555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

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September 13, 2007

VIA FEDEX

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Comments on CMS-1392-P; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (High-Energy Extracorporeal Shock Wave Therapy)**

Dear Mr. Weems:

On behalf of SANUWAVE, Inc. ("SANUWAVE"), a leader in the provision of high-energy extracorporeal shock wave technology ("High-Energy ESWT") for the treatment of chronic plantar fasciitis and lateral epicondylitis, we write to urge the Centers for Medicare and Medicaid Services ("CMS") not to adopt the proposed Payment Indicator for High-Energy ESWT for plantar fasciitis. Although the final rule on ambulatory surgery center ("ASC")[1] payments recognizes the appropriate site of service as a facility setting, the proposed 2008 payment schedule suggests that the procedure is performed mostly in the physician office setting. SANUWAVE strongly believes that this is incorrect. Further, unless the appropriate Payment Indicator is recognized, Medicare beneficiaries will be denied access to meaningful and effective treatment. We therefore urge the agency to retain the Payment Indicator ("G2") for CPT code 28890, as published in the final 2008 ASC rule.

Background

SANUWAVE's OssaTron® is a Class III device that employs High-Energy ESWT for the noninvasive surgical treatment of chronic plantar fasciitis and lateral epicondylitis.[2] It was the first medical device approved by the Food and Drug Administration for the provision of High-

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1 The proposed rule was published in the Federal Register on August 2, 2007. *See* 72 Fed. Reg. 42,628 (Aug. 2, 2007).

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

Energy ESWT to treat plantar fasciitis (October 12, 2000) and was later approved for the provision of High-Energy ESWT for the treatment of lateral epicondylitis (March 14, 2003). The procedures effect healing through the use of shock waves created by very strong acoustic energy delivered to the affected part of the body. Although the mechanism of action is physiologically different, the technique and service is similar to how lithotripsy targets high-dose shock pulses to disrupt kidney stones. Like lithotripsy, High-Energy ESWT procedures are surgical procedures most appropriately performed using anesthesia in the facility setting.

The CPT code descriptors for High-Energy ESWT procedures for both plantar fasciitis and lateral epicondylitis identify that the procedures are performed with "anesthesia other than local." The code descriptors became effective July 1, 2005, when the American Medical Association refined its Category III CPT codes for ESWT procedures to distinguish High-Energy from Low-Energy ESWT.[3] Thereafter, effective January 1, 2006, a Category I code was established for plantar fasciitis. CPT code 28890 describes the procedure as: "Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia." It is this code that is at issue here.

High-Energy ESWT procedures to treat plantar fasciitis typically are performed in a hospital outpatient department or an ambulatory surgical center by physicians trained in the surgical treatment of foot and ankle conditions, and certified to use the device for surgery. Because the procedures are painful, anesthesia (either general anesthesia or a regional block) is administered prior to the treatment. Resources thus include surgical suite expenses, as well as trained nursing staff costs for pre- and post-op care. In addition, anesthesia drug expenses are incurred. A technologist, trained in the use of the High-Energy ESWT device and procedure protocol, assists the physician with management of the device and is present throughout the procedure. Upon completion of the procedure, the patient is placed in a post-operative recovery room and is monitored until he or she has stabilized and it is determined that there have been no adverse effects from the anesthesia or the procedure.[4]

SANUWAVE's OssaTron® currently is used for the majority of High-Energy ESWT procedures for plantar fasciitis performed in the United States. The Company's data show that CMS's proposed classification of the High-Energy ESWT procedure billed under CPT code 28890 as "performed predominantly" in a physician office is inconsistent with how physicians practice. For the reasons discussed below, the Company urges CMS to retain the "G2" Payment Indicator included in its final ASC rule.[5] This would also be consistent with the way all other High-Energy ESWT procedure codes were classified in the proposed rule.

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3 Effective July 1, 2005, code 0020T—now Category I code 28890—defined ESWT for plantar fasciitis and Code 0102T defined High-Energy ESWT for lateral epicondylitis. Other conditions treated using High-Energy ESWT are defined under Code 0101T. Low-Energy ESWT procedures are defined by Code 0019T. *See http://www.ama-assn.org/ama/pub/category/3885.html.*

4 *See, e.g.,* Ogden, John A., *et al., Electrohydraulic High-Energy Shock-Wave Treatment for Chronic Fasciitis,* J. BONE JOINT SURG. AM., 2004 Oct.; 86-A(10):2216-28.

5 72 Fed. Reg. 42,470, 42,572 (Aug. 2, 2007) ("Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008").

Comments Regarding Payment Indicator for CPT Code 28890

In its Final Rule for CY 2008, CMS identified all High-Energy ESWT procedures as "performed predominantly" in a facility (*i.e.*, with Payment Indicator "G2").[6] This includes procedures currently defined by three CPT codes—one Category I (code 28890 for plantar fasciitis) and two Category III codes (code 0102T for lateral epicondylitis and code 0101T for other conditions treated using High-Energy ESWT). In the agency's proposed rule, however, and without explanation regarding its rationale for doing so, CMS revisits that classification for plantar fasciitis (CPT code 28890) only. CMS proposes to transition the Payment Indicator for code 28890 from "G2" (non-office based surgical procedure added in CY 2008) to "P3" (office-based surgical procedure added in CY 2008 or later with a non-facility relative value unit under the Medicare physician fee schedule).[7] CMS made its decision to do so based on expectedly limited Medicare claims experience for this relatively new procedure code. It is a particularly surprising decision given that the American Medical Association's Specialty Society Relative Value Scale Update Committee ("RUC") declined to develop relative value units for the in-office setting for this high energy ESWT procedure following vociferous objections by the orthopedic community.[8]

As a leader in the provision of High-Energy ESWT, SANUWAVE's experience has been that equipment sufficient to achieve High-Energy ESWT is generally not used in the office setting. The Company's data show that since 2006, only 4.8 percent of 3,622 patients treated for plantar fasciitis were treated in the office setting using SANUWAVE equipment. This volume cannot be characterized as "performed predominantly" in the office setting. Further, if adopted as proposed, the payment rate of $175.11 could not sustain the inclusion of this service in any ASC and Medicare beneficiaries would be denied access to the procedure in the most medically-appropriate setting.

As addressed below, CMS should retain the "G2" Payment Indicator because: (1) High-Energy ESWT is performed predominantly in a facility setting; (2) The ASC is the clinically appropriate setting for High-Energy ESWT; and (3) Proposed payment levels would deny beneficiary access to ASC-based services.

1. High-Energy ESWT is not "performed predominantly" as an office-based procedure

In its proposed rule, CMS suggests that its data support that procedures performed under code 28890 are "performed predominantly" in the physician office setting, which CMS defines as occurring more than 50 percent of the time.[9] SANUWAVE believes that the information

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6 72 Fed. Reg. at 42,572.

7 72 Fed. Reg. at 42,786.

8 CMS determined a value, stating that it "disagree[d] with the RUC's recommendation to value this procedure only in the facility setting," and developed a payment amount that became effective in January 2006. 70 Fed. Reg. 70,116, 70,282-70,283 (Nov. 21, 2005).

9 72 Fed. Reg. at 42,779.

relied upon by CMS was flawed. SANUWAVE's own experience, as the largest manufacturer and provider of High-Energy ESWT equipment and services for plantar fasciitis, is that the vast majority of such procedures are performed in an ASC or hospital outpatient department due to safety and clinical efficacy concerns.

For the period from January 1, 2006 to August 31, 2007, SANUWAVE's data show that 3,622 patients with plantar fasciitis have been treated using its OssaTron® equipment. Of those, only 4.8 percent, or 174 patients, were treated in an office setting; the vast majority of patients (2,667) were treated in an ambulatory surgery center. Of those 174 patients treated in an office setting, only 18 patients were over 65 years of age. There is no question that High-Energy ESWT is not "performed predominantly" as an office-based procedure, particularly for those patients over the age of 65. Rather, the procedure is performed predominantly in an ambulatory surgery center. The breakdown of all treatments for plantar fasciitis using SANUWAVE's OssaTron® equipment in the specific sites of service is illustrated below:

	Ambulatory Surgery Center	**Hospital Outpatient Department**	**Physician Office**
Patients Treated	2,667	781	174

It would appear that in contrast to robust data concerning the High-Energy procedure for non-Medicare patients, CMS's Medicare data are limited. This is in large part due to the fact that the procedure is performed primarily on younger individuals, but is also explained by the fact that the procedure is not on the current Medicare ASC list. CPT code 28890 did not go into effect until January 1, 2006, and because the ASC payment process was being transitioned, the procedure code was not added to the ASC list. As a result, Medicare claims information for the ASC is not available. Although the procedure has been covered by Medicare in the hospital outpatient setting since 2004, the prevalence in this setting also remains relatively limited.[10]

In its proposed rule, CMS states that it made a determination to designate certain procedures as office-based relying on "volume and site of service utilization data."[11] CMS did not provide information for specific procedures in the proposal. Moreover, CMS stated in its proposed rule that it relied on admittedly speculative data.[12] At minimum, before making any decision to transition the Payment Indicator from G2 to P3, CMS should wait until sufficient time has passed to collect and review adequate Medicare data for decision-making. Critically,

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10 Since January 1, 2004, CMS established national payment rates for High-Energy ESWT under Medicare's Hospital Outpatient Prospective Payment System. *See* 72 Fed. Reg. 65,682, 66,105 (Nov. 15, 2004). For Calendar Year ("CY") 2005, two HCPCS codes were assigned—C9720 (High-Energy ESW treatment for lateral epicondylitis) and C9721 (High-Energy ESW treatment for plantar fasciitis). The "C" codes were later replaced with CPT codes. *See supra* note 3.

11 72 Fed. Reg. at 42,779.

12 72 Fed. Reg. at 42,826.

the failure to appropriately classify the procedure will severely compromise the ability of Medicare beneficiaries to benefit from High-Energy ESWT for plantar fasciitis.

2. High-Energy ESWT is most appropriately provided in a facility setting

High-Energy ESWT procedures require the use of general or regional anesthesia to achieve successful outcomes.[13] This level of anesthesia helps ensure that only a single treatment is administered; patients otherwise cannot tolerate energy levels sufficiently high to achieve maximum clinical efficacy. In SANUWAVE's experience, patients undergoing anesthesia, particularly the Medicare population, generally are better monitored and achieve better clinical outcomes in a facility setting.

Importantly, the appropriate level of anesthesia for High-Energy ESWT generally cannot be administered in an office setting. This stems in part from the need to ensure that emergency precautions must be made available to patients undergoing general or regional anesthesia, such as cardiac monitoring, crash carts, and intubation equipment, among other things. Because such measures generally are not available in physician offices, the ambulatory surgery center and hospital outpatient department remain the most appropriate settings to perform High-Energy ESWT on patients, particularly Medicare beneficiaries who often suffer from multiple co-morbidities.

SANUWAVE also believes that the high costs of services without adequate payment recognition in the office setting will result in less effective and clinically unproven services being performed. It is the Company's understanding that certain services being performed in the office setting indeed are being performed without the appropriate level of anesthesia contemplated for procedures assigned to CPT 28890. The code descriptor requires both high energy and anesthesia other than local. The lack of proper anesthesia limits patient tolerance for the painful procedure; this may result in administration of reduced energy levels or the risk of a decoupling of the foot from the device, both of which may significantly reduce efficacy. Further, the use of other protocols that limit appropriate anesthesia may result in low-energy applications that require multiple procedures and that drive up the total reimbursement without achieving the clinically effective outcomes of High-Energy ESWT.

Finally, as discussed below, given the intensity of resources for providing this service, including technologists trained in the administration of the equipment, the costs of the services are more aligned with a facility-based surgical procedure.

3. Proposed payment levels for High-Energy ESWT in the ASC are too low to cover associated costs and will deny Medicare beneficiaries access to this site of service

Setting Medicare payment for High-Energy ESWT procedures using the physician fee schedule results in a gross underpayment for the technology and removes this site of service as a

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13 *See, e.g.,* Rodolà F, et al., *Anaesthesia for Shock Wave Therapy in Musculoskeletal Disorders: A Preliminary Report*, EUR. REV. MED. PHARMACOL. SCI., 2002 Nov-Dec; 6(6):133-8 (concluding that because of the pain associated with high energy ESWT, anesthesia is necessary; both regional or general anesthesia are suitable for this purpose).

viable option for Medicare beneficiaries. We recognize that CMS is attempting to ensure "that Medicare payment policy does not create financial incentives for [office-based] procedures to shift unnecessarily from physicians' offices to ASCs."[14] SANUWAVE agrees that it is important to recognize financially appropriate settings. High-Energy ESWT, however, is not an office-based procedure and the Medicare payment rate for the office setting simply does not recognize the associated costs.

Given the intense resources, including those costs associated with the capital expenditures for the device, surgery suite, ESWT technologist, nursing staff, recovery room, oxygen and supplies, and anesthesia drugs, among other costs, the proposed payment rate of $175.11 falls far short of the amount needed to furnish quality equipment with demonstrated clinical outcomes. This is also a stark contrast to the proposed payment amount for other High-Energy ESWT procedures—$1,214.11—and unquestionably will prevent physicians from performing High-Energy ESWT in the ambulatory surgery center. The proposed payment amount effectively denies beneficiary access to an effective treatment option at this important site of service. SANUWAVE believes that more invasive procedures would be prescribed, which will result in greater expenditures by the Medicare program.

* * * * *

Based on the foregoing, CMS should retain the "G2" ASC Payment Indicator for code 28890, which was designated in the ASC Final Rule and which was assigned to the Category III High-Energy ESWT codes. High-energy ESWT for any and all indications is predominantly performed in a facility setting, where general or regional anesthesia can be most safely administered.

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

Stuart Kurlander
Esther R. Scherb
of LATHAM & WATKINS LLP

cc: SANUWAVE, Inc.
Betty Pang, M.D., Latham & Watkins LLP

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14 72 Fed. Reg. at 42,826.

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Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard, Baltimore, MD 21244–1850.

September 13, 2007

CMS Proposed Rule (CMS-1392-P)
Hospital Outpatient Prospective Payment System
OPPS: Specified Covered Outpatient Drugs
Federal Register pages 42733 – 42736

CMS has proposed in the Medicare Outpatient Prospective Payment System (OPPS) for CY2008 filed August 7, 2007, that hospitals be required to report pharmacy overhead charges to provide data for possible future payment changes. The final rule would require hospitals remove the overhead cost from the price charged for drugs and biologicals and report it on a separate revenue code line. The policy would apply to all drugs, biologicals, and contrast agents irrespective of the item's packaged or separately payable status for CY 2008.

Once the claims data became available for rate-setting, the proposal could lead to pharmacy overhead for drugs and biologicals being packaged within the APC payment of the associated procedure. Since claims data is not expected to be available until CY 2010, CMS is proposing to continue a combined payment rate for acquisition costs and pharmacy overhead for separately payable drugs and biologicals in 2008 similar to CYs 2006 and 2007, based on the average hospital acquisition cost plus pharmacy overhead cost which CMS has calculated at ASP + 5% for both pass-through and separately payable non-pass-through drugs and biologicals.

