CMS-1506-P-453 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : Mr. Patrick Monahan **Date & Time:** 10/10/2006

Organization : Connecticut Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

OPPS: New HCPCS and CPT Codes

OPPS: New HCPCS and CPT Codes

Please see attached comments.

CMS-1506-P-453-Attach-1.DOC

#453

CHA CONNECTICUT HOSPITAL ASSOCIATION

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P; Comments on Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates

Dear Dr. McClellan:

Please accept these comments from the Connecticut Hospital Association (CHA) on behalf of its not-for-profit acute care hospital members regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates. We specifically object to the portion of the rule that proposes that only emergency departments that are operated on a 24 hour basis are entitled to payment at the hospital emergency department rate. We believe that CMS should pay hospital emergency departments at the emergency department rate irrespective of whether they are on the main campus of the hospital or at a provider-based facility of the hospital that is open less than 24 hours a day.

The State of Connecticut hospital emergency services network includes separate, hospital-based, satellite emergency department locations that operate on less than a 24 hour per day basis. Each of these satellite emergency departments conform to all federal Medicare standards to operate at a location other than the hospital's main campus under provider-based rules, and each operates as an integral component of the full-time main hospital emergency department, which is open 24 hours per day. In addition, the Medicare program holds each of these hospital satellite facilities fully accountable as "dedicated emergency departments" subject to all Emergency Medical Treatment & Labor Act (EMTALA) requirements.

In the proposed rule, CMS states that emergency departments that are open for less than 24 hours per day would be considered "Type B" emergency departments, and paid at rates substantially lower than full-time "Type A" emergency departments. Whether a facility is open 24 hours per day is not the appropriate standard to determine which

facilities should be paid at the full hospital emergency rate. Section 1833(t) of the Social Security Act requires that the outpatient prospective payment system pay for hospital resource use. The proposed rule fails to meet this standard. Patients who receive emergency department services at hospital provider-based emergency departments that operate for less than 24 hours per day use emergency department medical resources, and the proposed clinic rates do not reflect the emergency department capital, technology, skilled labor, and other specialized procedure costs and medical resources required to treat these patients.

CMS states in the proposed rule that payment of the Type B rates for emergency department visits to hospital provider-based emergency departments under the proposed rule will permit CMS "to specifically collect and analyze the hospital resource costs of visits to these facilities in order to determine in the future whether a proposal of an alternative payment policy may be warranted." CHA appreciates that more cost analysis may be warranted, but the full emergency department rate should be paid to the three affected emergency departments in Connecticut during the period of any such analysis, because payment of the insufficient Type B rates threatens access to the critical services offered by these facilities. As CMS is well aware, emergency department care is at a crisis point, and limiting access to emergency services would only exacerbate the problem.

For these reasons, CHA urges CMS to reconsider its proposed payment policy for provider-based emergency departments that are not open 24 hours per day and revise the rule to pay these emergency departments at the full emergency department rate. In addition, if CMS believes an interim rule is appropriate while it conducts further cost analysis, the presumption should be in favor of paying the full emergency department rate during such interim period to minimize the threat to access to emergency care in Connecticut.

We appreciate the opportunity to comment and thank you for your consideration.

Sincerely,

Patrick J. Monahan II
General Counsel and Vice President, Patient Care Regulation

PJM:mb
By e-mail

Submitter : Ms. Mary Hayter **Date:** 10/10/2006

Organization : Smith & Nephew Wound Management

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Smith & Nephew is pleased to submit comments regarding the proposed rule - Medicarce Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.

See Attachment.

CMS-1506-P-454-Attach-1.PDF

CMS-1506-P-454-Attach-2.PDF

#4524

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Tuesday, October 10, 2006

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

RE: [CMS-1506-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

Smith & Nephew is pleased to submit comments regarding the proposed rule *Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.*[1] Smith & Nephew Wound Management is a global leader with an ever-expanding range of products, services and treatment solutions for acute, chronic, and traumatic wounds, as well as skin and burn care.

We appreciate the opportunity to provide our perspectives on the proposed rule to the Centers for Medicare and Medicaid Services [CMS]. We write to you today to share our concerns regarding specific decision-making processes as it relates to our product, known as the VERSAJET® Hydrosurgery System.

VERSAJET is a relatively new technology currently used in the inpatient hospital setting for tissue excision and contaminant vacuum removal for severe acute, chronic, traumatic and burn wounds and is a significant technological advance in wound care. In light of the success and benefits to the patient when VERSAJET is used in the Operating Room, some physicians are using it in outpatient settings.

We are now looking to expand the VERSAJET Hydrosurgery System to the outpatient setting to help meet the growing needs of patients who suffer from the painful complications of acute and chronic wounds, including diabetic foot ulcers, venous leg ulcers, and pressure ulcers.

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

First, however, it is important to place VERSAJET in context. Chronic wounds plague more than four million people in the United States – many are Medicare beneficiaries. Chronic wounds are also a major cause of amputation, infection, morbidity, disability, and economic costs. In 2002, it was estimated that about 1.5 to 3.0 million Americans suffered from pressure ulcers, 1.0 million had venous-insufficiency-related ulcerations, and 0.6 million were afflicted with chronic ulcers due to diabetes and other causes.[2] The socioeconomic burden imposed by these complex, debilitating and often limb and/or life threatening wounds is significant, including the resources required for the protracted care and management of patients refractory to conventional wound therapies.

Among other instigating factors, the aging of the general population has contributed to the growing prevalence of chronic wounds. According to the U.S. Census Bureau's *Census 2000 Profile*, the number of adults over the age of 65 is approximately 35 million and is expected to double by the year 2030.[3] As the aging population increases, the number of bedridden patients and those with limited mobility may be expected to escalate. Additionally, higher rates of obesity and a greater tendency toward sedentary lifestyles have been cited as underlying causes for an increased incidence of Type 2 diabetes, which is associated with a high rate of diabetic foot and venous leg ulcers.

Diabetic foot ulcers occur at an annual incidence rate of two to three percent.[4] Of the estimated 16 million people in the United States who have diabetes, approximately two million or 15 percent will develop a foot ulcer during their lifetime. More than 54,000 diabetes-related amputations are performed in the United States each year. Costing as much as $40,000 each, more than half of these amputations could have been prevented with proper foot care.[5]

Preventing wounds from deteriorating clinically is vital. Smith & Nephew is dedicated to preventing wounds of this nature from escalating into costly long-term treatments. In order for this to happen, CMS must be committed to properly addressing new technologies such as VERSAJET® in the coding and payment systems of the Medicare program.

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[2] Limova M. New therapeutic options for chronic wounds. *Dermatol Clin* 2002; 20(2):357-363,ix.

[3] U.S. Census Bureau, Population Division, Population Projections Branch. U.S. Summary: 2000. Issued July 2002. Available at: http://www.census.gov/prod/2002pubs/c2kprof00-us.pdf. Accessed October 1, 2006.

[4] Mekkes JR, Loots MAM, Van Der Wal AC, Bos JD. Causes, investigation and treatment of leg ulceration. *Br J Dermatol* 2003;148:188-401.

[5] United States National Institute of Diabetes & Digestive & Kidney Diseases of the National Institutes of Health. National Diabetes Statistics. Available at http://diabetes.niddk.nih.gov/. Accessed October 1, 2006.

New Technology APCs

VERSAJET® is a high-powered surgical system that utilizes a high-powered stream of sterile saline for complete wound excision and contaminant vacuum removal. VERSAJET also enables physicians to precisely target and remove damaged tissue and maintain viable healthy, tissue permitting the healing process to progress naturally. Current debridement techniques involve "pulling off" necrotized tissue usually through the manual use of a scalpel, often causing damage to underlying healthy tissue leading to increased risk of infection, longer healing times and lower quality of life.[6]

New technology APCs were created to allow emerging technologies an opportunity to gain adoption into the outpatient setting as well as promote access to innovative technologies to Medicare beneficiaries. We understand that determination of relative payment weights for the Ambulatory Payment Classification System [APCs] is based on clinical coherence and relative resources that may be comparable or otherwise relevant to the technology. This is not clearly the case for wound care, where we observe a coding and payment structure for wound debridement services that fails to properly recognize the potential for the advent of important technological improvements. We do recognize that the coding structure requires a different effort and we will explore those options.

