjacent vertebrae in order to provide a minimally invasive alternative to conservative treatment (exercise and physical therapy) and invasive surgery (spinal fusion). It works by limiting the spine extension that compresses the nerve roots while still preserving as much motion as possible. [3]

In the recent IPPS final rule, CMS determined that the X STOP qualified for additional payments as a new technology service, reflecting the agency's determination that it is a substantial clinical improvement over existing technologies. The agency determined that the "X STOP represents a new level of treatment on the continuum of care for patients with lumbar spinal stenosis that previously did not exist."[4] In the new technology add-on process, as noted in the IPPS final rule, there was some confusion about the frequency of use in the inpatient and outpatient settings. SFMT clarified for CMS that, currently, 10% of the procedures are being

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[2] Except as noted, all of the comments on the Proposed Rule contained herein relate to "OPPS: New HCPCS and CPT Codes" issues.

[3] 71 Fed. Reg. 47870, 48002-03 (Aug. 18, 2006).

[4] Id. at 48004.

done on an outpatient basis. [5] In our comments on the IPPS proposed rule, we noted that, as the X STOP is used more widely, it is very possible that more procedures will be done on an outpatient basis than we understand currently to be the case, but we would expect any such migration to be determined by clinicians. Subsequent to the release of the IPPS final rule, CMS granted our application for pass-through status for the X STOP device, again confirming that it represents a substantial clinical improvement over existing technologies.

Since the issuance of the Proposed Rule, the American Medical Association ("AMA") announced the establishment of CPT codes 0171T and 0172T effective January 1, 2007. These codes cover the procedure for implanting the X STOP and, importantly, the AMA made these codes comprehensive in that they include both the imaging component of the procedure as well as the removal of bone or ligament during the procedure. Under OPPS, given the granting of the pass-through application for the device, payment for these codes should capture the resources (other than the X STOP device(s)) for implanting the X STOP at a single level (0171T) and at each subsequent level (0172T). The hospital resources involved in the procedure include operating room time, anesthesia time, pharmacy services for pain management, medical and surgical supplies, radiology services (fluoroscopic guidance confirming placement of the X STOP), and recovery room time. As discussed later, the added level of resources when implanting the X STOP at a second level is less than, although not duplicative of, the resources to implant the X STOP at the first level.

DISCUSSION

We note that, in the Proposed Rule, CMS indicates that it intends to continue to implement new Category III codes effective January 1 in the OPPS final rule.[6] SFMT believes that this policy is appropriate and that the agency should move expeditiously to develop payment rates for new Category III codes. In that spirit, we believe that it is appropriate for CMS to determine an APC assignment for CPT codes 0171T and 0172T, which were established in June of this year with a January 1, 2007 effective date. SFMT notes that there are a limited number of APCs for spinal procedures, which makes it more challenging to find a good fit for 0171T and 0172T from a clinical and resource coherence perspective. Moreover, the APCs for the different level musculoskeletal procedures (49-52), seemingly the best fit clinically, all are subject to the multiple procedure reduction, which could be problematic for these codes. Considering all of these factors, for reasons discussed below, we believe that 0171T and 0172T should be assigned to APC 51.

In determining the appropriate APCs for these codes, it is critical to consider all of the cost components of the procedures. For 0171T, this includes:

- 1-2 hours of operating room time;

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5 Id.

6 71 Fed. Reg. at 49548-59.

- 1.25-2.50 hours of anesthesia time;[7]
- Operating room supplies such as:
    - Modifications to the operating room table using an Andrews Spine kit, a Jackson Spine kit, or a Wilson Frame for proper patient positioning;
    - A C-arm (a radiographic and fluoroscopic systems in which the image receptor and X-ray tube housing assembly is positioned by the C-shaped support);
    - A laminectomy pan;
    - SFMT instrumentation set – includes (i) a mainbody insertion instrument; (ii) a universal wing insertion instrument; (iii) torque limiting hex driver; (iv) small curved dilator; (v) large curved dilator; (vi) distracting sizing instrument; and (vii) instrument sterilization tray;
- Pain management services through the pharmacy, such as pharmaceuticals, facet blocks, trigger blocks;
- 2-12 hours of recovery time in the surgery recovery area; and
- Radiology services – fluoroscopic guidance to confirm the placement of the device.

For 0172T, the cost components to be considered include:

- 30-60 minutes of operating room time;
- 30-60 minutes of anesthesia time;
- Additional pain management services, beyond those used for a single level procedure, through the pharmacy such as pharmaceuticals, additional facet blocks, additional trigger blocks; and
- Additional radiology services beyond those used for a single level procedure – fluoroscopic guidance to confirm interspace, distraction, and the placement of the device(s).