Banner Health is pleased to have the opportunity to comment on this proposed rule for the Medicare Outpatient PPS, CY2008 filed August 7, 2007 in the Federal Register pages 42733 – 42736, on reporting of pharmacy overhead costs. Banner Health commends CMS for their continued efforts to provide accurate claims payments to providers and supports CMS in reducing Medicare spending identified as incorrect or wasteful. However, Banner Health urges CMS to further consider the implications of making the proposed changes. CMS has recalculated the wage index, restructured APC payments, packaged services, including observation, bundled many procedures, and instituted Quality Reporting Requirements that would result in a 2% market basket reduction for CY2009 for those providers who fail to comply. Although not expected to cause irreversible financial damage to providers, the proposed changes combined with the associated modification costs for billing, patient accounting and clinical documentation systems could easily become a financial burden for many providers. Additionally, we are concerned with the limited time providers will have to complete system changes and evaluate the modifications prior to the January 1 effective date. Banner Health has conferred with vendors and operational system directors and determined that completing modifications to meet with CMS' requirements would be very difficult and would leave little time for testing prior to implementation. We also project significant added costs for labor related to these changes necessary to meet CMS' requirements, impacting our revenue for the current fiscal year as well as fiscal year 2008.

Banner Health would additionally like to comment on the requirement to report overhead as an uncoded revenue code line. We respectfully ask CMS to clarify the meaning of "un-coded revenue code line." Does CMS intend providers to bill with two separate lines on the UB04 for "each medication", "total overhead" per claim, or "total overhead per day" for claims with multiple dates

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of service? Billing multiple lines for "each medication", per administration, per day could create claims with several pages just for pharmacy when associated with Medicare outpatients who receive multiple medications which span several dates of service. This also presents the issue that most billing software has limitations in the number of billable lines per claim. Additionally, hospital Charge Description Masters would need to reflect the changes in reporting overhead costs, each entry would have to be reviewed and edited to remove the cost and an additional entry created for the line item required to separately report it. Considering the number of items this would affect, it would be a large undertaking to complete before 2008 implementation. We respectfully ask CMS to consider the complicated modifications and financial stress the proposed rule could cause providers and their ability to continue to provide patient care in compliance with CMS regulations. We further ask CMS to reconsider implementing all proposed changes for CY2008 with effective dates of January 1st, and to allow providers more time to complete modifications, systems upgrades, and process evaluations that will ensure their ability to comply with Federal Standards.

Thank you for this opportunity to express our opinions and concerns.

Respectfully,

Paul Dzurinda
System Director
Reimbursement Services

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602-495-4000
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Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard, Baltimore, MD 21244–1850.

September 12, 2007

CMS -1392-P Medicare Outpatient PPS proposed rule for CY 2008
RE: PROPOSED ADJUSTMENTS TO APCS IN CASES OF NO COST OR FULL OR PARTIAL CREDIT FOR REPLACED DEVICES (42725)

Banner Health, a multi-hospital health care system that operates 20 hospitals in addition to other health care facilities in seven states appreciates the opportunity to comment on CMS' Proposed Rule for the Hospital Outpatient Prospective Payment System for CY 2008. Specifically, Banner Health would like to comment on the portion of the rule related to the CY 2008 OPPS Device Dependant APCs and the reduction in reimbursement for devices received at reduced or no cost.

APC payment reduction for partial credit

Banner Health is in agreement with CMS regarding the appropriateness of a reduction in the APC payment in the event of a partial credit or no cost device supplied to the hospital. Banner Health, however, respectfully requests that CMS further clarify the method of reduction outlined in the proposed rule. The statement reads "we are proposing to create a HCPCS modifier to be reported on a procedure code in Table 38 below, if a device listed in Table 39 below is replaced with partial credit from the manufacturer that is greater than or equal to 20 percent of the cost of the replacement device and to reduce the payment for the procedure by 50 percent of the amount of the estimated packaged cost of the device being replaced when the modifier is reported with a procedure code that is assigned to an APC in Table 38. We believe that this policy is necessary to pay equitably for these services when the hospital receives a partial credit for the cost of the device being implanted." Banner Health strongly disagrees with the statement that this rule would "pay equitably" for services furnished if imposing a 50% reduction for a 20% credit received by the hospital. Banner respectfully requests CMS to consider that although this would reflect positively on behalf of Medicare and even for some providers who may receive a greater percentage of credits in excess of 50%; this could also be detrimental to providers who typically receive a large percentage of cases with credits ranging near 20%.

Additionally, there has been little to no research or data available to providers pertaining to the number of devices this rule could affect annually. Providers are unable to compare their own data with national averages to identify areas with higher frequencies of device failure, patterns associated with early upgrades for certain kinds of patients, or products with a pattern of problematic related replacements which could potentially help providers to choose a device that would be beneficial for the patient and cost effective on a long term basis.

Banner Health would also like to comment on the difference between the required reporting of outpatient and inpatient device credits. Partial credits of 50% or greater for inpatient devices, and partial credits of 20% or greater for outpatient devices is being proposed for CY 2008. Among our concerns is the risk for reporting errors due to differences in the minimum percentage of credit required to be reported based on patient type. Creation of a system to identify credits correctly according to patient type will be operationally difficult. There is little time to evaluate and modify current systems used for implementation of the full device/no cost rule instituted for the OPPS CY2007.

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Banner Health respectfully asks CMS to publish any data specific to the number of cases reported nationally since the 2007 rule became final, and to consider increasing the OPPS final rule to equal the inpatient rule of reporting reduced costs of 50% or greater with the FB modifier for CY2008, and to evaluate the effects of this change before instituting the 20% requirement.

Lastly, Banner Health would like to thank CMS for the opportunity to provide comments and voice concerns to CMS regarding this proposed rule.

Respectfully,

Paul Dzurinda
System Director
Reimbursement Services

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602-495-4000
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Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard, Baltimore, MD 21244–1850.

September 12, 2007

CMS Proposed Rule (CMS-1392-P)
Hospital Outpatient Prospective Payment System
OPPS: Packaging of Observation Services (HCPC code G0378)

Banner Health, a multi-hospital health care system that operates 20 hospitals in addition to other health care facilities in seven states appreciates the opportunity to comment on CMS' Proposed Rule for the Hospital Outpatient Prospective Payment System for CY 2008. Specifically, Banner Health would like to comment on the portion of the rule for packaging of observation services.

CMS has proposed packaging payment for all observation care reported under HCPCS code G0378 (Hospital observation services, per hour). CMS believes that packaging observation services would help address its concerns about increased OPPS spending. For example, while the cost of observation services has remained quite stable based on data from CY 2005 through CY 2006, the Association of American Medical Colleges, the frequency of claims has increased sharply. CMS also expressed concern that the current criteria for separate payment for observation services, which requires that observation services must last a minimum of 8 hours, provides disincentives to hospitals to make timely decisions with regard to patients' placement after observation care ends. CMS believes that packaging would contribute to more efficient use of observation services and improve the flow of patients through emergency departments.

Banner Health appreciates the opportunity to provide CMS comments on the proposed packaging of observation services reported under HCPCS code G0378 for CY 2008. Banner Health agrees with CMS regarding billing under observation code G0378 has endured misuse and warrants increased restriction in time and resource management issues. However, Banner Health disagrees with CMS in the decision to package all observation services provided under HCPCS code G0378, as we believe there are patients who do meet the guidelines for continuous observation monitoring for whom hospitals will receive reduced payments for the care and treatment associated with those patients. We also feel that packaging payment for all observation would further influence providers to forego observation altogether and admit patients to reduce reimbursement issues. Banner Health questions the decision to institute packaging of observation in cases of care extended beyond 24 hours for patients who do not meet Interqual criteria for inpatient admission but who continue to exhibit symptoms which could be associated with a life threatening condition which would prevent the hospital from safely discharging the patient.

Banner Health strongly recommends that CMS reconsider packaging of all observation billed with HCPC code G0378, and revise the proposed rule to consider on a case by case basis is determined to be medically necessary in the treatment of the patient. Lastly, Banner Health would like to thank CMS for the opportunity to provide feedback and comments on the proposed OPPS for 2008.

Respectfully,

Paul Dzurinda
System Director
Reimbursement Services

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Marion R. McMillan MD

Foothills Regional Pain Center
457 Bypass 123
Seneca, SC 29678
(864) 886-9888
Electronic mail: marionmc@att.net
Internet: www.foothillspain.com

September 11, 2007

Re: File Code: CMS-1392-P
Addition of Endoscopic Spinal Surgical Procedures to the Medicare ASC list
CY 2008 OPPS/ASC annual rulemaking cycle

First supplement to previous comment September 9, 2007

Please accept this first supplemental submission in support of my previous request for addition of certain CPT codes for endoscopic spinal surgery to the Medicare list of procedures approved for ambulatory surgical center reimbursement. I am enclosing comments from JOIMAX and Richard Wolf Endoscopy describing typical invoice costs for patient specific hardware disposable devices required for endoscopic spinal surgery, described in the previous communication of September 9, 2007.

Please let me know if any additional information is required.

Respectfully submitted,

Marion R. McMillan MD

Enclosures (2):

Documentation of patient specific consumable supplies for endoscopic spinal surgery, JOIMAX, Inc., and Richard Wolf Endoscopy

Joimax,Inc
718 University Avenue,
Suite 116,
Los Gatos, Ca 95032

Centers for Medicine & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

September 6th, 2007

Re: File Code:CMS-1392-P, Addition of Endoscopic Spinal Surgical Procedures to the Medicare ASC list. CY2008 OPPS/ASC annual rulemaking cycle.

Dear CMS panel;

The following per case disposable items are usually required when Endoscopic Spinal Surgical Procedures are carried out.

1 each Disposable Access kit	$ 598.00
1 each Crown Reamer	$ 139.00
1 each Disposable Trigger-Flex hand piece	$ 498.00
1 each Disposable Neutral plate	$ 14.00
1 each Disposable Patient Isolation Drape	$ 59.00
1 each Disposable Camera Cover	$ 10.00
1 each Disposable Patient Irrigation Tubing Set	$ 37.00
TOTAL	$1,355.00

All prices quoted are for calendar year 2008.

Should you have any questions please do not hesitate to contact me.

Sincerely

Michael Stek
CEO

RICHARD WOLF
Medical Instruments Corporation

Todd Bouwkamp
Corporate Spine Specialist
Richard Wolf Medical Instruments Corporation
9379 Boone Dr.
Baton Rouge, LA 70810
(847) 707-0419 Cell

September 9, 2007

To Whom It May Concern:

I am writing to update your organization for the current disposable cost associated with the ambulatory surgery centers' outpatient posteriolateral transforaminal endoscopic discectomy surgery for Richard Wolf Medical Instruments Corporation. The following items are currently used by spine surgeons for each surgical case:

ITEM	DESCRIPTION	COST
1. 4792.802	NEEDLE SET, SPINAL NEEDLE 1.3MM, 260MM WL, WITH GUIDEWIRE/BOX OF10	$338.00
2. 4792.803	NEEDLE SET, SPINAL NEEDLE 1.3MM 150MM WL, WITH GUIDEWIRE/BOX OF 10	$338.00
3. 4793.692	DISPOSABLE ELLMAN TRIGGER FLEX HANDLE WITH ATTACHED BIPOLAR CABLE AND ELECTRODE	$450.00

Each case the doctor may use one each of the spine needles of two lengths for access to the disc and or delivering local anesthetic.

Sincerely,

Todd R. Bouwkamp
Richard Wolf Medical Instruments

MAYO CLINIC

4500 San Pablo Road
Jacksonville, Florida 32224
904-953-2000

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September 12, 2007

Herb Kuhn
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1392-P** Revisions to the Hospital Outpatient PPS and 2008 Payment Rates

New CPT Codes 22526 and 22527 to be Classified into APC 51 and Added to ASC List

Dear Mr. Kuhn:

Thank you for this opportunity to comment on the 2008 Proposed Medicare Hospital Outpatient Prospective Payment System (OPPS) rule. I am an interventional neuroradiologist at the Mayo Clinic in Jacksonville, Florida, and I am writing to recommend that CMS place the new CPT procedure codes for intradiscal electrothermal annuloplasty into APC 51 Level III Musculoskeletal Procedures.

In 2006, I sponsored an application to the American Medical Association (AMA) to bifurcate Category III CPT Codes 0062T and 0063T, intradiscal annulopasty, *any method,* and create new CPT codes for intradiscal *electrothermal* annuloplasty (also known as IDET). The AMA CPT Editorial Panel approved this proposal, and new CPT codes became effective January 1, 2007. In last year's OPPS rule, CMS then assigned these codes to the same APC as the former Category III code, APC 50.

In order to ensure continued access to this important procedure, I urge CMS to assign the new Category I CPT codes to an APC that adequately reimburses hospitals for their costs. In light of the costs for the equipment and necessary supplies to my hospital, I recommend that the new CPT codes be placed in APC 51 with a proposed payment rate of $2,776. This APC reassignment and payment level would be a better fit clinically and with respect to the resources involved. Such a move would also be consistent with the hospital cost data that my hospital previously supplied to the APC Advisory Panel, and the mean cost ($2,371) in CMS's own claim file data.

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

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

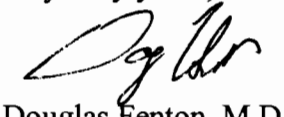
involve similar resources and also covers conditions of the spine. Moreover, it reimburses hospitals at a rate that reflects the hospital's surgical resources required for this procedure.[1]

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

In addition, the IDET procedures can be safely performed in the ASC setting and should be added to the ASC list, effective 2008.

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

Very truly yours,



Douglas Fenton, M.D.

[1] CMS data shows considerable variability in hospital "costs" for 0062T, ranging from $308 to $11,319. Clearly, hospitals have not been reporting costs correctly for the Category III code. An examination of the cost data for just IDET procedures, though, shows that costs for the disposable equipment alone are nearly $1,800 (see attached price list from Smith & Nephew).

Smith & Nephew Endoscopy
150 Minuteman Road
Andover, MA 01810

T 978-749-1000
F 978-749-1199
www.smith-nephew.com

We are smith&nephew

U.S. Price List

Spine Generator Equipment	Catalog #	Price
ELECTROTHERMAL™ 20S Spine System	7210644	$27,995[1]
Universal Extension Cable, 8 pin	7209693	$304

IDET Catheters and Needles		
SpineCATH™ Intradiscal Catheter , 8 pin	7210440	$1,795[2]
SpineCATH™ XL Intradiscal Catheter , 8 pin	7210441	$1,795
SpineCATH™ Intradiscal Catheter , 4 pin	7209599	$1,795
SpineCATH™ XL Intradiscal Catheter , 4 pin	7209598	$1,795
Introducer Needle Gen. II; box of 5	7209601	$299
Introducer Needle Gen. I; box of 5	7209603	$299

** Price level is determined by purchase of an Electrothermal 20S Spine System and/or product purchase volumes.*

Prices subject to change without notice.

[1] Generator has an expected life of three years after which replacement or significant software updates are required.
[2] Disposable Catheter – single use only.