Separately, CMS has proposed to move certain technologies into clinical APCs with only a year or even less of claims data and has invited comment on this point. Smith & Nephew is concerned if CMS prematurely moves new technologies from New Technology APCs to existing clinical APCs prior to allowing the technology to properly diffuse into the healthcare system and build a proper base of claims data and associated hospital charge data, CMS risks incorrect APC assignments that do not reflect the real resources of the new technology. We recommend CMS adopt a 2-year minimum policy for retention of new technology APCs prior to assignment into a clinical APC.

Thank you for the opportunity to share our views on the proposed rule. If you have any questions, please feel free to contact me at 202.626.8235.

Best regards,

Mary E. Hayter

Mary E. Hayter
Vice President, Government Affairs/Health Economics
Compliance Officer

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[6] Granick, M., Jacoby, M. Clinical and Economic Impact of Hydrosurgical Debridement on Chronic Wounds. Wounds 2006; 18[2]: 35-39

#454 (2)

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We are smith&nephew

Tuesday, October 10, 2006

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

RE: [CMS-1506-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

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Best regards,

Mary E. Hayter

Mary E. Hayter
Vice President, Government Affairs/Health Economics
Compliance Officer

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[6] Granick, M., Jacoby, M. Clinical and Economic Impact of Hydrosurgical Debridement on Chronic Wounds. Wounds 2006; 18[2]: 35-39

Submitter : **Ms. Mary Whitbread** **Date: 10/10/2006**

Organization : **Henry Ford Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-455-Attach-1.DOC

1455

Mary Whitbread, Vice President
Reimbursement and Contracting
One Ford Place
Detroit, Michigan 48202

Ph: (313) 874-9533
Fax: (313) 876-9229

October 10, 2006

Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department for Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1506 - P — Medicare Program; Hopstial Outpatient Prospective Payment Sstem and CY 2007 Payment Rates Proposed Rule, August 23, 2006 *Federal Register*

Dear Dr. McClellan:

On behalf of the Henry Ford Health System, we appreciate the opportunity to provide input on the proposed rule for the 2007 Medicare Outpatient Prospective Payment System, published in the August 23, 2006 *Federal Register*. We do have significant concerns regarding some of the proposals and hope you will take our comments into consideration.

Proposed Payment for Specified Covered Outpatient Drugs

The mean cost method that CMS used to calculate the APC payments for drugs should, in theory, capture both the direct pharmacy salary costs and indirect costs, as CMS states in the discussion. We have consistently found, however, that the cost data for drugs are understated overall using this method and we are being underpaid for drugs as a result.

In order to determine if the payment levels for separately payable drugs were adequate, we reviewed cost data from our pharmacy. We found that salaries, wages and other non-drug direct pharmacy costs were about 18% of our total direct pharmacy costs. This was lower than MEDPACs report, which found that, on average, 25% of total pharmacy direct costs were for pharmacy salary and benefits (June 2005 MEDPAC Report). Even with lower than average non-drug direct costs, we found that the proposed payments were still inadequate. At the proposed rate, we will recoup only 92% of direct pharmacy costs. When we add in the indirect costs (at the cost report rate of 14% of direct costs), we found that we were being paid, on average, 80.6% of

total costs. The table below shows the full cost of our most frequently provided outpatient drugs:

HCPC Code	Drug Name and Billing Quantity	Units Dispensed (August YTD)	Unit Cost	2007 APC Payment	Total Acquisition Costs	Total Direct Costs (1)	Total Costs (2)	Payments	Total Margin
J0180	Agalsidase beta, 1mg	1,366	99.37	126.00	135,741	165,538	188,714	172,116	(16,598)
J0881	Darboepotein Alfa, 1 mcg	253,187	2.22	3.00	562,645	686,152	782,214	759,561	(22,653)
J0885	Epotein Alfa, 1000 units	56,713	11.14	9.25	631,641	770,294	878,135	524,595	(353,540)
J1260	Dolasetron mesylate 10mg	9,700	3.79	6.76	36,763	44,833	51,110	65,572	14,462
J1566	IG lyophilized, 500mg	5,423	14.95	22.05	81,074	98,871	112,712	119,577	6,865
J3396	Verteorfin 0.1mg	7,660	7.50	8.89	57,418	70,022	79,825	68,097	(11,727)
J3487	Zoledronic acid 1mg	1,160	197.25	200.82	228,810	279,037	318,102	232,951	(85,151)
J7317	Sod.Hyaluronoate 20-25mg	795	91.04	112.04	72,377	88,264	100,621	89,072	(11,550)
J9035	Bevacizumab, 10mg	4,711	53.27	56.36	250,946	306,031	348,876	265,512	(83,364)
J9041	Bortezomib 0.1mg	4,836	35.83	29.81	173,290	211,329	240,915	144,161	(96,754)
J9055	Cetuximab, 10mg	2,760	46.49	49.39	128,307	156,472	178,378	136,316	(42,061)
J9170	Docetaxel 20mg	582	307.00	294.48	178,564	217,761	248,247	171,387	(76,860)
J9206	Irinotecan, 20mg	300	118.80	125.28	35,640	43,463	49,548	37,584	(11,964)
J9217	Lupron 7.5mg	1,876	156.67	242.99	293,907	358,423	408,602	455,849	47,247
J9263	Oxaliplatin, 0.5mg	8,000	8.41	8.47	67,280	82,049	93,536	67,760	(25,776)
J9305	Pemetrexed, 10mg	3,619	39.00	40.90	141,141	172,123	196,220	148,017	(48,203)
J9310	Rituximab, 100mg	466	440.00	465.23	205,040	250,049	285,056	216,797	(68,258)
					3,280,583	4,000,711	4,560,810	3,674,926	(885,884)

(1) Total direct costs are based on the pharmacy departments ratio of drug acquisition costs to total direct costs of 82%
(2) Total costs are based on the cost report indirect/step-down allocation of 14%.

The drugs listed in the table above constitute 71% of our total Medicare outpatient drug costs and 76.7% of the Medicare cost of separately payable drugs. To validate the non-drug cost allocations were reasonable, we calculated the percentage of total drug expense (all payers, inpatient and outpatient) that the drugs we analyzed above represented. The $3.3 million in acquisition costs of these drugs is 7.1% of our total drug acquisition costs through August 2006. The $1.3 million in non-drug expense allocated to these same drugs is 7.1% of the total non-drug expense allocated to pharmacy based on the 2005 cost report.

Even allowing for the fact it is possible that packaged drugs absorbed an inordinate amount of non-drug costs, given the CMS methodology, the small proportion of drugs that are packaged (8% of the total based on the HFHS utilization) could not materially

offset the losses for the separately paid drugs. Our overall negative margins in our oncology department support this contention.
Given MEDPAC's findings that non-drug expenses averaged 25% of direct costs, we would expect our losses of 20% on outpatient drugs is probably conservative. Since teaching hospitals tend to have oncology programs, and tend to administer high cost drugs at a higher rate than other hospitals, this may be one of the reasons teaching facilities have had a continually eroding outpatient margin under OPPS. We urge CMS to continue to analyze this issue to ensure equitable and fair payments for hospitals that provide expensive drugs.

Visits

CY 2007 Proposed Coding

The proposed interim reporting of "G" codes would cause hospitals significant problems for both non-Medicare patients and for cross-over claims. We strongly urge CMS to maintain the current reporting requirements until final guidelines are published. For those few providers that we suspect have a Type B emergency room, a modifier or distinct code could identify the ER type.

