ACADEMY OF MOLECULAR IMAGING
www.ami-imaging.org ami@mednet.ucla.edu

Box 951735
Los Angeles, CA
90095-1735
310.267.2614
Fax: 310.267.2617

September 19, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-1506-P, Hospital Outpatient Payment System and CY 2007 Payment Rates, published in the Federal Register on August 23, 2006. AMI is comprised of academicians, researchers and nuclear medicine providers utilizing positron emission tomography (PET) technology. AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, providers, and patients with regard to this lifesaving technology, and has worked closely with CMS over the past two years to increase beneficiary access to both standard PET and PET with computed tomography (PET/CT) through the development of the National Oncology PET Registry (NOPR).

Summary

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is premature and unsupported by reliable cost data. The proposed payment rate of $865 represents a decrease of over 30% from the 2006 rate; moreover, is far below the true costs of providing PET/CT, and fails to recognize either the unique clinical benefits of PET/CT or that PET/CT is associated with substantially higher costs than conventional PET. The proposed reassignment of PET/CT would seriously underpay hospitals, and risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

This comment focuses on two crucial points. First, PET/CT is a clinically distinct technology from conventional PET, and entails substantially higher capital, maintenance, and operational costs. Second, the CPT codes for PET/CT were only implemented for Medicare payment in April 2005. Because hospitals typically do not update their charge masters more than once every year, hospital claims data from the last nine months of 2005—the period cited by CMS as its evidentiary basis for the proposed rule—does not accurately reflect the true cost to hospitals of providing PET/CT. For these reasons, PET/CT should remain in New Technology APC 1514 (Level XIV) at a rate of $1,250 for one more year.

On August 23, 2006, the APC Advisory Panel heard presentations on PET/CT from CMS and from outside groups, including AMI. The APC Advisory Panel voted in favor of maintaining PET/CT in its current New Technology APC at a rate of $1,250. AMI supports the recommendation of the APC Advisory Panel. AMI has engaged in an extensive provider education effort with CMS as part of the implementation of the NOPR, and is committed to working with CMS to educate hospitals about PET/CT.

PET/CT Should Be Paid Under a Separate APC from PET

The proposed CY 2007 rule would assign conventional PET and PET/CT to the same APC classification for the first time. The assignment of PET and PET/CT to the same APC is inconsistent with Medicare regulations. As the proposed rule states, all of the items and services within a given APC group must be "comparable clinically and with respect to resource use." With regard to CMS's determination of a clinically appropriate APC, the agency has stated:

> After we gain information about actual hospital costs incurred to furnish a new technology service, *we will move it to a clinically-related APC group with comparable resource costs*. If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, we will create a separate APC for such service. (65 FR 18476, 18478 (April 7, 2000))

The combination of PET and CT into a single device, known as a PET/CT, represents a clinical breakthrough in imaging. The integration of the two scans provides the most complete non-invasive information available about cancer location and metabolism. PET/CT identifies and localizes tumors more accurately than either of the component images taken alone. In addition, PET/CT technicians can perform both scans without having to move the patient. The resulting images thus leave less room for error in interpretation.

The benefits of PET/CT to the patient are tremendous: **earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy**. A PET/CT image can distinguish between malignant and benign processes, and reveal tumors that may otherwise be obscured by the scars and swelling that result from

therapies such as surgery, radiation, and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor. For all of these reasons, PET/CT now represents the standard of care for most oncology patients.

FDA has consistently concluded in both premarket approvals and its regulations that PET/CT is a distinct medical device from PET. New PET/CT devices are specifically cleared by FDA for marketing under the 510(k) process on the basis of currently marketed (or predicate) PET/CT devices, not PET devices. Moreover, as we have explained, PET/CT is technologically and clinically unique and entails substantially higher capital, maintenance, and operational costs than conventional PET. Due to these highly relevant dissimilarities, PET/CT should not be assigned to the same APC as conventional PET.

Background on Medicare Payment for PET/CT

During the rulemaking process for the CY 2005 Hospital Outpatient Prospective Payment System, PET/CT was a new technology with no identifiable Medicare claims data. At the time CMS set payment rates for CY 2005, PET/CT did not have an established CPT code. In the final hospital outpatient rule, published on November 15, 2004, CMS referred to PET/CT in its comments, but did not set a payment rate. CMS stated in the final rule:

> The current G code descriptors do not describe PET/CT scan technology, and should not be reported to reflect the costs of a PET/CT scan. At present, we have decided not to recognize the CPT codes for PET/CT scans that the AMA intends to make effective January 1, 2005, because we believe the existing codes for billing a PET scan along with an appropriate CT scan, when provided, preserve the scope of coverage intent of the PET G-codes as well as allow for the continued tracking of the utilization of PET scans for various indications. (69 FR 65682, 65717 (November 15, 2004))

The American Medical Association (AMA) subsequently granted three new CPT codes (78814, 78815, and 78816) to describe PET with concurrent CT when it is used solely for attenuation correction and anatomical localization, rather than for diagnostic purposes. In March 2005, in the Hospital Outpatient Quarterly Update Transmittal 514, CMS assigned these three new codes to New Technology APC 1514, at a payment rate of $1,250. PET/CT remained in New Technology APC 1514, at a payment rate of $1,250, for CY 2006.

Medicare Claims Data Under-represents the Costs of Providing PET and PET/CT

In anticipation of the 2007 hospital outpatient rule, AMI contracted with a leading hospital network, Premier Inc., to collect external hospital cost data for PET and PET/CT. The Premier data obtained by AMI for conventional PET indicates an average cost to hospitals significantly higher than the proposed payment rate of $865. The 14 Premier hospitals that calculate costs according to the ratio-of-costs-to-charges (RCC) method reported an average cost for PET CPT 78812—the PET code most commonly paid by Medicare—of $1,336. The 19 Premier hospitals that use the relative value unit (RVU) method reported an average cost of $1,143.

The data for PET/CT showed improbably wide variation in hospitals' reported "average costs" of providing PET/CT, ranging from as low as $400 per scan to more than $2,400 per scan for PET/CT CPT 78815—the PET/CT CPT code most commonly paid by Medicare. The "average cost" of administering PET/CT also varied substantially depending on the method of cost accounting employed by the hospital. The reported average cost to RCC hospitals of $1147 is significantly higher than the proposed rate. The results of the Premier analysis are included with this comment as Attachment A.

AMI has asked Premier to audit the hospitals to determine the reason for the dramatic variability in reported costs. It is highly likely, however, that many hospitals have not yet properly updated their charge masters since the PET/CT CPT codes were introduced for Medicare payment in April 2005. Hospitals typically update their charge masters at most once per year, and sometimes less frequently than that. Contracts with private payers often limit a hospital's ability to change its charge master during a fiscal year. Accordingly, it is not uncommon for it to take two to three years after the implementation of a CPT code for a new technology until the new code is reflected in hospital costs data. Vanguard Health Systems testified at the August 23 APC Advisory Panel meeting that hospitals typically do not update charge masters for new technologies for two to three years. This is precisely the rationale behind the New Technology classification, which affords hospitals two to three years to obtain reliable cost data for new technologies. This fact strongly supports leaving PET/CT in New Technology APC 1514, with a payment rate of $1,250, for at least one more year.

Hospital Costs are Higher for PET/CT than for Conventional PET

The proposed rate reduction, and particularly CMS's intention to pay PET and PET/CT at the same rate, ignores the fact that it is significantly more expensive for hospitals to provide PET/CT services than conventional PET. AMI believes that the respective payment rates should reflect the relatively higher cost to hospitals of acquiring, maintaining, and operating a PET/CT scanner than a conventional PET scanner. AMI has undertaken a cost analysis of PET/CT using a published, peer-reviewed cost model.[1]

[1] *See* Keppler JS and Conti PS, A Cost Analysis of Positron Emission Tomography, Am. J. Radiology: 177, July 2001.

AMI contracted with Jennifer Keppler to develop an external analysis of the cost to hospitals of providing PET/CT. The study is based on fixed capital and operating costs, and incorporates national averages to account for scan volume. The study, which is included as Attachment B for your review, places the average cost of furnishing PET/CT at $1,368.

Hospitals incur significantly higher capital, maintenance, and operating costs with PET/CT than with conventional PET. The current price for a new PET/CT scanner is approximately $1.8 million, compared to $1 million for a conventional PET scanner. Further, a PET/CT scanner entails an annual maintenance cost of approximately $216,000, compared to $100,000 for a conventional PET scanner. Finally, the average salary for a technologist qualified to operate a PET/CT scanner is $70,000, compared to $45,000 for the operation of a conventional PET scanner.

In the final rule for CY 2006, CMS acknowledged that *"PET/CT scanners may be more costly to purchase and maintain that dedicated PET scanners,"* but suggested that *"a PET/CT scanner is versatile and may also be used to perform individual CT scans [in the event that] PET/CT scan demand is limited."* (70 Fed. Reg. 68516, 68581 (November 10, 2005)). The proposed rule for CY 2007 appears to reiterate a similar rationale when it attributes claims data suggesting an apparent similarity between the median cost of PET and PET/CT to the fact that *"many newer PET scanners also have the capability of rapidly acquiring CT images for attenuation correction and anatomical localization . . . ."* The implication appears to be that the high capital and maintenance costs associated with PET/CT scanners can be offset by their supplemental performance of CT-only scans.

However, CMS has provided no data on the actual utilization of PET/CT scanners to support this assertion. In fact, a survey of AMI member PET/CT providers indicates that a solid majority do not use their PET/CT scanners to provide CT-only scans. Keppler's cost analysis nevertheless assumes that each PET/CT scanner is used to perform an average of 4.5 stand-alone diagnostic CT scans per day. Even after incorporating this conservative assumption, Keppler calculated a cost estimate of $1,368 per PET/CT scan.

CMS Should Continue to Pay PET/CT In a New Technology APC in 2007

The New Technology APCs were created specifically because it takes several years for hospital charges to reflect the costs of new transformative products. CMS has stated that it expects to assign an item or service to a new technology APC for at least two years, or until the agency can obtain sufficient hospital claims data to justify reassigning the item or service to an existing APC. As we noted above, CMS first implemented New Technology APC 1514 for PET/CT in April 2005. CMS now proposes to reassign PET/CT from a new technology APC to an existing APC after only 21 months, based on the agency's analysis of Medicare claims data *from nine months in CY 2005.*

This proposal is at odds with the common hospital practice of updating their charge master once per year, if not less frequently. A hospital that updated its charge master at the end of CY 2005 would not have reported cost data specific to PET/CT until *after* the period on which CMS proposes to base the reassignment of PET/CT. The "close relationship between median costs of PET and PET/CT" that CMS discovered in the claims data of 362 providers reflects not the cost similarity between PET and PET/CT, but rather the fact that hospitals generally do not update their charge masters frequently enough to account for new CPT codes that are implemented mid-way through a calendar year. Nine months worth of cost data is not a sufficient basis for terminating a new technology classification.

As the proposed rule explains, CMS will "retain a service within a new technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group." The decision to remove PET from a new technology classification is based on a review of five years worth of claims data. By contrast, because the PET/CT CPT codes and payment rate were only implemented in April 2005, sufficient Medicare claims data for PET/CT is not yet available. In light of CMS's own new technology guidelines, both the newness of the PET/CT CPT codes and the absence of accurate and reliable claims data militate heavily in favor of maintaining PET/CT's new technology status for CY 2007.

Payment for Myocardial PET

Finally, AMI believes that CMS's proposal to assign HCPCS code 78492, for multiple myocardial PET scans, to the same APC as the HCPCS codes describing single myocardial PET will significantly underpay providers for multiple scanning procedures. Multiple scans require greater hospital resources, as well as longer scan times, than single scans. The current two-tiered APC structure, under which single and multiple scanning procedures are paid at $800.55 and $2,484.88, respectively, reflects this fact.

CMS speculates that, as myocardial PET scans "are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly." However, CMS provides no data to support this assertion. Further, the hospital claims data relied upon by CMS to justify consolidating single and multiple scanning procedures into one unified APC (APC 0307) with a payment rate of $721.26 show an improbably dramatic reduction over the course of a single year—CY 2005—in the cost to hospitals of providing multiple myocardial PET. Stakeholders and CMS require additional time to gather data and to study the reasons that the 2005 claims data shows such precipitous decline in hospital costs.

AMI appreciates the serious attention that CMS has afforded this important issue, and looks forward to working with the agency to ensure that Medicare beneficiaries retain access to this breakthrough technology.

Sincerely,

Johannes Czernin, M.D.
President
Academy of Molecular Imaging

Attachment A

PREMIER

Table 2: Average Cost and Charge by ROC Hospitals

Indication: Procedure Code 78812, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**765**	**100.00%**	**$1,336**	**$2,824**	**761**	**100.00%**	**$277**	**$662**
Number of Hospitals	14				13			
Hospital Detail								
HOSPITAL 613009	5	0.65%	$1,135	$3,975	5	0.66%	$127	$445
HOSPITAL 623328	30	3.92%	$1,568	$3,323	30	3.94%	$198	$420
HOSPITAL 623332	56	7.32%	$1,509	$3,323	54	7.10%	$193	$420
HOSPITAL 623333	101	13.20%	$1,890	$3,226	101	13.27%	$160	$494
HOSPITAL 623336	42	5.49%	$1,668	$3,323	42	5.52%	$211	$420
HOSPITAL AL0122	104	13.59%	$808	$2,535	104	13.67%	$242	$758
HOSPITAL IL2028	267	34.90%	$1,533	$2,501	267	35.09%	$364	$593
HOSPITAL MD0048	1	0.13%	$1,582	$2,065				
HOSPITAL MS0028	5	0.65%	$1,243	$3,323	4	0.53%	$156	$420
HOSPITAL MS0057	37	4.84%	$557	$3,184	37	4.86%	$105	$602
HOSPITAL OH2278	21	2.75%	$704	$3,292	21	2.76%	$419	$1,959
HOSPITAL PA2006	56	7.32%	$856	$1,820	56	7.36%	$311	$662
HOSPITAL VA0001	1	0.13%	$1,025	$3,115	1	0.13%	$207	$629
HOSPITAL WV0036	39	5.10%	$984	$3,786	39	5.12%	$383	$1,473

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges by EVU Hospitals

Indication: Procedure Code 78812, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**1,426**	**100.00%**	**$1,143**	**$3,502**	**1,340**	**100.00%**	**$236**	**$933**
Number of Hospitals	19				19			
Hospital Detail								
HOSPITAL 600501	2	0.14%	$392	$3,149	2	0.15%	$349	$822
HOSPITAL CA2011	8	0.56%	$348	$4,457	8	0.60%	$491	$1,681
HOSPITAL FL0287	101	7.08%	$732	$3,600	100	7.46%	$544	$1,147
HOSPITAL FL9120	173	12.13%	$2,214	$3,787	166	12.39%	$228	$1,147
HOSPITAL GA0126	124	8.70%	$1,103	$5,589	124	9.25%	$103	$525
HOSPITAL KS2072	141	9.89%	$915	$3,109	141	10.52%	$233	$791
HOSPITAL MO2190	1	0.07%	$1,178	$2,247	1	0.07%	$300	$600
HOSPITAL MT2001	8	0.56%	$1,290	$3,469	8	0.60%	$322	$867
HOSPITAL MT2003	85	5.96%	$1,503	$3,872	85	6.34%	$487	$802
HOSPITAL NC0153	1	0.07%	$2,026	$3,411	1	0.07%	$541	$910
HOSPITAL NC0302	1	0.07%	$1,544	$2,625	1	0.07%	$463	$788
HOSPITAL NE2001	16	1.12%	$992	$3,032	16	1.19%	$334	$1,021
HOSPITAL OH2004	192	13.46%	$2,444	$3,894	192	14.33%	$32	$1,306
HOSPITAL SC0053	106	7.43%	$1,695	$2,379	105	7.84%	$366	$564
HOSPITAL SC0074	1	0.07%	$367	$2,900	1	0.07%	$246	$1,034
HOSPITAL WI2004	6	0.42%	$1,115	$3,737	6	0.45%	$763	$761
HOSPITAL WI2007	4	0.28%	$490	$4,093	4	0.30%	$388	$693
HOSPITAL WI2033	1	0.07%	$1,426	$3,000	1	0.07%	$561	$641
HOSPITAL WV0013	455	31.91%	$189	$2,954	378	28.21%	$189	$895

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average cost and Charge by Rec Hospital

Indication: Procedure Code 78815, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET/CT SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**1,688**	**100.00%**	**$1,147**	**$3,248**	**1,315**	**100.00%**	**$211**	**$748**
Number of Hospitals	14				13			
Hospital Detail								
HOSPITAL 626723	133	7.88%	$726	$2,186	133	10.11%	$287	$863
HOSPITAL CO2087	365	21.62%	$2,321	$4,866				
HOSPITAL FL0091	93	5.51%	$771	$2,900	93	7.07%	$153	$577
HOSPITAL FL0161	322	19.08%	$699	$3,125	322	24.49%	$307	$1,375
HOSPITAL GA2039	2	0.12%	$1,792	$4,901	2	0.15%	$272	$745
HOSPITAL KY0106	74	4.38%	$1,029	$3,429	71	5.40%	$282	$939
HOSPITAL MS0052	3	0.18%	$1,366	$3,650	3	0.23%	$178	$475
HOSPITAL NC0001	379	22.45%	$690	$2,011	376	28.59%	$59	$171
HOSPITAL NE2008	28	1.66%	$1,393	$3,032	28	2.13%	$604	$1,021
HOSPITAL NE2033	1	0.06%	$700	$2,917	1	0.08%	$133	$556
HOSPITAL OH2017	25	1.48%	$720	$3,320	25	1.90%	$102	$416
HOSPITAL PA2006	10	0.59%	$834	$1,789	10	0.76%	$309	$662
HOSPITAL VA0001	222	13.15%	$1,171	$3,685	220	16.73%	$237	$744
HOSPITAL VA0095	31	1.84%	$831	$3,115	31	2.36%	$195	$706

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges by PET Hospital

Indication: Procedure Code 78815, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET/CT SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**3,607**	**100.00%**	**$846**	**$4,027**	**3,545**	**100.00%**	**$403**	**$769**
Number of Hospitals	23				23			
Hospital Detail								
HOSPITAL 600501	166	4.60%	$401	$3,155	166	4.68%	$347	$824
HOSPITAL 609531	61	1.69%	$1,024	$3,143	61	1.72%	$228	$625
HOSPITAL 620028	184	5.10%	$1,202	$6,064	177	4.99%	$198	$1,000
HOSPITAL AL0051	309	8.57%	$1,521	$2,884	309	8.72%	$512	$585
HOSPITAL CA2013	411	11.39%	$760	$4,426	406	11.45%	$382	$779
HOSPITAL FL0287	420	11.64%	$753	$3,800	412	11.62%	$545	$1,147
HOSPITAL GA0126	78	2.16%	$906	$4,493	74	2.09%	$103	$500
HOSPITAL GA0178	16	0.44%	$1,896	$3,946	16	0.45%	$433	$901
HOSPITAL KY0022	9	0.25%	$445	$2,127	9	0.25%	$138	$662
HOSPITAL MO2190	6	0.17%	$1,311	$2,247	6	0.17%	$300	$600
HOSPITAL NE2001	69	1.91%	$1,004	$3,032	69	1.95%	$338	$1,021
HOSPITAL OH2004	78	2.16%	$2,404	$3,894	78	2.20%	$32	$1,306
HOSPITAL SD2018	59	1.64%	$731	$2,377	59	1.66%	$296	$1,155
HOSPITAL TX0083	198	5.49%	$851	$3,916	198	5.59%	$846	$806
HOSPITAL TX0393	246	6.82%	$446	$4,379	208	5.87%	$33	$324
HOSPITAL VA0106	6	0.17%	$1,023	$5,182	6	0.17%	$1,023	$410
HOSPITAL VA0112	177	4.91%	$677	$5,182	177	4.99%	$215	$410
HOSPITAL VA2038	108	2.99%	$1,414	$5,182	108	3.05%	$222	$410
HOSPITAL WA2005	41	1.14%	$873	$3,497	41	1.16%	$873	$827
HOSPITAL WI2004	89	2.47%	$1,130	$3,734	89	2.51%	$756	$761
HOSPITAL WI2007	841	23.32%	$481	$4,093	841	23.72%	$388	$693
HOSPITAL WI2008	1	0.03%	$465	$4,093	1	0.03%	$388	$693
HOSPITAL WI2009	34	0.94%	$875	$3,221	34	0.96%	$90	$528

* Represents discharges with cost and charges > 0.

Attachment B

Cost Analysis of PET: Modification of Model for PET/CT

Jennifer S. Keppler

In 2001, a paper was published describing the results of a multi-year evaluation of the costs of providing PET services (*A Cost Analysis of Positron Emission Tomography, American Journal of Radiology: 177, July 2001* (Keppler JS and Conti PS), "Cost Model"). The publication was the result of a 3-year study funded under a *Cost-Effective Health Care Technologies* award by the National Science Foundation/Whitaker Foundation. The purpose of the study was to identify the cost of PET to providers using several different operating models. In the Cost Model, a one-way sensitivity analysis found that throughput, the number of scans/day, was found to be the most significant success factor.

Since the paper was published, the utilization of PET technology has evolved. Commercial providers for the F-18 FDG have penetrated nearly all of the major population centers in the US, obviating the need for cyclotron-based PET centers. Accurate data are now available to show the average number of scans performed per day, based on FDG sales. The most significant change to the field was the introduction of a new technology in 2000, the PET-CT scanner. This new device provides a significant advancement in imaging capabilities, as well as additional complexity in the operation. Nearly 100% of all devices sold currently that image PET isotopes are PET/CT scanners.

To account for this changing environment, the authors have modified the original cost model for PET to the new technology of PET/CT. Outlined below (in **Tables 1, 2, and 3**)are the key assumptions that were changed, as well as the results of the addendum to the cost analysis.

Table 1: Model General Assumptions

Parameter	Previous value	New value	Source of new value
Number of PET/CT scans per day	2.9 PET scans/day	3.8 PET-CT scans/day	Bio-Tech Systems Industry report, 2006; AMI 2005
Stand alone diagnostic CT scans on patients not having a PET scan	None	Average 4.5 diagnostic CT scans billed per day	AMI Survey: 30% of sites perform 8 additional CT scans /day (not on PET pts)
CT scan revenues to offset costs	None	Average $280 payment/CT scan for total of ~$300,000 add'l revenues	50:50 blend of Thorax CT w/ contrast and w:w/o contrast (APC 283 and 333)
Professional Component	PC included in the total "cost" in the study	Reduce costs $128	CMS PFS payment is $128 (APC1514 in 2006)
FDG	FDG included in the total "cost" in the study	$ -	Eliminate cost of FDG because paid separately

Table 2: Capital Costs

Parameter	Previous value	New value	Source of new value
Scanner purchase price	$1,000,000	$1,800,000	NEMA

Table 3: Operating Costs

Parameter	Previous value	New value	Source of new value
Technologist Salary	$45,000/year	$69,837/year*	Avg of 2004 NMT estimates by AMA & ASRT, increased 8.5% for "PET" (which was the 2001 NMT:PET differential by NMTCB survey)
Service Contract	10% of scanner purchase price	12% of scanner purchase price = $216,000/yr	Informal survey of RBMA members indicate CT, and PET-CT service higher (range 12 – 20%)
Sealed Source	$15,000	$ -	Not needed: CT used for attenuation correction

* Corroborated by PET-CT job advertisements on the web: Baton Rouge, LA = $56 – 83K; NY $55 – 85K; CA $66 – 94K

Results:

Incorporating these new assumptions adequately and conservatively address the change in the technology from PET to PET/CT. Survey data from professional associations, as well as other published data were utilized to assure that the assumptions were appropriate.

Table 4 shows the average cost for a PET/CT scan, less the payment for FDG and professional component.

Table4: Cost of the PET/CT scan

All costs (including TC, PC, Rx)	**$1,717**
Minus FDG	$ 221
Minus MD paymt	$ 128
PET-CT cost	**$1,368**

Notably, since the average number of scans performed by a site per day has increased, the overall average cost per scan is less. At current levels of utilization, taking into account use for CT scans only, the cost of a PET-CT scan is $1,368.