Cleveland Clinic

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September 13, 2007

Centers for Medicare and Medicaid Services
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: CMS-1392-P, Medicare Hospital Outpatient Prospective Payment System for CY 2008

Cleveland Clinic is an integrated not-for-profit health care provider dedicated to patient care, teaching and research. We are pleased to have the opportunity to comment on the Medicare Hospital Outpatient Prospective Payment System (OPPS) for CY 2008. We appreciate the dedication of the Agency staff on behalf of the Medicare Program and the work they devote to its administration. We believe it is important for hospitals to work with the staff of CMS, so that CMS staff has an understanding of the challenges and practicality faced by the hospitals regarding the proposed changes.

Cleveland Clinic supports the general direction of the proposed OPPS rule. However, due to the complexity of the OPPS coding system and the time period provided for comment, it is difficult for the institution to ascertain the overall impact. The Cleveland Clinic proposes that in the future, CMS lengthen the comment period so that providers have the opportunity to conduct a more thorough financial and care impact analysis.

Accordingly, we have limited our comment to two specific areas: the quality reporting initiative and the proposed changes to OPPS payment for observation services.

QUALITY REPORTING

The Cleveland Clinic understands the congressional mandate on CMS to expand quality reporting to the hospital outpatient setting and appreciates the work CMS has devoted to bring this initiative on-line. We believe that CMS should reduce the number of measures and scale the initiative back, particularly for the first and second years, due to several important factors:

1. OPPS data reliability: It is our understanding that among providers there are disparities in coding because of the high volume of many closely related codes and the variation in judgment as to which is appropriate.
2. NQF Review of Measures: Allocate ample time for the NQF to review and approve of the measures.
3. Cost Benefit Analysis: Allow providers the opportunity to conduct an in-depth review of the data collection costs to report these measures and provide information to CMS and the public as to whether the cost is commiserate with the value of the information to be produced.

4. Measure Selection: The proposed measures are complex in nature as indicated by not only principal diagnosis but also secondary or other diagnosis on the E/M visit. The data elements necessary for complete and accurate data collection are not discreet data elements in the outpatient population. As a result, all outpatient measures will again need to abstracted from the outpatient record requiring significant resources.
5. Sampling Methodology: The proposed sampling methodology will place a significant burden on all institutions.
6. Validation Criteria: Elimination of the validation criteria for the first full calendar year will allow institutions sufficient time to address data quality and collection issues.

OBSERVATION SERVICES

From our initial review, it appears that the proposed bundling of three observation codes - chest pain, heart failure, and asthma - into a level 5 Emergency Department (ED) visit has a negative impact on patient care along with a negative financial impact to the Cleveland Clinic. It has been our experience that paying attention to these conditions is important in the treatment of the patient in the emergency department to avoid subsequent hospitalizations. We believe our position is supported by research in the field demonstrating the value of special observation units for chest pain and heart failure in the emergency department. A study by A. Kugelmass[1] of 4,477 patients found that the addition of a chest pain center reduced acute mortality rates in the ED by 37%. On average, about 80% of heart failure patients are admitted to the inpatient hospital setting, which is more expensive than the outpatient department. Because of the Clinic's specialized observation unit, admission rates have been reduced to 65%. This translates to better patient care, cost-savings to Medicare and the health care system. Reducing resource use in this setting would lead to a reversal of this trend and additional costs to the Medicare Program. CMS has estimated that these specific visit codes constitute only 12% of ED level 5 codes. Through our review, we have found that these codes are closer to 40%. We have a much lower admit rate from the ED to the hospital than do EDs nationally, and we believe this is due to the special care and attention these patients receive. We request that CMS not bundle these observation visit codes with an ED level 5 visit or any other level of ED visit.

1) Kugelmass AD, Anderson AL, Brown PP, Tarkington LG, Battaglia SL, Sutton RL, Jones CL, Culler SD, Rollins, Becker ER, Simon AW. Does Having a Chest Pain Center Impact the Treatment and Survival of Acute Myocardial Infarction Patients? Circulation. Vol 110, No 17, October 26, 2004

This concludes our comments. Once again, we thank you for the opportunity to voice our concerns.

Sincerely,

Steven C. Glass
Chief Financial Officer

J. Michael Henderson
Chairman, Quality and
Patient Safety Institute

Oliver C. Henkel, Jr.
Executive Director
Government, Community and
Education Relations

NORTH SONOMA COUNTY
HOSPITAL DISTRICT
Quality, Compassionate Care

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September 13, 2007

CMS
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir and Madam:

Healdsburg District Hospital is one of California's 25 CAH's. Healdsburg District Hospital services a population of approximately 50,000 within its District, and has a legacy back to 1905. We are opposed to the proposed CY-2008 Hospital Outpatient Perspective Payment System OPPS proposed to rule the limit the ability of Critical Access Hospitals to operate off site provider based facilities. There are many reasons for our concerns in California in respect to this proposed rule. Some but not all are as follows:

- California is subject to mandatory seismic retrofitting (SB1953) for all of its general acute care facilities, thus requiring modifications that may impact the co-location rule in which some facilities may be land locked or otherwise compromised with their physical plant.

- California encompasses many HPSA's, MUA's, PSA's (Physician Scarcity Areas). In California and other provider shortage areas, rural hospitals can provide necessary services (such as a Provider Based Health Center) as a safety net for hospitals to a remote location via thirty-five mile radius rule in California. This necessary service could be compromised with any co-location issues in which HPSA's/MUA's co-locate with the Critical Access Hospitals/Necessary Provider.

- Market conditions in this geographic area continue to be turbulent with the closure of a major tertiary facility within a year. This will leave an increased need for certain services such as behavior health services, obstetric services, women's health services, and other critical services necessary to the support of a county close to 500,000 in population. These market dynamics draw upon the need of the strength of the remaining facilities to provide high caliber care that are currently being compromised through market changes as well as potential rule changes. The

1375 University Avenue • Healdsburg, CA 95448 • Phone: 707.431.6500 • Facsimile: 707.431.6588

remaining hospitals must be allowed to be flexible in the scope of what they provide in regards to best meet the needs of an economically challenged medical environment.

- Sonoma County based on its rural status is currently underpaid in its Medicare physician reimbursements. Sonoma County physicians are currently compensated 7% to 8% less than Marin and Napa Counties. While the GPCI bill is potentially slated for some relief, mass exits of physicians leaving the area for a less volatile environment has caused significant voids in Primary Care Physicians and jeopardizing safety net hospitals. The proposed rule change could inhibit creative vehicles to maintain strong Primary Care Provider support and relations, and other specialist/ super specialty support that would enable stabilizing the physician community with in Sonoma County.

We hope this information is supportive in regards to our opposed position to CMS rule changes, and would suggest other creative thoughts on supporting Rural Hospitals throughout the United States and California in their fight to survive and provide high caliber health care to California's large rural presence.

We support federal legislation such as Health Care Access of Rural Equity Act(H-CARE) of 2007, and is a direction we believe not only supports the infrastructure of health care throughout rural United States and California but also assist in stabilizing some of the challenges in health care California faces.

Thank you for your time and consideration on this matter.

Sincerely,

Evan J. Rayner
Chief Executive Officer

cc: Mike Thompson
Member of Congress

EPSTEIN BECKER & GREEN, P.C.
ATTORNEYS AT LAW
1227 25TH STREET, NW, SUITE 700
WASHINGTON, DC 20037-1175
202.861.0900
FAX: 202.296.2882
EBGLAW.COM

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ROBERT WANERMAN
TEL: 202.861.1885
FAX: 202.861.3585
RWANERMAN@EBGLAW.COM

September 13, 2007

VIA FEDERAL EXPRESS

Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Att: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1392-P:
CY 2008 Medicare Hospital Outpatient PPS

Dear Mr. Kuhn:

Thank you for the opportunity to submit comments on the proposed changes to the Medicare Hospital Outpatient Prospective Payment System ("HOPPS") for the 2008 calendar year. On behalf of Sicel Technologies, Inc., the manufacturer of the DVS® Dosimeter, the comments in this letter will focus on the APC assignment and payment rate for HCPCS code C9728. In the proposed rule published on August 2, 2007, CMS specifically invited comments on this issue. 72 Fed. Reg. 42628, 42701 (2007). As explained in more detail below, the coding assignment and corresponding reimbursement determination in the proposed rule does not reflect the cost of the implantable device itself, and as a result is inconsistent with the basic requirements under HOPPS. This comment will conclude with recommended remedies for this problem.

Background

The DVS® Dosimeter is an implantable device that is intended for use in radiation therapy to verify treatment planning and radiation dosage to tissue and organs in or near the irradiated areas of the patient. It measures the dose delivered in tissue including the combined effects of tissue inhomogeneity, organ movement, patient set-up errors and intra-fractional movement. All of these are factors that can result in a significant difference between the planned radiation treatment and the radiation that is actually delivered to the tumor site.

The DVS® Dosimeter can be inserted at the tumor periphery, tumor bed or surrounding normal tissue during surgery or percutaneously. A surgeon or interventional radiologist performs the procedure in an operating suite. An anesthesiologist may be required to administer general anesthesia. A pair of dosimeters are implanted during this procedure.

The DVS® Dosimeter is one component of the Dose Verification System, which includes (1) implantable radiation dosimeters; (2) a telemetric reader for obtaining dose measurements; (3) insertion tools designed for minimally invasive surgical placement of the dosimeters; and (4) plan and review software designed to compile and store data.

On March 30, 2007, CMS approved the assignment of a New Technology APC to the DVS® Dosimeter for non-prostate applications. See Tab 1. That letter then described how CMS would assign codes for the implantation of the DVS® Dosimeter for both prostate and non-prostate applications. On June 1, 2007, CMS issued Medicare Program Transmittal 1259, which assigned a new HCPCS C9728 code to the implantation of the DVS® Dosimeter for non-prostate applications, and tracked that new C code to APC 0156. Under the Program Transmittal, the only HOPPS payment for the DVS® Dosimeter would be $209.48 for the implantation of the device. Throughout the period between March and June, CMS did not address the reimbursement for the DVS® Dosimeter itself, and CMS has not placed the device in one of the New Technology APCs. See Tab 2.

This omission was not remedied in the proposed HOPPS update for the 2008 calendar year. CMS explained that it believes that both 55876 and C9728 are "clinically similar" and has proposed setting the reimbursement rate at $194.11. 72 Fed. Reg. at 42784, 42701, and 42955.

Reimbursement for the DVS® Dosimeter
Under HOPPS Must Include The Cost of the Device Itself

As the rationale offered by CMS for setting the same proposed reimbursement rate for both 55876 and C9728 vividly illustrates, CMS has focused exclusively on the procedure for implanting the DVS® Dosimeter and overlooked establishing equitable reimbursement for the device itself. This has occurred notwithstanding the data presented to CMS on the cost of the DVS® Dosimeter, and CMS's approval of a New Technology APC for the DVS® Dosimeter. As a result, this omission must be remedied promptly. Although this comment is a response to the proposed rule, there is no reason why a remedy cannot be implemented immediately. The discussion below explains what we believe to be the most likely reason for this omission, and also highlights the remedy itself.

In 2006, the CPT Editorial Panel established a new CPT code for the placement of interstitial devices in the prostate for radiation therapy guidance. The new CPT code, which took effect on January 1, 2007, has the following descriptor:

> 55876 Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple
>
> (Report supply of device separately)
>
> (For imaging guidance, see 76942, 77002, 77012, 77021)

At the time that this new CPT code was established, the CPT Editorial Panel explained that both the device to be implanted and the imaging guidance for the implant procedure were <u>not</u> included in this code:

> Cross-references have been added to instruct users to report the supply of the device and the imaging guidance separately. Because any one of the several modalities of imaging guidance are used for this procedure, each of the appropriate codes (76942, 77002, 77012, 77021) is referenced.
>
> CPT Changes 2007 – An Insider's View at 137-38 (2006).

When the new 55876 code was included in the 2007 HOPPS update, the reimbursement was set at $209.48 based on grouping CPT code 55876 into APC 156.[1] 71 Fed. Reg. 67960, 68330 (2006). The imaging guidance codes referenced in the code descriptor for 55876 were not bundled into APC 156.

Based on this information, it is our understanding that when CMS approved the New Technology APC application for the DVS® Dosimeter in March 2007, it first sought to assign an existing APC based on a similar code. That code was 55876. However, because the descriptor for 55876 referred to the procedure for prostate applications, a new code was needed for non-prostate applications. See Tab 1. As a result, C9728 was established using a slightly different descriptor:

> C9728 Placement of interstitial device(s) for radiation therapy/surgery guidance (eg, fiducial markers, dosimeter), other than prostate (any approach), single or multiple.[2]

Apart from the non-prostate application, the key difference is that the descriptor for C9728 omits the plain directive in 55876 that the device be reported separately. Nevertheless, the HOPPS reimbursement rate established for C9728 is the same as that for 55876, $209.48. At that time and since, CMS has neither created a new HCPCS code for the DVS® Dosimeter or tracked the device to a New Technology APC. Therefore, none of the codes that can be used for reporting the procedure to implant the DVS® Dosimeter and the corresponding reimbursement includes the cost of the DVS® Dosimeter.

As a result of the decisions made to date, under the present scenario a hospital outpatient department or ASC can receive payment for the professional service of implanting the DVS® Dosimeter, but has no way to report the device itself or to receive reimbursement. Similarly, a carrier has no way to accurately process a claim for the DVS® Dosimeter or to make an appropriate payment for the device.

---

[1] The descriptor for APC 0156 is "Level III Urinary and Anal Procedures."

[2] To our knowledge, this is the first time that CMS has approved a New Technology APC application and created a new HCPCS code as a result of the approval that is broader in scope than the description in the application. The C9728 descriptor could apply to technologies other than the DVS® Dosimeter, and could overlap with other existing codes.

The DVS® Dosimeter Should Be Assigned To A New Technology APC Based Solely On Its Cost

As discussed in the preceding sections, CMS has not addressed the reimbursement for the DVS® Dosimeter, even though it approved the New Technology APC application. Not only the established codes, but basic logic directs that if the procedure to implant a device is covered, coded, and reimbursed, then the device itself must be covered, coded, and reimbursed as well. This is all that is being requested in this comment. As discussed below, this critical omission can be remedied immediately, and need not wait for the formal process of approving a final HOPPS rule for 2008.

When the application for a New Technology APC was submitted by Sicel Technologies, it plainly disclosed that the cost of a pair of DVS® Dosimeters is $1200. CMS has established that when an item or service is assigned to a New Technology APC and is eligible for pass-through payment, the only relevant factor for establishing the Medicare reimbursement rate is the cost of that item or service. When New Technology APCs were initially established in 2000, CMS stated that "[i]n contrast to the other APC groups, the new technology APC groups do not take into account clinical aspects of the services they are to contain, but only their costs." 65 Fed. Reg. 18434, 18477 (2000).

This principle was repeated in 2001, when CMS set out the basic standard relied on in the letter approving a New Technology APC for the DVS® Dosimeter. At that time, the agency explained that "New Technology APCs are defined on the basis of costs and not on the clinical characteristics of a service." 66 Fed. Reg. 59856, 59897 (2001); see also 66 Fed. Reg. 44672, 44702 (2001).