Coding Guidelines

Establishing and implementing national guidelines for outpatient E/M coding may be the most daunting task in the implementation of OPPS. We appreciate the caution and deliberation CMS has shown regarding this issue, which is of great concern to us.
We have reviewed the AHA/AHIMA guidelines and, with some refinements, believe that they can be applied without undue burden in the emergency department. However, we believe that, outside of the emergency room, CMS should allow for greater flexibility in how hospitals code E/M services. In particular, we believe that CMS should allow hospitals to use physician coding guidelines as the basis for determining the hospital E/M code for a given encounter.

We believe that the level of service as determined by the physician E/M coding guidelines is a valid proxy of hospital resource utilization. For instance, the greater the complexity of the patient, the longer the patient is utilizing a hospital examination room and other non-physician resources. Patients are considered to be of higher complexity under the physician E/M coding system if, for instance, the physician needs to complete a comprehensive history or a multisystem examination. These patients thus take longer to diagnose and treat than patients with mere problem focused histories and examinations. Similarly, the higher the complexity of the medical decision-making, the greater the likelihood that multiple diagnostic tests will be ordered or performed. Coordinating these tests and procedures is generally a function of the nursing staff. *See, e.g.*, 2006 CPT Manual (stating that the complexity of medical decision-making is measured in part by the "amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained reviewed, and analyzed.") These tests

consume hospital resources, and thus, to the extent that a physician codes a visit using a higher-level E/M code, the hospital's resource utilization is predictably intense.

Using physician coding guidelines as the basis for hospital coding also ensures that no undue documentation burdens are imposed upon hospitals. Much of the data that would be required under the AHA/AHIMA guidelines is typically not provided in the detail needed in standard medical record documentation. As a general principle, Medicare is supposed to use documents that are widely accepted as standard within the industry as the basis for determining the propriety of Medicare payments. 42 C.F.R. § 413.20(a). Yet, under the AHA/AHIMA guidelines, hospitals would need to maintain in their medical records copious information that has no relevance to the diagnosis or treatment of patients. Needless to say, this new mandate will divert hospital resources that could otherwise be employed in provision of patient care.

Using the physician E/M guidelines/coding to guide hospital coding also resolves CMS' program integrity concerns. Historically, CMS has taken issue with numerous proposed hospital E/M coding models because of the risk of upcoding. If CMS allows hospitals to rely on physician billing as the determinant for hospital billing for E/M services, CMS would effectively remove the possibility of hospital upcoding. The hospital simply would have no discretion in what code it uses, and therefore there would be no possibility that the coding system could be manipulated to the hospital's advantage.

Notably, allowing hospitals to use physician billing as the basis for billing hospital E/M services would also mitigate any concerns CMS has about the redistributive impact of a completely new system. CMS could readily determine what impact using such a system would have because physician claims data is readily available. CMS could thus model this data and price these services accordingly.

If CMS believes that the AHA/AHIMA guidelines have merit, notwithstanding the numerous flaws discussed in the OPPS NPRM, then CMS should consider offering hospitals the option to use either the AHA/AHIMA guidelines or physician E/M billing as the basis for hospital E/M billing. Each hospital could decide for itself which system will better reflect resource utilization at its institution. In any event, given the significance of the changes to be brought with the implementation of an E/M system, we very much support CMS' decision to give hospitals 12 months to implement the system CMS ultimately chooses.

We appreciate your review and consideration of our comments. Please do not hesitate to contact me if you should need further information. I can be reached at 313-874-9533 or via email, mwhitbr1@hfhs.org.

Sincerely,

Mary Whitbread
Vice President, Reimbursement and Contracting

Submitter : Mr. Kent Thiry **Date:** 10/10/2006

Organization : Kidney Care Partners

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-456-Attach-1.PDF

#1156

KIDNEY CARE
PARTNERS

October 10, 2006

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

Re: **CMS-1506-P:** Hospital Outpatient Prospective Payment System and CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program— HCAHPS® Survey, SCIP, and Mortality Proposed Rule

Dear Administrator McClellan,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[6] *Id.* at 1626.

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

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

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

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

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

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

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

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

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

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

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

IV. Conclusion

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

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

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

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Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

Submitter : Mr. David McClure **Date:** 10/10/2006

Organization : Tennessee Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-457-Attach-1.DOC

#457

October 10, 2006

Mark McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1506–P and CMS-4125-P
7500 Security Boulevard
Baltimore, MD 21244–1850

Ref: [CMS-1506-P and CMS-4125-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program – HCAHPS Survey, SCIP, and Mortality (71 Federal Register 49506), August 23, 2006.

Dear Dr. McClellan:

The Tennessee Hospital Association (THA), on behalf of our over 200 healthcare facilities, including hospitals, home care agencies, nursing homes, and health-related agencies and businesses, and over 2,000 employees of member healthcare institutions, such as administrators, board members, nurses and many other health professionals, appreciates the opportunity to submit comments on the proposed rule related to the Medicare Prospective Payment System (PPS) for outpatient services. Below are our comments, arranged by topic area.

The THA appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me or David McClure, vice president of finance, at (615) 256-8240 or dmcclure@tha.com.

Sincerely,

Craig Becker, FACHE
President

cc: Rick Pollack, AHA, Executive Vice President

Hospital Quality Data

CMS proposes to require compliance with the inpatient PPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program to receive a full payment update in the outpatient setting for calendar year (CY) 2007. Under the inpatient PPS, the annual payment update is linked to the collection of inpatient quality measures and hospitals that do not comply with the program requirements receive a reduction to the inpatient PPS update. The CMS proposal would reduce the outpatient PPS conversion factor update by 2% in CY 2007 for those hospitals that are required to report quality data under the inpatient PPS RHQDAPU program in order to receive the federal fiscal year (FFY) 2007 update, and fail to meet the requirements for receiving the full FFY 2007 inpatient PPS payment update.

CMS states in the proposed rule that the statute permits the Secretary to ". . . *establish, in a budget neutral manner, . adjustments as determined to be necessary to ensure equitable payments*" under the OPPS. CMS holds that the promotion of high quality care qualifies as an issue of payment equity. **THA believes that CMS exceeds its statutory authority in linking outpatient payments to inpatient quality submissions and requests that CMS withdraw the proposal.**

CMS should not attempt to link the outpatient update to either inpatient or outpatient quality measures without explicit legislative authority. The update has been linked to quality reporting for both the inpatient PPS and the home health PPS. However, in both cases the link was authorized by statute. This is a clear indication that Congress regards such policies as subject to determination by legislation and does not intend that such actions be undertaken administratively. **CMS should seek statutory authorization before proposing to extend the link between quality and payment updates to other settings.**

While we agree that the promotion of high quality care is an admirable goal, it is not a matter of payment equity. Moreover, the quality of outpatient care will not be improved by linking the outpatient update to the submission of inpatient data on quality measures that are designed for acute inpatient care. **CMS should not propose any outpatient reporting requirements until quality measures specific to outpatient services have been proposed and validated by the Hospital Quality Alliance and the Ambulatory Quality Alliance.**

Visits

Currently, hospitals are instructed to use the current procedural terminology (CPT) codes used by physicians to report clinic and emergency department (ED) visits and critical care services on claims paid under the OPPS. However, CMS realizes that the CPT Evaluation and Management (E/M) codes reflect the activities of physicians but do not describe the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters. In addition, there is no national policy to determine the assignment of E/M codes and hospitals are instructed to develop internal hospital guidelines to determine what level of visit should be reported for each patient.