Organogenesis Inc.
LIVING TECHNOLOGY

150 Dan Road, Canton MA 02021

September 13, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule; Skin Replacement Surgery and Skin Substitutes

Dear Administrator McClellan:

Organogenesis, Inc. appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year (CY) 2007. Our comment addresses the section of the proposed rule concerning Skin Replacement Surgery and Skin Substitutes. Organogenesis is a biotechnology company based in Canton, Massachusetts, that manufacturers and markets Apligraf® (J7340), a unique human skin substitute for diabetics and others who suffer from chronic ulcers. As set forth below, Organogenesis supports the Centers for Medicare and Medicare Services' (CMS) proposal to assign the new CPT codes for the application of Apligraf to APC 25, thus correcting the substantial reduction effected by the final hospital outpatient rule for CY 2006. This proposal reflects the work that is billed under the new skin substitute codes assigned by the American Medical Association (AMA) CPT Editorial Panel in 2005. Organogenesis will continue to work with the AMA CPT Editorial Panel and other professional societies on the new skin substitute CPT codes.

Background

Organogenesis filed a comment letter on January 3, 2006, addressing CMS's assignment of the new CPT codes in the final rule on November 1, 2005.

The publication of the final rule was the first time that Organogenesis learned either of the new CPT codes or their APC assignment. Organogenesis met with CMS on February 6, 2006 to discuss the assignment of the new CPT codes. Organogenesis also attended the March APC Advisory Panel discussion on skin substitutes, at which Dr. Robert Kirsner of the University of Miami presented on the application on Apligraf. Organogenesis again met with CMS on June 8, 2006 to discuss payment for application of skin substitutes, in anticipation of the proposed rule for CY 2007. We appreciate CMS' attention to this issue and willingness to meet over the past year.

Apligraf is a Medically Necessary Cost-Saving Product

Apligraf is a unique, bioengineered, cell-based human skin substitute for the treatment of chronic, hard-to-heal venous leg ulcers and diabetic foot ulcers. Like human skin, it is comprised of two layers, a dermis and an epidermis, consisting of living, functioning, responsive cells that stimulate the would to heal. The incidence of chronic wounds in the United States is approximately 5 to 7 million per year, with an annual management cost in excess of $20 billion.

Apligraf is the only active wound-healing product that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of venous leg ulcers, in addition to diabetic ulcers. Before Apligraf was available, physicians had few treatment options for hard-to-heal venous ulcers. Apligraf has preserved and improved the qualify of life of tens of thousands of diabetics and other elderly patients suffering from chronic leg and foot ulcers. Many of those patients would have had to undergo limb amputations without the benefit of Apligraf.

Apligraf and similar advanced bioactive products have been specified by leading clinicians in published algorithms as the standard of care for wounds that have not responded to conventional therapy. Apligraf is a proven cost-effective therapy for chronic foot ulcers, providing savings in wound care costs averaging $7,500 per patient.

New CPT Codes for the Application of Apligraf

Prior to November 2005, Apligraf was billed under CPT codes 15342 and 15343. When clinically appropriate, physicians could additionally bill code 15000 for wound bed creation and site preparation. CPT codes 15342 and 15343 were assigned to APC 24 (Level I Skin Repair). CPT code 15000 was assigned to APC 25 (Level II Skin Repair). In November, 2005, the AMA discontinued codes 15342 and 15343, and created two new CPT codes—15340 (*Tissue cultured allogeneic skin substitute, first 25 sq cm or less*) and 15341 (*Tissue cultured allogeneic skin substitute, each additional sq cm*)—to describe the work formerly billed under codes 15342 and 15343.

The new codes additionally included the work formerly billed under CPT 15000. The AMA CPT Editorial Panel thus stated in its coding manual, published *after* the release of the final hospital outpatient rule for CY 2006, that the new codes 15340 and 15341 could not be billed in conjunction with code 15000. Notwithstanding this expansion of the scope of work covered by the two new codes, the Final Rule for CY 2006 used the claims data for the old codes (15342 and 15343) to assign the new codes (15340 and 15341) to APC 0024. In other words, CMS inadvertently crosswalked the old CPT codes to the new CPT codes, without accounting for the fact that the work previously billed under CPT 15000 had been added to the new CPT codes. As a result, total hospital payment for the application of Apligraf decreased from approximately $370.73 in 2005, to $138.48 in 2006 as illustrated by the following chart.

2005	15000 15342 15343	APC 25 - $269.62 APC 24 - $101.10 /2 = $50.55 APC 24 - $101.10 /2 = $50.55 **Total: $370.72**
2006	15000 15340 15341	Not billable APC 24 - $92.32 APC 24 - $92.32 /2 = $46.16 **Total: $138.48**

APC Advisory Panel Recommendations

At the March, 2006 meeting of the APC Advisory Panel, the Panel heard testimony from skin replacement experts and hospital administrators on the assignment of CPT codes for skin replacement and skin substitute procedures. Multiple presenters argued to the Panel that the codes for the first increment of body surface area, including CPT 15340, should be assigned to APC 0027 (Level VI Skin Repair), on the ground that such codes are similar to CPT code 15300 (Allograft skin for temporary would closure, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children). Accordingly, the Advisory Panel recommended that CMS assign CPT 15340 to APC 0027, and CPT 15341 to APC 0025.

In the proposed rule, however, CMS disagrees with Advisory Panel presenters that the clinical and hospital resource characteristics of CPT code 15300 were appropriately placed in APC 0027. On that basis, the proposed rule rejects the APC Advisory Panel recommendation that CPT 15340 be assigned to APC 0027.

Skin Substitute Products in 2007

The proposed rule for CY 2007 would correct the substantial reduction in payment for Apligraf effected by the CY 2006 final rule, by assigning the CPT codes for "tissue cultured allogeneic skin substitute" to APC 0025. Organogenesis believes that this proposal represents a significant step toward ensuring that hospitals are appropriately reimbursed for Apligraf, and thus ensuring that Medicare beneficiaries suffering from chronic, hard-to-heal wounds have access to this vital treatment.

Moreover, external analysis of Medicare claims data strongly supports this adjustment. At the request of Organogenesis, the Moran Company compared charges for CPT code 15000 and the old CPT codes 15342 and 15343 to median charges for APCs 0024, 0025, and 0027. The Moran analysis demonstrated that the charges for the new codes would correspond to the upper end of the charges for APC 0025 and the lower end of charges for APC 0027. The full Moran analysis is included with this comment for your review. The below chart shows the median costs of Apligraf compared to the APC 24, 25 and 27.

24	$92.32	492,617	$167.24	$92.22
25	$315.74	30,696	$560.22	$315.37
27	$1,082.84	65,631	$1,187.19	$1081.66

Organogenesis is committed to working with professional societies and CMS to ensure proper coding and payment for all skin substitutes. Organogenesis thanks CMS for its close attention to this important issue, and looks forward to working closely with the agency to ensure that Medicare beneficiaries suffering from chronic, hard-to-heal wounds have access to the best therapy available.

Sincerely,

Geoff MacKay
President & CEO

1655 N. FORT MYER DRIVE, SUITE 1250 ARLINGTON, VA 22209 (703) 465-9970 FAX (703) 465-9969

Memorandum April 27, 2006

TO: Antonio S. Montecalvo, Organogenesis Inc.

FROM: Mary Jo Braid-Forbes, The Moran Company

SUBJECT: Recalculating median costs of application codes

Two new skin substitute application CPT® codes (15340 for the first 25 sq cm and 15341 for each additional 25 sq cm) replaced 15342 and 15343 effective January 2006. Unlike their predecessor codes these new codes include preparation of the site and do not allow the concurrent billing of CPT® code 15000 for preparation of the wound site. The final 2006 Hospital Outpatient Prospective Payment System (OPPS) payment rates for the new skin substitute application codes do not fully account for this change in code definition. This memorandum describes the payment rate changes from 2005 to 2006 and presents the results of an analysis of an alternative methodology for calculating the median costs of the codes for CPT® code 15340, application of bilaminate skin substitute/neodermis, 25 sq cm, formerly 15342. We also describe the median costs of the three relevant APCs (0024, 0025, and 0027).

Findings:

- We calculated the median cost of 15342 in a manner consistent with the CMS methodology that also takes into consideration the change in the code definition which incorporates 15000. We found a median cost of ***$439.68***, 123 percent greater than the median cost we calculated without incorporating 15000. Incorporating 15000 as a packaged item on these claims also resulted in 30 percent more 'single' claims being used. If we restrict these claims further to only claims that always have both 15342 and 15000 the median cost is ***$555.31***.
- CMS used less than half of the occurrences of 15342 to calculate the median cost. Our calculations under the revised methodology (claims with 15342 which may or may not have 15000) use 60 percent.
- The median cost we calculated under the revised methodology is higher than the median cost CMS reports for APC 0024 and 0025, but lower than the median cost reported for APC 0027.

Background

The following codes are discussed below:

- 15000 Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues); first 100 sq cm or once percent of body area of infants and children
- 15342 Application of bilaminate skin substitute/neodermis; 25 sq cm
- 15343 each additional 25 sq cm

Two new application codes (15340 and 15341) replaced 15342 and 15343 effective January 2006. Unlike their predecessor codes these new codes do not allow the concurrent billing of 15000 (APC 0025). CMS in the final 2006 rule kept these new codes in APC 0024 with payment rates of $ 92.32. These payment rates are slightly below the prior year payment rates of $101.10 (APC 0024) for 15342 and 15343. However, the new codes include the preparation of the wound site which formerly could be billed under 15000. So the payment for the procedure as a whole was cut due to the change in the meaning of the CPT codes that was not taken into consideration by CMS in setting the payment rate. In 2006 15000 is paid at $315.71. All of these codes have a status indicator of 'T' so a 50% multiple procedure reduction applies. Table 1 below summarizes the payment for the procedure in 2005 and 2006.

Table 1: Summary of payment changes in 2006

	2005	2006	% change
15000	$269.62	NA	
15342/15340	$101.10/2=$50.55	$92.32	
15343/15341	$101.10/2=$50.55	$92.32/2=$46.16	
Total procedure 25cm or less	$320.17	$92.32	-71%
Total procedure greater than 25 cm	$370.72	$138.48	-63%

Replicate the CMS "single bill" methodology to identify the claims that were used to set the payment rates.

CMS uses a methodology to identify "single bill" claims that they use in rate-setting. The median cost of these single bill claims (including packaged items) is used to calculate a relative weight. We can replicate the CMS median cost to with 5 percent. Table 2 below shows the results of our replication of the CMS single bill and median cost methodology.

Table 2: Replication of CMS single and median cost calculations, 2006 final rule (2004 data)

	TMC Single Count	CMS Single Count	Percent Difference	TMC Median	CMS Median	Percent Difference
15000	5,262	4,797	9.7%	$ 316.85	$ 334.10	-5.2%
15342	7,749	7,480	3.6%	$ 196.91	$ 188.39	4.5%
15343	674	679	-0.7%	$ 137.14	$ 133.34	2.8%

Determine what percentage of the total claims available is used by CMS for rates-setting.

CMS uses only claims that are determined to be 'single procedure' claims. Single procedure claims under this definition include both claims that have only one payable procedure on the claim and 'psuedo singles' that CMS creates by breaking apart claims that have multiple procedures. Even after the creation of 'pseudo singles' there are claims that remain that CMS does not use for the median cost and weight calculations. CMS used only about a quarter of all

the occurrences of 15000 for the median cost calculation and less than half of the occurrences of 15342. See Table 3.

Table 3: CMS singles as a percent of total, 2006 final rule (2004 data)

	Total	CMS Single Count	Singles % of Total
15000	17,896	4,797	26.8%
15342	16,655	7,480	44.9%
15343	2,410	679	28.2%

Calculate a new median cost for 15342 simulating both the new definition of the code (including 15000) and using the CMS methodology.

We simulated a new median cost for 15342 in two ways. First, we applied CMS's single/multiple claim logic to the 15342 claims but changed the definition of 15000 on these claims to be a packaged service rather than a separately payable service. This resulted in 30 percent more single claims. We then calculated the median cost of these claims including the costs associated with 15000. We calculated a median cost of $439.68, which is 123 percent greater than the median cost we calculated in our replication of the CMS medians without packaging 15000. Second, we created a subset of these single claims including only those with both 15342 and 15000. The subset included 58 percent of the claims in the first simulation and these claims had a median cost of $555.31.

Table 4: Simulation of median cost using new definition of the code using 2004 data used for the 2006 final rule

	Simulation Single Count	Percent Difference	Simulation Median	Percent Difference
15342 and 15000 packaged	10,053	29.7%	$ 439.68	123%
15342 AND 15000 on claim and 15000 packaged	5,890	-24.9%	$ 555.31	182%

Investigate APC medians that correspond to the median cost calculated under the revised methodology

In the 2006 final rule the 15340 and 15341 were kept in the same APC as their predecessor codes (APC 0024). The "true" median cost for APC 0024 as reported by CMS is $92.22. The median costs we calculated for 15340 code incorporating the revision to the code definition is at least $439.68 and as high as $555.31, depending on whether 15000 is required to be on the claims used in the median calculation. These revised median costs are much higher than the median cost of APC 0024 and even higher than the $315.37 median cost of APC 0025. However, it is

much lower than CMS's reported median cost of $1,081.66 for APC 0027. Table 5 below shows the CMS reported final rule median costs for these APCs.

Table 5: CMS 2006 final rule APC medians for APC 0024, 0025 and 0027

APC	Payment	"Single Frequency"	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CMS Adjusted Median of Total Cost	CV
0024	92.32	492617	2.24	7241.45	167.24	92.22	.	180.984
0025	315.71	30696	10.89	8035.92	560.22	315.37	.	160.384
0027	1082.84	65531	21.60	9779.11	1187.19	1081.66	.	64.15

THE UNIVERSITY
OF KANSAS HOSPITAL
KUMED

September 21, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

We are writing on behalf of The University of Kansas Hospital in Kansas City, KS to address an issue of great importance to Medicare beneficiaries with cancer. The University of Kansas Hospital is a leading Oncologic treatment center in the greater Kansas City metropolitan area, and treats approximately 23,000 cancer patients annually. We appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. We are deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth on the proposed hospital outpatient rule will seriously underpay hospitals, and could compromise beneficiary access to this vital technology.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

CMS proposes to reduce the Medicare payment rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. Based on my experience, I believe that $865 is far below the true cost to our hospital outpatient department of providing PET/CT services, and that such a reduction would significantly underpay The University of Kansas Hospital. The proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to The University of Kansas Hospital of acquiring, maintaining, and operating our PET/CT scanner vs. our previous conventional PET scanner is 24% higher. The payment rate for PET/CT should reflect this difference.

KU Medical Center
Department of Radiology
3901 Rainbow Boulevard, Kansas City, Kansas 66160-7234

Furthermore, CMS bases the proposed rate reduction on only nine months of hospital claims data from 2005. During this timeframe, there was confusion regarding coding for these services as evidenced by the attached transmittals. The PET/CT CPT codes were listed as non-covered from 1/1/04 - 4/4/05. The fee schedule was then updated retroactively for these CPT codes to become covered. In October 2005, there were further changes to CMS edits regarding the billing of radiopharmaceuticals as well as edits for billing for skilled nursing patients. Again, in 2006, the edits for radiopharmaceuticals were not updated until August so our claims for PET/CT scans for the period 1/1/06 - 8/1/06 were not paid until August.

The proposed payment rate reduction for PET/CT would seriously underpay hospitals, and risk limiting beneficiary access to this vital technology. We respectfully request that CMS maintain the current PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact us for additional information.

Sincerely,

Reginald W. Dusing, M.D.

Reginald W. Dusing, MD
Medical Director
Division of Nuclear Medicine
University of Kansas Hospital
3910 Rainbow Blvd.
Kansas City, KS 66160-7234
(913) 588-6805
rdusing@kumc.edu
www.rad.kumc.edu/nucmed

James V. Traylor, CNMT
Supervisor
Division of Nuclear Medicine
University of Kansas Hospital
3910 Rainbow Blvd.
Kansas City, KS 66160-7234
(913) 588-6816
jtraylor@kumc.edu
www.rad.kumc.edu/nucmed

JT/attachments

MLN Matters CMS
Information for Medicare Fee-for-Service Health Care Professionals

Related Change Request (CR) #: 4010
Related CR Release Date: August 5, 2005
Related CR Transmittal #: 641
Effective Date: January 28, 2005
Implementation Date: October 3, 2005

MLN Matters Number: MM4010

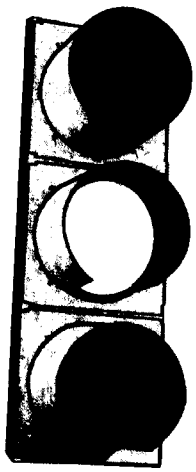
October 2005 Quarterly Update to Skilled Nursing Facility (SNF) Consolidated Billing (CB)

Note: This article was revised to contain Web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

Physicians providing Positron Emission Tomography (PET) scan professional component services to SNF patients affected by SNF CB.

Provider Action Needed



STOP – Impact to You

Medicare established HCPCS codes, 78459, 78491, 78492, 78608, 78609, 78811, 78812, 78813, 78814, 78815, and 78816 for Positron Emission Tomography (PET) scans effective for dates of service on or after January 28, 2005. The physician professional component of these services may be paid separately outside of SNF CB. These codes will be added to editing on October 3, 2005.

Since April 18, 2005, your Medicare carrier may not have paid you correctly for these services, but the carrier will adjust the claims on or after October 3, 2005 if you bring such claim(s) to your carrier's attention.

GO – What You Need to Do

Should you have received a denial for these services after April 18, 2005, for claims with dates of service on after January 28, 2005, through October 2, 2005, contact your carrier to have those claims adjusted.

Background

The affected HCPCS codes are as follows:

- 78459 Myocardial imaging, positron emission tomography (PET), metabolic evaluation
- 78491 Myocardial imaging, positron emission tomography (PET), perfusion, single study at rest or stress
- 78492 Myocardial imaging, positron emission tomography (PET), perfusion, multiple studies at rest and/or stress
- 78608 Brain imaging, positron emission tomography (PET); metabolic evaluation
- 78609 Brain imaging, positron emission tomography (PET); perfusion evaluation
- 78811 Tumor imaging, positron emission tomography (PET); limited area (e.g., chest, head/neck)
- 78812 Tumor imaging, positron emission tomography (PET); skull base to mid thigh
- 78813 Tumor imaging, positron emission tomography (PET); whole body
- 78814 Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g., chest, head/neck)
- 78815 Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid thigh
- 78816 Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body

Implementation Date

This change will be made to Medicare systems on October 3, 2005.

Additional Information

For complete details, please see the official instruction issued to your carrier regarding this change. That instruction may be viewed by going to **http://www.cms.hhs.gov/Transmittals/downloads/R641CP.pdf** on the CMS web site.

For more information on SNF CB, see MLN Matter Special Edition SE0431, Skilled Nursing Consolidated Billing, available at **http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0431.pdf** on the CMS web site.

If you have any questions, please contact your Medicare carrier at their toll-free number, which may be found at **http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.pdf** on the CMS web site.

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 503

Department of Health & Human Services
Center for Medicare and &
Medicaid Services
Date: MARCH 11, 2005
Change Request 3750

SUBJECT: April Update to the Medicare Non-OPPS Outpatient Code Editor (OCE) Specifications Version 20.2

I. SUMMARY OF CHANGES: This CR informs the Fiscal Intermediaries (FIs) that the Non-OPPS OCE, used to process bills from hospitals not paid under the OPPS has been updated with new additions, changes, and deletions to HCPCS codes, diagnosis codes and procedure codes.

NEW/REVISED MATERIAL :
EFFECTIVE DATE : Various dates as described in the CR
IMPLEMENTATION DATE : April 04, 2005

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

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

R/N/D	Chapter / Section / SubSection / Title

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Recurring Notification Form

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 503	Date: March 11, 2005	Change Request 3750

SUBJECT: April Update to the Medicare Non-OPPS Outpatient Code Editor (OCE) Specifications Version 20.2

I. GENERAL INFORMATION

A. Background: This Change Request (CR) informs you that the Non-OPPS OCE has been updated with new additions, changes, and deletions to Healthcare Common Procedure Coding System/Current Procedural Terminology, Fourth Edition (HCPCS/CPT-4) codes. This OCE is used to process bills from hospitals not paid under the OPPS. CMS sent detailed information about these changes in separate communications.

B. Policy:
The following are changes made to version 20.2 of the Non-OPPS OCE:

- Changes retroactive to 8/1/00 (OCE v15.2)

  The following codes have been **removed** from the **Non-Reportable list, effective 8/1/00:**

Code	Description
93042	Rhythm ECG, report
93233	ECG monitor/review, 24 hrs
93237	ECG monitor/review, 24 hrs
93722	Plethysmography report

- Changes retroactive to 1/1/04 (OCE v19.1)

  The following code has been **deleted** from the list of valid HCPCS, **effective 1/1/04:**

Code	Description
C9408	FDG, per dose, brand

  The following code has been **added** to the **Non-Covered list, effective 1/1/04**

Code	Description
E0637	Sit-stand w seatlift

  The following codes have been **removed** from the **Non-Reportable list, effective 1/1/04:**

Code	Description
E1019	HD feature power seat
E1021	Ex hd feature power seat
E0637	Sit-stand w seatlift

- Changes retroactive to 10/1/04 (OCE v20.0)

The following codes have been **added** to the list of valid HCPCS, **effective 10/1/04:**

Code	Description
S0109	Methadone oral 5mg
S0166	Inj olanzapine 2.5mg
S0167	Inj apomorphine HCl 1mg
S0168	Inj azacitidine 100mg
S0515	Scleral lens liquid bandage
S2215	UGI endoscopy inj implant
S8093	CT angiography coronary
S9097	Home visit wound care

The following codes have been **deleted** from the list of valid HCPCS, **effective 10/1/04:**

Code	Description
G0330	PET image initial dxs cervcal
G0331	PET image restage ovarian ca
S2370	Intradiscal electrothermal
S2371	Each additional interspace

The following codes have been **added** to the **Non-Reportable list, effective 10/1/04:**

Code	Description
S0109	Methadone oral 5mg
S0166	Inj olanzapine 2.5mg
S0167	Inj apomorphine HCl 1mg
S0168	Inj azacitidine 100mg
S0515	Scleral lens liquid bandage
S2215	UGI endoscopy inj implant
S8093	CT angiography coronary
S9097	Home visit wound care

- Changes retroactive to 1/1/05 (OCE v20.1)

The following codes have been **added** to the list of valid HCPCS, **effective 1/1/05:**

Code	Description
C9127	Paclitaxel protein pr
C9128	Inj pegaptamib sodium
C9440	Vinorelbine tar,brand
G0235	PET not otherwise specified
G0369	Pharm fee 1st month transpla
G0370	Pharmacy fee oral cancer etc
G0371	Pharm dispense inhalation 30
G0374	Pharm dispense inhalation 90
G9021	Chemo assess nausea vomit L1
G9022	Chemo assess nausea vomit L2
G9023	Chemo assess nausea vomit L3
G9024	Chemo assess nausea vomit L4

G9025	Chemo assessment pain level1
G9026	Chemo assessment pain level2
G9027	Chemo assessment pain level3
G9028	Chemo assessment pain level4
G9029	Chemo assess for fatigue L1
G9030	Chemo assess for fatigue L2
G9031	Chemo assess for fatigue L3
G9032	Chemo assess for fatigue L4
K0670	Stance phase only
K0671	Portable oxygen concentrator
S0142	Colistimethate inh sol mg
S0143	Aztreonam inh sol gram
S0197	Prenatal vitamins 30 day
S0595	New lenses in pts old frame
S0625	Digital screening retinal
S3005	Eval self-assess depression
S8434	Interim splint upper extrem
S8940	Hippotherapy per session

The following codes have been **deleted** from the list of valid HCPCS, **effective 1/1/05**

Code	**Description**
A4534	Youth size brief each
C2666	Unassigned #71
C2667	Unassigned #72
C2668	Unassigned #73
C2669	Unassigned #74
C2670	Unassigned #75

The following codes have been **added** to the **Non-Covered list, effective 1/1/05**

Code	**Description**
E0203	Therapeutic lightbox tabletp
G0235	PET not otherwise specified

The following codes have been **removed** from the **Non-Covered list, effective 1/1/05**