The consistent principles set out by CMS linking a New Technology APC to its costs have been accepted without question. In its report to Congress in March 2004 on hospital inpatient and outpatient systems, the Medicare Payment Advisory Commission stated that "[s]ervices are placed in a new technology APC based only on their expected costs." MEDPAC, Report to the Congress, Medicare Payment Policy at 86 (2004). Similarly, the House Ways and Means Committee wrote in 2003 that "[i]n contrast to the other APC groups, services are assigned to new technology APCs based on their expected costs; the groups do not account for clinical aspects of its packaged services." House Ways and Means Committee, 2003 Green Book at 2-112.

As a result of the unambiguous guidance published in the Federal Register and referenced in the application for a New Technology APC, it is immediately apparent that once the application for the DVS® Dosimeter was approved, CMS was required to set the APC assignment for that device based on the cost data included in the application. As

discussed above, since there is no current code to identify the DVS® Dosimeter, providers, suppliers, and carriers will all be confused and frustrated if any entity seeks to be reimbursed for a device that is an indispensable part of a covered procedure that expressly does not include the cost of the implantable device (whether for a prostate application or a non-prostate application).

The omission of any reimbursement for the DVS® Dosimeter (as opposed to the procedure to implant it) can be remedied immediately. As noted above, the codes established for implanting the device were established outside the annual HOPPS update process; therefore, CMS can remedy this omission now. It does not require any further evidentiary development, since the New Technology APC application that was approved in March 2007 already contains ample cost data.

All of the information that is needed to remedy this omission is contained in the application that CMS has already approved. Based on that application, CMS should assign the DVS® Dosimeter to a New Technology APC that reflects the true cost of the pair of devices, which is APC 1514 ($1200-1300).[3] In the alternative, CMS can bundle all of the items and services (along with a pair of DVS® Dosimeters) needed to implant the device into a single code; based on the costs as stated in the application, this would track to APC 1522 ($2000-2500).

Although it would have been preferable for all concerned that the errors and omissions described in this letter had never occurred, Sicel Technologies will be happy to work with CMS to resolve these errors quickly and informally. In order to expedite a fair remedy, we are prepared to meet with you and your staff to answer any questions. Once again, please accept our thanks for your consideration of this comment and for your efforts to reach an equitable conclusion.

Sincerely,

Robert Wanerman

Enclosures

[3] If CMS elects to assign a New Technology APC based on each separate dosimeter, then APC 1508 ($600-$700) would be appropriate.

cc: Carol M. Bazell, M.D.
Division of Outpatient Care

Barry I. Levi
Centers for Medicare and Medicaid Services

Michael Riddle
Sicel Technologies

Kathy Francisco
The Pinnacle Health Group

MAR 30 2

Ms. Kathy Francisco
The Pinnacle Health Group
301 Oxford Valley Road
Suite 601B
Yardley, PA 19067

Dear Ms. Francisco:

Thank you for requesting a reconsideration of our denial of the application for the service called **Implantation of the DVS Patient Dose Verification System** for consideration as a new technology service under Medicare's hospital outpatient prospective payment system (OPPS). Thank you also for meeting with us in December 2006 to provide additional information and to discuss the application.

We have carefully reviewed the additional information provided, the original application and other information on similar services to the "Implantation of the DVS Patient Dose Verification System" service application. We reviewed this information based on the provisions for placement of a service into a New Technology APC established in the OPPS rule published in the Federal Register notice on November 30, 2001. Based on our review of the application and additional information, it has been determined that this service does meet our criteria to have a new code assigned for some applications of the service, while other aspects of the service can be described by existing HCPCS codes. Specifically, the "Implantation of the DVS Patient Dose Verification System" service qualifies for new coding for non-prostate applications, while it does not qualify for a New Technology APC for prostate applications under the hospital OPPS for the following reasons.

- The service is described by existing HCPCS codes or combination of HCPCS codes.

The prostate implantation of the DVS System can be described by HCPCS code 55876, Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeters), prostate (via needle, any approach), single or multiple. However, HCPCS code 55876 does not describe placement of dosimeters for non-prostate applications. Therefore, we have determined that the "Implantation of the DVS Patient Dose Verification System" service can be described by existing HCPCS codes for placement of dosimeters into the prostate. On the other hand, the "Implantation of the DVS Patient Dose Verification System" service cannot be described by existing HCPCS codes for placement of dosimeters into non-prostate areas of the body. We will create a new C-code and descriptor for this service for non-prostate applications and place it into an appropriate clinical or New Technology APC, effective July 1, 2007.

Specific coding information regarding this new service will be published in an upcoming program transmittal, which will be accessible on the CMS website, at
http://www.cms.hhs.gov/transmittals/

Thank you for your application, and I hope this information is helpful. Should you have questions on this decision, please contact me.

Sincerely,

Carol M. Bazell, M.D.
Acting Director
Division of Outpatient Care
Center for Medicare Management
Centers for Medicare & Medicaid Services

cc: Mr. Michael D. Riddle, President and CEO, Sleef Technologies, Inc., 3800 Gateway Centre Blvd., Suite 308, Morrisville, NC 27560

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 1259

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: JUNE 1, 2007

Change Request 5623

Subject: July 2007 Update of the Hospital Outpatient Prospective Payment System (OPPS): Summary of Payment Policy Changes

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to, and billing instructions for various payment policies implemented in the July 2007 OPPS update. The July 2007 OPPS Outpatient Code Editor (OCE) and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this notification.

New / Revised Material
Effective Date: July 1, 2007
Implementation Date: July 2, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1259	Date: June 1, 2007	Change Request: 5623

SUBJECT: July 2007 Update of the Hospital Outpatient Prospective Payment System (OPPS): Summary of Payment Policy Changes

Effective Date: July 1, 2007

Implementation Date: July 2, 2007

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to, and billing instructions for various payment policies implemented in the July 2007 OPPS update. The July 2007 Integrated Code Editor (I/OCE) and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this notification.

July 2007 revisions to I/OCE data files, instructions, and specifications are provided in Change Request (CR) 5617, "July 2007 Integrated Outpatient Code Editor (I/OCE) Specifications Version 8.2."

B. Policy:

1. Changes to Device Edits

The Medicare OPPS procedure to device edits and device to procedure edits are posted on the CMS website at www.cms.hhs.gov/HospitalOutpatientPPS/ under "downloads".

There are no new device to procedure edits for the July 2007 OCE. Therefore, the April 2007 file of device to procedure edits remains unchanged for the July 2007 OCE quarter.

The following new procedure to device edits are being implemented in the July 2007 OCE with the effective dates shown.

Although the device edits for G0392 and G0393, new HCPCS codes for 2007, are effective for services furnished on or after January 1, 2007, no action is required on claims for these services that were processed before the implementation of the July 2007 I/OCE.

Table 1- New Procedure to Device Edits for Implementation in the July 2007 I/OCE

CPT/ HCPCS	SI	Description	2007 APC	Device A	Device A Description	Effective Date of Edit (DOS)	Reason
G0392	T	AV fistula or graft arterial	0081	C1725	Cath, translumin non-laser	1/1/2007	new code for 2007
G0392	T	AV fistula or graft arterial	0081	C1874	Stent, coated/cov	1/1/2007	new code for

CPT/ HCPCS	SI	Description	2007 APC	Device A	Device A Description	Effective Date of Edit (DOS)	Reason
					w/del sys		2007
G0392	T	AV fistula or graft arterial	0081	C1876	Stent, non-coa/non-cov w/del	1/1/2007	new code for 2007
G0392	T	AV fistula or graft arterial	0081	C1885	Cath, translumin angio laser	1/1/2007	new code for 2007
G0392	T	AV fistula or graft arterial	0081	C2625	Stent, non-cor, tem w/del sy	1/1/2007	new code for 2007
G0393	T	AV fistula or graft venous	0081	C1725	Cath, translumin non-laser	1/1/2007	new code for 2007
G0393	T	AV fistula or graft venous	0081	C1874	Stent, coated/cov w/del sys	1/1/2007	new code for 2007
G0393	T	AV fistula or graft venous	0081	C1876	Stent, non-coa/non-cov w/del	1/1/2007	new code for 2007
G0393	T	AV fistula or graft venous	0081	C1885	Cath, translumin angio laser	1/1/2007	new code for 2007
G0393	T	AV fistula or graft venous	0081	C2625	Stent, non-cor, tem w/del sy	1/1/2007	new code for 2007
50688	T	Change of ureter tube	0122	C2625	Stent, non-cor, tem w/ del	10/1/2005	Device added

2. New Services

The following new service is assigned for payment under the OPPS:

Table 2-New Service Payable as of July 1, 2007

HCPCS	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Payment	Minimum Unadjusted Copayment
C9728	7/1/2007	T	0156	Place device/marker, non pros	Placement of interstitial device(s) for radiation therapy/surgery guidance (eg, fiducial markers, dosimeter), other than prostate (any approach), single or	$209.48	$41.90

					multiple		

3. Category III CPT Codes

The AMA releases Category III CPT codes in January, for implementation beginning the following July, and in July, for implementation beginning the following January. Prior to CY 2006, we implemented new Category III CPT codes once a year in January of the following year.

As discussed in the CY 2006 OPPS final rule with comment period (70 FR 68567), we modified our process for implementing the Category III codes that the AMA releases each January for implementation in July to ensure timely collection of data pertinent to the services described by the codes; to ensure patient access to the services the codes describe; and to eliminate potential redundancy between Category III CPT codes and some of the C-codes that are payable under the OPPS and were created by us in response to applications for new technology services. Therefore, on July 1, 2007, we implemented in the OPPS five Category III CPT codes that the AMA released in January 2007 for implementation in July 2007. The codes, along with their status indicators and APCs, are shown in Table 3 below.

Table 3-Category III CPT Codes Implemented as of July1, 2007

HCPCS Code	Long Descriptor	SI	APC	Payment Rate	Minimum Unadjusted Copayment
0178T	Electrocardiogram, 64 leads or greater, with graphic presentation and analysis; with interpretation and report	B	Not applicable	Not applicable	Not applicable
0179T	Electrocardiogram, 64 leads or greater, with graphic presentation and analysis; tracing and graphics only, without interpretation and report	X	0100	$155.74	$31.15
0180T	Electrocardiogram, 64 leads or greater, with graphic presentation and analysis; interpretation and report only	B	Not applicable	Not applicable	Not applicable
0181T	Corneal hysteresis determination, by air impulse stimulation, bilateral, with interpretation and report	S	0230	$48.55	$9.71
0182T*	High dose rate electronic brachytherapy, per fraction	S	1519	$1,750.00	$350.00

* As indicated by CPT, do not report CPT code 0182T in conjunction with CPT codes 77761-77763, 77776-77778, 77781-77784, 77789. Additionally, when a high dose rate electronic brachytherapy service described by 0182T is provided, along with a procedure to place and remove (if performed) an applicator into the breast for radiation therapy described by HCPCS code C9726, both services are separately reportable.

4. Payment for Brachytherapy Sources

The Medicare Modernization Act of 2003 (MMA) requires us to pay for brachytherapy sources in separately paid APCs, and for the period of January 1, 2004 through December 31, 2006, to pay for brachytherapy sources at hospitals' charges adjusted to their cost. Effective January 1, 2007, we continued to pay for specified brachytherapy sources separately, pursuant to MMA, and at hospitals' charges adjusted to their cost pursuant to the Tax Relief and Health Care Act of 2006, which extends the charges adjusted to cost payment for brachytherapy sources until

January 1, 2008. The Tax Relief and Health Care Act of 2006 also requires that we create separate APC groups for stranded and non-stranded sources furnished on or after July 1, 2007.

We are currently aware of three sources that come in stranded and non-stranded forms: iodine, palladium and cesium. We have therefore created six new codes to reflect these three sources in stranded and non-stranded versions. At the same time, we are deleting the three non-specific brachytherapy source codes for iodine, palladium and cesium. The deleted brachytherapy source codes, effective July 1, 2007, are listed in Table 5 below.

a. Billing for Stranded and Non-stranded Brachytherapy Sources

The new codes for these separately paid sources, long descriptors and APCs are listed in Table 4, the comprehensive brachytherapy source table below, payable as of July 1, 2007. Please note that when billing for stranded sources, providers should bill the number of units of the appropriate source HCPCS C-code according to the number of brachytherapy sources in the strand, and should not bill as one unit per strand. If a hospital applies both stranded and non-stranded sources to a patient in a single treatment, the hospital should bill the stranded and non-stranded sources separately, according to the differentiated HCPCS codes listed in Table 4 below.

b. Comprehensive List of Brachytherapy Sources Payable as of July 1, 2007

Below is coding information for all brachytherapy sources payable as of July 1, 2007. Please note that we have added the term "non-stranded" to the descriptors for all sources that are described as "per source," other than iodine-125, palladium-103 and cesium-131, for which we have separate stranded or non-stranded codes. All changes, i.e., new codes and descriptors and changes to existing code descriptors are noted in bold.

Table 4- Comprehensive List of Brachytherapy Sources Payable as of July 1, 2007

CPT/ HCPCS	Long Descriptor	SI	APC
A9527	Iodine I-125, sodium iodide solution, therapeutic, per millicurie	H	2632
C1716	Brachytherapy source, **non-stranded,** Gold-198, per source	H	1716
C1717	Brachytherapy source, **non-stranded,** High Dose Rate Iridium-192, per source	H	1717
C1719	Brachytherapy source, **non-stranded,** Non-High Dose Rate Iridium-192, per source	H	1719
C2616	Brachytherapy source, **non-stranded,** Yttrium-90, per source	H	2616
C2634	Brachytherapy source, **non-stranded,** High Activity, Iodine-125, greater than 1.01 mCi (NIST), per source	H	2634
C2635	Brachytherapy source, **non-stranded,** High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source	H	2635
C2636	Brachytherapy linear source, **non-stranded,** Palladium-103, per 1MM	H	2636
C2637	Brachytherapy source, **non-stranded,** Ytterbium-169, per source	H	2637
C2638	**Brachytherapy source, stranded, Iodine-125, per source**	**H**	**2638**

CPT/ HCPCS	Long Descriptor	SI	APC
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	H	2639
C2640	Brachytherapy source, stranded, Palladium-103, per source	H	2640
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	H	2641
C2642	Brachytherapy source, stranded, Cesium-131, per source	H	2642
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	H	2643
C2698	Brachytherapy source, stranded, not otherwise specified, per source	H	2698
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source	H	2699

c. Coding for Not Otherwise Specified Brachytherapy Sources and New Sources

If we receive information that any of the sources listed above now designated as non-stranded (i.e., other than iodine, palladium and cesium sources) are also FDA-approved and marketed as a stranded source, we will create coding information for the stranded source. We have also established two Not Otherwise Specified codes for stranded and non-stranded sources that are not yet known to us and for which we do not have source-specific codes. If a hospital purchases a new FDA-approved and marketed radioactive source consisting of a radioactive isotope, (consistent with our definition of a brachytherapy source eligible for separate payment, discussed in the November 24, 2006 final rule, 71 FR 68113), for which we do not yet have a separate source code established, the hospital should bill such sources using the appropriate NOS codes found in Table 4 above, i.e., C2698 for stranded NOS sources, and C2699 for non-stranded NOS sources. For example, if a new FDA-approved stranded source comes onto the market and there is currently only a billing code for the non-stranded source, the hospital should bill the stranded source under C2698 (stranded NOS source) until a specific stranded billing code for the source is established.