We must emphasize that the listed components for 0172T are all costs incurred separately and in addition to the costs incurred in performing a single level procedure. Thus, it would be inappropriate to slot 0172T based on these resources and then subject the code to the multiple procedure reduction, which would lower the payment rate by 50% (since, by its nature, 0172T would be a second surgical procedure). Alternatively, CMS could account for the lower resources utilized in the second and subsequent level implants by placing 0172T in the same APC as 0171T, which would allow the multiple procedure reduction to adjust for the lesser resources utilized in 0172T.

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[7] This amount of time for anesthesia is based on our understanding of the current clinical use of the X STOP. In submitting information for the inpatient new technology add-on, we may have reported less anesthesia time based on our understanding from clinical trials. While we may not be able to explain the difference in what we were told from the clinical trials and what we are now told, we think it is appropriate to consider the current level of anesthesia time in clinical practice.

In an effort to assist CMS in determining the appropriate APC assignments for CPT codes 0171T and 0172T, we obtained charge information on seven claims from six different facilities that performed a single level X STOP procedure (which would be billed under 0171T). These services were furnished between February and July of 2006. Two of the services were provided on an outpatient basis (Facilities A & E), while the remaining five were provided on an inpatient basis, a one day stay in each circumstance. Given the short stay for these 4 inpatient claims, the only added charge compared to an outpatient case is the room and board charge. Thus, all room & board charges specific to an inpatient hospital stay were removed from our calculations and considerations such that it is appropriate to consider these claims in our assessment of outpatient costs.

As is evident from the attached spreadsheet summarizing these data, we were able to obtain charges broken down by revenue code in three facilities (B, C, D), while two facilities (A, E) only provided us with total charges. These data do not reflect charges for the X STOP since CMS will reimburse for the device separately as a pass-through (i.e., not through CPT code 0171T or 0172T), and we asked the facilities to exclude charges for the device in what they provided to us. For each claim, we used the operating cost to charge ratio from PRICER on the CMS website for each specific Facility to adjust the claims to cost, which is what the "Prospective Costs" line represents. If the median of the figures in this line is computed, the result is $2727.00. This figure is squarely within the range of the median costs by code for services grouped to APC 51. Indeed the $2727.00 figure is on the high side – of the 56 codes assigned to APC 51, only 13 codes have a higher median cost.[8] We understand that a hospital that has examined its own charges for the X STOP procedure in relation to charges for other OPPS payable procedures and similarly determined that APC 51 is the appropriate grouping for a single level implant.

Unfortunately, we were not able to obtain data that separately track the second level procedure to be used for setting the rate for CPT 0172T. Given the relative level of resources for the second and subsequent level noted above and the fact that APC 51 is subject to the multiple procedure reduction, we believe that APC 51 is the right APC assignment for 0172T. Since 0172T would be billed also when 0171T would be billed, the 50% reduction would apply. We believe that 50% of the payment rate for APC 51 would be sufficient to ensure beneficiaries needing more than a single X STOP implant would have access to the procedure.

Finally, although we expect the X STOP device to be treated as a pass-through at least through calendar year 2008, under the current OPPS scheme, ultimately it will be included in an APC into which the implant procedure is assigned. At that time, the device costs likely will dominate the resources expended by the hospital, perhaps by as much as 2:1. Our concern is with the current mechanism by which CMS accounts for a particular hospital's wage index –

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[8] While some might question whether the comparison to APC 51 is appropriate given that the cost of the X STOP device is not included in the median, we note that there are device costs built into 0171T and 0172T. For example, there are device costs related to the imaging aspect of the code. Since there are device costs, other than the X STOP, in these codes, we do not believe that the comparison to APC 51 can be rejected because the cost of the X STOP is not included.

60% of the rate is adjusted by the wage index. [9] This percentage to be adjusted by the wage index would be much too high for the eventual payment for the X STOP implant procedure because perhaps as much as (if not more) 67% of the hospital resources is for the X STOP device. The pricing of the device to the hospital does not correlate to the hospital's wage index. In other words, hospitals in rural areas with wage indices below 1.0 do not purchase the device for less than hospitals in urban areas with a wage index above 1.0. SFMT is concerned that the method by which CMS adjusts the payment rate for the wage index will make it more difficult for hospitals in areas with a wage index below 1.0 to provide the X STOP to their patients in the future. We ask that CMS address this issue so that when the X STOP no longer has pass-through status, hospitals in areas with a wage index below 1.0 will be able to continue to offer the procedure to their patients.

Conclusion

Again, SFMT appreciates the opportunity to comment on the Proposed Rule. As CMS has recognized in granting pass-through status, the X STOP is precisely the type of technology that Medicare beneficiaries should have access to in the hospital outpatient setting. Proper APC assignment for the procedures (billed under 0171T and 0172T) that are performed in inserting the device is crucial to making this technology available in this setting. Based on the information provided herein and other information available to CMS, we believe that 0171T and 0172T should be assigned to APC 51.