Code	**Description**
0020T	Extracorp shock wave tx, ft
78608	Brain imaging (PET)
78609	Brain imaging (PET)
78811	Tumor imaging (pet), limited
78812	Tumor image (pet)/skul-thigh
78813	Tumor image (pet) full body
78814	Tumor image pet/ct, limited
78815	Tumor image pet/ct skul-thigh
78816	Tumor image pet/ct full body

The following codes have been **added** to the **Non-Reportable list, effective 1/1/05:**

Code	Description
C9127	Paclitaxel protein pr
C9128	Inj pegaptamib sodium
C9440	Vinorelbine tar,brand
G0345	IV infuse hydration, initial
G0346	Each additional infuse hour
G0347	IV infusion therapy/diagnost
G0348	Each additional hr up to 8hr
G0349	Additional sequential infuse
G0350	Concurrent infusion
G0351	Therapeutic/diagnostic injec
G0353	IV push, single orinitial dru
G0354	Each addition sequential IV
G0355	Chemo administrate subcut/IM
G0356	Hormonal anti-neoplastic
G0357	IV push single/initial subst
G0358	IV push each additional drug
G0359	Chemotherapy IV one hr initi
G0360	Each additional hr 1-8 hrs
G0361	Prolong chemo infuse>8hrs pu
G0362	Each add sequential infusion
G0363	Irrigate implanted venous de
G0368	EKG interpret & report preve
G0369	Pharm fee 1st month transpla
G0370	Pharmacy fee oral cancer etc
G0371	Pharm dispense inhalation 30
G0374	Pharm dispense inhalation 90
G9021	Chemo assess nausea vomit L1
G9022	Chemo assess nausea vomit L2
G9023	Chemo assess nausea vomit L3
G9024	Chemo assess nausea vomit L4
G9025	Chemo assessment pain level1
G9026	Chemo assessment pain level2
G9027	Chemo assessment pain level3
G9028	Chemo assessment pain level4
G9029	Chemo assess for fatigue L1
G9030	Chemo assess for fatigue L2
G9031	Chemo assess for fatigue L3
G9032	Chemo assess for fatigue L4
K0671	Portable oxygen concentrator
S0142	Colistimethate inh sol mg
S0143	Aztreonam inh sol gram
S0197	Prenatal vitamins 30 day
S0595	New lenses in pts old frame
S0625	Digital screening retinal
S3005	Eval self-assess depression
S8434	Interim splint upper extrem
S8940	Hippotherapy per session

The following codes have been **removed** from the **Non-Reportable list, effective 1/1/05**

Code	Description
36416	Capillary blood draw
78491	Heart image (pet), single
78492	Heart image (pet), multiple
Q0081	Infusion ther other than che
Q0083	Chemo by other than infusion
Q0084	Chemotherapy by infusion

- Changes effective 4/1/05 (OCE v.20.2)

The following codes have been **added** to the list of valid HCPCS, **effective 4/1/05:**

Codes	Description
C9223	Inj adenosine, tx dx
C9723	Dyn IR Perf Img
C9724	EPS gast cardia plic
G9041	Low vision serv occupational
G9042	Low vision orient/mobility
G9043	Low vision rehab therapist
G9044	Low vision rehab teacher
Q4079	Injection, natalizumab
Q9941	IVIG lyophil 1 G
Q9942	IVIG lyophil 10 MG
Q9943	IVIG non-lyophil 1 G
Q9944	IVIG non-lyophil 10 MG
Q9945	LOCM <= 149 mg/ml iodine, 1 ml
Q9946	LOCM 150-199 mg/ml iodine, 1 ml
Q9947	LOCM 200-249 mg/ml iodine, 1 ml
Q9948	LOCM 250-299 mg/ml iodine, 1 ml
Q9949	LOCM 300-349 mg/ml iodine, 1 ml
Q9950	LOCM 350-399 mg/ml iodine, 1 ml
Q9951	LOCM >=400 mg/ml iodine, 1 ml
Q9952	Inj Gad-base MR contrast, ml
Q9953	Inj Fe-based MR contrast, ml
Q9954	Oral MR contrast, 100 ml
Q9955	Inj perflexane lip micros, ml
Q9956	Inj octafluoropropane mic, ml
Q9957	Inj perflugren lip micros, ml

The following codes have been **deleted** from the list of valid HCPCS, **effective 4/1/05:**

Codes	Description
G0030	PET imaging prev PET single
G0031	PET imaging prev PET multple
G0032	PET follow SPECT 78464 singl
G0033	PET follow SPECT 78464 mult

G0034	PET follow SPECT 76865 singl
G0035	PET follow SPECT 78465 mult
G0036	PET follow cornry angio sing
G0037	PET follow cornry angio mult
G0038	PET follow myocard perf sing
G0039	PET follow myocard perf mult
G0040	PET follow stress echo singl
G0041	PET follow stress echo mult
G0042	PET follow ventriculogm sing
G0043	PET follow ventriculogm mult
G0044	PET following rest ECG singl
G0045	PET following rest ECG mult
G0046	PET follow stress ECG singl
G0047	PET follow stress ECG mult
G0125	PET image pulmonary nodule
G0210	PET img wholebody dxlung
G0211	PET img wholbody init lung
G0212	PET img wholebod restag lung
G0213	PET img wholbody dx
G0214	PET img wholebod init
G0215	PETimg wholebod restag
G0216	PET img wholebod dx melanoma
G0217	PET img wholebod init melan
G0218	PET img wholebod restag mela
G0220	PET img wholebod dx lymphoma
G0221	PET imag wholbod init lympho
G0222	PET imag wholbod resta lymph
G0223	PET imag wholbod reg dx head
G0224	PET imag wholbod reg ini hea
G0225	PET whol restag headneckonly
G0226	PET img wholbody dx esophagl
G0227	PET img wholbod ini esophage
G0228	PET img wholbod restg esopha
G0229	PET img metaboloc brain pres
G0230	PET myocard viability post
G0231	PET WhBD colorec; gamma cam
G0232	PET whbd lymphoma; gamma cam
G0233	PET whbd melanoma; gamma cam
G0234	PET WhBD pulm nod; gamma cam
G0253	PET image brst dection recur
G0254	PET image brst eval to tx
G0296	PET imge restag thyrod cance
G0336	PET imaging brain alzheimers

The following code has been **removed** from the **Non-Covered list, effective 4/1/05:**

Code	**Description**
J8501	Oral aprepitant

The following codes have been **added** to the **Non-Reportable list, effective 4/1/05:**

Code	Description
C9223	Inj adenosine, tx dx
C9723	Dyn IR Perf Img
C9724	EPS gast cardia plic
J1563	IV immune globulin
J1564	Immune globulin 10 mg

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3750.1	The Shared System Maintainer shall install Non-OPPS OCE Version 20.2 into their systems.					X				
3750.2	FIs shall inform providers of the Non-OPPS OCE changes for Version 20.2 detailed in this recurring change notification.	X	X							

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3750.1	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the									

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: Various dates as described in the CR **Implementation Date:** April 4, 2005 **Pre-Implementation Contact(s):** Taneka Rivera 410-786-9502 or TRivera@cms.hhs.gov and Diana Motsiopoulos 410-786-3379 or DMotsiopoulos@cms.hhs.gov **Post-Implementation Contact(s):** Regional Office	**No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.**

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

Attachment

Attachment

Specifications for Outpatient Code Editor v20.2

MVS-BATCH/MS-DOS

Effective April 1, 2005

Last Modified 1/28, 1/31, 2/1, 2/4, 2/7, 2/10/05

Table of Contents

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0 – Changes to Specifications since 1/31/05

1. Code C9723 added to the valid HCPCS and to the NRL, effective 4/1/05
2. Code C9724 added to the NRL, effective 4/1/05
3. Codes C9127, C9128, C9440 added to the NRL, effective 1/1/05

2/4/05:

4. Corrected effective date for 4/1/05 NRL code changes listed as 1/1/05 in error
5. Added four new HCPCS codes, Q9941 - Q9944, effective 4/1/05
6. Added two codes, J1563 and J1564, to the NRL, effective 4/1/05
7. Two codes, G0330 and G0331, placed on the delete list (instead of NCL), effective 10/1/04

2/7/05:

8. Fourteen new codes added to the valid HCPCS list, effective 4/1/05

2/10/05

9. Corrected effective date for 10/1/04 HCPCS deletions listed as 1/1/04 in error

---

I – Software Modifications:

Version Number and Effective Dates

- Create OCE v20.2 with date range from 4/1/05 to 9/30/05

Change the effective date for OCE v20.1 as follows:

- OCE v20.1 date range from 1/1/05 to 3/31/05

Modify all specified previous OCE versions to incorporate retroactive changes

---

II – Clinical Specifications:

Overview

These specifications include code and edit modifications.

Code Descriptions:
Update the Code Description Database with the same codes and descriptions used for OPPS OCE v6.1.

A) Changes retroactive to 8/1/00 (OCE v15.2)

Non-Reportable List Changes:

- **Remove** the following codes from the Non-Reportable list, effective 8/1/00:

Code	Description
93042	Rhythm ECG, report
93233	ECG monitor/review, 24 hrs
93237	ECG monitor/review, 24 hrs
93722	Plethysmography report

B) Changes retroactive to 1/1/04 (OCE v19.1)

HCPCS Code Changes

- **Delete** the following code from the list of valid HCPCS, effective 1/1/04:

Code	Description
C9408	FDG, per dose, brand

Non-Covered List Changes

- **Add** the following code to the Non-Covered list, effective 1/1/04

Code	Description
E0637	Sit-stand w seatlift

Non-Reportable List Changes:

- **Remove** the following codes from the Non-Reportable list, effective 1/1/04:

Code	Description
E1019	HD feature power seat
E1021	Ex hd feature power seat
E0637	Sit-stand w seatlift

C) Changes retroactive to 10/1/04 (OCE v20.0)

HCPCS Code Changes

- **Add** the following codes to the list of valid HCPCS, effective 10/1/04:

Code	Description
S0109	Methadone oral 5mg
S0166	Inj olanzapine 2.5mg
S0167	Inj apomorphine HCl 1mg
S0168	Inj azacitidine 100mg
S0515	Scleral lens liquid bandage
S2215	UGI endoscopy inj implant
S8093	CT angiography coronary
S9097	Home visit wound care

- **Delete** the following code from the list of valid HCPCS, effective **10**/1/04:

Code	Description
G0330	PET image initial dx cervcal
G0331	PET image restage ovarian ca
S2370	Intradiscal electrothermal
S2371	Each additional interspace

Non-Reportable List Changes:

- **Add** the following codes to the Non-Reportable list, effective 10/1/04:

Code	Description
S0109	Methadone oral 5mg
S0166	Inj olanzapine 2.5mg
S0167	Inj apomorphine HCl 1mg
S0168	Inj azacitidine 100mg
S0515	Scleral lens liquid bandage
S2215	UGI endoscopy inj implant

S8093	CT angiography coronary
S9097	Home visit wound care

D) Changes retroactive to 1/1/05 (OCE v20.1)

HCPCS Code Changes

- **Add** the following codes to the list of valid HCPCS, effective 1/1/05:

Code	Description
C9127	Paclitaxel protein pr
C9128	Inj pegaptamib sodium
C9440	Vinorelbine tar,brand
G0235	PET not otherwise specified
G0369	Pharm fee 1st month transpla
G0370	Pharmacy fee oral cancer etc
G0371	Pharm dispense inhalation 30
G0374	Pharm dispense inhalation 90
G9021	Chemo assess nausea vomit L1
G9022	Chemo assess nausea vomit L2
G9023	Chemo assess nausea vomit L3
G9024	Chemo assess nausea vomit L4
G9025	Chemo assessment pain level1
G9026	Chemo assessment pain level2
G9027	Chemo assessment pain level3
G9028	Chemo assessment pain level4
G9029	Chemo assess for fatigue L1
G9030	Chemo assess for fatigue L2
G9031	Chemo assess for fatigue L3
G9032	Chemo assess for fatigue L4
K0670	Stance phase only
K0671	Portable oxygen concentrator
S0142	Colistimethate inh sol mg
S0143	Aztreonam inh sol gram
S0197	Prenatal viatamins 30 day
S0595	New lenses in pts old frame
S0625	Digital screening retinal
S3005	Eval self-assess depression
S8434	Interim splint upper extrem
S8940	Hippotherapy per session

- **Delete** the following code from the list of valid HCPCS, effective 1/1/05

Code	Description
A4534	Youth size brief each
C2666	Unassigned #71
C2667	Unassigned #72
C2668	Unassigned #73

C2669	Unassigned #74
C2670	Unassigned #75

Non-Covered List Changes

- **Add** the following code to the Non-Covered list, effective 1/1/05

Code	Description
E0203	Therapeutic lightbox tabletp
G0235	PET not otherwise specified

- **Remove** the following codes from the Non-Covered list, effective 1/1/05

Code	Description
0020T	Extracorp shock wave tx, ft
78608	Brain imaging (PET)
78609	Brain imaging (PET)
78811	Tumor imaging (pet), limited
78812	Tumor image (pet)/skul-thigh
78813	Tumor image (pet) full body
78814	Tumor image pet/ct, limited
78815	Tumorimage pet/ct skul-thigh
78816	Tumor image pet/ct full body

Non-Reportable List Changes:

- **Add** the following codes to the Non-Reportable list, effective 1/1/05:

Code	Description
C9127	Paclitaxel protein pr
C9128	Inj pegaptamib sodium
C9440	Vinorelbine tar,brand
G0345	IV infuse hydration, initial
G0346	Each additional infuse hour
G0347	IV infusion therapy/diagnost
G0348	Each additional hr up to 8hr
G0349	Additional sequential infuse
G0350	Concurrent infusion
G0351	Therapeutic/diagnostic injec
G0353	IV push,single orinitial dru
G0354	Each addition sequential IV
G0355	Chemo adminisrate subcut/IM
G0356	Hormonal anti-neoplastic
G0357	IV push single/initial subst
G0358	IV push each additional drug
G0359	Chemotherapy IV one hr initi
G0360	Each additional hr 1-8 hrs
G0361	Prolong chemo infuse>8hrs pu
G0362	Each add sequential infusion

G0363	Irrigate implanted venous de
G0368	EKG interpret & report preve
G0369	Pharm fee 1st month transpla
G0370	Pharmacy fee oral cancer etc
G0371	Pharm dispense inhalation 30
G0374	Pharm dispense inhalation 90
G9021	Chemo assess nausea vomit L1
G9022	Chemo assess nausea vomit L2
G9023	Chemo assess nausea vomit L3
G9024	Chemo assess nausea vomit L4
G9025	Chemo assessment pain level1
G9026	Chemo assessment pain level2
G9027	Chemo assessment pain level3
G9028	Chemo assessment pain level4
G9029	Chemo assess for fatigue L1
G9030	Chemo assess for fatigue L2
G9031	Chemo assess for fatigue L3
G9032	Chemo assess for fatigue L4
K0671	Portable oxygen concentrator
S0142	Colistimethate inh sol mg
S0143	Aztreonam inh sol gram
S0197	Prenatal viatamins 30 day
S0595	New lenses in pts old frame
S0625	Digital screening retinal
S3005	Eval self-assess depression
S8434	Interim splint upper extrem
S8940	Hippotherapy per session

- **Remove** the following codes from the Non-Reportable list, effective 1/1/05

Code	**Description**
36416	Capillary blood draw
78491	Heart image (pet), single
78492	Heart image (pet), multiple
Q0081	Infusion ther other than che
Q0083	Chemo by other than infusion
Q0084	Chemotherapy by infusion

E) Changes effective 4/1/05 (OCE v20.2)

- **HCPCS Code Changes**

  - **Add** the following codes to the list of valid HCPCS, effective 4/1/05

Codes	**Description**
C9223	Inj adenosine, tx dx
C9723	Dyn IR Perf Img
C9724	EPS gast cardia plic
G9041	Low vision serv occupational

G9042	Low vision orient/mobility
G9043	Low vision rehab therapist
G9044	Low vision rehab teacher
Q4079	Injection, natalizumab
Q9941	IVIG lyophil 1 G
Q9942	IVIG lyophil 10 MG
Q9943	IVIG non-lyophil 1 G
Q9944	IVIG non-lyophil 10 MG
Q9945	LOCM <= 149 mg/ml iodine, 1 ml
Q9946	LOCM 150-199 mg/ml iodine, 1 ml
Q9947	LOCM 200-249 mg/ml iodine, 1 ml
Q9948	LOCM 250-299 mg/ml iodine, 1 ml
Q9949	LOCM 300-349 mg/ml iodine, 1 ml
Q9950	LOCM 350-399 mg/ml iodine, 1 ml
Q9951	LOCM >=400 mg/ml iodine, 1 ml
Q9952	Inj Gad-base MR contrast, ml
Q9953	Inj Fe-based MR contrast, ml
Q9954	Oral MR contrast, 100 ml
Q9955	Inj perflexane lip micros, ml
Q9956	Inj octafluoropropane mic, ml
Q9957	Inj perflugren lip micros, ml

- **Delete** the following codes from the list of valid HCPCS, effective 4/1/05

Code	**Description**
G0030	PET imaging prev PET single
G0031	PET imaging prev PET multple
G0032	PET follow SPECT 78464 singl
G0033	PET follow SPECT 78464 mult
G0034	PET follow SPECT 76865 singl
G0035	PET follow SPECT 78465 mult
G0036	PET follow cornry angio sing
G0037	PET follow cornry angio mult
G0038	PET follow myocard perf sing
G0039	PET follow myocard perf mult
G0040	PET follow stress echo singl
G0041	PET follow stress echo mult
G0042	PET follow ventriculogm sing
G0043	PET follow ventriculogm mult
G0044	PET following rest ECG singl
G0045	PET following rest ECG mult
G0046	PET follow stress ECG singl
G0047	PET follow stress ECG mult
G0125	PET image pulmonary nodule
G0210	PET img wholebody dxlung
G0211	PET img wholbody init lung
G0212	PET img wholebod restag lung
G0213	PET img wholbody dx
G0214	PET img wholebod init
G0215	PETimg wholebod restag
G0216	PET img wholebod dx melanoma

G0217	PET img wholebod init melan
G0218	PET img wholebod restag mela
G0220	PET img wholebod dx lymphoma
G0221	PET imag wholbod init lympho
G0222	PET imag wholbod resta lymph
G0223	PET imag wholbod reg dx head
G0224	PET imag wholbod reg ini hea
G0225	PET whol restag headneckonly
G0226	PET img wholbody dx esophagl
G0227	PET img wholbod ini esophage
G0228	PET img wholbod restg esopha
G0229	PET img metaboloc brain pres
G0230	PET myocard viability post
G0231	PET WhBD colorec; gamma cam
G0232	PET whbd lymphoma; gamma cam
G0233	PET whbd melanoma; gamma cam
G0234	PET WhBD pulm nod; gamma cam
G0253	PET image brst dection recur
G0254	PET image brst eval to tx
G0296	PET imge restag thyrod cance
G0336	PET imaging brain alzheimers

Remove the following code from the Non-Covered list, effective 4/1/05

Code	Description
J8501	Oral aprepitant

Non-Reportable List Changes:

- **Add** the following codes to the Non-Reportable list, effective 4/1/05:

Code	Description
C9223	Inj adenosine, tx dx
C9723	Dyn IR Perf Img
C9724	EPS gast cardia plic
J1563	IV immune globulin
J1564	Immune globulin 10 mg

III – Additional Items

Documentation Notes

1. Update the edit lists to add and delete codes as appropriate.

IV – Production/Shipping Notes

MVS software and documentation will be delivered electronically to CMS and Standard System Maintainers by or before 2/25/05.

Ground shipment of software and documentation will take place at the same time as the OPPS OCE final release, by or before 3/7/05.

Release package for OCE v20.2 will consist of the following:

- Software media
- Updated User Manuals
- Summary of Modifications
- Client Letter

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 628

Department of Health & Human Services

Centers for Medicare & Medicaid Services

Date: JULY 29, 2005

CHANGE REQUEST 3945

SUBJECT: Radiopharmaceutical Diagnostic Imaging Agents Codes Applicable to PET Scan Services Performed on or After January 28, 2005

I. SUMMARY OF CHANGES: This instruction updates Pub. 100-4, chapter 13, section 60, to include the applicable HCPCS codes for radiopharmaceutical diagnostic imaging agents (tracers) when billing for CPT codes effective for PET scan services performed on or after January 28, 2005.

NEW/REVISED MATERIAL :
EFFECTIVE DATE :October 31, 2005
IMPLEMENTATION DATE : October 31, 2005

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

II. CHANGES IN MANUAL INSTRUCTIONS:
R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	13/Table of Contents
R	13/60.3.1/Appropriate CPT Codes Effective for PET Scans Services Performed on or After January 28, 2005
N	13/60.3.2/Tracer Codes Required for PET Scans

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 628	Date: July 29, 2005	Change Request 3945

SUBJECT: Radiopharmaceutical Diagnostic Imaging Agents Codes Applicable to PET Scan Services Performed on or After January 28, 2005.

I. GENERAL INFORMATION

A. Background: This instruction updates Pub. 100-4, chapter 13, section 60, to include the applicable HCPCS codes for radiopharmaceutical diagnostic imaging agents (tracers) when billing for CPT codes effective for PET scan services performed on or after January 28, 2005.

B. Policy: No changes are being made to the current policy. This instruction simply reflects current policy more accurately.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3945.1	Contractors shall be aware of the revisions made to chapter 13, section 60, of the Medicare Claims Processing Manual.	X		X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3945.2	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web site and include information about it in a listserv message within 1 week of the release of this instruction. In addition, the entire instruction must be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic.	x		x						

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: October 31, 2005 **Implementation Date:** October 31, 2005 **Pre-Implementation Contact(s):** Institutional Billing: Wendy.Tucker@cms.hhs.gov, 410-786-3004 Carrier Billing: Yvette.Cousar@cms.hhs.gov 410-786-2160	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.**

Post-Implementation Contact(s): Appropriate RO	

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

Medicare Claims Processing Manual

Chapter 13 - Radiology Services and Other Diagnostic Procedures

Table of Contents

(Rev. 628, 07-29-05)

60.3.1 - Appropriate CPT Codes Effective for PET Scans for Services Performed on or After January 28, 2005

(Rev. 628, Issued: 07-29-05; Effective: 10-31-05; Implementation: 10-31-05)

NOTE: *All PET scan services require the use of a radiopharmaceutical diagnostic imaging agent (tracer). The applicable tracer code should be billed when billing for a PET scan service. See section 60.3.2 below for applicable tracer codes.*

CPT Code	Description
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation
78491	Myocardial imaging, positron emission tomography (PET), perfusion, single study at rest or stress
78492	Myocardial imaging, positron emission tomography (PET), perfusion, multiple studies at rest and/or stress
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78811	Tumor imaging, positron emission tomography (PET); limited area (eg, chest, head/neck)
78812	Tumor imaging, positron emission tomography (PET); skull base to mid thigh
78813	Tumor imaging, positron emission tomography (PET); whole body
78814	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g., chest, head/neck)
78815	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid thigh
78816	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body

60.3.2 Tracer Codes Required for PET Scans

(Rev.)

Tracer codes applicable to CPT 78491 and 78492:

Institutional providers billing the fiscal intermediary

HCPCS	***Description***
Q3000	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Rubidium RB-82*
A9526	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Ammonia N-13*

Physicians / practitioners billing the carrier:

A4641	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified*
A9526	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Ammonia N-13*

Tracer codes applicable to CPT 78459, 78608, 78609, 78811-78816:

Institutional providers billing the fiscal intermediary:

C1775 (OPPS Only)	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Fluorodeoxyglucose F18*
A4641	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified*

Physicians / practitioners billing the carrier:

A4641	*Supply of Radiopharmaceutical Diagnostic Imaging Agent, Not Otherwise Classified*

CYTOGEN

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September 25, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Attn: CMS 1506-P: CMS proposed Rule on Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

Cytogen Corporation is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule on changes to the hospital outpatient prospective payment system (71 Fed. Reg. 49,506, August 23, 2006).

Cytogen Corporation is dedicated to improving the lives of patients with cancer by developing innovative products that target cancer progression. Cytogen provides a diagnostic radiopharmaceutical, ProstaScint® (capromab pendetide), that is the first and only FDA approved product targeting prostate-specific membrane antigen (PSMA), a unique marker that is abundantly expressed on prostate cancer cells at all stages of disease. Prior to ProstaScint, there were no reliable, noninvasive tests to identify metastatic disease in newly diagnosed and recurrent prostate cancer patients.