CMS proposes to replace the current E/M codes with new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. In response to concerns about implementing code definitions without national guidelines, CMS specified in an earlier outpatient PPS rule that they would not create new codes to replace the existing E/M codes until national guidelines were developed. However, in this proposal CMS states that while they do not yet have a formal set of national guidelines to report different levels of hospital clinic and emergency department visit and to report critical care services, they *"have made significant progress in developing potential guidelines and, therefore, are proposing for CY 2007 the establishment of HCPCS codes to describe hospital clinic and emergency department visits and critical care services. Prior to our implementation of national guidelines for the new hospital visit HCPCS codes, we are proposing that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with these codes."*

Implementation of new codes in CY 2007 without implementation of national guidelines will require hospitals to evaluate their current internal guidelines and revise them to be consistent with the new codes. Then, when national guidelines are implemented in a subsequent year, hospitals may again need to revise their coding procedures. This will cause an unnecessary burden and possible confusion for hospitals. **THA joins the American Hospital Association (AHA) in opposing the proposed creation of temporary level II G-codes while continuing to allow hospitals to apply their own internal guidelines to these codes. Instead, CMS should defer creation of new evaluation and management codes until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and published.**

OPPS: RURAL SCH PAYMENTS

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that CMS conduct a study to determine if the cost of providing outpatient care in rural hospitals exceeded that of urban hospitals. The CMS analysis showed that rural Sole Community Hospitals (SCH) demonstrated significantly higher cost per unit than urban hospitals. CMS stated that its analysis showed that other rural hospitals did show some levels of higher cost per unit; however, CMS did not believe it was significant enough to justify an adjustment for other rural hospitals. Therefore, in CY 2006 provided an adjustment of 7.1% for SCHs but provided no adjustment for other rural hospitals. CMS proposes to continue this policy in CY 2007.

The MMA mandated report was intended to coincide with the scheduled expiration of hold-harmless payments for small rural hospitals on December 31, 2005. The payments were subsequently extended through December 31, 2008 with a gradual phase-down of the payment amount.

THA supports the continuation of the 7.1% adjustment for rural SCHs. However, given the phase-down and eventual elimination of rural hold-harmless payments, we urge CMS to revisit their analysis of the cost of providing outpatient care in rural hospitals and to propose an adjustment for other rural hospitals in CY 2008 or CY 2009 if justified by the analysis.

CAHs: Emergency Medical Screening

CMS proposes to revise the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel for emergency medical screenings. **THA supports this proposal which will provide CAHs with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services.**

APC RELATIVE WEIGHTS

Proposed Recalibration of APC Relative Weights for 2007. Current law requires CMS to review and revise the relative payment weights for APCs at least annually. The THA continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates, as this information more accurately reflects the costs hospitals incur to provide outpatient services. Since the August 2000 implementation of the outpatient PPS, payment rates for

specific APCs have fluctuated dramatically. For 2007, the proposed rates continue to show significant volatility.

In the proposed rule, CMS uses the most recent claims data for outpatient services to set the 2007 weights and rates. The THA continues to support the use of the most recent claims and cost report data to set the 2007 payment weights and rates. We also continue to support the use of multi-procedure claims, as we believe these data improve hospital cost estimates. The THA also supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures.

Proposed Changes to Packaged Services. The THA commends CMS and the APC Packaging Subcommittee for continuing to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. In the rare circumstances in which a hospital provides services described by these "N" status codes alone, there is no way for the hospital to be reimbursed for the cost of providing these services.

The THA supports the proposed designation of specific CPT codes as "special packaged codes" with status indicator "Q" that will be used for separate payment of these services when they are billed on a date of service without any other separately payable outpatient PPS service. We encourage CMS to continue to work with the APC Packaging Subcommittee to further review "N" status codes and identify those services that should be paid separately.

PARTIAL HOSPITALIZATION

The THA is concerned that an additional proposed 15 percent reduction in the per-diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services and could endanger Medicare beneficiary access to them. This will be the second consecutive year that the per-diem rate was reduced by 15 percent. Hospitals cannot sustain further reductions in the per-diem rates. These services are quite vulnerable, with many programs in recent years closing or limiting the number of patients they accept.

We share CMS' concern about the volatility of the community mental health center (CMHC) data and support the agency's intent to monitor and work with CMHCs to improve their reporting.

The THA recognizes that CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived

from using the combined hospital-based and CMHC median per-diem cost; however, hospitals offering partial hospitalization services should not be penalized for the instability in data reporting of CMHC-based services.

The THA recommends that in the final rule for 2007, CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

OPPS: Rural Hospital Hold Harmless Transitional Payments

The THA is concerned about the impact that the phase-out of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. The THA supports S. 3606, *Save Our Safety (SOS) Net Act of 2006*, which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, CMS proposes to raise the fixed-dollar threshold to $1,875 – $625 more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment amount and at least $1,875 more than the APC payment amount.

We are concerned that CMS has set the threshold for outliers too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the THA is concerned that Medicare may not spend the targeted outlier pool.

New Technology APCs

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. CMS generally retains a service within a new technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, CMS proposes to

assign some services that have been paid under the new technology APCs for less than two years to clinically appropriate APCs. For example, positron emission tomography (PET)/computed tomography (CT) scans, which had been assigned to new technology APC 1514 in 2005, is scheduled to move to a clinical APC in 2007. Some hospitals that adopt these new technologies may be unable to quickly change their charge masters, including changing codes and setting charges that reflect actual costs of the new service. Additionally, the data that CMS obtains in the first year or two of adoption of these technologies may not appropriately reflect the use and cost of these services because diffusion of new technologies can be slow, and waiting additional years for more hospitals to adopt and use new technology is important. **Therefore, the THA recommends that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.**

RADIOLOGY PROCEDURES

In the proposed rule, CMS indicates that it will continue to defer the implementation of a multiple imaging procedure payment reduction policy pending further analyses. **The THA supports CMS' decision not to implement this policy.** As we commented last year, the THA opposes this policy without better justification and more substantial hospital-based data analyses. Hospital cost data currently reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures.

In the proposed rule CMS requests comments on ways that hospitals can uniformly and consistently report charges and costs related to all cost centers that also acknowledge the tradeoff between a greater precision in developing CCRs and the administrative burden associated with reduced flexibility in hospital accounting practices.

The THA appreciates CMS' evenhanded presentation of this issue in the proposed rule. As CMS notes, any step taken to ensure greater uniformity in the reporting of costs and charges would have to carefully balance the additional administrative burden and loss of flexibility in a hospital's accounting system.

The difficulty in applying CCR ratios to arrive at cost is that it presupposes that there is consistency in how HCPCS procedure codes relate to the service categories indicated on the cost report. The cost report relies on service categories that reflect the general descriptor of a provider's service departments. But other departments can now safely and effectively perform services that were once performed by a specialized departmental unit. For instance, bedside lab tests are now performed in the ED; procedures can be furnished in an operating room, treatment room, or outpatient surgery area; and supplies cross multiple

departments. Consequently, inconsistencies occur when determining the cost of a service if the CCR assignment is made to a different cost report service category.

CMS also must recognize the current limitations and inconsistencies in preparing the cost report. Today, providers must reconcile the Medicare Provider Statistical & Reimbursement reports to determine how FIs not only paid the claim but also how they recorded the units and revenue code assignment to the billed services. Often the FI makes changes that affect how the services and revenue matches are made. Such changes by the FI, however, fail to match the revenue as reported by the provider on the cost report.

The THA urges CMS to proceed with care in this area. Hospitals need the flexibility to set charges and allocate costs in a manner that makes the most sense for the particular mix of services it offers. In addition, even relatively small changes in practices and procedures need to take into account the varying levels of sophistication of provider accounting systems. CMS must allow adequate time for dissemination of changes, and provider education on any changes is imperative.

DEVICE-DEPENDENT APC

Devices Replaced without Cost or with Credit to the Hospital. CMS proposes to reduce the APC payment and beneficiary co-payment for selected APCs when an implanted device is replaced without cost to the hospital or with full credit for the removed device. This is in response to device recalls and field actions involving the failure of implantable devices for which manufacturers offer to replace devices without cost to the hospital or to offer credit for the device being replaced if the patient requires a more expensive one. CMS proposes to calculate the reduction to the APC payment rate using the same method it uses to calculate the pass-through rate for implanted pass-through devices. The adjustment would be implemented through the use of an appropriate modifier specific to a device that has been replaced.