Hospitals and other parties are invited to submit recommendations to us for new HCPCS codes to describe new sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. We will continue to endeavor to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis. Please direct such recommendations to the Division of Outpatient care, Mail Stop C4-05-17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

d. Brachytherapy Source Codes Deleted as of July 1, 2007

We are deleting the following codes for iodine, palladium and cesium sources, effective July 1, 2007, which do not specify whether sources are stranded or non-stranded.

Table 5 - Brachytherapy Source Codes Deleted as of July 1, 2007

CPT/ HCPCS	Long Descriptor
C1718	Brachytherapy source, Iodine-125, per source
C1720	Brachytherapy source, Palladium-103, per source
C2633	Brachytherapy source, Cesium-131, per source

5. Billing for Drugs, Biologicals, and Radiopharmaceuticals

Hospitals are strongly encouraged to report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective July 1, 2007

In the CY 2007 OPPS final rule, it was stated that payments for separately payable drugs and biologicals based on average sale prices (ASPs) will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary based on the most recent ASP submissions, we will incorporate changes to the payment rates in the July 2007 release of the OPPS PRICER. The updated payment rates effective July 1, 2007, will be included in the July 2007 update of the OPPS Addendum A and Addendum B, which will be posted on the CMS Web site at the end of June.

b. Updated Payment Rates for Certain Drugs and Biologicals Effective January 1, 2007 through March 31, 2007

The payment rates for the drugs and biologicals listed below were incorrect in the April 2007 OPPS PRICER. The corrected payment rates will be installed in the July 2007 OPPS PRICER effective for services furnished on January 1, 2007, through March 31, 2007.

Table 6-Updated Payment Rates for Certain Drugs and Biologicals Effective January 1, 2007 through March 31, 2007

HCPCS	APC	Long Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
C9350	9350	Microporous collagen tube of non-human origin, per centimeter length	$485.91	$97.18
J0152	0917	Injection, adenosine for diagnostic use, 30 mg (not to be used to report any adenosine phosphate compounds; instead use A9270)	$69.20	$13.84
J0215	1633	Injection, alefacept, 0.5 mg	$26.28	$5.26

HCPCS	APC	Long Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
J0289	0736	Injection, amphotericin b liposome, 10 mg	$16.66	$3.33
J7342	9054	Dermal (substitute) tissue of human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter	$31.66	$6.33
J8560	0802	Etoposide; oral, 50 mg	$30.53	$6.11
J9268	0844	Pentostatin, per 10 mg	$1,828.98	$365.80

c. Updated Payment Rates for Certain Drugs and Biologicals Effective April 1, 2007 through June 30, 2007

The payment rates for the drugs and biologicals listed below were incorrect in the April 2007 OPPS PRICER. The corrected payment rates will be installed in the July 2007 OPPS PRICER effective for services furnished on April 1, 2007 through June 30, 2007.

Table 7-Updated Payment Rates for Certain Drugs and Biologicals Effective April 1, 2007 through June 30, 2007

HCPCS	APC	Long Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
Q2017	7035	Injection, teniposide, 50 mg	$264.43	$52.89
J2503	1697	Injection, pegaptanib sodium, 0.3 mg	$1107.54	$221.51

d. Newly-Approved Drug Eligible for Pass-Through Status as of July 1, 2007

The following drug has been designated as eligible for pass-through status under the OPPS effective July 1, 2007.

Table 8-Newly-Approved Drug Eligible for Pass-Through Status as of July 1, 2007

HCPCS Code	APC	SI	Long Description
J9261	0825	G	Injection, nelarabine, 50 mg

The payment rate for this drug can be found in the July 2007 update of OPPS Addendum A and Addendum B which will posted on the CMS Web site at the end of June. While this drug code was made effective January 1, 2007, its pass-through status does not become effective until July 1, 2007. J9261 has been assigned to status indicator "K" under the OPPS effective January 1,

2007. However, the status indicator for J9261 will change from "K" to "G" effective July 1, 2007.

e. New HCPCS Drug Codes Separately Payable Under OPPS as of July 1, 2007

The following seven HCPCS drug codes will be made effective July 1, 2007. These HCPCS codes will be separately payable under the hospital OPPS. The payment rates for these drugs can be found in the July 2007 update of OPPS Addendum A and Addendum B which will be posted on the CMS Web site at the end of June.

Table 9-New Drug Codes Separately Payable under OPPS as of July 1, 2007

HCPCS Code	APC	SI	Long Descriptor
Q4087	0943	K	Injection, immune globulin, (Octagam), intravenous, non-lyophilized, (e.g. liquid), 500 mg
Q4088	0944	K	Injection, immune globulin, (Gammagard liquid), intravenous, non-lyophilized, (e.g. liquid), 500 mg
Q4089	0945	K	Injection, rho(d) immune globulin (human), (Rhophylac), intramuscular or intravenous, 100 iu
Q4090	0946	K	Injection, hepatitis b immune globulin (Hepagam B), intramuscular, 0.5 ml
Q4091	0947	K	Injection, immune globulin, (Flebogamma), intravenous, non-lyophilized, (e.g. liquid), 500 mg
Q4092	0948	K	Injection, immune globulin, (Gamunex), intravenous, non-lyophilized, (e.g. liquid), 500 mg
Q4095	0951	K	Injection, zoledronic acid (Reclast), 1 mg

f. Billing for Zometa and Reclast Under OPPS as of July 1, 2007

Effective as of July 1, 2007, two HCPCS codes will exist for zoledronic acid. Hospitals are advised to report HCPCS code J3487 for Zometa and Q4095 for Reclast.

Table 10 – Drug Codes for Zometa and Reclast Under the Hospital OPPS as of July 1, 2007

HCPCS Code	APC	SI	Long Descriptor	Drug Name
J3487	9115	K	Injection, zoledronic acid, 1 mg	Zometa
Q4095	0951	K	Injection, zoledronic acid (Reclast), 1 mg	Reclast

g. Drug HCPCS Code J1567 Not Reportable Under the Hospital OPPS as of July 1, 2007

HCPCS code J1567 will no longer be recognized by Medicare effective July 1, 2007. Therefore, HCPCS code J1567 will no longer be reportable under the hospital OPPS. To report those drugs previously reported under HCPCS code J1567, refer to HCPCS codes Q4087, Q4088, Q4091, or Q4092.

Table 11-Drug Code Not Reportable Under the Hospital OPPS as of July 1, 2007

HCPCS Code	Long Descriptor
J1567	Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), 500 mg

h. Correct Reporting of Units for Drugs

Hospitals and providers are reminded to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in the HCPCS descriptor. For example, if the description for the drug code is 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. As another example, if the description for the drug code is 50 mg but 200 mg of the drug was administered to the patient, the units billed should be 4. Providers and hospitals should not bill the units based on the way the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, bill 10 units, even though only 1 vial was administered. HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

6. Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal intermediaries determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, fiscal intermediaries determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5623.1	Medicare contractors shall install the July 2007 OPPS PRICER.	X		X			X	X				
5623.2	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service that fall on or after January 1, 2007, but before April 1, 2007; 2) Contain at least one of the HCPCS codes listed in Table 6; and 3) Were originally processed prior to the installation of the July 2007 OPPS PRICER.	X		X			X					

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5623.3	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service that fall on or after April 1, 2007, but before July 1, 2007; 2) Contain at least one of the HCPCS codes listed in Table 7; and 3) Were previously processed through the April 2007 OPPS PRICER.	X		X			X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5623.4	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X			X					

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova at marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Regional Office

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. *For Medicare Administrative Contractors (MAC)*:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

W. L. GORE & ASSOCIATES, INC.

Creative Technologies Worldwide

3750 WEST KILTIE LANE • P.O. BOX 2400 • FLAGSTAFF, ARIZONA 86003-2400
PHONE: 928/779-2771 • MAIN FAX: 928/779-1456 • MARKETING FAX: 928/774-3525

MEDICAL PRODUCTS DIVISION

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September 11, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Herb B Kuhn
Mail Stop C5-01-14
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-1392-P

We commend CMS for continuing refinement of the OPPS payment methodology and implementation of the new ASC reimbursement. The following comments and recommendations are submitted for your serious consideration.

Section XVI.A.C.1. Covered Surgical Procedures Under the Revised ASC Payment System, a. Definition of Surgical Procedure, Page 42778

Comment: We support CMS identification of safety criteria useful in the determination of surgical procedures to be covered in the ASC setting. As device, technology and procedure advances are developed, it provides an opportunity for treatments to be provided in a variety of settings. A physician will have more flexibility in determining the most appropriate treatment setting for a patient that will provide quality and efficiency. We commend CMS for inclusion of procedures that will permit ASC facilities to perform procedures for peripheral vascular disease, dialysis access and dialysis access revisions. However, there are some procedures that were not proposed for coverage that are necessary to treat these conditions.

We submit the following recommendation for your serious consideration.

Recommendation: We recommend inclusion of CPT® Code 37205, Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel, and CPT® Code 37206, each additional vessel, as a covered procedure in the ASC setting. In a physician's professional judgment, some patients may be safely treated in an ASC setting because medical monitoring at midnight is not required for peripheral vascular disease and dialysis access procedures. This will align coverage of these procedures for the hospital outpatient, ASC and physician office settings

Table A, page 3, lists the Dialysis Access procedure CPT® Codes by provider setting. The columns for CY2007 and CY2008 list either a "yes" or "no" to indicate if CMS will cover that procedure in that setting. Table B, page 4, lists the same information for the Lower Extremity procedure CPT® Codes. In addition, there are three clinical articles attached to support the provision of these procedures in outpatient settings. The first article, "Safety of Short Stay Observation after Peripheral Vascular

Intervention," concludes that, "...many interventional vascular procedures can be performed safely on an outpatient basis with relatively short observation times." The second article, "Peripheral angioplasty with same-day discharge in patients with intermittent claudication" concludes that, "Same-day discharge after peripheral angioplasty is safe and cost-effective." The third article, "Covered Stent Use in Vascular Access Rescue", concludes that, "Patency of the access was re-established in all patients in an outpatient setting with immediate return to the hemodialysis unit without loss of dialysis days."

Section XVI.A.C.1.c.(3) Device-Intensive Procedures, Page 42779

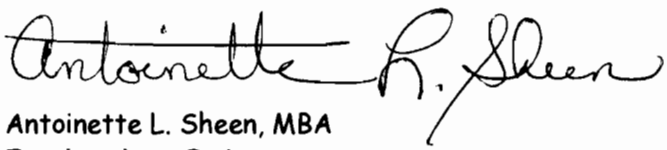
Comment: We commend CMS for establishing an ASC payment calculation to provide for the cost of devices in device-dependent APCs. However, limiting this calculation to only device-dependent APCs in which the device offset percentage is greater than 50 percent of the APCs' median cost will limit the ASC facilities flexibility in providing the appropriate device for a patient.

Recommendation: We recommend that the proposed ASC payment calculation for device-dependent APCs is applied to all and not limited to the APCs with the device offset percentage greater than 50 percent.

Final Recommendation

In the future proposed OPPS and ASC rules that may include innovative methodology such as composite APCs or packaging by episode, we recommend CMS provide data files and detailed information when the proposed rule is published. This will provide sufficient time for the public to evaluate the proposed changes, submit comments and provide meaningful recommendations.

Sincerely yours,



Antoinette L. Sheen, MBA
Email: asheen@wlgore.com
Phone: 800-528-1866 Ext. 42420

TABLE A - Medicare AV Access Allowed Procedures by Setting

Products: GORE-TEX® Vascular Grafts, GORE PROPATEN Vascular Graft, GORE VIABAHN® Endoprosthesis

Procedure Description	Physician Non-Facility		Hospital Outpatient		ASC	
	CY2007	Proposed CY2008	CY2007	Proposed CY2008	CY2007	Proposed CY2008
Creation of Native Fistula (36818 - 36821)	No	No	Yes	Yes	Yes	Yes
Creation of AV Fistula with Autogenous Graft (36825)	No	No	Yes	Yes	Yes	Yes
Non-Autogenous Graft for Dialysis Access (36830)	No	No	Yes	Yes	Yes	Yes
Central Venous Catheter Insertion, Replacement & Removal (36555 - 36590)	Yes	Yes	Yes	Yes	Yes	Yes
Mechanical Removal of Intraluminal (Intracatheter) Obstructive Material From CVC Through Device Lumen (36596)	Yes	Yes	Yes	Yes	No	Yes
Central Venous Catheter Repositioning (36597)	Yes	Yes	Yes	Yes	No	Yes
Insertion of Cannula for Hemodialysis (36800 - 36815)	No	No	Yes	Yes	Yes	Yes
Thrombectomy, Open; Revision, Open; Plastic Repair; Thomas Shunt; (36831 - 36835)	No	No	Yes	Yes	Yes	Yes
Distal Revascularization and Interval Ligation (DRIL) Upper Extremity Hemodialysis Access (36838)	No	No	Yes	Yes	No	No
External Cannula Declotting (36860 - 36861)	No	No	Yes	Yes	Yes	Yes
Thrombectomy, Percutaneous (36870)	Yes	Yes	Yes	Yes	Yes	Yes
PTA for AV Access Revision, Arterial (35475 or G0392)	Yes	Yes	Yes	Yes	Yes	Yes
PTA for AV Access Revision, Venous (35476 or G0393)	Yes	Yes	Yes	Yes	Yes	Yes
Transcatheter Therapy, Infusion for Thrombolysis Other Than Coronary (37205)	No	No	Yes	Yes	No	No
Stent Placement, Percutaneous (37205 - 37206)	No	Yes	Yes	Yes	No	No

TABLE B - Medicare Lower Extremity Allowed Procedures by Setting
Products: GORE-TEX® Vascular Grafts, GORE PROPATEN Vascular Graft, GORE VIABAHN® Endoprosthesis

Procedure Description	Physician Non-Facility		Hospital Outpatient		ASC	
	CY2007	Proposed CY2008	CY2007	Proposed CY2008	CY2007	Proposed CY2008
PTA, Open; femoral-popliteal (35456)	No	No	No	No	No	No
PTA, Percutaneous; femoral-popliteal (35474)	Yes	Yes	Yes	Yes	No	Yes
Atherectomy, Open; femoral-popliteal (35483)	No	No	No	No	No	No
Atherectomy, Percutaneous; femoral-popliteal (35493)	No	No	Yes	Yes	No	No
Stent Placement, Percutaneous (37205, 37206)	No	Yes	Yes	Yes	No	No
Stent Placement, Open (37207, 37208)	No	No	Yes	Yes	No	No

Safety of Short Stay Observation after Peripheral Vascular Intervention[1]

Janice R. Kruse, RD
Andrew H. Cragg, MD

Index terms: Angiography, complications • Angioplasty, complications

JVIR 2000; 11:45–49

Abbreviation: SSU = short stay unit

PURPOSE: To determine whether short observation periods (less than or equal to 4 hours) are safe in outpatients undergoing arterial peripheral vascular interventions.