ProstaScint is a FDA approved kit for the preparation of Indium In111 Capromab Pendetide, a diagnostic imaging agent used by intravenous injection. The use of ProstaScint for early detection of lymph node involvement has potentially significant impact on the management of medical treatment of cancer patients and on the decrease of cost of care. ProstaScint is reported by hospitals using HCPCS A9507 and is been paid separately under the APC system.

CMS proposes to set fixed payment for all radiopharmaceuticals in 2007 after only one year of transition to the charge reduced to cost (CCR) methodology. There is support from a number of sources for CMS to continue CCR including the APC Advisory Panel on August 24, 2006.

We understand that the APC initiative is to assure that hospitals are appropriately paid for products and services provided to patients. However, when a high cost product such as ProstaScint is utilized by the hospital, an appropriate payment methodology must be established to ensure payment is based upon the cost to prevent severe payment reductions that undermine the hospitals ability to provide these products to patients.

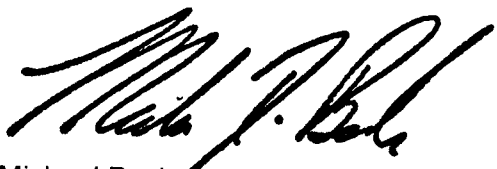
CYTOGEN Corporation • 650 College Road East • CN 5308 • Suite 3100 • Princeton, NJ 08540-5308 • TEL: (609) 750-8200 • FAX: (609) 452-2317

Cytogen supported the 2006 payment methodology change for radiopharmaceuticals to charges reduced to cost because this offered a reliable methodology for providing appropriate payments to hospitals, and permitted CMS to collect more accurate claims data. However, this payment methodology was implemented in 2006 and the claims data utilized for the 2007 proposed payment system is the 2005 claims data. Use of the median payment rate proposed for 2007 fails to reflect the average acquisition cost for ProstaScint and will impose a radical reduction in the payment level, thus limiting patient access to this important diagnostic cancer study. Under the APC payment system, CMS has continued to show concern when radical payment reductions are proposed and has continued to make adjustments to protect hospitals and patients.

Cytogen respectfully recommends that CMS continue the current CCR payment system for ProstaScint in 2007 to ensure that hospitals make this important diagnostic radiopharmaceutical available to patients. CMS should be aware that if the proposed payment rate for 2007 is implemented, hospitals will not be able to make this diagnostic cancer product available to Medicare beneficiaries.

Thank you again for the opportunity and reconsideration of the proposed changes in payment methodology under the 2007 hospital outpatient prospective payment system.

Sincerely,



Michael Becker
President and CEO
Cytogen Corporation
650 College Road East Suite 3100
Princeton, NJ 08540

cc: Carol Bazell, M.D.

Radiation Oncology
Mississippi, P.A.

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Gregg A. Dickerson, M.D.
Richard B. Friedman, M.D.
S. Albert Johnson, Jr., M.D.
David A. Wahl, M.D.
Steven E. Zachow, M.D.

September 22, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear CMS Administrator:

I am the President of the Mississippi Radiological Society, a Fellow of the American College of Radiology, and a Diplomate of the American Board of Radiology. I practice at St. Dominics / Jackson Memorial Hospital in Jackson, MS.

I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am extremely concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs and the proposed new payment methodology for brachytherapy sources in 2007.

I highly recommend CMS continue with CPT codes 19296 and 19297 being assigned to New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	-37.0%

Should CMS finalize the proposed APC assignments, the cost of the device will surpass the proposed payment rate. This will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC assigned, must cover the cost of the device. Of note: the cost of the brachytherapy device is the same when implanted at time of lumpectomy or during a separate procedure.

Additionally, our hospital purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with the cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospitals must be able to cover the costs of the radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In closing, and as the President of the Mississippi Radiological Society, I recommend:

1. that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.

2. that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

I respectfully request that CMS heed my recommendations. I would like to continue providing this important service to your Medicare beneficiaries.

Regards,

Gregg Dickerson, M.D., FACR

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee
Senator Sam Brownback, Co-Chair, Senate Cancer Committee
Senator Thad Cochran, Chairman, Senate Appropriations Committee
Representative Michael Bilirakis, Energy and Commerce Health Subcommittee
Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues
Representative Katherine Harris, Member House Cancer Caucus
Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

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Sharyn Sowell

14922 Valley View Drive
Mount Vernon WA 98273

The Honorable Mark McClellan, MD
Department of Health & Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Sept. 10, 2006

Dear Dr. McClellan,

I understand the CMS is soliciting comments for procedure codes for a new type of surgery- MRgFUS, which uses ultrasound and an MRI to give women an alternative to hysterectomy due to uterine fibroid tumors, the most common cause of hysterectomy (CMS-1506-P).

I had this surgery May 18, 2006 and would like to offer you a patient's perspective. This highly technical procedure required a sophisticated MRI suite so it wasn't cheap but the risk of complications was minimal and I was back to work the day following surgery. There is no incision with MRgFUS and you'd be shocked at the change it made in my health immediately.

Friends who had the alternative procedure, hysterectomy, had far higher initial surgical costs and they missed an average of six weeks work. Complications like infection, blood loss and so on are common. I had surgery on Thursday, and on Saturday morning I opened the largest trade show of my career.

This surgery had two CPT codes created in 2004- 0071T and 0072T, which was a problem because they were part of APCs 195 and 202, for Female Reproductive Procedures which take place in an operating room. In reality, MRgFUS is not a treatment for a reproductive issue but for tumors, which are treated in a very sophisticated MR imaging suite with procedures that are far more complex.

I'm asking that you re-examine the coding and ask the committee to assign codes 0071T and 0072T to APC 127 Stereotactic Radiosurgery on an interim basis or reassign another similar code with a similar payment schedule.

The reality of the situation for women like me is this:

We are forced to choose between a hysterectomy, a radical procedure that costs much more and brings more trauma to body and psyche, and forces 6 weeks off work, or MRgFUS, which is a far gentler high tech solution that takes only a day or two of recovery. Hysterectomy is covered fully by insurance. MRgFUS, because it's new technology, is not yet covered and the level of HOPPS coverage is still uncertain.

MRgFUS costs a hospital about $7500 to $9400. If it doesn't get a code that makes this new technology economically viable, women like me will be forced into a far more extreme solution for their problem.

In my case, I was bleeding to death because of uterine fibroid tumors and could no longer ignore it. I faced a complete hysterectomy which would have meant disaster for the business I own. I was blessed to get treatment as part of an FDA study this May and am now completely healthy again. If you have any questions or would like to talk with someone who has actually had the new surgery, I would love to hear from you.

I appreciate your time, Dr. McClellan.

Thank you,

Sharyn Sowell

14922 Valley View Drive
Mount Vernon WA 98273

Tel. 360-424-5846
Email: sowell@fidalgo.net

Timothy Ravenscroft
President
Tel 978.671.8100 Fax 978.436.7521 timothy.ravenscroft@bms.com

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September 26, 2006

Via Overnight Mail

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1506-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1506-P Comments to the 2007 HOPPS Proposed Rule on Payment for Radiopharmaceuticals/Radionuclides, Pharmacy Handling and Overhead Costs, and Threshold for Separate Payment

Dear Dr. McClellan:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments on the Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) for Calendar Year (CY) 2007, 71 Fed. Reg. 49,506 (August 23, 2006).

A subsidiary of Bristol-Myers Squibb Company (BMS), the global pharmaceutical and related health care products company, BMSMI is one of the leading manufacturers of radiopharmaceuticals and radionuclides (RPs) and other medical imaging drugs. Accordingly, BMSMI has a keen interest in CMS's proposed changes to HOPPS for 2007.

In brief, we support CMS's efforts to preserve Medicare beneficiary access to high quality RPs and CMS's work to recognize the complexity of RPs through appropriate Medicare payment for RPs. BMSMI urges CMS to fully integrate the unique features of RPs into workable reimbursement/payment methods, especially with respect to calculating and determining the unique RP overhead and handling costs. CMS should pay for all RPs separately and eliminate the $55 threshold for separate Medicare payment. Further refinements and alternatives are needed. Below, we summarize and then present in detail our comments and recommendations.

I. EXECUTIVE SUMMARY RECOMMENDATIONS

A. Radiopharmaceuticals and Radionuclides (RPs)

- BMSMI acknowledges that CMS's 2007 proposal for setting fixed payments for all RPs is a positive starting point to develop appropriate Medicare payments for RPs. However, the current CMS proposal needs critical refinements/adjustments to make such fixed Medicare payments appropriate and fair for many RPs, and ensure compliance with the standard of "average acquisition cost."

Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

- Consequently, BMSMI recommends that CMS refine/adjust the current proposed 2007 fixed payments for RPs (as described below) or that CMS continues using cost-to-charge ratios (CCRs) as a methodology for payment of RPs through 2007, consistent with the APC Advisory Panel's August 24, 2006, recommendation. It is important to note that CMS advised hospitals to include overhead and handling costs together with their charges for the RPs on the claims they submitted in 2006. This process of generating new and accurate data has only started and further time is needed so that CMS may acquire and analyze at least a full year of updated 2006 claim data.
- We support CMS's decision to use the "mean" cost as the basis for payment for RPs, (if CMS would not continue CCR for one additional year), **but only if** an appropriate amount, for example, **10 to 20 percent**, can be added to reflect the unique overhead costs required for patient and hospital staff protections and regulatory compliance associated with these RPs.
- Hospital charges do not uniformly or accurately include pharmacy overhead and handling costs for RPs. RPs are unique radioactive products which require special shielding, waste disposal, and handling. In the June 2005 Report to Congress, MedPAC addressed the issue of Medicare payment for pharmacy handling costs in hospital outpatient departments and indicated that hospitals' handling costs for RPs exceed costs for all other types of drugs. The Report also recommended that CMS establish separate payments to cover the costs that hospitals incur for handling drugs and RPs. We agree with MedPAC and urge CMS to increase payment for RPs to accurately reflect these costs, and implement a mechanism to track pharmacy overhead and handling costs, which are not otherwise included in hospital charges.
- We recommend that CMS update HOPPS payment for RPs on an annual basis.
- Finally, given the unique nature of RPs, we recommend that CMS eliminate the threshold for separate payment and pay separately for all RPs to ensure that payments appropriately cover pharmacy overhead and handling costs for these unique drugs. At minimum, if CMS maintains a threshold, there should be no inflationary adjustment.

B. <u>Contrast Drugs</u>

- In the interest of parity and harmonization of payment rates across the various outpatient settings, we recommend that CMS use ASP+6% rather than ASP+5% as the basis for payment for medical contrast imaging drugs.
- In 2006 NPRM, CMS said hospital average acquisition costs for drugs including pharmacy overhead and handling costs would be covered by the average sales price plus 8 percent (ASP+8%). Subsequently, in 2006 Final Rule, CMS indicated that ASP +6% would cover the hospitals average acquisition costs for drugs. In the 2007 proposed rule, CMS is proposing that average acquisition costs for drugs and handling are equal to ASP+5%. We are concerned because CMS has never disclosed the full data on which these determinations have been made. Accordingly, BMSMI requests that CMS provide the data and rationale supporting these changes.

C. Drug Payment Methodology / Stability

- Stability in drug payment and drug payment methodology is needed. In addition to the HCPCS coding changes, drug payment methods have changed each year since 2002. CMS should maintain a stable method/parity with other outpatient settings until it has several years' data to suggest that a different method is warranted.

II. DETAILED COMMENTS AND RECOMMENDATIONS

A. Payment Methodology for Radiopharmaceuticals and Radionuclides (RPs)

CMS's proposal for setting fixed payments for RPs is a positive starting point to develop appropriate Medicare payments for RPs. However, we believe some additional critical refinements are needed to make such fixed Medicare payments appropriate and fair for many RPs and comply with the statutory standard for payment based on "average acquisition costs".

For this reason, BMSMI recommends (1) CMS implement much needed refinements (as described below) if the agency moves forward with fixed payments for RPs in 2007 or, (2) in the alternative, consistent with the APC Advisory Panel's August 24, 2006, recommendation, CMS continue using cost-to-charge ratios (CCRs) as a methodology for payment of RPs through 2007.

1. Use of mean costs as a basis for payment

When CMS transitions to a fixed payment methodology, BMSMI supports CMS's decision to use the mean cost as the basis for payment for RPs, but only if an appropriate amount, such as 10 - 20 percent can be added to reflect overhead, inventory, and costs associated with patient and hospital staff protections.

The use of mean cost is appropriate for several reasons. First, "mean" is defined as the arithmetic average. Therefore, mean cost rather than median cost as a basis for payment is more consistent with statutory mandate for "average hospital costs" for SCODs, which includes RPs.

Second, several detailed studies support the addition of a substantial margin for pharmacy handling and overhead costs. One study of cost report data from 55 hospitals found that labor and administrative costs (excluding acquisition costs) accounted for about one-third of the expenses in the pharmacy cost centers (Kathpal Technologies 1999). MedPAC analyzed cost report data from more than 3,300 hospitals and determined that hospital reporting of pharmacy costs varied greatly. And while the variability made it difficult to separate drug acquisition costs from pharmacy handling costs, MedPAC did find that in nearly 1,200 hospitals overhead and handling, including salaries, wages and fringe benefits, made up about 25 percent of the direct costs in pharmacy cost centers.

With regard to RPs, MedPAC determined that the overhead and handling costs were assigned to the nuclear medicine department and while MedPAC could not determine the magnitude of these costs, MedPAC did determine that RPs required far greater resources than any other category of drugs, including cytotoxic/chemotherapy agents.

In sum, "mean" is a better starting point proxy for average acquisition costs for drugs and RPs and, as such, complies better with the statutory standard for payment. However, the majority of hospitals do not yet factor in the overhead and handling costs related to RPs when they establish the charge for the RP itself. For this reason, if CMS adopts "mean" as the basis for payment of RPs, we recommend that CMS add 10 to 20 percent for overhead and handling costs.

2. Continuation of CCR for one more year

It is important to note that CMS advised hospitals to include overhead and handling costs together with their charges for the RPs on the claims they submitted in 2006. This process of generating new and accurate data has only started and further time is needed so that CMS may acquire and analyze at least a full year of updated 2006 claim data. In addition, hospitals need some stability in billing, coding, and payment mechanisms. There have been numerous, almost annual changes in coding and payment for RPs. Such changes could undermine hospitals' good faith efforts in following CMS's instructions on billing and charges. It is also important to note the APC Advisory Panel's recommendations to CMS to continue using CCR as a basis for payment for RPs.

B. Pharmacy Overhead and Handling

Hospital charges for RPs do not uniformly or accurately include pharmacy overhead and handling costs for these special products, as noted above. With respect to RPs, all the overhead and handling costs that are required for traditional drugs also apply to RPs. In addition, RPs are unique radioactive products which require special shielding, waste disposal, and handling. The additional safety and shielding requirements affect every component of handling costs. For example, because the products are radioactive, hospitals must use lead-lined storage containers. In addition, staff must wear special protection (leadlined gloves, aprons, and glasses) during preparation of the products. Likewise, hospitals' disposal of RPs must comply with the Nuclear Regulatory Commission (NRC) and state radiation safety requirements. Staff must wear special badges so their exposure to radioactivity can be measured and monitored. Finally, the hospital must establish a radiation safety office with a radiation compliance officer and obtain and comply with the NRC licensure requirements.

The June 2005 MedPAC report indicated that hospitals' handling costs for RPs exceed costs for all other types of drugs. Therefore, BMSMI urges CMS to fully integrate the unique features of RPs into a workable reimbursement method, especially with respect to calculating and determining pharmacy overhead and handling costs. Thus, whether CMS adopts "mean" + as a basis for payment of RPs or continues CCR for another year, we recommend that CMS implement a mechanism to track pharmacy overhead and handling costs, which are not otherwise included in hospital charges.

C. Annual Update of HOPPS Payment for RPs

We recommend that CMS update HOPPS payment for RPs on an annual basis. Rather than use claims data and mean costs, which may not be feasible or practical, it may be appropriate for CMS to use the Pharmacy Price Index as a basis for these annual payment updates for RPs.

D. Threshold for Separate Payment

Hospitals incur all traditional pharmacy overhead and handling costs for RPs plus the additional licensing, handling, and monitoring costs related to radioactivity discussed above. These exceptional costs are incurred for every RP, i.e., products with acquisition costs of less than $50, as well as those products with costs that exceed $50. Because the use of any RP greatly increases the resources involved in a procedure, we recommend that CMS eliminate the threshold for separate payment and pay separately for all RPs to ensure that payments appropriately cover pharmacy overhead and handling costs for these unique drugs.

At minimum, if CMS maintains a threshold, there should be no inflationary adjustment.

E. Payment for Cardiac Contrast Agent Drugs – Separately Payable Covered Outpatient Drugs

In the 2006 proposed rule CMS said that hospitals' average acquisition cost for drugs plus overhead and handling was covered under ASP+8%. However, in the 2006 Final Rule, CMS said average acquisition cost plus overhead and handling was covered by ASP+6%. For 2007, the agency is claiming that average acquisition cost and handling is covered by ASP-5%. Because the Kathpal and MedPAC studies suggest that pharmacy overhead and handling costs are closer to 25 percent we request CMS provide greater detail to support its assertion that average acquisition cost plus overhead/handling are covered under ASP+5%.

* * * *

We appreciate your attention to these important matters and urge CMS to make the important refinements proposed above. Please contact Jack Slosky, Ph.D., FACNP, FASNC at jack.slosky@bms.com or (978) 671-8191 for any further information regarding this BMSMI comment letter.

Sincerely,

T Ravenscroft IV

Timothy Ravenscroft
President
Bristol-Myers Squibb Medical Imaging

cc: American Society of Nuclear Cardiology (ASNC)
Council on Radionuclides and Radiopharmaceuticals (CORAR)
Nuclear Medicine APC Task Force (NMAPCTF)

Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS
Terry Kay, Deputy Director, Hospital and Ambulatory Policy Group, CMS
Carol Bazell, M.D., Director, Division of Outpatient Care, CMS
Ken Simon, M.D., Medical Officer, CMS

Jack Slosky, Ph.D., BMSMI

Timothy Ravenscroft
President
Tel 978.671.8100 Fax 978.436.7521 timothy.ravenscroft@bms.com

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Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

September 26, 2006

Via FedEx and Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

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

Re: Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; the 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
CMS-1506-P - Comments on Drug Administration and CCI edits

Dear Dr. McClellan:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the above-captioned Proposed Rule updating the Medicare Hospital Outpatient Prospective Payment System ("HOPPS").[1] A subsidiary of Bristol-Myers Squibb Company (BMS), the global pharmaceutical and related health care products company, BMSMI is one of the leading manufacturers of radiopharmaceuticals and other medical imaging drugs, including DEFINITY®, Vial for Perflutren Lipid Microsphere Injectable Suspension, a contrast imaging drug used to enhance and delineate cardiac structures during echocardiography procedures.[2]

In these comments, BMSMI would like to call to your attention a specific issue with respect to payment for the intravenous (IV) administration of echocardiography contrast imaging drugs, like DEFINITY®.**

** Please note that a separate comment letter is being submitted to Dr. McClellan/CMS by BMSMI with respect to the 2007 proposed Medicare HOPPS payment for radiopharmaceuticals

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

[2] Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

As described more fully below, under current coding policies, Medicare is aggregating the payment for the IV injection of the echocardiography contrast imaging drug into the payment for the associated echocardiography procedure. This policy is impractical for two reasons:

1. It ignores the fact that the echocardiography procedure codes do not describe the use of contrast imaging drugs, and

2. There is no evidence that the costs for administration of the contrast imaging drugs are included in the claims-based cost estimates for the associated echocardiography procedures.

We request, therefore, that CMS remove any coding edits from the Outpatient Code Editor (OCE) and hospital version of the Correct Coding Initiative (CCI) that aggregate the IV administration code C8952 "Therapeutic, prophylactic or diagnostic injection; intravenous push"[3] with the associated rest echocardiography procedure codes 93307 and 93308.[4]

Background

Echocardiography procedures are used to evaluate patients with known or suspected cardiac disorders. In most cases, echocardiograms can be interpreted by physicians, and the information can be used in patient management. However, in up to 20-percent of cases[5], unenhanced echocardiograms are suboptimal and repeat studies or additional testing may be required. Echocardiography contrast imaging drugs are FDA-approved intravenously-administered drugs that can enhance images in patients with suboptimal echocardiograms. Clinical studies have shown that echocardiography contrast imaging agents can salvage up to 58-91-percent of unevaluable images.[6] Published papers have estimated that substantial cost savings can be obtained from use of contrast-enhanced echocardiography in cases with suboptimal unenhanced echocardiograms.[7]

Issue

The American Medical Association (AMA) released new Current Procedural Terminology (CPT) codes effective January 1, 2006, to report IV administration of drugs. In the notes accompanying the new codes, the AMA instructed providers not to use the new codes when an IV injection is an inherent part of a procedure. Administration of contrast imaging drugs in diagnostic imaging is given as an example of when the new codes should not be used because IV injection is considered part of the procedure. This limitation on use of the new codes in diagnostic imaging *generally* makes sense because outside of echocardiography, there are specific codes for contrast-enhanced diagnostic imaging procedures which

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[3] Should CMS adopt all of the CPT drug administration codes for HOPPS in 2007, the relevant code would be CPT 90774 "Therapeutic, prophylactic or diagnostic injection (specify substance or drug); Intravenous push, single or initial substance/drug."

[4] 93307 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete;" 93308 "Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; follow-up or limited study"

[5] Waggoner AD, Ehler D, Adams D, et al. Guidelines for the cardiac sonographer in the performance of contrast echocardiography: Recommendations of the American Society of Echocardiography Council on cardiac sonography. *J Am Soc Echocardiogr.* 2001;14:417-20.

[6] Package insert for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension (September 2004).

[7] Shaw LJ, Gillam L, Feinstein S, et al. Use of an intravenous contrast agent (Optison™) to enhance echocardiography: efficacy and cost implications. *Am J Man Care.* 1998;4: SP169-SP176.

differentiate between procedures that do and do not involve IV administration of contrast. **However, this is not the case with echocardiography procedures. Echocardiography procedure codes were developed before echocardiography contrast imaging drugs were approved by the FDA, and the echocardiography procedure codes do not mention use of contrast imaging drugs.**

Consistent with the AMA instruction, CMS's CCI is now aggregating payment under the new IV injection codes into the payment for contrast-enhanced imaging procedures, when performed. Unfortunately, CCI has included echocardiography procedures under this aggregating policy. Although it may be reasonable to aggregate the new IV administration codes when there are specific contrast-enhanced diagnostic imaging procedure codes, there is no justification for aggregating the IV administration of contrast into the payment for echocardiography procedures.

Echocardiography procedure codes do not describe use of contrast imaging drugs because these drugs are not used in the majority of procedures. Therefore, it is unlikely that hospitals—which typically would assign a single chargemaster rate to each echocardiography procedure code—have included costs for the IV administration of contrast imaging drugs into the charge for the echocardiography procedure. As the HOPPS payment rates for the echocardiography procedures are based upon hospital charges, the HOPPS payment for these codes would not cover any expenses related to IV administration of contrast imaging drugs.

The costs for the IV administration of echocardiography contrast imaging drugs are not insubstantial relative to the costs of the associated echocardiography procedures. The IV administration of echocardiography contrast imaging drugs involves the same resources as required for other IV drug administration procedures. The claims data released to support the Proposed Rule indicate a median cost of $50.81 for IV injection procedures[8] versus median costs of $196.18 and $124.55 for the associated rest echocardiography procedures (93307 and 93308, respectively). Therefore, the cost of the IV injection procedure is approximately 25-40 percent of the cost of the associated echocardiography procedure. These amounts are too substantial to aggregate into the payment for the echocardiography procedure.

By aggregating payment for IV administration of echocardiography contrast imaging drugs into payment for echocardiography procedures, providers will not be compensated for any of the time, skills and supplies required for the IV administration of echocardiography contrast imaging drugs. Without fair reimbursement/payment for these services, providers may avoid use of echo contrast even in suboptimal echocardiography cases where use of contrast may salvage the image and may preclude the need for repeat or additional testing.