Neither the Medicare program nor Medicare beneficiaries should be required to pay hospitals for devices that were provided to the hospital at no cost. In addition, while there are additional burdens on hospitals associated with imposing this new policy, hospitals have been required since January 1 to use the FB modifier with the HCPCS code for a device that was furnished to the hospital without cost. Therefore, this is not an entirely new type of policy for hospitals. **The THA requests that CMS clarify whether and how this FB modifier would be used once the new policy goes into effect.**

Further, as CMS acknowledges in the proposed rule, the FB modifier may not be used appropriately if the replacement device is an upgrade from the device that is being removed from the patient. In any given recall, 10-20 percent of replaced devices could result in upgrades – the physician opts to use a higher functioning device over the one being replaced in order to meet the patient's current clinical needs. In these cases, the hospital would be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed. This price difference may be significant. For instance, in the case of implantable cardiac defibrillators, the hospital payment for the difference between the upgraded and replaced device could range between $1,000 and $7,000.

The THA recommends that CMS revise its proposal to account for the additional cost that the hospital would bear in the event of a device upgrade. This could be accomplished through the use of a second modifier or another approach to identify when the replacement procedure involves an upgraded device. The APC offset for an upgraded device replacement should be set at a lower percentage than the APC offset made for an "even" device replacement.

OPPS: NON PASS-THROUGH DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Packaging Threshold. Due to the expiration of the *Medicare Modernization Act's* (MMA) $50 drug packaging threshold, CMS evaluated four options related to drug packaging in the proposed rule: (1) pay all drugs separately; (2) set a high-dollar threshold; (3) continue the $50 threshold; or (4) update the current packaging threshold for inflation. CMS settled upon the fourth option, opting to establish a $55 packaging threshold for outpatient drugs.

Historically, the THA has supported more extensive packaging of drugs into the services with which they are provided because integrating these costs is a fundamental principle of a PPS, as opposed to a fee schedule. More packaging eliminates financial incentives to use the more costly drugs because they are paid separately. We also in the past have expressed concern about the coding burden related to keeping track of and educating coding staff on which drugs fall inside or outside of the packaging threshold.

However, this year we re-evaluated our rationale for supporting drug packaging and have determined that, for a variety of reasons listed below, eliminating the drug packaging threshold may pose less of a coding and financial burden than was previously the case.

- CMS has encouraged hospitals 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. Thus, for hospitals following this advice, revising payment policy to pay separately for all drugs with HCPCS codes would not pose an additional coding burden.

- Eliminating the packaging threshold for drugs also would eliminate the incentive for physicians and hospital staff to base drug choice on whether it is separately paid or not and focus exclusively on a drug's clinical value for the individual patient.

- Eliminating the threshold would provide equity across settings. It would make payment in the hospital outpatient department more consistent with payment in the physician office. In the past, CMS has expressed concern that inconsistencies in payment across care settings could inappropriately drive patient site of care. But this is precisely what could happen if CMS were to maintain a drug packaging threshold in hospital outpatient departments while at the same time paying for all drugs separately, and at a higher rate, in the physician office.

- The current drug administration codes do not allow additional payment for a second or subsequent intravenous (IV) push of the same drug. Under this policy, if a second or subsequent IV push involves a packaged drug, then not only is the drug administration not reimbursed, neither is the drug itself. If these drugs were separately paid, then the hospital could charge for the drug itself and be reimbursed.

Therefore, the THA recommends that CMS eliminate the drug packaging threshold for all drugs, biologicals and radiopharmaceuticals with HCPCS codes.

OPPS: NON PASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

The Medicare Modernization Act required that payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug for that year as determined by the Secretary of Health and Human Services (HHS), subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accounting Office (GAO). For CY 2006, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a rate based on the average sale price (ASP) plus 6%.

For CY 2007, CMS proposes to set payment for these drugs at the ASP plus 5%. CMS states that they believe that this payment level would serve as the best

proxy for the combined acquisition and overhead costs of separately payable drugs and biologicals in CY 2007.

The proposed payment reduction would result in hospital outpatient department rates that are less than the payment for the same drugs and biologicals provided in physician office settings where the rate would remain at ASP plus 6%. We believe that there is no justification for lower payments in hospital outpatient departments and **we recommend that CMS maintain the payment rates for separately paid drugs and biologicals at the rate of ASP plus 6% for CY 2007.**

Payment Policy for Radiopharmaceuticals. CMS proposes to no longer pay for radiopharmaceutical agents at the hospital charge reduced to cost and instead to pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. We believe the claims data still are incomplete and may be incorrect as a result of frequent code and descriptor changes for radiopharmaceuticals. **Therefore, the THA recommends that for 2007, CMS continue to use the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

DRUG ADMINISTRATION

In 2005, CMS transitioned from using daily per visit drug administration Q codes to CPT codes. In the 2006 final rule, CMS implemented 20 of the 33 new 2006 CPT codes for drug administration. The 13 CPT codes that were not implemented included concepts such as initial, subsequent and concurrent administration, which were operationally problematic for hospitals to report. CMS instead created six HCPCS C codes that generally paralleled the 2005 CPT codes for the same services.

While hospitals were grateful for CMS' responsiveness to their concerns regarding the operational difficulties of implementing the full range of 2005 CPT codes for drug administration services, they nevertheless had to implement these CPT codes for non-Medicare payers. As such, hospitals have had to overcome those operational challenges while implementing two sets of codes for reporting certain drug administration services, depending on the payer.

The THA recommends that in 2007, CMS implement the full set of CPT drug administration codes and eliminate the six HCPCS C codes created to parallel the 13 drug administration codes that were not implemented in

2006. This policy change eliminates the burden of having to apply and maintain two sets of codes for essentially the same services.

In addition, in 2005 and 2006, CMS provided special instructions to hospitals for the use of modifier 59 in order to ensure proper outpatient PPS payments, consistent with their claims processing logic. Since CMS did not expect any changes to coding structure for 2007 and because the agency has updated service-specific claims data from 2005, CMS no longer needs specific drug administration instructions regarding modifier 59. **The THA supports CMS' proposal that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other outpatient PPS services.**

CMS also proposes six new APCs in 2007 that are intended to better distinguish costs related to infusions of different types and furnished over different lengths of time. Previously, payment for additional hours of infusion has been packaged due to the inability to use claims data to distinguish costs associated with infusions of different duration. However, in 2005, codes used in the outpatient department distinguished between the first hour of infusion and additional hours of infusion. Using newly available 2005 claims data, CMS proposes to assign CPT/HCPCS codes to six new drug administration level APCs, with payment rates based on the median costs from this 2005 claims data. **The THA supports CMS' proposal to create six new drug administration APC levels which will provide more accurate payment for complex and lengthy drug administration services.**

In addition, as part of the implementation of new drug administration codes in 2006, CMS decided to no longer allow for the reporting of separate IV pushes of the same drug. This coding instruction created a situation in which no payment is made for packaged drugs that are given as separate IV pushes. The prime example is pain management where a patient may require multiple IV pushes of morphine, but only one drug administration code could be reported. Because morphine is a packaged drug, not only would the administration services involved in the subsequent IV pushes of morphine not be reimbursed, the drug itself would not be paid. We do not believe CMS' intent was to discontinue payment for this drug when it is medically necessary. **The THA recommends that CMS make payment for a second or subsequent IV push of the same drug** by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in 2007 so that an appropriate payment is made for this service.

Further, the THA also recommends that CMS allow providers to use all available HCPCS codes for reporting drugs to reduce the administrative burden associated with reporting drugs using only HCPCS codes with the lowest increments in their descriptors.