If you have questions concerning this letter, please do not hesitate to contact me at 510-337-2600. Thank you for your consideration.

Sincerely,

Kevin Sidow/AR

Kevin Sidow
President and CEO

Attachment

[9] 71 Fed. Reg. at 49540. Our comments on the issue pertain to the caption "OPPS: Wage Indices."

Single Level X STOP Facility Costs/Charges

Revenue Code	Description	Facility A	Facility B	Facility B	Facility B	Facility C	Facility D	Facility E
250-259	Pharma		$804.32	$604.77	$964.77	$1,374.16	$1,153.00	
300	Lab		$252.40	$0.00	$239.40	$0.00	$481.00	
320	Radiology		$440.50	$212.30	$358.90	$315.00	$2,106.00	
360	OR		$3,033.10	$2,772.10	$3,965.70	$2,909.75	$6,588.00	
370	Anesthesia		$138.70	$160.90	$138.70	$813.25	$356.00	
710	Recovery Rm		$546.60	$634.10	$546.60	$1,101.50	$561.00	
730	ECG		$49.40	$0.00	$49.90	$0.00	$314.00	
921	Peri/Vasc Lab		$316.90	$0.00	$0.00	$0.00	$0.00	
Non Specified:		$11,252.00						$9,000.00
Non-Device Billed Charges:		**$11,252.00**	**$5,581.92**	**$4,384.17**	**$6,263.97**	**$6,513.66**	**$11,559.00**	**$9,000.00**
CCR:		0.169	0.506	0.506	0.506	0.483	0.190	0.303
Prospective Costs:		**$1,901.59**	**$2,824.45**	**$2,218.39**	**$3,169.57**	**$3,146.10**	**$2,196.21**	**$2,727.00**

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October 10, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20202

Re: Comments on CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

On behalf of Medical Technologies International, Inc. (MTI), I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule concerning the calendar year 2007 hospital outpatient prospective payment system (OPPS) payment rates.[1]

Our comments on the Proposed Rule pertain to the treatment of the ArterioVision™ carotid artery intima-media thickness (CIMT) procedure, under OPPS. This procedure is billed under Current Procedural Terminology (CPT) code 0126T (common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment). CMS currently identifies this code as a procedure that is packaged into another Ambulatory Payment Classification (APC), meaning that no separate payment is made for the procedure itself. The agency again proposes to identify 0126T as a packaged procedure in the Proposed Rule. We believe that this assignment is inappropriate, because the procedure is a stand-alone service that is the only service provided during this outpatient encounter. **We urge CMS to assign 0126T into a new technology APC (APC 1504).** Because this code became effective January 1, 2006, there are no 2005 claims data for 0126T upon which CMS can determine the appropriate non-new technology APC for this procedure.

[1] 71 Fed. Reg. 49506 (Aug. 23, 2006) (the "Proposed Rule"). Our comments relate exclusively to the caption "New Technology APCs."

Medical Technologies International, Inc.
75-145 St. Charles Place, Suite 1, Palm Desert, California 92211
Tel: (760) 837-4778 ♦ Fax: (760) 837-4779 ♦ Web: www.i-mti.com

I. BACKGROUND

The CIMT test is a standardized ultrasound procedure that enables the physician to **safely, non-invasively, and accurately measure and monitor atherosclerosis**, the underlying cause of heart attack and stroke. CIMT is an **accepted quantitative measurement of atherosclerotic vascular disease burden, as evidenced by in excess of 2,000 peer-reviewed, published manuscripts** that link CIMT with subclinical atherosclerosis, cardiovascular disease risk factors, and cardiovascular disease that, in turn, directly translate into future cardiovascular events.

In the test, the beneficiary's right and left common carotid arteries are scanned using high resolution B-mode ultrasound equipment. The images are then analyzed with a diagnostic software package such as our product, ArterioVision™. ArterioVision™ is a patented image analysis device that was cleared by the Food and Drug Administration (FDA) in April of 2005, and is used in conjunction with MTI's patented image acquisition protocol for reproducible imaging. This software package analyzes the ultrasound images and generates the beneficiary's CIMT values – the thickness of the first two layers (the intima and the media) of the carotid artery wall. Additionally, ArterioVision™ accesses a database of CIMT values that provide the physician with an age and sex appropriate cardiovascular event risk assessment. The higher the CIMT value, the greater the likelihood of a heart attack, stroke or coronary death. Thus, for patients with medical conditions such as diabetes mellitus, hyperlipidemia, hypertension, family history of cardiovascular disease, obesity, tobacco use, metabolic syndrome, kidney disease, or cardiovascular disease, monitoring CIMT is an important tool for physicians in making appropriate treatment decisions for these patients.