MATERIALS AND METHODS: A retrospective review of 203 patient medical records from the Interventional Vascular Department for 239 lower extremity or abdominal procedures (161 men and 78 women) during a 5-year period was completed. The average patient age was 62.2 years (range, 32–83 years). Thirty-six patients had more than one procedure. Indication, intervention, coagulation status, complication rate, and hospitalizations within 7 days after discharge from the short stay unit (SSU) were reviewed and the outcome was measured. Patients were grouped according to the length of their observation period (≤4 hours or >4 hours) for statistical analysis.

RESULTS: In 85% of the procedures (204 procedures), claudication was the primary indication for intervention. Angioplasty (203 procedures) was also commonly performed. Ninety procedures (38%) required stent placement, and other interventional procedures performed were pulse-spray thrombolysis (eight procedures), atherectomy (two procedures), and stent-graft placement (one procedure). None of the patients required hospitalization as a result of their radiologic intervention within 7 days after discharge from the SSU. Specifically, there were no major "at home" complications in patients discharged after an observation period of ≤4 hours. Two patients were admitted for outpatient procedures and were subsequently hospitalized as a result of a complication from the procedure. The complication rate (including minor complications) was 8% (seven of 87) in the ≤4 hour observation period group compared with 24.3% (37 of 152) in the >4 hour group ($P < .01$). This difference was due to a greater number of minor hematomas in the >4 hour group.

CONCLUSION: Based on the authors' findings, many interventional vascular procedures can be performed safely on an outpatient basis with relatively short observation times. Early discharge from the SSU did not result in an increased readmission rate to the hospital because of delayed complications.

COMPLICATIONS related to vascular interventional procedures have been well documented for the hospitalized patient (1,2). However, partially because of changes in the healthcare market, outpatient angiography and intervention have become more common in the last 5 years. As a result, short stay units (SSU) have been created as cost-effective patient care units for monitoring outpatient's vital signs (and other variables) prior to discharge. Traditionally, patients have been monitored in the SSU for a minimum of 4 hours and up to 23 hours after the procedure (1,3–5).

For the past 5 years, our facility

[1] From Minneapolis Vascular Institute, 6545 France Ave., Edina, MN 55435. Received November 24, 1998; revision requested January 4, 1999; revision received August 5; accepted August 6. **Address correspondence to** A.H.C.

has performed angiography and other interventional procedures, such as angioplasty, stent placement, thrombolysis, and atherectomy, as outpatient procedures. In the past several years, a trend toward shorter observation periods has developed. Observation periods of 2–4 hours are now common. The actual length of stay is individually determined by the treating physician, taking into account the patient's overall medical status. Patients are discharged to their home under the supervision of an adult companion for the next 24 hours.

We were interested in assessing the safety of discharging patients in less than 4 hours after their interventional procedure. We were also interested in determining if we provided the appropriate level of monitoring and care (and, if necessary, hospitalization) required by the patient.

MATERIALS AND METHODS

We retrospectively reviewed the medical records of 203 consecutive patients who were admitted on an outpatient basis to our SSU for observation after peripheral lower extremity or abdominal vascular intervention from February 1992 to February 1997. Inpatients or patients admitted directly to the hospital from the interventional suite were not included in the study. Patients who underwent procedures not performed in the lower extremity or abdomen were also excluded.

Prior to the procedure, all patients and their medical histories were evaluated by a physician for the appropriateness of undergoing angiography and an interventional procedure performed on an outpatient basis. Another factor leading to outpatient rather than inpatient observation was physician practice. Some physicians had a preference for longer observation periods and inpatient observations. Diagnostic angiography and the associated intervention were performed in the same procedure. Interventions performed included angioplasty, stent placement, thrombolysis, stent-graft placement, and atherectomy of the aortoiliac or infrainguinal arteries. No arterial closure devices were used in this population and puncture site bleeding was controlled with use of manual compression. Patients were not treated as outpatients if they had any of the following: poorly controlled insulin-dependent diabetes, uncontrolled hypertension, electrolyte imbalances, severe renal insufficiency, symptomatic cardiopulmonary failure, or coagulopathies. The decision to treat a patient as an outpatient was based on general criteria for a group of clinical patients rather than precise laboratory or clinical parameters.

Data collection included (i) indication for the procedure, (ii) comorbidity of the patient, (iii) intervention performed, (iv) sheath size, (v) length of procedure, (vi) length of recovery time, (vii) complications, and (viii) the location where the complications were discovered (in the hospital or outside of the hospital). Major complications were defined as those that required the patient to be hospitalized. Minor complications were defined as those noted in the medical record not requiring hospitalization. In the case of minor hematomas, no distinction was made between the size of the hematoma. A hematoma that required a transfusion or admission as part of the treatment was classified as a major complication.

The patients were admitted to the SSU of the hospital as outpatients 1 hour prior to angiography to obtain laboratory blood analysis and undergo clinical examination performed by an interventional radiologist. After the interventional procedure, the patient was returned to the SSU. The patient's vital signs and puncture site(s) were monitored every 15 minutes for 1 hour, and then hourly while the patient was in the SSU. Patients were positioned with the upper torso at a 45° angle in a patient recliner and were allowed to move from side to side. The routine length of stay in the SSU was 2–6 hours. Prior to discharge, a SSU nurse examined the patient's puncture site(s), checked the vital signs, and made sure the patient was alert, oriented, able to ambulate, and tolerated oral fluids. If these criteria were judged by the nurse to be abnormal or not met, the physician was consulted and the patient was required to stay in the SSU for further observation. Patients also received instructions on activity restrictions, fluid intake, and emergency care should bleeding or other complications arise. Normal activity was restricted until the following day and strenuous physical activity was restricted for 72 hours. Pressure over the puncture site was also recommended during coughing, laughing, or sneezing. Fluids were also encouraged during the 24-hour period after the procedure. Preprocedure medications were resumed after the discharge. The patients were required to have someone transport them home and to be under the supervision of an adult for 24 hours.

A nurse telephoned the patients the next morning from the SSU. The nurse assessed the status of each patient with a short telephone interview and answered additional questions for the patients. Patients were reminded to call the SSU should future complications develop. Information on rehospitalization was obtained by reviewing the medical record. Most of the patients had health insurance and, as a result, would be required to seek emergency care at the same facility that provided treatment.

During the approximate 5-year period, 203 patients underwent 239 procedures (161 men, 78 women). The average patient age was 62.2 years (range, 32–83 years). In the study group, 36% of patients spent 4 hours or less in the SSU. Sixty-four percent spent more than 4 hours **(Fig 1)**. Thirty-six patients underwent more than one procedure during this 5-year period.

Subanalysis of the data was performed by grouping the patients according to the recovery time (≤4 hours or >4 hours) spent by the patient in the SSU, as documented in the patient's medical record. The use of heparin during the procedure was not used as criteria for a longer

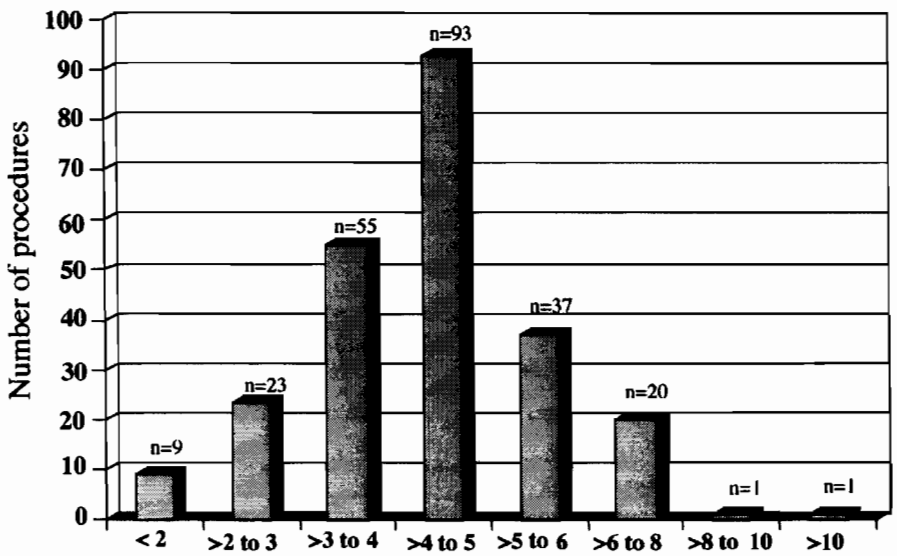


Figure 1. Length of recovery, in hours.

observation period. The complication rate was calculated and the chi-squared test was performed on related variables. Statistical significance was specified as $P \leq .05$.

RESULTS

The primary indication for the intervention was claudication in 204 (85%) of the procedures. Angioplasty was performed in 203 (85%) of the procedures.

Stents were placed in 90 (38%) of the procedures. Other interventional procedures performed were atherectomy ($n = 2$), stent-graft ($n = 1$), and pulse-spray thrombolysis ($n = 8$). The interventions were almost equally performed in the iliac and femoralpopliteal region, 42% and 55%, respectively. Eleven percent of the procedures were performed while the patient was taking an anticoagulant, such as warfarin. The use of heparin during the procedure was also equally split, with 48% of the patients receiving heparin while 52% did not receive heparin.

The majority of sheaths used in all procedures were 6-F (68%), whereas some procedures required a 7-F sheath (8%). In 20% of the procedures, the sheath size was not able to be determined. A 6-F sheath was used in approximately 70% in both observation period groups. The femoral puncture site was used almost exclusively (89%) in all procedures. Femoral access was used in 84% of the procedures in the short observation period group versus 93% in the long observation period group. However, bilateral access was more common in the >4 hour group versus the ≤4 hour group (27% vs. 14%). Many of the procedures lasted approximately 1–2 hours (70%), although in some cases the procedure lasted less than 1 hour (23%). Both observation groups had equal (79%) distribution of the procedure length at 1–2 hours. Claudication as the indication for intervention was also equally distributed (approximately 85%) in each group. Lastly, the presence of heart disease was twice as likely in the >4 hour observation group (28%) versus the ≤4 hour group (13%).

However, there was not a statistically significant relationship between groups for certain variables, such as indication for the procedure, type or location of the intervention, or the patient age greater than 75 years.

In our analysis, there appeared to be two principal reasons for observation periods that were longer than 4 hours. These were physician preference and the need for additional monitoring because of a minor complication or medical condition.

None of the patients who had outpatient procedures required hospitalization as a result of their radiologic intervention within 7 days after discharge. Specifically, no patients who were discharged after the short observation period required readmission for a complication.

The overall major complication rate was the same for both recovery period groups (0%). Minor complications (primarily minor hematomas) were more common in the ≤4 hour group ($P < .003$). **(Table 1)**.

Five patients (six procedures) were admitted to the hospital for other reasons within 7 days after their interventional radiology procedure. The admissions were for nonemergent surgeries, such as bypass surgery ($n = 3$), endartarectomy ($n = 2$), and an amputation of a toe ($n = 1$).

• Complications

There were two patients who were not discharged but admitted directly from the SSU to the hospi-

Table 1
Complication Rates for Length of Recovery Times

Variable	≤4 hrs	>4 hrs	*P* value
Major complications (required readmission to hospital)	0%	0%	NS
Minor complications	8.0% (7/87)	24.3% (37/152)	.003

Note.—NS = not statistically significant.

tal as a result of major complications due to the interventional procedure. The complications were diagnosed in the SSU. One patient who had a stent placed in the common and external iliac arteries developed a moderate hematoma with a small amount of external bleeding and pain in the groin area. The patient was hospitalized as a precautionary measure for overnight observation and did not receive a blood transfusion. The remaining patient, who had an angioplasty in the superficial femoral artery, was hospitalized for 48 hours for medical management of hypertension after symptoms of nausea, vomiting, and vertigo worsened in the SSU. Both patients were discharged from the hospital without any further complications. There were no deaths in this study within 30 days after discharge.

Puncture site hematomas were the most prevalent minor complication and were seen in 15% (n = 37) of the cases, accounting for 84% of the complications. Any evidence of extravascular bleeding was recorded as a hematoma. This included skin induration 1 cm or greater. In all but one case, patients were discharged without further complications. None of these patients received transfusions as part of their treatment.

Heparinization was also more common in the >4 hour group ($P <$ .001) **(Table 2)**. Among those patients who received heparin, the rate of minor complications was not different between shorter and longer observation periods (χ^2 = 3.16). However, among the patients who did not receive heparin, there were fewer complications for those in the short observation period group than those in the long observation period group ($P <$ .01) **(Table 3)**.

Table 2
Variables for Length of Recovery Times

Variable	≤4 hours	>4 hours	P value
Indication for procedure			
Claudication	82.8% (72/87)	86.8% (132/152)	NS
All other indications	17.2% (15/87)	13.2% (20/152)	
Intervention			
Angioplasty	84.0% (73/87)	85.5% (130/152)	NS
Stents	32.2% (28/87)	40.8% (62/152)	NS
Procedure location			
Iliac	34.5% (30/87)	46.7% (71/152)	NS
Femoral-popliteal	54.0% (47/87)	55.9% (85/152)	
Heparin use during the procedure			
Received heparin	32.2% (28/87)	57.2% (87/152)	.001
Age of patient			
≤75 y	92.0% (80/87)	85.6% (130/152)	NS
>75 y	8.0% (7/87)	14.5% (22/152)	

Note.—NS = Not statistically significant.

• DISCUSSION

The complication rate associated with angiography has been defined for the hospitalized patient (3). In the past few years, a small number of articles have been published on the complication rates of outpatient angiography and angioplasty.

Recently, Payne et al (3) documented a 4% complication rate for 168 outpatient angioplasties after a minimum observation period of 4 hours. The complication rate included patients requiring hospitalization as a result of the angioplasty. Struk et al (4) showed there was no greater risk of complication in outpatients who received angioplasty and a 6-hour recovery period as compared to hospitalized patients. They documented a complication rate of 5% for 141 outpatient procedures. Hematomas comprised most of the complications requiring hospitalization. Rogers et al (5) also described outpatient angioplasty with a recovery period of 4–6 hours. In this series of 149 angioplasties, one patient required hospitalization as a result of the angioplasty procedure.

Heparin was more common in the longer observation period group. The reasons for differences in the heparinization during the procedure were not readily identifiable in our study, but were likely due to physician practice and individual patient requirements. The fact that heparinized patients tended to stay longer after the procedure likely reflected physician judgment that longer observation was needed.

In our experience, the hospitalization rate of 0% within 7 days after discharge from the outpatient radiology procedure substantiates the safety of performing interventional vascular procedures on an outpatient basis, and discharging these patients with a recovery time of ≤4 hours. Our minor complication rate of 8% for the group that had a recovery time of ≤4 hours is similar to published reports for less complicated vascular intervention (1,4,5). It is important to note that our analysis group included many patients with complex intervention, such as stent placement and thrombolysis.

The rate of minor hematomas was relatively high in both groups in this analysis. This was, in part, a

Table 3
Heparin Use

Variable	≤4 hours	>4 hours	P value
Heparin Use–Minor complications	17.8% (5/28)	25.3% (22/87)	NS
No Heparin Use–Minor complications	3.4% (2/59)	23.1% (15/65)	.01

reflection of the close monitoring of patients by the SSU nurses. Any area of induration >1 cm was recorded as a hematoma. Importantly, none of the patients with minor hematomas required further care or resulted in postdischarge sequelae. Our analysis also found a significant relationship between the occurrence of a minor complication and prolonged observation. We believe this reflected appropriate judgment on the part of the SSU nurses and physicians.