OPPS: Observation Services

For 2007, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The THA continues to support CMS' concept of allowing the Outpatient Claims Editor logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, now that the process for determining whether observation is separately payable is largely "automated," CMS should explore a narrow expansion in the diagnoses for which observation may be separately paid. **Therefore, the THA recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.** This is consistent with a recent recommendation from the Advisory Panel on APC Groups.

Proposed Procedures that will be Paid Only as Inpatient Procedures

CMS proposes to remove eight codes from the inpatient-only list, which identifies services that are ineligible for payment if they are performed in an outpatient setting, and assign them to clinically appropriate APCs.

The THA remains concerned about the inconsistency between Medicare payment policy for physicians and hospitals with regard to procedures on the inpatient-only list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient-only list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient-only list changes annually, physicians may not always be aware that a procedure they have scheduled in an outpatient department is on the inpatient-only list. There also may be other reasonable, but rare, clinical circumstances that may result in these procedures occurring in the absence of an inpatient admission.

The THA continues to recommend that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient-only list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical

condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

MEDICARE CONTRACTING REFORM MANDATE

In the rule, CMS proposes regulation changes required to implement the Medicare contracting reform provisions of the MMA. Hospitals will be integral customers of the Medicare Administrative Contractors (MACs), and a significant proportion of hospital revenue will depend on these contractors operating in a timely and judicious manner.

The MMA requires that the Secretary consult with providers on the MAC performance requirements and standards, and the THA appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the THA believes that such provider input is critical.

However, we encourage CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so low that they may be unable to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is used often to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

In addition, given that each defined Medicare A/B MAC jurisdiction will include several states, CMS must ensure that the chosen contractor is able to maintain a local presence. This includes the ability to work within different time zones, availability within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

CMS proposes to assign providers to the MAC that is contracted to administer the types of services billed by the provider within the geographic locale in which the provider is physically located. However, CMS also proposes to allow large national hospital chains that meet the agency's criteria as *"qualified chain providers"* to request an opportunity to consolidate their Medicare billing activities to the MAC with jurisdiction over the geographic locale in which the chain's home office is located. In addition, qualified chain providers that were formerly granted single FI status (prior to October 1, 2005) would not need to re-request such privileges at this time.

The THA is pleased that the proposed rule will allow chain-provider organizations to receive "single MAC" status. However, we also believe that there should be a mechanism for a chain provider with facilities in many A/B MAC jurisdictions to consolidate into a smaller number of MACs instead of a single MAC in the chain's home office location. This might apply to a chain provider that has its home office and several of its facilities within the same MAC jurisdiction but other facilities located in another MAC's jurisdiction. For a chain organization that includes multiple kinds of providers – hospitals, freestanding imaging centers, physician offices, etc. – there should be a mechanism to allow some facilities to stay with the MAC in their geographic locale while others migrate to the MAC of the chain's home office.

The THA also seeks clarification on how chain providers that currently report to a single intermediary will be managed in the coming stages of the MAC transition. If a chain hospital is in a jurisdiction that is transitioning to a MAC, but the chain's home office is not in that jurisdiction, may the chain hospital continue to report to the intermediary it has been using, or must it transition to the contracted MAC in its jurisdiction? The THA recommends that CMS expeditiously provide instructions on how a chain organization may convert to a single MAC to avoid the need for multiple transitions for chain hospitals.

HEALTH INFORMATION TECHNOLOGY

In the proposed rule, CMS repeats questions posed in the proposed inpatient PPS rule regarding:

- Its statutory authority to encourage adoption and use of information technology (IT);
- The appropriate role of IT in any value-based purchasing program; and
- The desirability of including use of certified health IT in hospital conditions of participation.

Health IT is a critical tool for improving the safety and quality of health care, and the THA's members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a shared investment between the providers and purchasers of care.

As summarized in the final inpatient PPS rule, most commenters, including the THA, noted that health IT is a costly tool, requiring both upfront and ongoing spending. While providers bear the burden of those costs, the financial benefits of having IT systems often flow to the payers and purchasers of care, including Medicare. **Given that they reap many of the financial benefits of IT, the THA**

believes that the payers and purchasers of care should share in its costs. An add-on payment to Medicare is one possible mechanism for doing so.

With regard to value-based purchasing, the THA believes that these programs should build on the consensus measures endorsed by the broad spectrum of organizations, including CMS, which participate in the HQA. In general, the HQA favors measures that address quality process and outcomes, rather than the tools used to get there. Health IT, however, can play a role in reducing the burden of quality reporting.

In the FY 2007 final inpatient PPS rule, CMS stated that it would not make use of certified, interoperable health IT a condition of participation in Medicare, but might revisit the issue in future rulemaking. **The THA opposes including health IT in the Medicare conditions of payment for hospitals.** The conditions of participation address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, current commercial health IT applications do not always meet hospitals' needs, and certification efforts are in their infancy. As noted in a recent report by the Agency for Healthcare Research and Quality (AHRQ), the evidence on health IT does not yet support this level of requirement. Imposing it would amount to an unfunded mandate.

TRANSPARENCY OF HEALTH CARE INFORMATION

Significant progress has been made in making quality information more transparent. The AHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with CMS and others to form the HQA. The work of the HQA has led to the voluntary reporting and sharing of 21 quality measures with the public on the *Hospital Compare* Web site, and more measures of hospital quality and patient satisfaction are planned for the future. This effort has been tremendously successful, with nearly all inpatient PPS hospitals voluntarily reporting quality information. Efforts to further expand public availability of hospital quality information must continue to be pursued through the HQA.

More can and should be done to explain pricing information to consumers clearly and consistently. Hospitals will work together to create common terms, definitions and explanations of complex pricing information. HHS should provide incentives to the states to improve transparency at the state and local level, and, through AHRQ, complete research on what consumers want and would use in purchasing health care services.

END OF COMMENTS

Submitter :

Date: 10/10/2006

Organization :

Category : Hospital

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

"see attached MUSC cost data"

CMS-1506-P-458-Attach-1.DOC

#458

MUSC
MEDICAL UNIVERSITY
OF SOUTH CAROLINA

Revenue Systems Department
1004 Harborview Towers
19 Hagood Avenue
Charleston, SC 29425

Placement of Mammosite® Breast Brachytherapy Catheters Cost Survey

Carol M. Bazell, M D., M.P.H.
Director – Outpatient Care Division
Centers for Medicare and Medicaid Services
Mail Stop: C4-05-07
7500 Security Blvd.
Baltimore, MD 21244

RE: Hospital Outpatient Valuation of Supply Items and other costs for:
Placement of Mammosite® Breast Brachytherapy Catheters for Interstitial Radioelement Application

Dear Dr. Bazell:

We respectfully request that the Centers for Medicare and Medicaid Services consider actual supply and other cost data in establishing the 2007 APC assignment for Placement of breast brachytherapy catheters for interstitial radioelement application (CPT codes 19296 and 19297). The cost data from our hospital outpatient department for this procedure is as follows:

Name of Hospital Medical University of South Carolina Medical Center

Provider Number # 420004

City/State Charleston, SC

Actual Costs of a Procedure

Equipment, clinical staff and Overhead Costs (ultrasound machine, surgical nurses, outpatient surgical suite, etc)	$ 4,213
Single-Use, Disposable Mammosite Catheter Placement Kit	$ 2,750
Number of Usages in a defined time period (12-month or 1 month or 1 invoice)	13
Did you receive a rebate that is tied to the purchase of these product (Yes or No)	No
When purchasing this product, did you reference a Group Purchasing Organization (GPO) contract price? If yes, enter "Y". If no, enter "N".	No

In addition we are in support of the APC Panel's recommendations specific to continuing use of the CY 2006 methodology of cost-to-charge for radiopharmaceuticals and brachytherapy sources for an additional year and urge CMS to adopt such recommendation

Reece A Smith

Director, Compliance and Revenue Systems

Date: 10-10-06

Submitter : **Dr. Dwight Reynolds** **Date: 10/10/2006**

Organization : **Heart Rhythm Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-459-Attach-1.DOC

#459

Heart Rhythm Society℠

October 10, 2006

Leslie Norwalk
Interim Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Ms. Norwalk:

The Heart Rhythm Society (HRS) welcomes the opportunity to comment on proposed rule CMS 1506-P entitled Medicare Program: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates published in the August 23, 2006 *Federal Register*.

HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Founded in 1979, HRS is the preeminent professional group representing more than 3,700 specialists in cardiac pacing and electrophysiology, known as electrophysiologists or heart rhythm specialists. HRS' members perform electrophysiology (EP) studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers and implantable cardioverter defibrillators (ICDs) in patients who have indications for these life-saving devices. After device implantation, heart rhythm specialists then monitor these patients and their implanted devices.

[illegible] | [illegible] | [illegible] | Phone 202.[illegible] | Fax 202.[illegible] | [illegible] | [illegible]

Heart Rhythm Society℠

Device-Dependent APCs

HRS appreciates CMS' efforts to ensure accurate and appropriate payment for replacement medical devices that are implanted at no or reduced cost to the hospital. However, we are concerned about the proposal to automatically reduce hospital payments for devices that have failed or have been recalled by their manufacturers. CMS is proposing that if a hospital receives a device that is replaced as a result of a warranty, field action, voluntary recall, involuntary recall, or is free of charge, the payment reduction would be triggered. In such cases, the reduced payment would cover only the procedural costs, not any device-related costs.

It is important to recognize that each device recall is a unique situation and should be reimbursed appropriately based on the costs that a hospital incurs. Therefore, HRS urges careful consideration of this issue as there needs to be acknowledgment that in many cases, the cost of replacing recalled devices is pro-rated. In these instances, hospitals have costs based on the device's service life as compared with its projected longevity. Therefore, there is a cost, albeit reduced, for hospitals. HRS supports calculating payments on a pro-rated basis to accurately account for costs. Additionally, many device manufacturers have warranty policies under which hospitals continue to bear some of the costs of recalled devices.

In the rule, CMS proposes usage of the –FB modifier to indicate a payment adjustment. However, the current descriptor for the –FB modifier is not appropriate to use in situations involving device upgrades. Therefore, HRS recommends creation of a new modifier to accurately account for all situations requiring a payment adjustment.

HRS supports appropriate payment for replacement devices and we urge CMS to work with us as well as with device manufacturers to address payment for devices that are no-cost as well as those that are full-cost and reduced-cost.

Device Performance

ICD and pacemaker device performance is a fundamental issue for the members of the Heart Rhythm Society. Our members are on the 'front lines' taking care of patient with these life-saving devices. Over the past year, the Heart Rhythm Society spearheaded a Task Force to establish recommendations to provide patients and physicians with clearer, timelier and more consistent information about device performance of pacemakers and ICDs. HRS released these recommendations to the public on September 28th and can be found at: http://www.hrsonline.org/uploadDocs/HRSTaskForceRecsFull.pdf

The recommendations offer specific guidance to physicians, industry, the Food and Drug Administration and Congress about performance issues and the critical role of post market

surveillance for implanted cardiac devices. The report calls for greater transparency in the post-market surveillance, analysis, reporting and communication of device information and recommends the following:

- The global scope of device performance issues requires enhanced cooperation among industry, physicians, government authorities (HHS, CMS, FDA, and AHRQ) and national health care systems to reduce the risk of injuries and deaths due to device malfunctions.

- The Heart Rhythm Society recommends that the National Cardiovascular Data Registry (NCDR) ICD Registry™, administered by the Heart Rhythm Society and the American College of Cardiology be modified to:
    - Collect detailed device-specific performance data including a report of device performance at the time of device replacement or death; and
    - Collect data regarding adverse device events, date of the event, and the outcome of the event or cause of each patient's death.

  This adjunctive information can assist in tracking device performance and the consequences of malfunctions. Implementation of this recommendation will require additional funding and resources from the federal government, private payers, device manufacturers, and hospitals.
- The use of standard definitions and terminology and the establishment of new systems to identify malfunctioning devices more quickly
- Standard industry notification and communication to physicians and patients from the manufacturer when a device malfunction is identified
- Post market surveillance needs to be prioritized by the FDA and recognized by Congress as needing more targeted resources
- Physicians are advised to return all devices to the manufacturer for analysis whether the replacement is routine or because of malfunction
- Physicians are urged to consider the risk of device removal and re-implantation when making clinical decisions regarding patients who may have a malfunctioning device. Consideration should be given to alternatives to re-implantation that may mitigate the consequences of device malfunction and decrease patient risk.

The recommendations have been officially endorsed by the American College of Cardiology Foundation and the American Heart Association.

The Heart Rhythm Society is committed to advocating for these changes as recommended in this Report. We look forward to working with CMS and our diverse partners throughout the next few months to initiate reforms that will, most importantly, increase patient safety and promote confidence in these life-saving devices.

HRS appreciates the recognition in the proposed rule of the American College of Cardiology – National Cardiovascular Data Registry (ACC-NCDR) for Implantable Cardioverter Defibrillators (ICD Registry™). However, HRS requests that in the future CMS accurately describe the ICD Registry™ as a partnership of the ACC and the Heart Rhythm Society. The Heart Rhythm Society is a partner of the ACC in the ICD Registry™ effort to collect data and maintain the ICD Registry™. HRS strongly believes that data from registries will help further the development of high quality, evidence-based clinical practice guidelines for the care of patients who may receive device-intensive procedures. Therefore, we request that CMS amend statements in the proposed rule to read as follows:

"Presently, the American College of Cardiology – National Cardiovascular Data Registry (ACC-NCDR) in partnership with the Heart Rhythm Society collects these data and maintains the registry."

HRS agrees with CMS' statement to "encourage the medical community to work to develop additional registries for implantable devices, so that timely and comprehensive information is available regarding devices, recipients of those devices, and their health status and outcomes." To that end, HRS currently spearheads the ICD Registry Working Group, which includes representatives from CMS, other government agencies, the ACC, other physician association groups, payers, and members-at-large to develop a new and separate longitudinal registry to focus on device firing therapy for a subset of patients in the ICD Registry™.

HRS appreciates CMS involvement on this new endeavor, which will inform clinical thinking on the long-term outcomes associated with ICD implants. We believe that data collected and analyzed through this effort has a direct connection with the Coverage With Evidence Development questions (i.e., "Group B" Questions). The importance of this effort is underscored by our recently released final "Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines." HRS submits these recommendations to CMS and requests the agency to consider them in their final rule-making.

HRS urges CMS to consider government funding sources to continue funding the existing ICD Registry™ and also provide financial resources to launch the longitudinal registry effort which has the potential to produce additional mechanisms for "early intervention to mitigate harm and improve the quality and efficiency of health care services." We believe that participants have funded registry participation through increased personnel and time to collect and submit data. We believe most participating hospitals are willing to submit data on all their ICD patients, instead of the minimum requirement of Medicare primary patient population as stated in the national coverage decision. To sustain this high level of participation over time, HRS believes that further funding for this necessary additional data collection should be funded by government sources as indicated in the recent Institute of Medicine's report on

Heart Rhythm Society℠

"Pathways to Quality Healthcare: Rewarding Provider Performance." Specifically, the Society supports the report's recommendation:

> "Recommendation 6: Because public reporting of performance measures should be an integral component of a pay-for-performance program for Medicare, the Secretary of DHHS should offer incentives to providers for the submission of performance data, and ensure that information pertaining to provider performance is transparent and made public in ways that are both meaningful and understandable to consumers."[1]

As discussed above, HRS supports efforts to address device performance issues and we look forward to continuing to work with CMS on these issues. As part of these efforts, HRS has been a partner in the ICD Registry™ and we encourage CMS to recognize our involvement in future publications.