Request

We urge CMS to remove any edits from the OCE and the hospital version of the CCI that aggregate the IV drug injection code(s) C8952 (or 90774) into the codes for the associated echocardiography procedures (93307 and 93308). Deleting the OCE and CCI edits should remove financial disincentives limiting appropriate use of echocardiography contrast imaging drugs for medicare beneficiaries to help salvage images when an unenhanced echocardiography image is suboptimal.

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[8] Median costs for code 90784 (deleted code used for rate-setting) from file CMS1506P_Median_Costs_for_Hospital_Outpatient_Services_BY_HCPCS_Code.xls (accessed from http://www.cms.hhs.gov August 9, 2006).

We appreciate your consideration of our comments. Please contact Jack Slosky, Ph.D. at jack.slosky@bms.com or at 978 671-8191 if you have any questions about the comments made in this letter.

Sincerely yours,

T Ravenscroft

Timothy Ravenscroft
President, Bristol-Myers Squibb Medical Imaging

Cc: American Society of Echocardiography (ASE)
American College of Cardiology (ACC)
Medical Imaging Contrast Agent Association (MICAA)
Jack Slosky, Ph.D., BMSMI

iScience
Interventional

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September 25, 2006

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, Maryland 21244-1850

VIA FEDERAL EXPRESS

RE: Calendar Year 2007 Update to the Ambulatory Surgical Center Covered Procedures List [CMS-1506-P]

Dear Sir or Madam:

We are respectfully requesting that CMS add the CPT codes, 0176T (Transluminal dilation of aqueous outflow canal; without retention of device or stent), and 0177T (Transluminal dilation of aqueous outflow canal; with retention of device or stent) to the Medicare ASC list for 2007. Transluminal dilation of the aqueous outflow canal is also known as canaloplasty, and it is an outpatient ophthalmic procedure for the treatment of glaucoma. More details on the procedure can be found in a New Technology APC application for canaloplasty that was submitted to CMS on August 31, 2006.

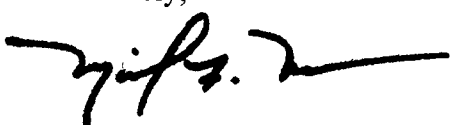
Similar to most other ophthalmic surgical procedures, the majority of canaloplasty interventions will be performed in an ASC. In fact, much of the clinical investigation for the canaloplasty procedure was performed by surgeons in an ASC setting. In order for these surgeons to continue to provide canaloplasty in ASCs, CPT codes 0176T and 0177T must be on the ASC list for 2007.

As a result of implementing this recommendation, we would request that CMS add the canaloplasty to payment group 9. As a point of reference, iScience Interventional has applied for a New Tech APC, and the application includes detailed cost information for the procedure supporting Group 9 placement.

4055 Campbell Avenue • Menlo Park, CA 94025 • Phone (650) 421-2700 / Fax (650) 421-2701

As a medical device manufacturer, we are eager to work with the agency to ensure that Medicare beneficiaries who have glaucoma have access to the best therapeutic technologies in the most appropriate and cost effective site of service. We appreciate the work entailed in developing the Proposed Rule, and we commend CMS on the effort involved in developing the new ASC payment system for 2008. We look forward to working with you on this important issue.

Sincerely,



Michael F. Nash, President & CEO
iScience Interventional

GE Healthcare

36

Jane Majcher
Director, Reimbursement Strategy
Medical Diagnostics
101 Carnegie Center
Princeton, NJ 08540
T 609 514 6701
F 609 514 6580
jane.majcher@ge.com

Via Federal Express

September 27, 2006

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

Dear Dr. McClellan:

GE Healthcare is a unit of General Electric Company with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery and biopharmaceuticals. Worldwide, GE Healthcare employs more than 42,000 people committed to service healthcare professionals and their patients in more than 100 countries.

We appreciate the opportunity to submit these comments on the proposed hospital outpatient prospective payment system (HOPPS) rule published on August 23, 2006 (71 Fed. Reg.,163, 49506). GE Healthcare is a member of the Council on Radionuclides and Radiopharmaceuticals (CORAR) and the Society of Nuclear Medicine's APC Task Force. We support the comments of these organizations.

Our comments relate to Section V. B. – "OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals".

Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

Consistent with recommendation #19 of the APC Advisory Panel at their August 2006 meeting, GE Healthcare supports the elimination of the drug packaging threshold for all radiopharmaceuticals.

CY 2007 Proposed Payment Policy for Radiopharmaceuticals

We support recommendation #20 made by the APC Advisory Panel to continue using the CY 2006 methodology of charges reduced to cost (CCR) for one more year. We appreciate the fact that CMS wanted to use CCR for only one year. However, the 2005 claims data that CMS used to propose the 2007 rates produce dramatic changes in rates that may have adverse effects on patient access to the drugs if not corrected.

Because there have been changes in codes and descriptors since 2005, it is necessary to "crosswalk" the codes. Moreover, CMS acknowledges that many 2005 claims with nuclear procedures did not have a radiopharmaceutical code. These two factors are reason enough not to rely on the 2005 claims data for setting payment rates.

In addition, the overhead costs of radiopharmaceuticals must be considered when setting payment rates. The 2006 data will be the first data set to reflect handling costs per CMS' directive. CMS asserts in the proposed rule that hospitals include such costs in their charges. However, our discussions with providers indicate that they do not always include the costs. If they do include the costs, they may not be in the charges for the drugs or they may be in various cost centers. Thus, using a hospital CCR rather than the department CCR would more accurately reflect the costs.

We are committed to working with CMS and our trade group and professional societies to find a better methodology for deriving a prospective payment rate. A new and better methodology should be developed based upon a stable, credible source of data. To that end, we suggest that CMS compare claims and invoices from rural and urban areas to analyze the difference in cost, both for price as well as handling costs. Data from external sources may be useful as well. Moreover, in order for mean costs to be valid, any rebates paid by manufacturers for product doses must be accounted for.

CMS should consider an expansion of correct coding initiatives in order to amass a more robust dataset. Specifically, providers should be instructed to include radiopharmaceuticals on claims for nuclear medicine procedures. By doing so, CMS would capture a larger sample of radiopharmaceutical codes. This would improve the coding as well as the payment for these drugs.

Table 26. —Proposed Payment Rates and Payment Crosswalk for CY 2007 – Separately Payable Radiopharmaceuticals

1. A9500 and A9502

There is a $9 disparity in the proposed CY 2007 payment rates for two myocardial perfusion imaging agents with the same indications. Technetium TC99m Tetrofosmin, Myoview™, coded as A9502, is a radionuclide tracer manufactured by GE Healthcare. TC99m Sestamibi, Cardiolite®, coded as A9500, is manufactured by another company.

The proposed payment rate for A9502 is $73.81 while the proposed rate for A9500 is $82.58. We believe that this pricing is an artifact from incomplete hospital reporting. There are a number of reasons that may have caused inaccurate reporting, including the fact that the manufacturer of Cardiolite offers manufacturer rebates that are not always captured on the invoice. These products, which are approved for rest and stress nuclear perfusion testing, compete vigorously in the marketplace on price.

Clinical trials demonstate comparable safety and efficacy for these products. For example, the Radiological Society of North America (RSNA) published the Salvador Borges-Neto, MD et al trial "Outcome Prediction in Patients at High Risk for Coronary Artery Disease: Comparison between 99mTc Tetrofosmin and 99mTc Sestamibi". This study included 1,818 consecutive patients who underwent a rest and stress single photon emission computer tomographic (SPECT) examination with either Tc99mTetrofosmin or Technetium Tc99m Sestamibi. The conclusion of the study shows that the type of clinically available 99m Tc-labeled myocardial perfusion agents should not affect interpretation of results for risk stratification and prognostic assessment.

Therefore, if CMS plans to go forward with a reimbursement rate in 2007 based on what we believe to be flawed reporting, we request that the reimbursement rates be averaged and that one rate be used for both technetium-based cardiac perfusion agents. This proposal will prevent one company from marketing the reimbursement rate as a reason to use its product and provide the patient and physician with choice based on the product's safety and efficacy.

2. A9521

The 2005 payment rate for Tc-99m Exametazime (Ceretec™) was $778.13 and the proposed payment rate for 2007 is $317.07. We realize that the 2005 rate was a percentage of Average Wholesale Price and that the proposed 2007 rate is based on 2005 claims data. However, as we pointed out above, such dramatic changes in payment may have an untoward effect on patient care.

Ceretec has two very distinct indications; brain (as an adjunct in the detection of altered regional cerebral perfusion in stroke), and infection (is indicated for leukocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease). The cost for a dose of Ceretec for brain imaging is approximately $400, and the cost for a dose of Ceretec for infection imaging is approximately $900. The difference in cost directly relates to the time and materials associated with the preparation of the radiopharmaceutical for the specific procedure for which it is intended.

GE Healthcare has applied, to no avail, to the HCPCS Panel for separate codes denoting the distinct uses and payment for Ceretec. We submitted the application because we were concerned that CMS would overpay in some cases and providers would lose money in others. The proposed CY 2007 rate for Ceretec would not cover the cost of the drug for either usage. This could have a particularly deleterious effect on patient access to the

drug as the preponderance of Ceretec claims are for the more expensive infection imaging.

Summary

Thank you for the opportunity to comment on the proposed HOPPS regulation. We recommend that CMS:

1. Eliminate the drug packaging threshold for all radiopharmaceuticals;
2. Continue CCR in order to amass a credible database upon which to develop a prospective payment rate for radiopharmaceuticals;
3. Use hospital overall CCR rather than departmental CCR to determine payment rates. The former would reflect overhead costs more accurately;
4. Promote correct coding initiatives, especially for nuclear medicine procedures, so that the data accurately reflect the use of radiopharmaceuticals;
5. Correct the payment rate for A9502, Myoview, so that there is parity with the drug A9500 Cardiolite or set one payment rate for both technetium-based cardiac perfusion agents;
6. Change the payment rate for A9521 Ceretec so that the extreme decrease in the proposed rate does not affect patient access to the drug.

If CMS wishes to discuss this comment letter in greater detail, I can be reached at 609-514-6701 or at jane.majcher@ge.com.

Sincerely,

Jane Majcher

Jane Majcher, Director
Reimbursement Strategy

Attachment:

Borges-Neto, MD et al trial, "Outcome Prediction in Patients at High Risk for Coronary Artery Disease: Comparison between 99mTc Tetrofosmin and 99m Tc Sestamibi"

Salvador Borges-Neto, MD
Robert H. Tuttle, MS
Linda K. Shaw, MS
William T. Smith IV, MD
Diwakar Jain, MD
R. Edward Coleman, MD
David Whellan, MD

Index terms:
Coronary vessels, diseases
Coronary vessels, radionuclide studies, 54.1217
Coronary vessels, SPECT, 54.12162
Radionuclides, comparative studies, 54.12162

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Abbreviations:
SDS = sum difference score
SRS = sum rest score
SSS = sum stress score

[1] From the Departments of Medicine (Cardiology) (S.B.N., R.H.T., L.K.S., W.T.S., D.W.) and Radiology (Nuclear Medicine) (S.B.N., R.E.C.) and Duke Clinical Research Institute and Drexel School of Medicine (Cardiology) (D.J.), Duke University Medical Center, PO Box 3949, Durham, NC 27710. Received February 13, 2003; revision requested May 7; revision received October 9; accepted November 12. This study was supported in part by an unrestricted grant from Amersham Health. Address correspondence to S.B.N. (e-mail: *borge001@mc.duke.edu*).

Author contributions:
Guarantor of integrity of entire study, S.B.N.; study concepts, S.B.N., D.W., W.T.S., D.J.; study design, S.B.N., R.H.T., L.K.S., D.W.; literature research, D.W., W.T.S.; clinical and experimental studies, S.B.N., R.E.C., D.W.; data acquisition, S.B.N., D.W., L.K.S., R.H.T., W.T.S.; data analysis/interpretation, S.B.N., D.W., L.K.S., R.H.T., D.J.; statistical analysis, L.K.S., R.H.T.; manuscript preparation, S.B.N., R.H.T., L.K.S., D.W., W.T.S., R.E.C.; manuscript definition of intellectual content, editing, revision/review, and final version approval, all authors

Outcome Prediction in Patients at High Risk for Coronary Artery Disease: Comparison between ^{99m}Tc Tetrofosmin and ^{99m}Tc Sestamibi[1]

PURPOSE: To determine if there was any difference in the ability of physicians to predict prognosis with technetium 99m (^{99m}Tc) sestamibi or ^{99m}Tc tetrofosmin in a large consecutive series of patients at high risk for coronary artery disease who underwent coronary angiography.

MATERIALS AND METHODS: This study included 1,818 consecutive patients who underwent a rest and stress single photon emission computed tomographic (SPECT) examination with either ^{99m}Tc sestamibi (n = 915) or ^{99m}Tc tetrofosmin (n = 903) and cardiac catheterization. A clinical index was generated and consisted of clinical and demographic variables. Information concerning death, cardiovascular death, and nonfatal myocardial infarction was 93% complete during the 1.5-year study period. Cox proportional hazards models were generated to help determine the incremental contribution of SPECT sum stress score (SSS) and the imaging agent variable to the clinical index.

RESULTS: Exercise was used for stress testing in 473 (52%) patients who received ^{99m}Tc tetrofosmin and 519 (57%) patients who received ^{99m}Tc sestamibi (P = .06). Cardiovascular death or myocardial infarction occurred in 130 patients. Resulting P values for χ^2 differences between models for the end points of *(a)* death from any cause, *(b)* cardiovascular death, and *(c)* cardiovascular death or myocardial infarction showed that SSS combined with clinical index was a significantly better model than adjusting for only baseline characteristics (P = .001, P < .001, P = .004, respectively). Incremental addition of either ^{99m}Tc tetrofosmin or ^{99m}Tc sestamibi to those models containing SSS and the clinical index did not show further significant improvement (P = .87, P = .88, and P = .26 for death from any cause, cardiovascular death, and cardiovascular death or myocardial infarction, respectively).

CONCLUSION: This study shows that the type of clinically available ^{99m}Tc-labeled myocardial perfusion agents should not affect interpretation of results for risk stratification and prognostic assessment.

Clinicians use a number of noninvasive cardiovascular stress testing modalities to determine the absence or presence and severity of coronary artery disease, to guide patient therapy, and to provide prognostic information (1–8). The information obtained with these studies may influence clinical decisions regarding the use of invasive procedures, including revascularization, and reassure patients with a lower risk who are undergoing medical therapy.

Coupled with cardiovascular stress testing, gated single photon emission computed tomography (SPECT) is a noninvasive imaging modality and is frequently used in the

evaluation of patients suspected or known to have ischemic heart disease (9). Technetium 99m (^{99m}Tc) sestamibi (Cardiolite; Bristol Myers Squibb, North Billerica, Mass) and ^{99m}Tc tetrofosmin (Myoview; Nycomed Amersham, Princeton, NJ) are the most commonly used ^{99m}Tc agents in clinical practice, with properties that are overall quite similar (10–12). The results of previous studies have demonstrated that both agents have similar accuracy in the detection of coronary artery disease (13–15). Our institution recently reported that ^{99m}Tc tetrofosmin improved the efficiency of our nuclear cardiology laboratory by decreasing the time needed to complete each examination and the need to repeat scanning because of extra cardiac activity (16).

Studies have shown that ^{99m}Tc sestamibi provided incremental prognostic value over clinical information in the prediction of survival and nonfatal myocardial infarction (17). More recently, in a multicenter registry, Shaw et al (18) showed that a normal ^{99m}Tc tetrofosmin study in a group of patients with low to intermediate risk of coronary artery disease has a low event rate, similar to that in ^{99m}Tc sestamibi studies; however, limited information is available regarding the prognostic value of a ^{99m}Tc tetrofosmin study in a group of patients at intermediate or high risk for coronary artery disease.

On the basis of the literature, given the equivalence in tracers in the detection of coronary artery disease (14,15), we hypothesized that the imaging agents ^{99m}Tc tetrofosmin and ^{99m}Tc sestamibi would provide equivalent prognostic value after we adjusted for differences in baseline clinical characteristics. Thus, we undertook the present study to determine if there is any difference in the ability of physicians to predict prognosis with ^{99m}Tc sestamibi or ^{99m}Tc tetrofosmin in a large consecutive series of patients at high risk for coronary artery disease who underwent imaging and who also underwent coronary angiography.

MATERIALS AND METHODS

Study Population

Our study included 1,818 consecutive patients who underwent a rest and stress SPECT myocardial perfusion study by using ^{99m}Tc sestamibi and ^{99m}Tc tetrofosmin in an alternating fashion, with each tracer being used for a 1-week interval, as part of our clinical routine at Duke University Medical Center from October 1, 1998, to December 31, 1999. All patients underwent cardiac catheterization within 180 days before or after the nuclear imaging study. This retrospective study was performed with Duke University Medical Center institutional review board approval, and informed consent was waived.

Clinical Information

Clinical characteristics, which consisted of multiple descriptors from each patient's history and physical examination, were prospectively collected by physicians and physician assistants from the nuclear cardiology laboratory for each patient at the time of cardiac catheterization and were stored in the Duke Databank for Cardiovascular Disease by personnel at the Duke Clinical Research Institute (19–22).

As previously described (8), a clinical index was generated by using a combination of the following clinical and demographic variables: age; sex; type, frequency, and electrocardiogram characterization of chest pain; variables used to assess myocardial damage and infarction history; descriptors of vascular disease; and electrocardiogram myocardial conduction data previously found to be independent predictors of outcome in patients undergoing cardiac catheterization (20).

Exercise Stress Test

Patients who were capable of exercising underwent an exercise treadmill stress test, which was the stress test of choice. Whenever possible, cardiac medications (particularly β-blockers) were not administered during the 48 hours prior to exercise. Patients exercised according to a standard Bruce protocol with 3-minute stages, unless the physician specifically requested another protocol or believed that a modified Bruce protocol was appropriate. Blood pressure, heart rate, and a continuous 12-lead electrocardiogram were monitored throughout the stress portion of the test and into recovery, until heart rate and blood pressure returned to preprocedure baseline levels. Interpretation of a 12-lead electrocardiogram was performed independent of interpretation of perfusion images. In addition, patients' symptoms were continually assessed and recorded.

Patients were instructed to inform the personnel administering the test when they approached their functional limit so that the ^{99m}Tc radioisotope could be injected approximately 1 minute prior to the conclusion of exercise.

Pharmacologic Stress Test

Patients who were unable to exercise or who had clinical contraindications to exercise underwent a pharmacologic stress test with one of three agents: dobutamine, dipyridamole, or adenosine. The use of different stress agents has been part of our clinical protocol rather than part of the prospective study. For all pharmacologic agents, a continuous 12-lead electrocardiogram was monitored throughout the study, and data was recorded at 1-minute intervals. Heart rate and blood pressure were monitored during the infusion of these agents at 3-minute intervals and during recovery until hemodynamic parameters returned to pretest baseline levels.

Dobutamine.—An intravenous infusion of dobutamine (Eli Lilly, Indianapolis, Ind) was initiated at a rate of 10 μg/kg/min and increased at a rate of 10 μg/kg/min every 3 minutes until a target heart rate of 85% of the age-predicted maximal heart rate was reached. The examination could also be terminated because of patient symptoms, evidence of significant ischemia, or prolonged arrhythmias, or when the dobutamine infusion rate reached a maximum rate of 40 μg/kg/min. Atropine sulfate (≤1 mg) was used when the target heart rate was not achieved despite maximum infusion rate of dobutamine. The ^{99m}Tc-labeled tracer was injected when one of the previously mentioned end points was reached.

Dipyridamole.—Dipyridamole (Persantin; DuPont Pharmaceuticals, North Billerica, Mass) was administered intravenously at an infusion rate of 0.142 mg/kg/min for 4 minutes. The ^{99m}Tc-labeled tracer was administered 2 minutes after completion of the dipyridamole infusion. Intravenous aminophylline (75–250 mg) was used to reverse dipyridamole-induced side effects. No caffeine intake was permitted within 12 hours of the performance of the stress test.

Adenosine.—Adenosine (Adenoscan; Fujisawa Healthcare, Deerfield, Ill) was administered at a rate of 0.142 mg/kg/min for 6 minutes. The ^{99m}Tc-labeled tracer was injected 3 minutes after adenosine infusion was started. No caffeine intake was permitted within 12 hours of the performance of the stress test.

Myocardial Perfusion SPECT Protocol

The protocol for performing SPECT myocardial perfusion imaging studies in our institution has been described previ-

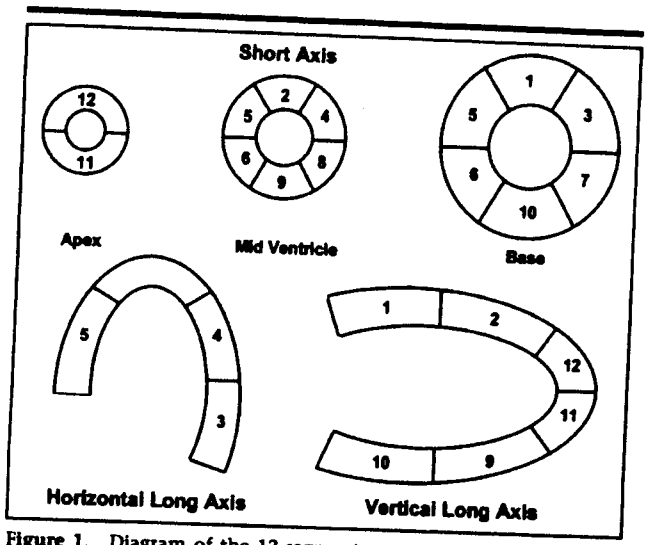

Figure 1. Diagram of the 12-segment system used to generate the perfusion score for rest and stress nuclear imaging. Segments were labeled as follows: *1*, high anterior; *2*, low anterior; *3*, high anterolateral; *4*, low anterolateral; *5*, anteroseptal; *6*, inferoseptal; *7*, high posterolateral; *8*, low posterolateral; *9*, inferior; *10*, posterobasal; *11*, inferoapical; *12*, anteroapical.

ously (16). We routinely used more than one camera system in our laboratory, and patients underwent imaging according to camera system availability. The 12-segment model was used because our database supported only 12 segments at the outset of the data collection period. In summary, SPECT data were obtained with two different systems that are used clinically, both of which use a step-and-shoot protocol. The rest images were obtained for 30 seconds per projection, and the stress images were obtained for 20 seconds per projection. The first camera system used 90 projections during a 360° rotation (4° per stop) with a three-headed gamma camera with low-energy high-resolution parallel hole collimators, and a hamming filter (cutoff, 0.6 cycles per centimeter) (Triad; Trionix, Twinsburg, Ohio). The second camera system employed 60 projections during a 180° rotation (3° per stop) by using a fixed 90° two-headed gamma camera with low energy, high resolution, parallel-hole collimators, and a Butterworth filter (cutoff, 0.35 cycles per pixel) and a power of 5.0 (ElScint, Haifa, Israel). Images were reconstructed with filtered backprojection and no attenuation correction.

Thallium 201 (^{201}Tl) was the agent of choice for obtaining rest images as part of our clinical dual isotope protocol. In patients who weighed more than 280 pounds (127 kg), however, either ^{99m}Tc tetrofosmin or ^{99m}Tc sestamibi was used to obtain rest images. All stress images were obtained with ^{99m}Tc tetrofosmin or ^{99m}Tc sestamibi. Images were obtained by using a rest and stress same-day protocol, except in very obese patients; in these patients, images were obtained by using the same ^{99m}Tc-based radiopharmaceutical and a 2-day protocol. Rest studies were performed with injection of 3 mCi for ^{201}Tl-labeled agents or 10–12 mCi for ^{99m}Tc-labeled agents, with SPECT performed 30 minutes later (60 minutes later for ^{99m}Tc sestamibi). Exercise or pharmacologic stress tests were performed with injection of 21–36 mCi, and SPECT started 20 minutes later for exercise stress tests and 30 minutes later for pharmacologic stress tests. In patients injected with ^{99m}Tc sestamibi during a pharmacologic stress test, a 60-minute waiting period was allowed prior to imaging.