The limitations to our analysis include its retrospective design and the fact that patients were selected for early discharge, in part on the basis of clinical judgment. Nonetheless, the patient populations appeared similar with respect to age, comorbidity, indication for intervention, and procedure length.

Our data suggest that selected patients can be safely sent home soon after extensive percutaneous revascularization procedures. Our principal concern about "at home" recovery from endovascular interventions, such as iliac stent placement, was the possibility of a catastrophic hemorrhagic complication at the treatment site. Our analysis does not exclude this possibility, but it does suggest that in properly selected patients, it should be rare.

There are many advantages to shorter recovery times for patients undergoing interventional procedures. Shorter stays may decrease the shortage of beds in the SSU caused by the increasing popularity of outpatient procedures. The shorter stay would also be cost-effective because these patients are charged an hourly fee for the monitoring. In addition, shorter recovery times may also allow later scheduling of cases, thus increasing interventional laboratory efficiency. Puncture closure devices may further shorten recovery times by potentially lowering the minor complication rate observed in our analysis.

In conclusion, the increased number of interventions performed on an outpatient basis, and shorter observation periods will require proper identification of patients requiring a higher level of care after interventional procedures.

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Peripheral angioplasty with same-day discharge in patients with intermittent claudication

Gabriel Akopian, MD, and Steven G. Katz, MD, *Pasadena, Calif*

Background: **As the number of endovascular interventions increase and resources become scarce, surgeons need to be aware of cost-effective and efficient practice options. Many surgeons routinely admit their patients for overnight observation after uneventful endovascular interventions. Although this may be appropriate for patients with tissue loss and rest pain, we believe that peripheral angioplasty in patients with claudication can be safely performed as an outpatient procedure with significant cost savings.**

Methods: **All patients with intermittent claudication undergoing peripheral angioplasty by a single vascular surgeon were enrolled prospectively in a same-day discharge protocol. Involved arteries and use of stent and closure device were recorded. Time to mobilization and time to discharge were determined. Patients were observed in an observation unit by a registered nurse, and were examined by the surgeon at the time of ambulation and before discharge. Patients were admitted to the hospital if complications arose during the predetermined observation period. Periprocedural complications and reasons for admission were noted. Patients were evaluated at 1 week, 6 weeks, and 3 to 6 months after the intervention.**

Results: **During 27 months, 112 interventions were performed in 97 patients. The superficial femoral artery was the most frequent site of intervention (47%). Multiple sites had angioplasty in 27 (24%) procedures. Nine (8%) procedures resulted in admission. One patient was admitted for a major puncture site hematoma requiring blood transfusion, two patients for observation of a minor hematoma at the puncture site, one for chest pain, and one for observation of transient bradycardia. The mean time to mobilization was 1.4 ± 1.3 hours, and the mean time to discharge was 2.8 ± 1.2 hours. The average postprocedural cost for patients undergoing same-day discharge was $320 per patient, which contrasts with $1800 for routine overnight observation. No deaths or unplanned admissions to the hospital occurred ≤30 days of intervention.**

Conclusions: **Same-day discharge after peripheral angioplasty is safe and cost-effective. Need for admission is evident within 2 hours. Routine admission after peripheral angioplasty for patients with claudication is unnecessary and should no longer be the standard of care. (J Vasc Surg 2006;44:115-8.)**

After the introduction of the coaxial catheter[1] in the 1960s and the subsequent creation of the balloon angioplasty catheter[2] a decade later, percutaneous transluminal angioplasty (PTA) became an acceptable form of treatment for patients with occlusive arterial disease. Over the last two decades, PTA has seen tremendous growth as a treatment option for peripheral vascular disease. With an ever-increasing population of elderly,[3] the prevalence of peripheral vascular disease and vascular interventions is expected to rise. Because catheter based procedures are now being performed with minimal complications, the appropriateness of routine hospitalization after these procedures should be brought into question.

The Society of Interventional Radiology Standards of Practice Committee guidelines[4] in 2003 called for overnight observation after PTA on the basis of the limited number of studies that addressed this issue. Although diagnostic angiography is routinely performed as a same-day procedure, outpatient PTA has been limited to a few centers. Our preliminary observation suggested that many patients having percutaneous interventions for intermittent claudication did not require hospital admission. In an attempt to determine the safety, efficacy, and cost benefits of outpatient PTA, we prospectively enrolled 112 patients in a study protocol of same-day discharge to test this hypothesis. This report focuses on the feasibility of same-day discharge from the short-term complication rates and cost analysis in this series of patients.

From the Department of Surgery, Division of Vascular Surgery, Keck School of Medicine, Huntington Hospital.

Competition of interest: none.

Correspondence: Steven G. Katz, MD, FACS, 10 Congress Street, Suite 504, Pasadena, CA 91105.

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MATERIAL AND METHODS

Between January 1, 2003, and March 31, 2005, all patients admitted for elective percutaneous interventions were prospectively enrolled in a same-day discharge protocol. Interventions were performed by or under the supervision of one vascular surgeon (S. G. K.). Data were collected according to the guidelines set forth by the Society for Vascular Surgery and the International Society for Cardiovascular Surgery,[5] stratified by Transatlantic Intersocietal Consensus (TASC) classification,[6] and analyzed on an intent-to-treat basis. When multiple segments underwent intervention at one setting, the highest TASC classification lesion was recorded. Patient demographics, presence of comorbidities, history of smoking, use of anticoagulants, stent placement, location of disease, use of closure device, and prior vascular interventions were recorded. The protocol was approved by the institutional review board, and patients gave written informed consent.

All patients were ambulating without assistance before the intervention and had adequate home support. None were from nursing homes, although16 were from assisted living facilities. The payer mix for this population of patients was 43% Medicare, 37% managed care, and 20% private pay. None of the payers require admission or discharge after endovascular interventions.

Patients did not undergo prescreening, and all interventions were planned within the same-day protocol. No patients were admitted the night before the intervention. Before the procedure, patients routinely underwent duplex evaluation of their lower extremities for planning purposes only. The preoperative duplex result did not change the decision to enroll the patients in the same-day protocol.

All patients were begun on clopidogrel (75 mg daily) beginning 4 days before the intervention. Patients able to tolerate aspirin were also given 325 mg daily. Warfarin was discontinued 72 hours before the procedure, and procedures were postponed if the international normalized ratio was >2.0.

Vascular access was obtained through a transfemoral approach using the micropuncture technique. Diagnostic arteriography was performed immediately before the intervention. All patients were systemically anticoagulated with heparin (5000 U). Stents were routinely placed after iliac angioplasty per surgeon preference and initially in infrainguinal vessels if flow-limiting dissection or incomplete angioplasty (residual stenosis >30%) was noted. Beginning in January 2004, stents were routinely placed after superficial femoral artery and popliteal artery angioplasty as part of an ongoing protocol studying the results of primary stenting of the infrainguinal vessels. For occlusions >5 cm, subintimal angioplasty techniques were used in almost all of the patients. For occlusions <5 cm, both transluminal and subintimal techniques were used.

Placement of the Angio-Seal Vascular Closure Device (St. Jude Medical, Inc., St. Paul, Minn) was attempted after all procedures if the puncture site was in the common femoral artery and if there was <40% stenosis ≤1 cm of the puncture site.[7,8] Feasibility of closure device deployment was angiographically determined. When a closure device was not successfully deployed, the physician performed manual groin compression at the groin access site for 10 minutes, re-evaluated for bleeding or hematoma, and pressure was reapplied if there was bleeding or an expanding hematoma. Heparin was not reversed at the conclusion of the procedure.

Patients were ambulated in 1 hour after having successful placement of a closure device and considered for discharge in 2 hours if their post-procedure course was uncomplicated. If manual compression was used, patients were ambulated after 4 hours and considered for discharge shortly thereafter.

Patients were observed in a four-bed observation unit staffed by one registered nurse. Time to ambulation and time to discharge were determined at the end of the procedure and adhered to if there were no complications. All procedures were started between 8 AM and 3 PM and completed between 9 AM and 5 PM. There were no payer requirements that would alter the decision to admit or discharge.

Table I. Comorbidities of study patients

Comorbidity	*N (%)*
Hypertension	88 (78.6)
Tobacco use	61 (54.5)
Hypercholesterolemia	57 (50.9)
Coronary disease	50 (44.6)
Diabetes mellitus	31 (27.7)
Arrhythmias	9 (8.0)
Renal disease*	5 (4.5)

*Defined as serum creatinine >2.0 mg/dL.

Patients underwent duplex evaluation at 6 weeks and every 3 months for the first year, and every 6 months thereafter. Patients were seen in the office at 1 week, 6 weeks, and every 3 months for the first year, and every 6 months thereafter. Additional phone calls were not routinely made, and patients were only seen outside of this follow-up schedule if problems arose.

Cost analysis data were collected from the hospital's business office. Cost analysis was performed on actual costs rather than patient charges. Hospital cost for a 1-hour stay in the observation unit is $115, and an overnight stay in an inpatient surgical bed is $1800. The average cost for patients being discharged was calculated by multiplying the average length of stay by $115. Data are provided as counts or means ± standard deviation. Analysis was performed using SAS (SAS Inc, Cary, NC).

RESULTS

During the 27-month study period, 112 consecutive procedures were performed in 97 patients. Twenty-eight additional interventions, which are not included in this analysis, were performed in other patients for tissue loss or rest pain. The mean age for the group was 74 ± 9 years. There were 49 men and 48 women. In 45 procedures (40%), the patient had undergone a prior vascular intervention.

The most common comorbidity was hypertension (79%), followed by tobacco use (55%) (Table I). In 70 procedures (63%) the patients had Rutherford category 3 (severe) claudication. In 42 procedures (38%) the patients had Rutherford category 2 (moderate) claudication. Interventions were not performed on patients with category 1 (mild) claudication. There were 87 interventions performed on TASC category A and B lesions, and 25 were performed on TASC C and D lesions.

The most common site of intervention was the superficial femoral artery (SFA) in 53 procedures (Table II). Angioplasty was performed on a single segment during 80 procedures (71%) and on multiple segments during 27 procedures (24%). Five patients (5%) failed treatment because the lesion could not be traversed. These patients are included in the analysis on an intent-to-treat basis.

Table II. Location of intervention

Location	*N (%)*
Common Iliac	20 (17.9)
External Iliac	18 (16.1)
Common femoral	4 (3.6)
Superficial femoral	53 (47.3)
Popliteal	41 (36.6)

Stents were deployed in 86 procedures (77%). A single stent was used in 46 procedures (41%), and multiple stents were placed in 40 procedures (36%). Of these, 75 stents were self-expanding, and the rest were balloon-expandable. A 6F sheath was used to perform 104 procedures (93%), seven procedures were performed through a 7F sheath, and one through an 8F sheath.

A closure device was attempted after 99 procedures (88%) and was successful in 92 attempts (93% success rate). Overall, a closure device was successfully placed at the conclusion of 82% of procedures; in the rest, hemostasis was obtained by manual groin compression.

The average length of the procedure was 72 ± 31 minutes (range, 17 to 175 minutes), with an average time to mobilization of 1.4 ± 1.3 hours and average time to discharge of 2.8 ± 1.2 hours. Same-day discharge was achieved after 103 procedures. Nine patients (8%) were admitted for overnight observation. Four patients were admitted for lack of support mechanisms at home. One patient was admitted for chest pain but was found not to have had a myocardial infarction, and one patient was admitted for observation of transient bradycardia, which spontaneously resolved. One patient had a major puncture site hematoma requiring blood transfusion, and two patients had minor hematomas. Of the three patients with hematomas, two had what was assumed to be successful deployment of a closure device, whereas in one patient, deployment of a closure device was not attempted. After procedures in which a closure device was successfully deployed, patients were discharged to home on the same day 95% of the time, while 80% of patients undergoing manual groin compression underwent same day discharge.

Eight of the admissions had TASC A or B lesions, and one patient had a TASC C lesion. Eight of the nine admissions had a length of stay of 1 day, and the patient with chest pain stayed 4 days. In patients discharged the same day, there were no deaths or unplanned readmissions ≤30 days of the procedure. The average postprocedural cost for patients discharged the same day was $320 per patient, which contrasts with $1800 for routine overnight observation.

There were three treatment failures, at 13 days, 17 days, and 27 days. These patients were successfully treated with open elective surgical intervention.

DISCUSSION

The last decade has witnessed striking technologic advances that have radically altered the manner in which care has been delivered to patients with arterial occlusive disease. With the development of catheter-based techniques to treat patients with intermittent claudication, it becomes the responsibility of the operator to perform these procedures in a safe, fiscally responsible, and cost-effective manner. In the past, it has been considered the standard of care to admit these patients to the hospital postprocedure for overnight observation in hopes of recognizing complications in a timely fashion. In our experience, complications have been infrequent and occurred in the early postprocedure period. This led us to attempt to modify our practice guidelines by routinely discharging patients on the day of their procedure. The results of this study confirm that peripheral angioplasty in patients with intermittent claudication can be performed in a cost-effective manner without compromising clinical outcomes.

Several studies[9-14] have addressed the topic of outpatient angioplasty. Although successful, most of their patients were prescreened or preselected for inclusion in the study. In addition, most of these procedures were performed on single arterial segments, and stents were rarely used. In contrast, we assumed that all patients with claudication undergoing PTA had an equal probability of being discharged, and thereby avoided selection bias by including patients having extensive procedures on multiple arterial segments in our study protocol. Still, we were able to discharge 92% of our patients on the day of their intervention. The safety of this approach is evidenced by the fact no patients died or had unplanned readmissions to the hospital ≤30 days of their procedure.

Although all of the patients in our series had claudication, we and others[15-18] have extended percutaneous interventions to those patients with limb threat, with gratifying results. We have found that selected patients with limb threat as their indication for intervention can be discharged on the day of the procedure. The site of intervention, length of the arterial segment treated, or the number of stents placed did not affect the chance of admission. Many complications of peripheral angioplasty are related to puncture site complications.[19,20] Interestingly, almost half of our admissions were unrelated to medical problems and were due to a lack of adequate social support at home. Perhaps with better planning and foresight on our part, some of these admissions could have been prevented.

Traditionally, patients undergoing peripheral angioplasty have been admitted to the hospital for overnight observation. However, preservation of health care resources has become increasingly important. In our area and in many parts of the country, hospitals are running at their maximum capacity, and bed space is at a premium. Limiting unnecessary admissions and optimal utilization of available resources would help to alleviate this problem. In addition, same-day discharge after PTA can result in significant cost savings. In our institution, our patients are observed in an observation unit rather than a recovery room, allowing for a substantial reduction in hospital cost. Our average postprocedural cost for patients undergoing same day discharge was $320 compared with the $1800 institu-

tional cost incurred for overnight admission to an unmonitored medical-surgical bed.