HRS appreciates the opportunity to provide input on Medicare payment policy and thanks CMS for your consideration of our comments. We look forward to continuing to work together to maintain access to medical services for Medicare beneficiaries. If you have any questions about HRS' comments, please contact Allison Waxler, Director, Reimbursement and Regulatory Affairs, at awaxler@hrsonline.org or 202.464.3433.

Sincerely,

Dwight Reynolds, MD, FHRS
President
Heart Rhythm Society

[1] Institute of Medicine "Pathways to Quality Healthcare: Rewarding Provider Performance," p. 82

Submitter : **Dr. Lawrence Ross** **Date: 10/10/2006**

Organization : **American Urological Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1506-P-460-Attach-1.DOC

#460

American
Urological
Association

Headquarters

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www.UrologyHealth.org
www.urologichistory.museum

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1506-P**: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed changes for the 2007 Hospital Outpatient Prospective Payment System and for policies affecting ambulatory surgical centers (ASCs) for 2007.

I. HOSPITAL OUTPATIENT DEPARTMENT ISSUES

For the reasons listed below, the AUA supports the recommendation made by the Advisory Panel on Ambulatory Payment Classification (APC) Groups at its August 23-24, 2006 meeting that CMS continue using the current CY 2006 methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources for one year and urges CMS to adopt the Panel's recommendation.

Brachytherapy

The proposed rule would change the way brachytherapy devices are reimbursed by adopting prospectively-set average payment rates to replace the current cost-to-charge methodology used to calculate payment for brachytherapy sources. The CMS proposal is based on data that are inaccurate, outdated and insufficiently detailed.

The APC Advisory Panel based its recommendation that CMS continue to use the current payment methodology for brachytherapy sources based on concerns about the validity of the data that CMS is using to calculate prospective payments for brachytherapy devices. Also, on August 28, 2006, the Practicing Physicians Advisory Council (PPAC) recommended—also based on data concerns—that CMS abandon its proposed payment methodology for all brachytherapy devices under the hospital outpatient prospective payment system. Both advisory bodies felt that problems with CMS's brachytherapy device data were so significant that CMS should not proceed with its August 23, 2006 proposal and thus recommended continuation of the current "charges adjusted to cost" reimbursement methodology for **all** brachytherapy devices.

There is significant variability in the number, radioactive intensities and types (configurations) of brachytherapy devices needed to treat individual cancer patients. Given this unique patient-to-patient variability, the use of prospectively-set average reimbursement runs the risk of creating significant barriers to access for individual cancer patients and placing financial pressures on hospitals to take shortcuts in the use of brachytherapy devices. Maintaining patient access to brachytherapy is critical, given that in many instances brachytherapy devices provide the safest and most effective treatment for prostate and other forms of cancer.

Barriers to patient access are accentuated by the ongoing problems with CMS's data for brachytherapy devices. Further, CMS's codes for brachytherapy devices are not keeping pace with changes in clinical practice. Brachytherapy is a complex medical treatment that requires the implantation or application of devices that vary in numerous, clinically-important ways. These important clinical nuances must be factored into codes and payment to ensure that Medicare's policies reflect clinical treatment and patient access.

In 2003, Congress enacted Section 621(b) of the Medicare Modernization Act (MMA) to protect access to brachytherapy for a vulnerable patient population in the hospital outpatient setting. By enacting Section 621(b) in 2003, Congress established a plan designed to prevent the implementation of new pricing policies for prostate brachytherapy devices in the absence of credible data. Specifically, Section 621(b):

- Established permanent safeguards from bundling by prohibiting CMS from bundling payment for brachytherapy devices with the implantation procedures.

- Created safeguards by directing CMS to refrain from setting prospective average payment rates for brachytherapy devices (as CMS planned under its November 2003 final rule) at least until the end of 2006. Specifically, Congress directed CMS to reimburse hospitals for the cost of each brachytherapy device prescribed to treat each patient (calculated from each hospital's charges adjusted to costs) through December 31, 2006.

- Recognized the need for more accurate data and an in-depth analysis by directing the GAO to complete a study on brachytherapy devices no later than December 31, 2004.

Congress established the 2004 deadline for the GAO report to allow at least two years for Congress, CMS and the public to digest, debate and further analyze brachytherapy device reimbursement data and access issues before the sunset of the "charges adjusted to costs" reimbursement provision. Importantly, the two-year period established under the statute was not established only to facilitate CMS's review of the study

Unfortunately, the GAO failed to complete its study within the timeframe established by Congress, and in addition, the GAO report reflects fundamental flaws in its implementation. The GAO did not publish its report until July 25, 2006 – over 1½ years after the Congressional deadline. By publishing the study so late, the GAO effectively eliminated the two-year period established in the MMA for debate and consideration of the GAO report. In fact, CMS stated that there was insufficient time for CMS to review the GAO report before publishing the recent proposed rule.

The GAO concluded that CMS could set prospective payment rates for brachytherapy devices, but the GAO made this recommendation without reportable data about the types of devices used in clinical practice, without reportable data on the radioactive intensities of brachytherapy devices used in clinical practice and without consideration of the potential impacts on patient access. In fact, one of the striking features of the GAO report is the lack of data presented in the study.

There are significant concerns regarding the accuracy of hospital reported brachytherapy data on which CMS is basing the proposed payment for brachytherapy sources in 2007.
At the outset, one of the fundamental problems with CMS' current data for brachytherapy devices involves the lack of separate data reflecting the use of stranded Iodine-125 and stranded Palladium-103 in clinical practice. As Congress highlighted in the MMA, one critical step in resolving the data problems facing CMS in the area of brachytherapy devices is for CMS to use separate codes that reflect clinically-relevant distinctions among different types of brachytherapy devices. These codes should evolve over time.

However, CMS's current 2005 data do not reflect the important new clinical protocols that have emerged over the past few years resulting in increased clinical use of "stranded" and "custom-stranded" brachytherapy devices for the treatment of prostate cancer. As described above, the GAO noted that one brachytherapy professional society reported that stranded brachytherapy devices are "more costly but considered clinically advantageous."

II. PROPOSED POLICIES AFFECTING AMBULATORY SURGICAL CENTERS (ASCS) FOR CY 2007

CPT Code 57288

In July 2005, based on the recommendation of the AUA and other groups, CMS added CPT code 57288, *Sling operation for stress incontinence (eg, fascia or synthetic)* to the ASC list in payment group 5, which pays an ASC facility fee of $717. Since 2003, when we first requested that the sling procedure be added to the ASC list, we have sought to clarify whether the sling material can be reimbursed separately. The cost of the sling material varies from $700 to over $850 depending on the manufacturer and type of kit purchased, and the ASC facility fee for payment group 5 doesn't even cover the cost of the sling material. We contend that the sling material qualifies as a separately-payable implant under the ASC payment system rules and regulations. **However, if CMS considers the sling material to be bundled into the ASC facility fee for this procedure, then CPT code 57288 should be moved to payment group 9, which pays an ASC facility fee of $1,339 and would cover the cost of the sling material.**

CPT Code 57267

CPT Code 57267, *Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)*, a new code in 2005, was not proposed to be added to the approved list in 2007. CPT 57267 is equivalent in intent and function to CPT code 49568, *Implantation of mesh or other prosthesis for incisional or ventral hernia repair (List separately in addition to code for the incisional or ventral hernia repair)*, which is on the ASC list under payment group 7. Also, CPT code 57267 is an add-on code that is billed on conjunction with CPT codes 45560, 57240, 57250, 57260 and 57265, which are all on the ASC list of covered services. **Therefore, we request that CPT code 57267 be added to the 2007 approved ASC list.**

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross M.D.

Lawrence S. Ross, M.D.

President