Image Interpretation and Candidate Nuclear Variables

Images were independently interpreted and clinically reviewed by either of two experienced (>15 years) nuclear medicine and nuclear cardiology physicians (S.B.N., R.E.C.). A 12-segment reporting system, which is illustrated in Figure 1, was used to quantify perfusion to various vascular territories and is similar to methods previously described with a 20-segment model (5,6). The 12-segment model was used because our database supported only 12 segments at the outset of the data collection period. The segments are illustrated in Figure 1. The relative perfusion to each segment was also quantified with four grades of perfusion defect, with each assigned a numeric value as follows: 0, no defect; 1, mild defect; 2, moderate defect; and 3, severe defect. A cumulative SPECT sum stress score (SSS) was obtained by summing the score for each of the 12 segments. Thus, a normal study would yield a SSS of 0, while the maximum score possible would be 36 (severe perfusion defect in all 12 segments). Similarly, a SPECT sum rest score (SRS) and sum difference score (SDS), which was the change from stress to rest, were derived. The score variables have been shown to be highly predictive of cardiovascular outcome with a 20-segment model (5,6,17).

Coronary Angiography

Coronary angiography was performed in multiple left and right anterior oblique projections. For each patient, prospective recordings of the coronary artery anatomy were obtained, including the location and the qualitatively determined degree of narrowing for each stenosis. Angiograms were interpreted in consensus by two angiographers with more than 25 years of experience by applying the following ordinal scale: 0, less than 25%, 25%, 50%, 75%, 95%, or 100% occlusion. The extent of coronary artery disease was determined by the traditional one-, two-, or three-vessel disease characterization. Significant disease was defined as more than 75% occlusion of a major epicardial coronary artery.

Follow-up Data

Patients or their relatives were contacted prospectively by research personnel, either with a mailed questionnaire or telephone interview at 6 months and 1 year and at yearly intervals thereafter after cardiac catheterization. The questionnaires and interviews were used to request follow-up information concerning death, rehospitalization, and nonfatal myocardial infarction. Follow-up was 93% complete during the study period. An independent clinical events review committee that did not have knowledge of the patients' clinical, catheterization, stress test, or perfusion data evaluated the cause of death in patients who died and the cause of nonfatal myocardial infarction in patients who survived. Data acquisition and follow-up techniques have been described previously (20,22).

Statistics

Baseline characteristics of the study patients are presented as percentages for discrete variables and as median, 25th, and 75th percentiles for continuous variables. Pearson χ^2 tests were used to test for differences in discrete variables for the two imaging agents.

The Wilcoxon rank-sum test was used to determine if there were significant differences between the distributions of continuous variables for the two imaging agents. Linear regression analysis was used to evaluate differences between the two imaging agents in their relationship to SSS, which was the dependent variable. A *P* value of less than .05 indicated a statistically significant difference between the two imaging agents for all test statistics.

Unadjusted, event-free survival curves stratified by the type of imaging agent used were generated by using Kaplan-Meier survival estimates for the three end points: death from any cause, cardiovascular death, and cardiovascular death or nonfatal myocardial infarction. The follow-up time for each estimate was 1.5 years. The log-rank χ^2 test was used to evaluate differences between the survival curves.

Cox proportional hazards models were constructed to assess the relationship of baseline clinical characteristics, SSS, and the imaging agent with each of the three outcomes. The model improvement after adding SSS and the tracer variable to the clinical index was evaluated. Similar Cox modeling schemes were used to evaluate the model improvement after incremental addition to the clinical index of SRS and SDS separately, followed by the imaging agent variable.

To determine whether the relationship between SSS and each of the outcomes was different for the two imaging agents, Cox models for each of the separate end points—both unadjusted and adjusted for differences in baseline clinical risk—were generated to test the significance of an interaction term, namely SSS according to the imaging agent variable. In a similar fashion, interactions between the imaging agent variable and SRS and SDS, respectively, were tested with adjusted and unadjusted Cox models. A *P* value of less than .05 for the interaction term in the model suggests that the imaging agent affects the relationship between SSS and the end point.

Demographic and Clinical Characteristics of Study Groups

Demographic and Clinical Characteristics*	^{99m}Tc-Tetrofosmin Study Group (n = 903)	^{99m}Tc-Sestamibi Study Group (n = 915)	*P* Value
Female sex	316 (35)	311 (34)	.49
Diabetes	298 (33)	265 (29)	.13
Hypertension	605 (67)	613 (67)	.92
History of congestive heart failure	289 (32)	329 (36)	.14
New York Heart Association congestive heart failure class IV	36 (4)	27 (3)	.25
History of peripheral vascular disease	126 (14)	137 (15)	.67
History of cerebral vascular disease	135 (15)	146 (16)	.64
Carotid bruits	117 (13)	119 (13)	.96
History of smoking	551 (61)	586 (64)	.28
History of angina	768 (85)	796 (87)	.36
Prior revascularization	587 (65)	595 (65)	.93
No. of diseased epicardial vessels			.81
0	253 (28)	247 (27)	
1	226 (25)	229 (25)	
2	163 (18)	183 (20)	
3	262 (29)	256 (28)	
Exercise stress	470 (52)	522 (57)	.06
Revascularization after stress test (angioplasty or coronary artery bypass graft)	236 (26)	238 (26)	.87

Note.—Data are number of patients, unless indicated otherwise. Data in parentheses are percentages.

* Median age was 63 years (25th percentile, 54 years; 75th percentile, 71 years) in patients who received ^{99m}Tc tetrofosmin and 63 years (25th percentile, 54 years; 75th percentile, 70 years) in patients who received ^{99m}Tc sestamibi. This characteristic was not significant (*P* = .59).

RESULTS

The total cohort in this analysis included 1,818 patients; 903 underwent SPECT myocardial perfusion stress imaging with ^{99m}Tc tetrofosmin, whereas 915 underwent the study with ^{99m}Tc sestamibi. As shown in the Table, there were no substantial differences in baseline characteristics between the two groups. The median age was 63 years for each group. The majority of patients had hypertension and a history of smoking, angina, and prior revascularization. Exercise was used for stress testing in 473 (52%) patients who received ^{99m}Tc tetrofosmin and in 519 (57%) patients who received ^{99m}Tc sestamibi (*P* = .06). The number of diseased epicardial vessels at cardiac catheterization was not significantly different between nuclear tracer cohorts (*P* = .81), with the majority of patients having either no disease or single vessel disease. Although the ejection fraction was not available for all patients (n = 1,505), there were no differences between the cohorts that did not have missing data (*P* = .73).

Imaging Agent in the Prediction of SSS

The median SSS was 3 for studies in which ^{99m}Tc tetrofosmin was used versus 4 for studies in which ^{99m}Tc sestamibi was used (*P* = .08); 25th and 75th percentile values were 0 and 8, respectively, for both studies. While SSS tended to be higher with ^{99m}Tc sestamibi, the difference was not statistically significant (*P* > .05). Linear regression was used to determine whether SSS could be reliably predicted with the imaging agent. When the linear regression model was generated after adjusting for important baseline clinical characteristics, the imaging agent variable was not a significant predictor of SSS (*P* = .15).

Follow-up Endpoints and Outcome Events

During follow-up, there were 49 deaths in the ^{99m}Tc tetrofosmin group and 61 in the ^{99m}Tc sestamibi group. Of these deaths, 68 (62%) were classified as cardiovascular. Cardiovascular death or myocardial infarction occurred in 130 patients. The median follow-up time for living patients was 1.5 years (25th percentile, 1.1 years; 75th percentile, 1.5 years) for the patients who received ^{99m}Tc tetrofosmin and 1.5 years (25th percentile, 1.5 years; 75th percentile, 1.5 years) for the patients who received ^{99m}Tc sestamibi.

The unadjusted overall mortality rate after 1.5 years of follow-up was 7.1%. Mortality rates of 6.5% and 7.5% were observed at 1.5-year follow-up in patients

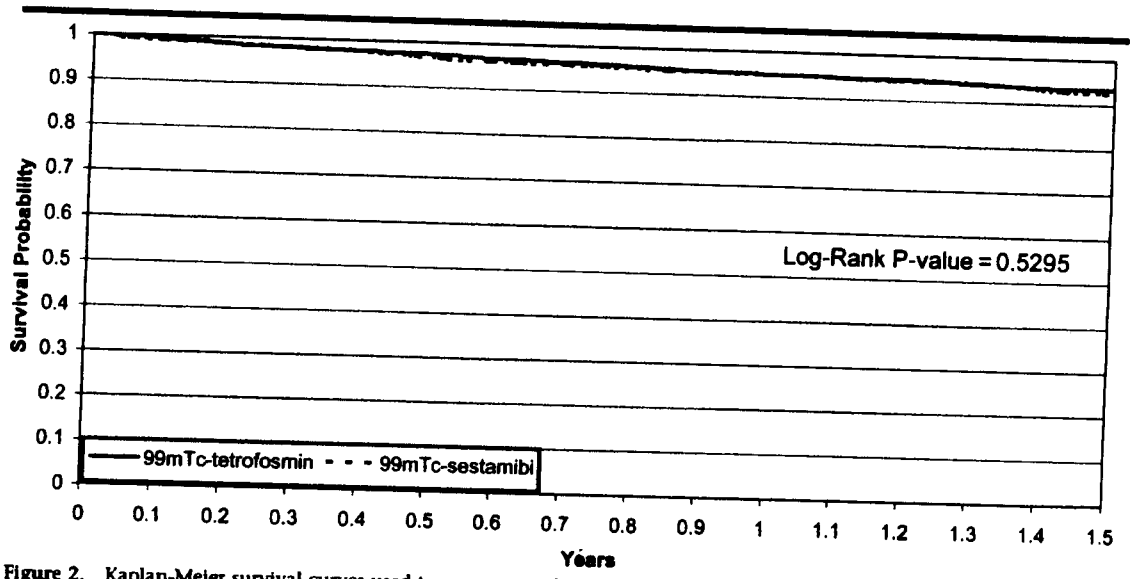

Figure 2. Kaplan-Meier survival curves used to compare patients undergoing nuclear stress testing with ^{99m}Tc tetrofosmin and ^{99m}Tc sestamibi. The *P* value for the log-rank test used to assess differences between the two curves is higher than .05, which signifies that there is no statistically significant difference between the cumulative survival distribution of patients imaged with ^{99m}Tc tetrofosmin compared with patients imaged with ^{99m}Tc sestamibi.

who received ^{99m}Tc tetrofosmin and ^{99m}Tc sestamibi, respectively, with no significant difference in mortality between the groups over the study period (*P* = .53, Fig 2). Similarly, there was no significant difference between ^{99m}Tc tetrofosmin and ^{99m}Tc sestamibi regarding cardiovascular death (4.4% vs 4.6%, respectively, *P* = .74) and the composite end point of cardiovascular death or myocardial infarction (8.9% vs 7.8%, respectively, *P* = .48).

Imaging Agent in Prediction of Outcome

Cox proportional hazards models that were adjusted for baseline characteristics were significant for each of the three end points. When SSS was added to the baseline models, the clinical index provided 80% of the prognostic information for survival, 70% for cardiovascular death, and 78% for cardiovascular death or myocardial infarction (Fig 3). The *P* values associated with the incremental χ^2 test when SSS was added to the baseline models were significant for death from any cause (*P* = .001), cardiovascular death (*P* < .001), and cardiovascular death or myocardial infarction (*P* = .004), which confirms the prognostic value of SSS in our study population. Inclusion of the imaging agent (^{99m}Tc tetrofosmin vs ^{99m}Tc sestamibi) in addition to the SSS and clinical index in each of these models did not, however, provide any additional statistically significant information (*P* = .87, .88, and .26, respectively). *P* values for the interaction term for SSS with imaging agent interaction in each of these models were not significant, which indicates that the imaging agent does not alter the effect of SSS for death, cardiovascular death, or the composite end point of cardiovascular death or myocardial infarction (*P* = .43, .51, and .55, respectively). When resting perfusion results as defined by SPECT SRS (reflecting infarction areas), calculated by using the same gradations as the SSS, and changes from stress to rest as defined by the SPECT SDS (reflecting ischemic areas) was analyzed, similar results were obtained (Figs 4, 5).

DISCUSSION

In this cohort of patients that underwent nuclear stress testing and cardiac catheterization, clinical factors contributed most of the prognostic information, while the SSS provided substantial additional prognostic information beyond those baseline clinical predictors for each of the outcomes. Most importantly, however, the type of tracer did not provide any substantial increase in the ability to predict outcome with the Cox proportional hazard model, nor did it affect the relationship between SSS and outcome.

These results show that SSS can be used to predict survival and to provide incremental prognostic information above and beyond clinical data, which confirms the conclusions drawn from the results of previous studies by using nuclear stress test results. Hachamovitch et al (5) used a dual-isotope protocol to demonstrate that SSS provided significant prognostic information when added to clinical data and exercise data in 2,113 patients (*P* < .001). In a follow-up study of 5,183 patients that included patients with pharmacologic stress and exercise stress, Hachamovitch et al (6) again confirmed their initial findings that SSS provided significant prognostic information beyond clinical variables (*P* < .001). Vanzetto et al (7) also found that myocardial perfusion imaging with ^{201}Tl provided significant prognostic information in addition to that provided by clinical variables and exercise stress tests (*P* < .01). The findings of Vanzetto et al (7) included 6 years of follow-up compared with the shorter 1.5 and 1.75 years of follow-up in the studies of Hachamovitch et al (5,6). In our more recent cohort of 3,287 patients at high risk for coronary artery disease (S.B.N., unpublished data, 2004), SSS from myocardial perfusion studies provided substantial prognostic information beyond both clinical data and anatomic descriptions from cardiac catheterization.

Potential Differences and Clinical Impact of Available Myocardial Perfusion Agents

Despite some potential differences between ^{99m}Tc tetrofosmin and ^{99m}Tc ses-

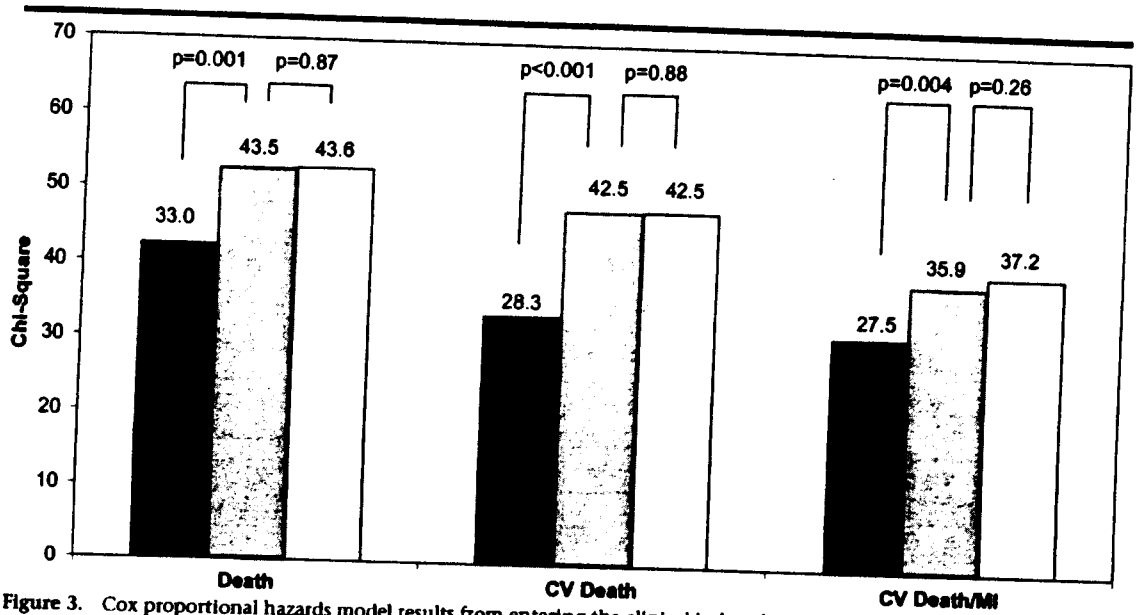

Figure 3. Cox proportional hazards model results from entering the clinical index alone (black bars), the clinical index and SPECT SSS (gray bars), and the clinical index, SPECT SSS, and type of imaging agent (white bars) in an incremental fashion. The number above each of the bars is the log-likelihood χ^2 value for that particular bar. When the imaging agent variable is added to each of the Cox models for the different outcomes, there is not a significant amount of information added ($P > .05$ for all models), which shows that while the clinical index and SSS are both important prognostic predictors, the type of imaging agent used does not affect patient outcome. *CV* = cardiovascular, *MI* = myocardial infarction.

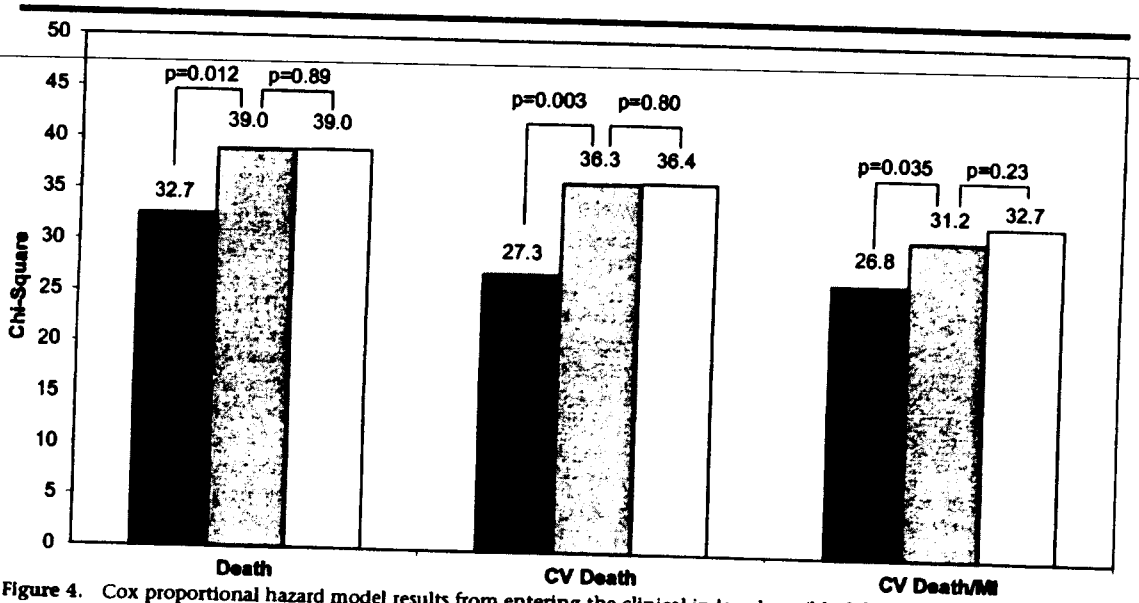

Figure 4. Cox proportional hazard model results from entering the clinical index alone (black bars), the clinical index and SPECT SSS (gray bars), and the clinical index, SPECT SSS, and type of imaging agent (white bars) in an incremental fashion. The number above each of the bars is the log-likelihood χ^2 value for that particular bar. When the imaging agent variable is added to each of the Cox models for the different outcomes, there is not a significant amount of information added ($P > .05$ for all models), which shows that while the clinical index and SRS are both important prognostic predictors, the type of imaging agent does not affect patient outcome. *CV* = cardiovascular death, *MI* = myocardial infarction.

tamibi in myocardial extraction at high coronary blood flow rates, previous results have shown equivalent sensitivity and specificity in the identification of patients with coronary artery disease, including defect detection and reversibility of defects (14,15). In a recently published report by Soman et al (23), investigators found a substantial difference between ^{99m}Tc sestamibi and ^{99m}Tc tetrofosmin in the identification of reversible defects in patients with mild to moderate coronary artery disease during pharmacologic stress testing. Several limitations, such as the presence of disease in multiple vessels, lack of specific correlation with vascular territory abnormalities, small sample size, absence of quantitative coronary

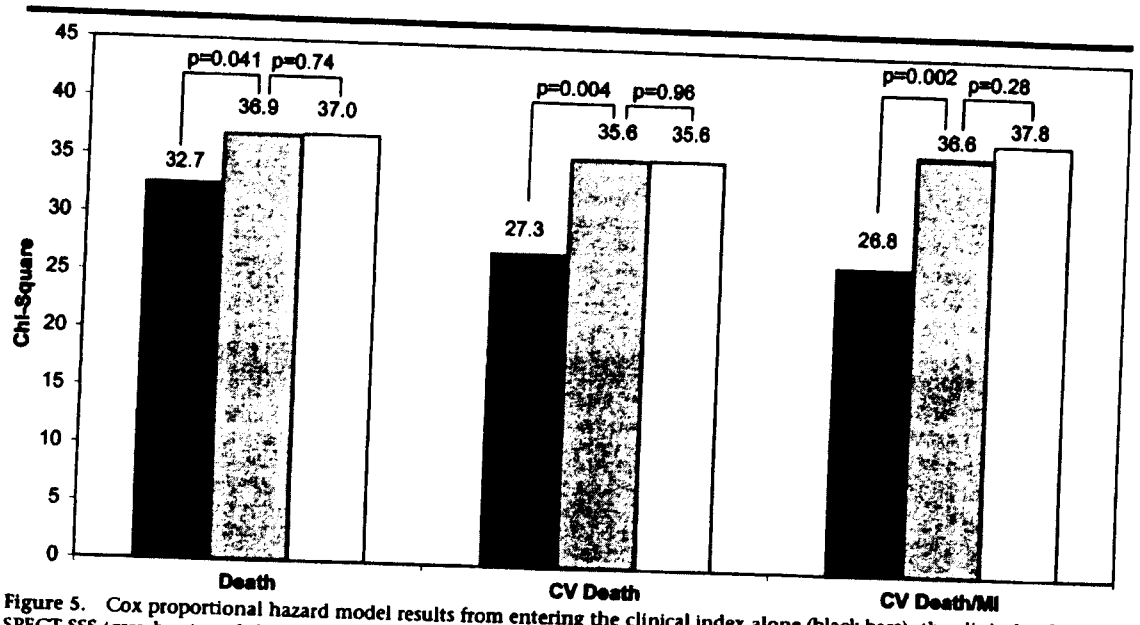

Figure 5. Cox proportional hazard model results from entering the clinical index alone (black bars), the clinical index and SPECT SSS (gray bars), and the clinical index, SPECT SSS, and type of imaging agent (white bars) in an incremental fashion. The number above each of the bars is the log-likelihood χ^2 value for that particular bar. When the imaging agent variable is added to each of the Cox models for the different outcomes, there is not a significant amount of information added ($P > .05$ for all models), which shows that while the clinical index and SDS are both important prognostic predictors, the type of imaging agent used does not affect patient outcome. *CV* = cardiovascular death, *MI* = myocardial infarction.

angiography, wide range of stenosis severity, and no evaluation of patients with normal coronary arteries for specificity, however, preclude definitive conclusions from being drawn on the basis of results of that study. Furthermore, no differences in treatment allocation or outcomes were reported.

Prognostic Value of ^{99m}Tc Tetrofosmin versus ^{99m}Tc Sestamibi

In the current study, which comes from a single institution, the prognostic value of the two clinically available ^{99m}Tc agents was directly compared in a large cohort of patients at high risk for coronary artery disease. Previously reported results in a low-risk cohort of patients have suggested effective risk stratification with ^{99m}Tc tetrofosmin (24,25). Because ^{99m}Tc tetrofosmin was approved for clinical use more recently than ^{99m}Tc sestamibi, the limited availability of prognostic information for this perfusion agent is not surprising.

In a recent large multicenter registry, Shaw et al (18) evaluated the prognostic value of a normal ^{99m}Tc-tetrofosmin SPECT study in 4,728 patients at intermediate or low risk for coronary artery disease. In contrast to our present findings, which include 50% of patients with pharmacologic stress and higher risk SSS, only one-third of the patients underwent a stress test with adenosine in the multicenter registry. The authors observed an annualized event rate of 0.6% with meta-analysis. By comparing previously reported outcome data for normal myocardial perfusion studies by using ^{201}Tl and ^{99m}Tc sestamibi with the results of Shaw et al, the overall survival rates were again very similar and ranged from 99.3% to 99.7%. Regardless of which tracer is used in low-risk populations, similar annualized event rates of less than 1% have been observed.

Limitations

This study had some unavoidable limitations. We used more than one camera system and a 12-segment model with a four-grade scoring system to describe the extent and severity of total perfusion abnormalities. We routinely used more than one camera system in our laboratory, and patients underwent imaging according to camera system availability. The 12-segment model was used because our database supported only 12 segments at the outset of the data collection period. Currently, the American Society of Nuclear Cardiology recommends a 17-segment model (26) and a five-step scoring system for grading the severity of any perfusion defect. While the recommended model would provide greater ability to define regions of defect within the myocardium and may provide a higher resolution of SSS, the 12-segment scoring systems were powerful, and the use of a 17-segment model would likely improve prognostic abilities with SPECT.