CONCLUSION

Same day discharge after peripheral angioplasty in patients with intermittent claudication is safe, cost-effective, and does not adversely affect patient outcomes. Determination of the need for admission can usually be made ≤2 hours after the procedure. Attention to the social needs of the patient and avoidance of puncture site complications should minimize hospital admission. Although we preferentially use closure devices, we were able to successfully discharge to home on the same day 80% of patients undergoing manual compression. Those who do not use closure devices should not be dissuaded from attempting same-day discharge. We conclude that routine admission after peripheral percutaneous intervention in patients with claudication is unnecessary and should no longer be considered the standard of care.

AUTHOR CONTRIBUTIONS

Analysis and interpretation: SGK, GA
Data collection: GA
Writing the article: SGK, GA
Critical revision of the article: SGK, GA
Final approval of the article: SGK, GA
Statistical analysis: GA
Obtained funding: Not applicable
Overall responsibility: SGK

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RP1245

COVERED STENT USE IN VASCULAR ACCESS RESCUE

Marcello A. Borzatta, M.D., F.A.C.S.
John Belville, M.D.
Mission Vascular Center
Mission Hospital Regional Medical Center,
Mission Viejo, California

Introduction

Complications associated with hemodialysis vascular access grafts, represent an important source of morbidity and mortality among chronic hemodialysis patients. Endovascular intervention utilizing thrombolytic agents, mechanical thrombectomy devices, balloon angioplasty and stent placement have proven to be as effective as surgical thrombectomy and graft revision in restoring patency of occluded dialysis grafts. However. they do not extend the life of the graft. Most dialysis access failures are not due to the graft itself, but to venous stenotic disease caused by neointimal hyperplasia. Initial balloon angioplasty techniques were employed to remedy this, but restenosis remained a problem. More recently, flexible self-expanding stents have been used. Although they appear to delay the onset of restenosis, neointimal hyperplasia occurring through the interstices and at the ends of the stent, will eventually lead to failure. The observation that the endothelial growth usually occurs within or at the ends of the stent is the basis for our premise that placing a graft lined stent may significantly extend the life of the dialysis graft by preventing neointimal growth.

Study Design

To assess the safety and effectiveness of a PTFE-lined nitinol stent graft (Viabahn, W.L.Gore& Assoc. Inc., Flagstaff, AZ) we undertook a prospective physician

sponsored IDE trial. Patients presenting with arterio-venous graft failure secondary to previously untreated venous outflow stenosis were enrolled. A registry group was also established to include all comers with failed AV grafts secondary to venous outflow lesions, regardless of the number of previous interventions.

Materials & Methods

The AV graft was cannulated in the standard fashion using an 18 gauge one-wall needle, often under ultrasound guidance. Percutaneous mechanical thrombectomy with or without pulse jet utilization of thrombolytic agents was performed. Prior to restoring inflow, a shuntogram was obtained to evaluate patency of the venous outflow. Percutaneous transluminal angioplasty of the affected area was performed. Arterial inflow was then re-established by removing the "plug" at the arterial anastomosis usually using a Fogarty balloon. Once arterial flow was re-established, the area of the venous anastomosis could be properly sized and the endoprothesis selected. The Viabahn endoprosthesis was then deployed across the target area, making certain that the entire segment treated with PTA would be covered. Post dilatation was performed to achieve complete apposition. A completion angiogram was obtained to image the arterial anastomosis, the entire graft and the venous outflow. After removal of the sheath, the patients were returned to the dialysis unit.

Follow up for the trial group included venous ultrasound and plain x-ray at one, three, six, and twelve month intervals. Clinical follow up only was performed for the registry patients at the same intervals. Primary and secondary patency rates were the selected end points.

Results

Trial Patients. Eighteen endoprosthesis were deployed in sixteen patients enrolled in the FDA trial with two patients receiving two devices simultaneously to cover longer segment stenosis. Nine males and seven females with a mean age of 74 years composed this group. Endoprothesis of the following sizes were utilized: ten 8×5, four 7×5, three 9×5 and one 6×5. Patency was successfully established in all grafts. All the stent grafts were successfully placed at the target lesions. All patients were returned to hemodialysis with a functional graft. Follow up ranges to date between six and twelve months.

The primary patency rate at three, six, and twelve months was respectively 62%, 58%, and 41%. At the same intervals, the secondary patency rate was 87%, 64%, and 58%.

There were four surgical revisions for either graft infections or repeated failures. Four patients died from unrelated causes.

Registry Patients. Twenty five patients were enrolled in this group, ten males and fifteen females with a mean age of 63 years. Successful placement of the stent graft was achieved in 100% of the patients. All stent grafts were patent and functional and

the patients were returned to hemodialysis at the end of the procedure. Clinical follow up ranges between six and twelve months. The primary patency rate was 54% at three months, 48% at six months and 31% at twelve months. The secondary patency rate was 94% at three months, 88% at six months, and 69% at twelve months.

There were two surgical conversions, and two deaths due to unrelated causes.

Conclusions

Arterio-venous graft rescue with stent graft implantation to treat venous outflow stenosis is a safe technique which yields encouraging preliminary results. Similar patency rates were obtained in both groups of patients. High secondary patency rates were achieved leading to the extension of the life of the access site and preservation of venous "real estate" for further access procedures. Patency of the access was re-established in all patients in an outpatient setting with immediate return to the hemodialysis unit without loss of dialysis days. Encouraging high patency rates favorably compare to historical controls but warrant further investigation.

DISCUSSION

Vascular Access for Hemodialysis IX
May 6-7, 2004
Lake Buena Vista, Florida

May 6, 2004
Abstract Session II

Dr. Marcello Borzatta
"Covered Stent Use in Vascular Access Rescue"

Question: The question that I actually have is that when I use these things and go back when they fail again, it almost is due to a development of a new stenosis. In other words, the stent is fine. That is actually not what fails. The primary patency rates are actually no better than angioplasty. So one would think that that would support not using this device. Did you find that in your study? When these failed it was not because of the stent graft, it was because of another problem at another location?

Borzatta: Most of the time the recurrence is because of a stenosis that occurs somewhere else in the device in the access graft and not necessary with the Viabahn, which is found to be completely patent. Although, we have encountered this in probably about thirty percent of the patients, that there is an edge stenosis at the distal leading edge of the device. So I say about 2/3 of the cases the device is perfectly patent and it is due to another stenosis or maybe no anatomical reason, which we encounter in about 40% of recurrent failure. They come back and there is no anatomical reason for the failure. The ones who do have an anatomical reason is about 2/3 and its somewhere else, and about 30% is at the leading edge of the device.

Question: Do you encourage or discourage cannulation through the device?

Borzatta: That is a very good question and the cannulation of the device should be discouraged because your device is usually placed right at the anastomotic level. You would not cannulate that area normally under normal circumstances anyway. Can you cannulate a Hemobahn or a Viabahn device? The company does not have an official policy on that. It has been done. It turns out actually that there is experience both with cannulating the wall graft device, which has a different construction. The Hemobahn seems to be at least conceptually easier to cannulate because you don't have continual struts, so you actually have spaces where you are going to be going through just PTFE and not the nitinol stent. If you look at the in vitro cannulation, and you can do it on your back table, the recoil of the PTFE is much greater than with the other covered stents. So can it be done, yes. Is it being encouraged, no. The company does not recommend it.

Comment/Question: This is a great technology for these of us who believe in doing local revision for the graft. Now we can do a revision by just interventional means, which allows the patient to go back to dialysis immediately without having the problem with the pain in surgery. My only concern is in many situations when these stents are placed by people who are not thinking in these terms. The deep vein might not be available in the future because the stent has already crossed that vein.

Comment: That is an excellent point but the important point to me is that you need to cover the area that you are going to be treating with your angioplasty balloon. I assume that you are treating the area that is stenotic and you should not extend your angioplasty into the native vein and therefore since you are only covering the area that you are treating with the balloon, you should not take your prosthetic device into native untouched vein. The whole idea of this is that you are going to preserve the native vein for further access sites. The only time when open surgical repair compares favorably within the interventional repair of av access graft is when you actually have done an interposition graft and you have extended your surgical reconstruction utilizing a new native vein. So the whole principle behind utilization of covered stents is that you should not extend the device into territory that you want to preserve for further access.

FLORIDA HOSPITAL ASSOCIATION
An Association of Hospitals & Health Systems

September 12, 2007

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Kerry N. Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1392-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: [CMS-1392-P] Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates (72 *Federal Register* 42628), August 2, 2007

Dear Mr. Weems:

The Florida Hospital Association, on behalf of its member hospitals and health systems, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed Medicare outpatient prospective payment system (OPPS) rule for calendar year 2008, as published in the August 2 *Federal Register*. Since its implementation, the outpatient prospective payment system has presented significant implementation challenges to hospitals, to CMS, and to the fiscal intermediaries. Since inception, we have been faced with repeated revision of policy, a trend that appears to continue with the proposed rule for CY2008.

In addition to the lack of a payment system that is consistent from year to year and devoid of significant and challenging changes, there are several areas of specific concern with the provisions included in the proposed rule. These include packaging of observation services, hospital coding for evaluation and management services, payment for drugs and biologicals, separate charges for pharmacy overhead, and requirements for reporting quality data. These concerns and comments are detailed below –

OPPS: Packaged Services

In the proposed rule, CMS proposes an expansion of those items that are packaged under OPPS to include certain dependent items and services into the payment for the independent services with which they are furnished. The dependent items and services include guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, contrast media, and observation services. We are comfortable with the intent behind this change, but do not believe that the expansion of packaging should include those patients presenting to the emergency department with a complaint of congestive heart failure, chest pain, or asthma and receiving observation services.

The rules related to outpatient observation have changed nearly annually since 2000. While the proposed change is to package these observation services, many articles and headlines are already addressing CMS' proposal to no longer pay for observation through the ED. We recognize that this is not CMS' intent, but repeated revisions to the observation policy cause great confusion for the hospitals and particularly for their physicians. If physicians are hesitant to order observation and instead admit the patient, hospitals could see a significant increase in the number of medically unnecessary short stays.

Corporate Office
306 East College Avenue
Tallahassee, FL 32301-1522
(850) 222-9800 Fax: (850) 561-6230

Regional Office
307 Park Lake Circle
Orlando, FL 32803
(407) 841-6230 Fax: (407) 422-5948

Washington, D.C. Office
444 N. Capitol Street, NW, #532
Washington, D.C. 20001
(202) 434-4848 Fax: (202) 434-4846

www.fha.org www.flacareers.com

OPPS: Device-Dependent APCs

In the proposed rule, CMS includes a reduction in payment of 50 percent of the packaged cost for devices received with a partial credit due to a recall or warranty issue. CMS addresses the issue of whether or not hospitals reduce their charges in proportion to the partial credit they receive for the device. While such a charge reduction is not consistent across all hospitals, it should be stressed that the cost associated with all devices has already taken these reduced costs and rebates into consideration. In determining costs for various items and services, the charges included on the claim are reduced by CMS based on a provider's reported costs – costs which reflect what was actually paid for services.

Under a similar provision finalized with the inpatient prospective payment system for FY2008, CMS applied the reduced payment methodology only to cases in which the hospital receives a credit of 50 percent or more of the cost of the device. Under OPPS, CMS has set this threshold at 20 percent. We urge CMS to be consistent across payment systems and to set the OPPS threshold at 50 percent.

OPPS: Packaging Drugs and Biologicals

The proposed rule addresses separate reporting of overhead costs for all drugs and biologicals, using a non-coded revenue line on the claim along with a separate line coded to reflect the specific drug. While this proposal is different than that proposed for CY2006, it continues to be extremely labor intensive and administratively complex for hospitals. Pharmacy chargemasters are often thousands of lines long and to add an additional overhead line for each drug and biological would be virtually impossible to achieve from the date of the final rule to a required compliance on January 1. The fact that this separation is informational only is of issue, as is the fact that hospital systems will have to roll the items into a single line for non-Medicare payers. It should also be noted that the cost-to-charge ratio used to adjust this charge to cost will be the same as that for the drug itself as the costs would continue to be captured in the pharmacy cost center.

In addition, throughout this discussion in the *Federal Register*, CMS refers to removing the pharmacy overhead charge from the charge for the drug. On the issue of payments, the rule references "... acquisition costs and pharmacy overhead." The rule also indicates that hospitals should "... report a charge for the drug and a charge for pharmacy overhead." We are confused as to the intended interpretation of the drug charge or drug cost. Is this intended to be the specific hospital's average buying price? Or last purchase price? Should this equate to a published average sales price? Does this include any markup or is that captured only under the pharmacy overhead charge?

Hospital Coding and Payments for Visits

Hospitals have developed their own coding matrix for evaluation and management services since the start of OPPS. While we would have liked to see a standardized coding methodology adopted by CMS, we now feel that we are "too far down the road" to ask providers to change. We would ask, however, that if CMS does not introduce a standardized coding matrix, the CPT codes used to describe these services should be replaced with hospital HCPCS codes. Hospitals are not HIPAA compliant if they continue to use already defined CPT codes, but without using their true definitions.

In addition, CMS clarified in the CY2007 final rule that code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes) could only be billed for critical care services of 30 minutes or longer. With CMS' DRG payment window requirements, the vast majority of these cases will be admitted – unless the patient dies – and, therefore, not paid under OPPS. We urge CMS to expand the use of the critical care code (or a new code from a HIPAA-compliance perspective) to address those situations in which a patient receives an intense level of care for at least 15 minutes but expires before 30 minutes are reached. If these cases are not captured as critical care, the calculated weight for critical care services will likely fall below that for a Level 5 ED visit. While for CY2008 the weight for critical care is greater than a Level 5 visit, this calculation was made using claims prior to the critical care clarification for CY2007.

We also urge CMS to eliminate the requirement for separate codes for new and established clinic patients. Using the definition of an established patient as one with an existing medical record at the facility within the last three years is untenable. Large hospitals with multiple clinics will not see savings in service time or resource use when treating an established patient vs. a new patient. Individuals new to a clinic but not the hospital complex will require the same resources as the patient without a history at the facility.

Quality Data

As required by Congress, CMS has proposed the implementation of 10 quality measures for outpatient reporting. While we recognize the need to move forward with reporting, we also believe that hospitals will have problems with the first reporting period due to infrastructure and system issues. Interfaces will need to be built between hospital outpatient clinics and EDs to the inpatient area for abstraction. The performance measurement vendors need time after the final rule to develop the needed screens and hospitals need time for staff education. From an historical perspective, the required infrastructure was in place when hospitals began submitting inpatient quality data as they had already been reporting on the core measures to The Joint Commission.

We urge CMS to adopt a phased-in approach with the outpatient measures, allowing hospitals to select three or four measures for reporting in the first year, with added measures in subsequent years. In addition, at least six months of reporting for any measure is required before data validation. The full market basket update for CY2009 should be tied to reporting only, with validation for learning purposes only and not required as a minimum reliability score until hospitals have more experience with the measures.

Again, the Florida Hospital Association appreciates the opportunity to provide these comments on the proposed rule for outpatient prospective payments for calendar year 2008. If there are questions on these comments, please do not hesitate to contact me at (407) 841-6230 or via email at kathyr@fha.org.

Sincerely,

Kathy Reep

Kathy Reep
Vice President/Financial Services