In the middle of 2005, the American Medical Association (AMA) established a Category III CPT code for the CIMT procedure – 0126T (common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment). Without any explanation of the basis for its decision, for purposes of the OPPS calendar year 2006 payment rates, CMS assigned a status indicator of "N" for 0126T, meaning that the agency believed that the service was being paid for through the payment for a different service.[2] The test can be performed in one of two settings: either as the sole item or service in a hospital outpatient encounter or in a physician's office. However, because ultrasound equipment is necessary for the procedure, it is often only in hospitals where the equipment is available and therefore able to perform the CIMT procedure. No indication was given as to the item or service into which CMS believed 0126T was packaged.

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[2] 70 Fed. Reg. 68516, 68881 (Nov. 10, 2005).

II. DISCUSSION

MTI strongly believes that CMS' current treatment of 0126T and its proposed treatment of this service for 2007 is mistaken for the simple reason that there is no other item or service furnished by the hospital to the beneficiary into which this procedure can be packaged. It is a stand-alone service since CIMT requires special imaging of the arterial wall and quantitative analysis (unlike other ultrasound procedures that image the vascular lumen with or without Doppler) and thus should be paid separately under OPPS. With no existing 2005 OPPS claims data for 0126T, we recommend that CMS assign the code to new technology APC 1504.

A. CMS Should Pay Separately for CPT Code 0126T

MTI cannot understand how CMS determined that the payment for the CIMT procedure is packaged into the payment for another item or service. As noted earlier, the procedure is the only item or service that the beneficiary receives in a hospital encounter and it requires specialized imaging and analysis offline. In other words, a physician treating a patient with diabetes mellitus, or coronary artery disease, may send the patient to the hospital solely for the CIMT test. The beneficiary goes to the outpatient department with the ultrasound equipment and the ArterioVision™, where the 45-60 minute procedure is performed, after which the beneficiary goes home. In that circumstance, there simply is no other item or service into which payment for 0126T can be packaged. Please see the listing for 0126T, from the *CPT 2006 Standard Edition*, page 337.

It is important to note that, concurrent with the AMA's establishment of CPT code 0126T, the AMA added the following direction to the CPT book under the listings for other carotid procedures, i.e. 93880 and 93882:

> "To report common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment, use Category III code 0126T." (from *CPT 2006, Standard Edition*, page 311)

In other words, AMA CPT coding does not permit bundling of 0126T with other codes. Because there may be no other procedure performed on a beneficiary in an outpatient encounter, CMS must pay separately for 0126T. This language makes clear that when a CIMT test is performed, physicians and hospitals are to report the 0126T code, and **are specifically not to report under other CPT codes**.

B. CMS Should Assign CPT Code 0126T to APC 1504

In determining how to pay separately for 0126T, we begin with the obvious fact that CMS has no OPPS claims data on 0126T that pre-dates 2006 since the code was first effective January 1, 2006. Since CMS is using 2005 claims data to set the 2007 payment rates, the agency

will have no data to determine the appropriate APC assignment for 0126T in 2007. **This is precisely the circumstance for which the new technology APCs were created.** As CMS stated in the initial OPPS final rule when the agency administratively created the concept of new technology APCs, these APCs give CMS a means for initiating payment at an appropriate level so that after "we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs."[3] **With 0126T, we are at the stage where there is the need to use the new technology APCs to initiate payments until OPPS claims data on the code can be obtained.** MTI will shortly be submitting a new technology APC application, which will provide support for our recommendation to assign 0126T to APC 1504.

III. CONCLUSION

The CIMT procedure is an important treatment tool in the care of beneficiaries that are at risk for cardiovascular disease, and for those requiring monitoring of treatment efficacy, such as patients with diabetes mellitus, hyperlipidemia, hypertension, family history of cardiovascular disease, obesity, tobacco use, metabolic syndrome, kidney disease, or cardiovascular disease. **Creating economic disincentives to the utilization of this procedure, as the current treatment under OPPS and the Proposed Rule do, ultimately may impose greater costs on the Medicare program and its beneficiaries through the diminished ability to avoid heart attacks and strokes.** The "packaged" status of CPT code 0126T is simply unsupportable for the reasons detailed above. Accordingly, MTI respectfully urges CMS to assign this code to APC 1504 in the final rule.

Thank you for the opportunity to comment on this important issue. We look forward to the appropriate resolution of the 2007 OPPS payment rate for CPT code 0126T effective January 1, 2007. Please contact me at 760-837-4778 if you have any questions regarding this comment letter.

Sincerely,

Gary F. Thompson
Chairman and Chief Executive Officer

[3] 65 Fed. Reg. 18434, 18477 (Apr. 7, 2000).