Since patients included in this study underwent both a nuclear stress test and cardiac catheterization, a selection bias for patients with a higher-risk profile is inherent and evidenced by an event rate that was higher than that seen in earlier studies. The higher event rate did, however, increase our power to identify differences between independent variables and strengthens our finding that no difference is documented between ^{99m}Tc tetrofosmin and ^{99m}Tc sestamibi myocardial perfusion tracers in the prediction of hard events outcome.

Despite previous studies that have identified poststress ejection fraction as a predictor of outcome, a gated SPECT ejection fraction was not incorporated into this analysis (27). At the time of data collection, gated SPECT was not a standard component of the diagnostic study; thus, it was not included in the database. Given previous results, it is likely that gated SPECT ejection fraction could provide further incremental prognostic value beyond the clinical variables and perhaps beyond the perfusion score, particularly for the prediction of death and cardiovascular death (28). The purpose of this

study, however, was to compare tracers and their effect on estimating outcomes on the basis of perfusion abnormalities.

Finally, the relationship between mortality and perfusion scores may have been minimized by means of revascularization procedures being preferentially performed in patients with positive stress tests. The finding that perfusion scores (SSS, SRS, and SDS) are substantial predictors of outcome in the face of revascularization only supports the use of these scores in predicting prognosis, even in patients who are undergoing revascularization. Furthermore, the similar percentage of revascularization between imaging agent cohorts suggests that treatment is independent of tracer type.

In conclusion, for the physician who refers patients for nuclear cardiology testing, the results of SPECT myocardial perfusion imaging provide important information that should influence the clinician in the decision-making process regarding appropriate therapy options, as well as help providers and patients understand the risk for future clinical events. Along with previously published reports and multicenter registry trial results, the findings of this study should reassure clinicians that the type of clinically available ^{99m}Tc-labeled myocardial perfusion agents used in nuclear cardiology examinations should not change the interpretation of the results for risk stratification and prognostic assessment. Furthermore, the development of clinical guidelines that address ^{99m}Tc-labeled myocardial perfusion imaging studies should be tracer independent.

References

1. Diamond GA, Forrester JS. Analysis of probability as an aid in the clinical diagnosis of coronary artery disease. N Engl J Med 1979; 300:1350–1358.
2. Mark DB, Shaw LK, Harrell FE Jr, et al. Prognostic value of a treadmill exercise score in outpatients with suspected coronary artery disease. N Engl J Med 1991; 325:849–853.
3. Brown KA, Boucher CA, Okada RD, et al. Prognostic value of exercise thallium-201 imaging in patients presenting for evaluation of chest pain. J Am Coll Cardiol 1983; 1:994–1001.
4. Iskandrian AS, Hakki AH, Kane-Marsch S. Prognostic implications of exercise thallium-201 imaging in patients with suspected or known coronary artery disease. Am Heart J 1985; 110:135–143.
5. Hachamovitch R, Berman DS, Kiat H, et al. Exercise myocardial perfusion SPECT in patients without known coronary artery disease: incremental prognostic value and impact on subsequent patient management. Circulation 1996; 93:905–914.
6. Hachamovitch R, Berman DS, Shaw LJ, et al. Incremental prognostic value of myocardial perfusion single photon emission computed tomography for the prediction of cardiac death: differential stratification for risk of cardiac death and myocardial infarction. Circulation 1998; 97:535–543.
7. Vanzetto G, Ormezzano O, Fagret D, Comet M, Denis B, Machecourt J. Long term additive prognostic value of thellium-201 myocardial perfusion imaging over clinical and exercise stress test in low to intermediate-risk patients: study in 1137 patients with 6-years follow-up. Circulation 1999; 100:1521–1527.
8. Pryor DB, Shaw L, McCants CB, et al. Value of the history and physical in identifying patients at increased risk for coronary artery disease. Ann Intern Med 1993; 118:81–90.
9. Gibbons RJ, Chatterjee K, Daley J, et al. ACC/AHA/ACP-ASIM guidelines for the management of patients with chronic stable angina: a report of American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 1999; 33:2092–2197.
10. Wackers FJ, Berman DS, Maddahi J, et al. Technetium-99m hexakis 2-methoxyisobutyl isonitrile: human biodistribution, dosimetry, safety, and preliminary comparison to thallium-201 for myocardial perfusion imaging. J Nucl Med 1989; 30:301–311.
11. Jain D, Wackers FJ, Mattera J, et al. Biokinetics of 99m Tc-tetrofosmin: myocardial perfusion imaging agent—implications for a 1-day imaging protocol. J Nucl Med 1993; 34:1254–1259.
12. Jain D, Zaret BL. Technetium 99m tetrofosmin. In: Iskandrian AE, Verani MS, eds. New developments in cardiac nuclear imaging. Armonk, NY: Futura, 1998; 29–58.
13. Jain D. Technetium-99m labeled myocardial perfusion imaging agents. Semin Nucl Med 1999; 29:221–236.
14. Flamen P, Bossuyt A, Franken PR. Technetium-99m-tetrofosmin in dipyridamole stress myocardial SPECT imaging: intraindividual comparison with technetium-99m-sestamibi. J Nucl Med 1995; 36:2009–2015.
15. Acampa W, Cuocolo A, Pasquale S, et al. Direct comparison of technetium 99m-sestamibi and technetium 99m-tetrofosmin cardiac single photon emission computed tomography in patients with coronary artery disease. J Nucl Cardiol 1998; 5:265–274.
16. Ravizzini G, Hanson MW, Wong T, et al. Efficiency comparison between Tc-99m tetrofosmin and Tc-99m sestamibi myocardial perfusion studies. Nucl Med Commun 2002; 23:203–208.
17. Berman DS, Hachamovitch R, Kiat H, et al. Incremental value of prognostic testing in patients with known or suspected ischemic heart disease: a basis for optimal utilization of exercise technetium-99m sestamibi myocardial perfusion single photon emission computed tomography. J Am Coll Cardiol 1995; 26:639–647.
18. Shaw LJ, Hendel R, Borges-Neto S, et al. Prognostic value of normal exercise and adenosine Tc-99m tetrofosmin SPECT imaging: results from the multicenter registry in 4,728 patients. J Nucl Med 2003; 44:134–139.
19. Pryor DB, Shaw LK, Harrell FE, et al. Estimating the likelihood of severe coronary artery disease. Am J Med 1991; 90:553–562.
20. Harris PJ, Harrel FE Jr, Lee KL, Behar VS, Rosati RA. Survival in medically treated patients with coronary artery disease. Circulation 1979; 60:1259–1269.
21. Pryor DB, Harrell FE Jr, Lee KL, Califf RM, Rosati RA. Estimating the likelihood of significant coronary artery disease. Am J Med 1983; 75:771–780.
22. Rosati RA, McNeer JF, Starmer CF, Mittler BS, Morris JJ Jr, Wallace AG. A new information system for medical practice. Arch Intern Med 1975; 135:1017–1024.
23. Soman P, Taillefer R, DePuey G, Udelson JE, Lahiri A. Enhanced detection of reversible perfusion defects by Tc-99m sestamibi compared to Tc-99m tetrofosmin during vasodilator stress SPECT imaging in mild to moderate coronary artery disease. J Am Coll Cardiol 2001; 37:458–462.
24. Groutars RG, Verzijlbergen JF, Zwinderman AH, et al. Incremental prognostic value of myocardial SPECT with dual-isotope rest. (201)Tl/stress (99m)Tc-tetrofosmin. Eur J Nucl Med Mol Imaging 2002; 29:46–52.
25. Galassi AR, Azzarelli S, Tomaselli A, et al. Incremental prognostic value of technetium-99m-tetrofosmin exercise myocardial perfusion imaging for predicting outcomes in patients with suspected or known coronary artery disease. Am J Cardiol 2001; 88:101–106.
26. Port SC, Berman DS, Garcia EV, et al. Imaging guidelines for nuclear cardiology procedures. II. American Society of Nuclear Cardiology. J Nucl Cardiol 1999; 6:G47–G84.
27. Sharir T, Germano G, Kang X, et al. Prediction of myocardial infarction versus cardiac death by gated myocardial perfusion SPECT: risk stratification by the amount of stress induced ischemia and the post stress ejection fraction. J Nucl Med 2001; 42:831–837.
28. Mast ST, Shaw LK, Ravizzini GC, et al. Incremental prognostic value of RNA ejection fraction measurements during pharmacologic stress testing: a comparison with clinical and perfusion variables. J Nucl Med 2001; 42:871–877.

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September 27, 2006

Mark B. McClellan, MD. PhD
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

9727 Pacific Heights Blvd.
San Diego, CA
92121-3719

Phone
858.453.6300

Fax
858.458.5698

www.4dneuroimaging.com

Re: Medicare Hospital Outpatient Prospective Payment System: Proposed Rule

Dear Dr. McClellan:

I appreciate the opportunity to offer comments on the proposed hospital outpatient prospective payment rates for 2007. These comments concern the costs of providing Magnetoencephalography (MEG) services, CPT Codes 95965, 95966 and 9596.

As background, MEG is a highly specialized service performed in a limited number of hospitals in the United States. MEG is a non-invasive procedure that helps identify seizure activity or evoked sensory activity, which can be overlaid onto MRI images of the brain. It is principally used for determining the appropriateness of surgery in epilepsy patients whose seizures cannot be well controlled by drug therapy. It also has application for certain other patients scheduled for a neurosurgical procedure of the brain. MEG is used to locate the precise regions of the brain responsible for sensation, movement, vision and hearing, relative to the surgical target. The images and data generated help guide the neurosurgeon and assure that parts of the brain critical to these functions are not injured.

By its very nature, Medicare beneficiaries represent a small number of the patients who receive MEG services since epilepsy surgery is rarely performed on elderly patients, but on younger patients that qualify for Medicare due to their disability. This helps explain the very low volume of these services in the Medicare database.

APC Assignments and Payment for MEG Services

The three MEG codes are currently assigned to new technology APC's as follows:

Code	Description	APC	Payment Rate
95965	MEG, spontaneous	1523	$2,750
95966	MEG Evoked	1514	$1,250
95967	MEG, Evoked, each add'l	1510	$850

CMS is proposing to move the MEG codes out of the new technology category and into appropriate clinical APCs. For Code 95965, there were a total of 23 single claims with a median cost of $3,166.30. Based on this data, CMS is proposing to assign Code 95965 to a new APC category, APC 0038, Spontaneous MEG, at a rate of $3,155.

For the other two MEG codes, CMS had only a handful of single claims—three for Code 95966 and one for Code 95967. CMS is proposing to assign these codes to APC 0209, Extended EEG and Sleep Studies, Level II. This APC has a median cost of $709.36. The rationale provided for placing these two MEG codes into the extended EEG category is that "MEG studies are similar to EEGs and sleep studies in measuring activity of the brain over a significant time period, and our hospital claims data show that their hospital resources are also relatively comparable".

The resources required to provide Code 95966 are significantly higher than the costs of providing the EEG and sleep testing codes assigned to APC 0209. The highest volume codes in this APC are the polysomnography codes 95810 and 95811. Under the physician fee schedule, CMS estimated the total equipment costs for providing polysomnography at less than $100,000. In contrast, the cost of purchasing a MEG system is in excess of $2.5 million. The annual maintenance on this equipment is about $100,000 and the costs of disposable supplies used for MEG are quite significant. In addition to the MEG equipment costs being substantially higher, because of the highly specialized nature of these services, MEG equipment utilization is at a much lower level than the EEG and sleep testing equipment.

I had previously shared data with CMS on a survey of the costs of providing MEG services in six hospitals. This data demonstrated that the cost of providing MEG is substantially higher than the proposed payment rates assigned. In the proposed rule, CMS did not utilize this external data noting the wide variation in costs and charges of the surveyed hospitals. I understand CMS' preference for using internal claims data when adequate data is available. Therefore, I concur with the proposed rate for Code 95965 given the fact that there is a reasonable volume of single claims upon which to base an APC rate. We also accept the proposed payment rate for Code 95967. Code 95967 is an "add on" code always provided with Code 95966 and is less costly to provide.

However, I am very concerned about the proposed payment rate of $706.89 for Code 95966 and believe this is a gross underestimate of the costs of providing this service. This rate will make it very difficult for hospitals to continue to offer this service to Medicare patients and to patients of other third party payers who follow the Medicare rate system.

I recommend that CMS assign code 95966 to its own APC at a rate equal to 50 percent of the rate assigned to Code 95965. This cost relationship is supported by the following:

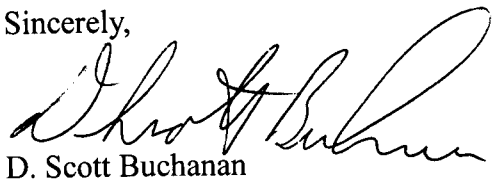
- The survey data for the six hospitals providing a high volume of MEG services indicates that the costs of providing 95966 are in excess of 50 percent of the costs of providing 95965. While CMS may not want to use the absolute cost information provided, the survey provides reliable data on the relative costs of providing these services.

- The new technology APC rates established by CMS for Code 95966 based on previously submitted cost data was 45 percent of the rate assigned to 95965. This is much closer to the actual cost relationship of these two services.

In conclusion, I support CMS' proposal to establish the new APC 0038 for MEG code 95965 and to include the MEG code 95967 under APC 0209, Extended EEG and Sleep Studies. I urge CMS to establish a separate APC for Code 95966 at a payment rate set at 50 percent of the rate for Code 95965 or approximately $1,550. I could not find any imaging or diagnostic APC paying approximately that rate which is clinically comparable to MEG. Thus, it would seem that a new APC category would be appropriate for this service—perhaps differentiated from Code 95965 as "MEG 1 and MEG 2 procedures".

Thank you for the opportunity to offer these comments.

Sincerely,



D. Scott Buchanan
President & CEO
4-D Neuroimaging

THERAGENICS CORPORATION

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September 28, 2006

VIA OVERNIGHT MAIL (original and two copies)

The Honorable 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, Maryland 21244-1850

Re: "OPPS Brachytherapy"
Comments on Medicare's Proposed Rule on the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Proposed Payment Rates (CMS-1506-P)

Dear Dr. McClellan:

On behalf of Theragenics Corporation®, I present these comments regarding Medicare's policies for cancer treatment provided through brachytherapy devices under the hospital outpatient prospective payment system (OPPS). These comments respond to the recent proposed rule published by the Centers for Medicare & Medicaid Services (CMS) at 71 *Federal Register* 49506 on August 23, 2006.

Specifically, these comments respond to the section of the proposed rule involving "OPPS Brachytherapy."

Theragenics Corporation® is based in Buford, Georgia with additional facilities in Garland, Texas and Portland, Oregon. In 1986, Theragenics Corporation® received FDA clearance for TheraSeed®, a radioactive medical device made with Palladium-103 and used to treat solid, localized cancerous tumors. Theragenics® is the only U.S. supplier of the Palladium-103 material.

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Corporate Offices

5203 BRISTOL INDUSTRIAL WAY, BUFORD, GA 30518

phone 770.271.0233 *fax* 678.482.4909

Theragenics® has been an active participant in the ongoing discussions with CMS, Congress and other policymakers regarding the reimbursement and coding of brachytherapy devices and procedures in the hospital outpatient setting. There are very important reimbursement issues under consideration this year that could have adverse impacts on beneficiary access to this cancer treatment under Medicare. To ensure a long-term solution that protects patients and provides for fair and stable reimbursement policies, we urge CMS to take the following actions.

> ***CMS should continue the current payment methodology for brachytherapy devices in the hospital outpatient setting (hospital's charges adjusted to cost for each device provided on a patient-by-patient basis) for all brachytherapy devices in 2007 and 2008.***
>
> ***CMS should establish two new HCPCS codes for stranded Iodine-125 and stranded Palladium-103 sources in 2007 to help remedy the flaws in CMS' existing data on brachytherapy devices.***

These recommendations are discussed below.

Discussion:

There is significant variability in the number, radioactive intensities and types (configurations) of brachytherapy devices used to treat individual cancer patients. Given this unique patient-to-patient variability, the use of prospectively-set average reimbursements 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 cancer and other forms of cancer.

These concerns are accentuated by the ongoing problems with CMS' data for brachytherapy devices, as well as the fact that CMS' codes for brachytherapy devices used in prostate cancer treatment are not keeping pace with important changes in clinical practice.

It is also important to note that there is no immediate need for Medicare to change reimbursement policies for brachytherapy devices. The current payment policy has been in place for over 2½ years and is working well for beneficiaries, hospitals and the Medicare program. Beneficiary access has been protected, and aggregate payments for brachytherapy remain stable.

A detailed discussion of the rationale for our two recommendations (listed above in bold) is provided in the following four subsections of this letter:

I. CMS should take steps to ensure ongoing access to brachytherapy because of the extraordinary clinical outcomes for prostate cancer patients and the concomitant economic savings achieved by the Medicare program.

II. CMS should follow the recommendations of two Congressionally-created advisory panels that counseled CMS to abandon the proposed rule and instead continue the current reimbursement methodology for brachytherapy devices. To this end, CMS should not take a piecemeal approach in which some (or any) brachytherapy devices are subject to prospectively-established average payments.

III. CMS should continue the current reimbursement methodology for brachytherapy devices for at least two more years to fulfill the brachytherapy provisions of the Medicare Modernization Act.

IV. CMS should continue the current reimbursement methodology for brachytherapy devices because of the flaws in CMS' current data for these devices. CMS should establish two new HCPCS codes for stranded Iodine-125 and stranded Palladium-103 sources in 2007 to help remedy these flaws as quickly as possible.

* * * * * * *

I. CMS Should Take Steps to Ensure Ongoing Access to Brachytherapy Because of the Extraordinary Clinical Outcomes for Prostate Cancer Patients and the Concomitant Economic Savings Achieved by the Medicare Program.

It is very important that Medicare beneficiaries throughout the United States continue to have meaningful access to brachytherapy. Brachytherapy is a well-established modality used primarily in the treatment of cancer. Brachytherapy involves the implantation of radioactive brachytherapy devices in and around cancerous tumors. Although prostate cancer is a common indication for brachytherapy, brachytherapy is used to treat breast, liver, eye, brain, esophageal, lung, cervical, skin and many other types of cancer.

Brachytherapy for prostate cancer involves a one-time, minimally-invasive procedure lasting approximately 45 minutes that typically is performed on an outpatient basis. In the case of prostate cancer, the long-term data (15+ years) show that brachytherapy devices cure cancer at rates that equal or often exceed other clinical options. In fact, the clinical literature now demonstrates remarkable cure rates exceeding 98 percent for prostate cancer using Palladium-103 brachytherapy devices.[1]

[1] Merrick GS, Wallner KE, Butler Wm, Galbreath RW, Allen ZA, Adamovich E, True L. *Brachytherapy in men aged < or = 54 years with clinically localized prostate cancer,* BJU Int. 2006 Aug; 98 (2): 324-8.

In addition to the successful treatment of prostate cancer, brachytherapy has lower incidence rates of serious side-effects – including impotence and urinary incontinence – than surgical removal of the prostate (called "radical prostatectomy").[2] The combination of high cure rates and low side-effects make brachytherapy both a desirable option for patients and a very cost-effective treatment for the Medicare program.

As a result, CMS should be especially cautious in changing the reimbursement methodology for brachytherapy devices. As Congress has highlighted in the past, brachytherapy devices are unique in many ways that complicate the application of a prospective payment methodology. CMS should exercise caution in proceeding with significant changes in this area without understanding the clinical impacts of such changes. This is not simply a math problem, but rather a complex issue involving an effective cancer treatment that – for the reasons discussed below – still does not readily lend itself to CMS' standard approach for calculating prospective average costs per device.

II. CMS Should Adhere to the Recommendations of Two Congressionally-Created Advisory Panels That Counseled CMS to Abandon the Proposed Rule and Instead Continue the Current Reimbursement Methodology for Brachytherapy Devices. To This End, CMS Should Not Take a Piecemeal Approach in Which Some (or Any) Brachytherapy Devices Are Subject to Prospectively-Established Average Payments.

Two separate Congressionally-created public advisory groups have recommended against proceeding with CMS' proposal for brachytherapy devices. In both instances, these recommendations followed the posting of CMS' proposed rule on August 8, 2006 and the publication of CMS' proposed rule on August 23, 2006.

On August 24, 2006, the APC Advisory Panel recommended that CMS continue the current "charges adjusted to cost" reimbursement methodology for all brachytherapy devices in 2007 (instead of implementing CMS' proposal to begin prospectively-set payment rates in 2007).[3] The APC Advisory Panel based this recommendation in large part (but not solely) on concerns about the validity of the data that CMS is using to calculate prospective payments for brachytherapy devices.

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[2] Fowler FJ Jr., McNaughton Collins M, Albertson PC, Zietman A, Elliott DB, Barry MJ. *Comparison of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer.* JAMA 2000; 283:3217.

[3] Advisory Panel on Ambulatory Payment Classification (APC) Groups, *Panel Recommendations* (Aug. 23-24, 2006), available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

Subsequently, on August 28, 2006, the Practicing Physicians Advisory Council (PPAC) recommended that CMS "abandon" its proposed payment methodology for all brachytherapy devices under the hospital outpatient prospective payment system.[4] The PPAC also based its decision on concerns regarding CMS' data.

These advisory panels, especially the APC Advisory Panel, are accustomed to working with imperfect data in establishing payment rates under Medicare. However, in this instance, the advisory panels identified the problems with CMS' brachytherapy device data as being *so significant* that CMS should not proceed with its recent proposal.

In addition, in both instances the advisory panels recommended against CMS' proposal for all brachytherapy devices.

To this end, CMS should not take a piecemeal approach to reimbursement for brachytherapy devices. Specifically, CMS should not attempt to apply prospective payment rates to a few (or any) types of brachytherapy devices. In the past, when CMS has taken a piecemeal approach to brachytherapy device reimbursement (applying one reimbursement methodology to some devices, but not others), tremendous and unnecessary confusion arose in the hospital community.

Based on our experience working closely with hospitals over the past two decades, it is clear that the piecemeal approach to brachytherapy device reimbursement that CMS implemented prior to the enactment of the MMA resulted in more confusion among hospital billing and coding personnel than any other change implemented since the beginning of the hospital OPPS in 2000. Such ill-conceived policies have had long-term effects on the data for brachytherapy devices and simply complicate the prospect of securing fair and stable reimbursement policies in this area.

Given the longstanding concerns about CMS' data and ensuring meaningful access to brachytherapy devices for cancer treatment, CMS should not disregard the well-reasoned recommendations from the Congressionally-created advisory panels to continue the current reimbursement methodology.

III. CMS Should Continue the Current Reimbursement Methodology for Brachytherapy Devices for At Least Two More Years to Fulfill the Brachytherapy Provisions of the Medicare Modernization Act.

The concern recently highlighted by the APC Advisory Panel regarding CMS' data on brachytherapy devices was a core rationale for the provisions on brachytherapy devices that Congress enacted in 2003. CMS should ensure that the plain meaning and intent of Congress'

[4] CMS, Practicing Physicians Advisory Council, available at: http://www.cms.hhs.gov/FACA/03_ppac.asp#TopOfPage.

provisions are satisfied in full before implementing significant changes in reimbursement policy for brachytherapy devices.

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 and to prevent the implementation of new pricing policies for prostate brachytherapy devices in the absence of credible data.[5] As a result of CMS' policies in place prior to enactment of the MMA, under-reimbursement for medically necessary brachytherapy devices was having a chilling effect on patient access.

Specifically, Section 621(b) 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. Instead, 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.[6]

In addition, recognizing the need for more accurate data and an in-depth analysis, Congress also directed the GAO to complete a study on brachytherapy devices no later than December 31, 2004.[7]

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 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' review.

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 Congress' deadline.[8] 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.

Based on this consideration alone, CMS should continue the current reimbursement methodology for brachytherapy devices for another two years. However, the fact that CMS stated that there was insufficient time for CMS to review the GAO report before publishing the recent proposed

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[5] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 621(b) (2003).
[6] Id. at § 621(b)(1).
[7] Id. at § 621(b)(3).
[8] U.S. Gov't Accountability Office, *Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively* (GAO-06-635, July 2006) [hereinafter *GAO Report*], available at: http://www.gao.gov/new.items/d06635.pdf.

rule is also concerning.[9] It is difficult to understand how CMS can justify proceeding with significant policy changes in this area without even considering the Congressionally-mandated study.

The two-year review period makes clear that Congress did not intend for CMS to blindly or hastily adopt the GAO's recommendations. Certainly, a hasty review of the report by CMS this fall is no substitute for the two-year review period that Congress established for CMS, Congress and other stakeholders to use in considering the best long-term policy for brachytherapy devices.

The fact that the GAO report has very significant flaws does not justify CMS going ahead with a significant change in the payment methodology for brachytherapy devices. The far better course is to continue the current methodology until the data issues are resolved.

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 a number of important observations and fundamental flaws regarding the GAO report. A partial list of these flaws and concerns follows below.

- **The GAO's data are significantly outdated and fail to reflect important changes in clinical practice over the past several years.** Both CMS' data and the GAO's data fail to reflect the new clinical protocols that have evolved over the past few years, including primarily the increased use of prescriptions for "stranded" and "custom-stranded" brachytherapy devices for prostate cancer. These devices, which improve patient safety and clinical outcomes, are distinct from traditional brachytherapy devices (requiring separate FDA clearances and having increased costs of production).

- **The importance of studying the clinical use of new configurations (such as stranded devices) to inform reimbursement policy is evident from the GAO report in several ways.** At the end of the report, the GAO notes that a professional society highlighted the need for the data to reflect the increased clinical use of stranded brachytherapy devices, which are "more costly but considered clinically advantageous."[10] Although a significant failing of the report is the GAO's failure to study this issue in greater detail, this clinical observation highlights the need for CMS to establish new codes for these important devices (see discussion in subsequent section below).

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[9] 71 Fed. Reg. 49506 (Aug. 23, 2006).
[10] *GAO Report, supra* note 10, at 15.

In addition, by attempting to collect data on device configurations, the GAO validated the importance of understanding the clinically-relevant distinctions among the configurations of brachytherapy devices used in clinical practice when considering reimbursement policies. As noted in an appendix, the GAO did not collect adequate samples to report any information regarding the configurations or radiation intensities of the brachytherapy devices used.[11] Thus, the GAO survey highlights the importance of reflecting clinically-relevant distinctions in configurations (such as the use of stranded versus non-stranded sources) among brachytherapy devices when considering pricing policies, although the GAO failed to implement the survey successfully to secure the necessary data.

- **Although the GAO recognized the importance of collecting data from rural areas, the GAO secured data from only one rural hospital.** This is not stated in the report, but the GAO staff acknowledged this important point verbally.[12] There are virtually no meaningful data in the report regarding the participation of different types of hospitals in the survey. At the end of the report, the GAO also noted that a professional society reviewed a draft of the report and cautioned the GAO that data used for payments must be representative of different hospital types.[13]

There are many more significant flaws with the GAO report. This is not surprising given that the GAO struggled for well over a year to figure out how to salvage a study from the flawed data set obtained in the initial GAO survey. This highlights that securing useful data in this area is difficult and requires extra effort. The GAO report also highlights the importance of refraining from making major pronouncements or policy changes on the basis of flawed data. Instead of proceeding with the proposed rule, CMS should follow the plan established by Congress in the MMA and adhere to the recent recommendations from the Congressionally-created advisory panels.

IV. CMS Should Continue the Current Reimbursement Methodology for Brachytherapy Devices Because of the Flaws in CMS' Current Data for These Devices. CMS Should Establish Two New HCPCS Codes for Stranded Iodine-125 and Stranded Palladium-103 Sources in 2007 to Help Remedy These Flaws as Quickly as Possible.

Past experience from 2003 highlights that the single greatest threat to ensuring medically-appropriate beneficiary access to brachytherapy occurs when hospitals perceive that Medicare is

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[11] *GAO Report*, *supra* note 10, at 22.
[12] Meeting with GAO staff and representatives from the Coalition to Advance Brachytherapy, Washington, D.C. (May 17, 2006).
[13] *GAO Report*, *supra* note 10, at 15.

under-reimbursing for the brachytherapy sources as a matter of policy. As a result, CMS must ensure that payment policies for brachytherapy devices are based on sound data.[14]

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 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' current 2005 data does 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 discussed above, the GAO noted that one brachytherapy professional society reported that stranded brachytherapy devices are "more costly but considered clinically advantageous."[15]

The absence of data or information about stranded brachytherapy devices is a significant flaw in CMS' current data. Blindly establishing prospective payment rates for brachytherapy devices without taking steps to protect patient access to these devices, which result in improved safety and efficacy, is ill-advised and inconsistent with Congress' direction to CMS under the Social Security Act. In contrast, CMS can easily address this issue by establishing two additional codes in addition to the existing code set.

Stranded sources are distinct from traditional brachytherapy devices in a number of fundamental ways, including the following:

- As demonstrated in the clinical literature and widespread clinical practice, stranded sources improve patient safety and clinical outcomes in the treatment of prostate cancer. For example, stranded sources can be placed at the periphery of the prostate or outside the prostate gland, permitting treatment of extra-prostatic extension of the disease without the potential for migration to other body organs. Migration of traditional loose sources can occur, resulting in embolization of the sources to the lung or other critical organs.[16,17,18,19,20]

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[14] In a prior meeting with CMS, a question arose whether confusion by hospitals regarding proper billing of brachytherapy devices results in barriers to beneficiary access for brachytherapy. As we discussed at the time, past experience from 2003 indicates that a far greater barrier to access arises when there is a perception by hospitals that Medicare under-reimburses for brachytherapy devices as a matter of policy.

[15] GAO Report, note 10, at 15.

[16] Fuller DB, Koziol JA, Feng AC. *Prostate brachytherapy seed migration and dosimetry: analysis of stranded sources and other potential predictive factors.* Brachytherapy. 3 (2004):10-19.

[17] Lee, WR, deGuzman AF, Tomlinson SK, McCullough DL. *Radioactive sources embedded in suture are associated with improved post-implant dosimetry in men treated with prostate brachytherapy.* Radiotherapy and Oncology. 65 (2002): 123-127.

- The radioactive intensities required for stranded Iodine-125 or Palladium-103 brachytherapy sources are greater than traditional loose sources used for prostate implants.[21]

- Stranded Iodine-125 and Palladium-103 sources have increased costs of production arising from a number of factors, including the cost of using increased radioactivity due to the additional preparation time, along with the material and labor costs associated with "stranding" the sources with spacing that reflects the treating physician's specific prescription for a particular patient.

- Stranded Iodine-125 and Palladium-103 sources require separate FDA clearances from traditional Iodine-125 and Palladium-103 sources.

Stranded sources also meet CMS' longstanding definition of brachytherapy devices, as well as both the spirit and plain meaning of the coding and reimbursement provisions in Section 621(b) of the MMA. Stranded sources reflect a clinically important option that requires increased radioactivity intensity in comparison to traditional brachytherapy sources.

Even setting aside other considerations, CMS has previously reflected clinically-relevant differences in configurations of the same isotope among the brachytherapy device codes established after the MMA (see the establishment of the code for linear Palladium-103). There certainly is no limitation under the statute that would prevent CMS from establishing new codes for stranded sources. In fact, CMS should establish new codes for stranded Iodine-125 and Palladium-103 to be consistent with the MMA.

In contrast to some of the codes that have low utilization, if separate codes for stranded Iodine-125 and stranded Palladium-103 existed in 2006, many thousands of Medicare's prostate cancer cases would already fall within each of these codes. Nonetheless, these devices remain lost in the existing codes for traditional loose seeds. Clinically, there will continue to be significant roles in the future for both traditional loose sources and for stranded sources in the treatment of prostate cancer.

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[18] Al-Qaisieh, B, Carey B, Ash D, Bottomley D. *The use of linked seeds eliminates lung embolization following permanent seed implantation for prostate cancer.* Int. J. Radiation Oncology Biol. Phys. 59 (2004): 397-399.
[19] Eshleman, JS, David BJ, Pisansky TM, Wilson TM, Haddock MG, King BF, Darby CH, Lajoie WN, Oberg AL. *Radioactive seed migration to the chest after transperineal interstitial prostate brachytherapy: extra-prostatic seed placement correlates with migration.* Int. J. Radiation Oncology Biol. Phys. 59(2004): 419-425.
[20] Fagundes, HM, Keys RJ, Wojcik MF, Radden MA, Bertelsman CG, Cavanagh WA. *Transperineal TRUS-guided prostate brachytherapy using loose seeds versus RAPIDStrand: A dosimetric analysis.* Brachytherapy. 3 (2004): 136-140.
[21] Meigooni AS, Awan SB, Rachabatthula V, Koona, RA. *Treatment-planning considerations for prostate implants with the new linear RadioCoil™ 103Pd brachytherapy source.* Journal of Applied Clinical Medical Physics. 6 (2005):23-36.

Given the clinical benefits of using stranded sources in clinical practice, new codes are required to ensure that all Medicare patients have meaningful access to the safest and most effective treatment modalities in the future. Moreover, the absence of these codes has emerged as a primary barrier to further refinement of the reimbursement methodology for brachytherapy devices, especially the sources used to treat prostate cancer. In fact, distinct source APCs for stranded sources would enable the data collection and cost analysis necessary for appropriate refinement of the APC system.

In the proposed rule, CMS invited the public to submit recommendations for new codes to describe new brachytherapy sources. We urge CMS to establish the following new codes for implementation on January 1, 2007:

1.) C26XX Brachytherapy device, Stranded Iodine-125, per source

2.) C26XX Brachytherapy device, Stranded Palladium-103, per source

The brachytherapy community has begun to study the existing data from CMS on brachytherapy, which highlight a number of additional flaws, inconsistencies and anomalies in the brachytherapy device data. These issues involve both high-utilization and low-utilization codes. Some of these issues are described in greater detail within the comments submitted by the Coalition for the Advancement of Brachytherapy (CAB).

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As discussed above, CMS should continue the current payment methodology for brachytherapy devices in the hospital outpatient setting (hospital's charges adjusted to cost for each device provided on a patient-by-patient basis) for all brachytherapy devices in 2007 and 2008. In fact, there is no immediate or urgent need for Medicare to change the reimbursement methodology, and CMS should maintain the current reimbursement methodology to adhere to Congress' direction under the MMA and the recent recommendations from two Congressionally-created advisory panels.

In addition, CMS should establish two new HCPCS codes for stranded Iodine-125 and stranded Palladium-103 sources in 2007 to help remedy the flaws in CMS' existing data on brachytherapy devices as quickly as possible.

We urge CMS to implement these straightforward policies as a means of ensuring ongoing access for cancer patients and adequate reimbursement for brachytherapy providers. Please do not hesitate to contact us if we may provide any further information.

You may contact Janet Zeman at (770) 831-5123 or ZemanJ@Theragenics.com with any questions.

Respectfully submitted,

M. Christine Jacobs

M. Christine Jacobs
President and Chief Executive Officer
Theragenics Corporation®

cc: Janet Zeman

#399976 v1

Holy Name Hospital

Member
NewYork-Presbyterian Healthcare System
Affiliate: Columbia University College of Physicians & Surgeons

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September 26, 2006

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

Re: Comments on Proposed CY 2007 APC Assignment for Myocardial PET

Dear Mr. McClellan:

I am writing on behalf of Holy Name Hospital in Teaneck, New Jersey in response to the 2007 proposed hospital outpatient prospective payment system (HOPPS) rule published in the August 23, 2006 Federal Register. Holy Name Hospital is a 361-bed acute care hospital located in Northern New Jersey. We offer a full complement of outpatient hospital procedures including myocardial PET perfusion imaging. In this letter we are specifically commenting on the 2007 proposed payment changes for myocardial Positron Emission Tomography (PET) perfusion imaging (CPT 78492).

We are concerned that CMS' proposed payment reductions for myocardial PET perfusion imaging (CPT 78492) will compromise Medicare beneficiary access to this essential service involving this technology. Hospitals need payment consistency to support budgetary allowances that have been made to support their operations for calendar year 2007. Implementing the proposed payment rate of $721.26 for myocardial PET perfusion imaging may result in hospitals ceasing to provide these procedures because the resource consumption outweighs the reimbursement. The proposed payment rate reduction for myocardial PET perfusion imaging studies would seriously underpay hospitals, and risk limiting CMS beneficiary access to this vital technology.

Myocardial PET Perfusion Imaging

Over the past several years, myocardial PET perfusion imaging has challenged conventional Single Positron Emission Computed Tomography (SPECT) myocardial perfusion imaging for the evaluation of coronary artery disease (CAD), and is quickly becoming the standard of care. Myocardial PET perfusion imaging has been clinically proven to be substantially more diagnostically accurate than conventional myocardial perfusion imaging utilizing SPECT. The benefits of myocardial PET perfusion imaging may ultimately reduce the number of invasive cardiovascular procedures, unnecessary admissions due to non-

diagnostic conventional myocardial perfusion imaging utilizing SPECT, and hospital length-of-stay. Thus sparing patients pain and discomfort and saving hospitals and CMS valuable resources. CMS resource utilization may be accurately appropriated as beneficiaries are diagnosed with a higher degree of certainty with myocardial PET perfusion imaging as opposed to SPECT.

CMS 2007 Proposed Changes

CMS proposes to reduce the payment rate for each myocardial PET perfusion imaging procedure (CPT 78492) to $721.26 from its current rate of $2,484.88. We believe that $721.26 is far below the true cost to our hospital outpatient department of providing myocardial PET perfusion imaging services, and that such a reduction would significantly underpay Holy Name Hospital. The proposal does not recognize true resource utilization and associated equipment, maintenance, and operating costs to Holy Name Hospital. The payment rate for myocardial PET perfusion imaging should reflect these associated costs.

The 2007 CMS proposal on myocardial PET perfusion imaging procedures are faulted due to the limited amount of claims data. Although, myocardial PET perfusion imaging has become more widespread and readily available, CMS should withhold any decision to reduce payment until they obtain adequate data from 2006 and 2007 claims. This would allow for an accurate assessment of the impact of myocardial PET perfusion imaging on patient care. In addition, CMS rationalization for reduction in payment is faulted. Resource utilization for myocardial PET perfusion imaging, multiple studies (CPT 78492) is significantly higher than myocardial PET perfusion imaging, single studies (CPT 78491).

We also support maintaining two separate APCs (0306 and 0307) for myocardial PET imaging procedures. Maintaining the two separate APCs allows CMS to collect claims data and to set payment based on more appropriate resource utilization for these procedures in the future. CMS should also consider the significant number of coding policy changes that it implemented regarding PET imaging procedures in 2005 and 2006 and the impact that these changes may have had on claims data for that calendar year. It is likely that hospitals have not adapted to these changes within this time frame. Thus, 2005 data may not accurately reflect accurate resource utilization. Therefore, 2006 and 2007 claims data is most likely a better source to determine the clinical and economic resources utilized in myocardial PET perfusion imaging.

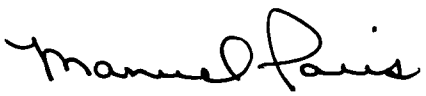
Recommendations

We believe that the 71% reduction that CMS proposes for multiple myocardial PET perfusion imaging procedures (78492) based on 2005 claims data qualifies as a substantial fall in payment. Therefore, we are recommending that CMS maintain the 2006 payment rate ($2,484.88) for myocardial PET perfusion imaging (78492) in 2007. CMS should continue to place both single study

myocardial PET imaging procedures (78491) and viability studies (78459) within APC classification 0306. Multiple studies for myocardial PET perfusion imaging (78492) should remain in APC classification 0307. In addition, CMS should explore additional reimbursement to hospitals performing myocardial PET/CT perfusion imaging.

Thank you for the opportunity to comment on this important rule. Should you have any questions, please do not hesitate to contact me at 201-833-3641 or via email at paris@mail.holyname.com.

Respectfully,



Manuel Paris, MA, BS/BA, CNMT, RT (N)
Manager, Research & Development
Department of Radiology

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MOSES CONE HEALTH SYSTEM
REGIONAL CANCER CENTER
501 North Elam Avenue
Greensboro, NC 27403-1199
Phone: 336.832.1100
Fax 336.832.0624

Radiation Oncology
Robert J. Murray, M.D.
James D. Kinard, PhD, M.D.
Justin J. Wu, M.D.
Matthew A. Manning, M.D.
Nancy M. Bednarz, M.D.

September 20, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Response to Rule # CMS-1506-P: Hospital Outpatient Payment System (OPPS)

Dear Administrator,

Thank you for allowing me the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have some serious concerns regarding our proposed changes.

CPT code 19296 was linked to APC #1524 in 2006 which = $3250 in reimbursement for the placement of the brachytherapy balloon catheter. CMS is proposing a 23% reduction by moving CPT codes 19296 & 19297 to a new APC#. The proposed 2007 APC# is 0030 which = $2508 in reimbursement for the placement of the catheter. This is less than the catheter cost of $2750.

The proposed APC reassignment from "New Technology" to "Clinical" is inadequate. Our facility may decline offering this service to your Medicare beneficiaries.

Our recommendation is for CMS to keep APC #1524 for at least one more year so additional data can be collected on this service. The Centers for Medicare and Medicaid Services should 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).

We would like to continue servicing our Medicare patients. Thank you for heeding these recommendations.

Respectfully,

Matthew Manning, MD

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee,
Co-Chair, House Cancer Caucus
Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)
James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)
W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

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Grutzmacher Lewis
A Medical Corporation
Surgical Eye Specialists

Richard D. Grutzmacher, M.D.
Cornea, Cataract and Laser Vision Correction
Richard A. Lewis, M.D.
Glaucoma and Cataract
Monica C. Robinson, O.D.
Optometry
Kristie L. Teets, O.D.
Optometry

Richard A. Lewis, MD
Grutzmacher & Lewis
1515 River Park Dr., Suite 100
Sacramento, CA 95815

September 24, 2006

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, Maryland 21244-1850

RE: Calendar Year 2007 Update to the Ambulatory Surgical Center Covered Procedures List [CMS-1506-P]

Dear Sir or Madam:

My name is Richard A. Lewis, MD and I am an ophthalmologist practicing in Sacramento, California. The purpose of this letter is to provide a response to recent CMS guidance documents re: ASC reimbursement for CAT III CPT codes. I appreciate the opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) on August 23, 2006, which proposes, among other things, updates to the ASC list effective for services furnished on or after January 1, 2007.[1]

As an owner of an ASC and an ophthalmologist with a broad-based surgical practice, I would strongly urge CMS to add the new CPT codes, 0176T (Transluminal dilation of aqueous outflow canal; without retention of device or stent), and 0177T (Transluminal dilation of aqueous outflow canal; with retention of device or stent), to the ASC list effective January 1, 2007. These codes will be implemented on January 1, 2007. Transluminal dilation of the aqueous outflow canal is also known as canaloplasty, and it is an outpatient ophthalmic procedure for the treatment of glaucoma. More details on the procedure can be found in a New Technology APC application for canaloplasty that was submitted to CMS on August 31, 2006.

CMS is not proposing changes to the criteria for adding or deleting items from the ASC list effective January 1, 2007. The current criteria are such that "if a procedure was performed on an inpatient basis 20 percent of the time or less, or in a physician's office 50 percent of the

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[1] See Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program -- HCAHPS® Survey, SCIP, and Mortality, 71 Fed. Reg. 49,506, 49,628, August 23, 2006).

time or more, it would be excluded from the ASC list. But CMS has acknowledged in the proposed rule that:

> The trend towards performing surgery on an ambulatory or outpatient basis grew steadily and, by 1995, we discovered that a number of procedures that were on the ASC list at the time fell short of the 20 percent and the 50 percent thresholds even through the procedures were obviously appropriate to the ASC setting.

In fact, CMS notes that two common ophthalmic surgical procedures, cataract extraction with IOL and IOL repositioning, do not meet the thresholds but are predominantly performed in an out patient setting. Canaloplasty is similar to modern cataract surgery in that this procedure would almost never be performed on an inpatient and also never done in a physician's office. Patients do not require general anesthesia and do not require hospitalization after the procedure. But the standard of care is such that a dedicated operating room is required and ophthalmologists would generally not do canaloplasty in their offices. Similarly, cataract surgery is generally not performed in physician offices and therefore there is no non-facility payment in the Medicare Physician Fee Schedule (MPFS) for cataract surgery. ASCs and hospital outpatient departments are effectively the only sites of service for canaloplasty.

Relative to most other specialties, ophthalmologists do a high percentage of their cases in ASCs. In fact, much of the clinical investigation for the canaloplasty procedure was performed by surgeons in ASCs. In order for these surgeons to continue to provide canaloplasty in ASCs, as they have been doing throughout the investigation phase, CPT codes 0176T and 0177T need to be on the ASC list for 2007. Also, because there will not be values assigned to these codes in the MPFS, surgeons will not have the option of performing canaloplasty in the ASC and billing for the MPFS amount, as described in Publication 100-04, Chapter 12, Section 20.4.

If CMS agrees with this recommendation and adds canaloplasty to the ASC list for 2007, we then recommend that it be assigned to payment group 9. Detailed information on the costs associated with this procedure was submitted to CMS on August 31, 2006, as part of a New Technology APC application. An examination of this information demonstrates that the most appropriate payment group for canaloplasty is group 9.

In closing I appreciate the work entailed in developing the Proposed Rule, and I commend CMS on the effort involved in developing the new ASC payment system for 2008. Since I have a large glaucoma component in my surgical practice, I am eager to work with the agency to ensure that Medicare beneficiaries who have glaucoma have access to the best therapeutic technologies in the most appropriate and cost effective site of service. Thank you for your timely review and consideration of my comments on this important issue.

Sincerely,

Richard A. Lewis, MD

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Facsimile: (949) 450-5319
Website: www.endocare.com

VIA FEDERAL EXPRESS

September 29, 2006

Mark B. McClellan, MD, PhD
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, Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Endocare, Inc., I am writing in response to the Proposed Rule for the CY 2007 Medicare Hospital Outpatient Prospective Payment System, published in the *Federal Register* on August 23, 2006. Endocare is a medical device company focused on the development and distribution of minimally invasive technologies for tissue and tumor ablation for cancer patients.

Our primary area of focus at Endocare has been on prostate cancer with the objective to dramatically improve men's health and quality of life. Endocare manufactures the medical technology needed to perform cryosurgery, including the *CryoProbes* (identified by HCPCS code C-2618) used in prostate cryosurgery procedures, the only procedures assigned to APC 674.

Proposed Payment Rate for APC 674: Cryoablation of the Prostate

Our comments on the proposed payment rate for APC 674 in CY 2007 reflect the same themes we have made in previous years in both formal written comments and a number of meetings with CMS staff:

- The proposed payment rate for APC 674 is too low, and does not reflect the actual costs hospitals incur in performing this procedure.
- There are two important reasons for this too-low payment rate:
  - *Inaccurate hospital reporting.* Hospitals sometimes incorrectly report the number (and the cost) of the CryoProbes used in the prostate cryosurgery procedure. In addition, hospitals may not fully report other (non-CryoProbe) costs associated with the procedure. For relatively new procedures, like prostate cryosurgery, hospital reporting irregularities are more common. There is little incentive for an individual hospital to correct incorrect reporting practices because it will have no immediate impact on payment.

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- *The methodology CMS uses to impute hospital costs.* The CMS methodology—reducing charges to costs through a cost-to-charge ratio—tends to under-weight procedures involving higher-cost medical technology (which is marked up less than lower-cost items). This impact, known as "charge compression," is most pronounced in those APCs whose costs include a high proportion of medical technology costs, the APCs CMS has identified as "device-dependent APCs," which include APC 674.

We believe that CMS can remedy this situation by factoring in external data—information on the costs hospitals incur to acquire the medical technology used in performing prostate cryosurgery procedures, as well as the cost of the procedure itself. We also believe that hospital claims data that clearly does not reflect these costs, should not be used in establishing a payment rate for APC 674.

External Data Illustrates Underpayment. We have shared data with CMS on the costs hospitals incur when they perform prostate cryoablation procedures. For the past four years, we have provided copies of UB-92s illustrating hospitals' charges for all the individual components of the procedure, including the acquisition cost of CryoProbes. We provided copies of invoices and cancelled checks written by hospitals to Endocare illustrating that hospitals pay on average more than $4,000 per case for CryoProbes and other cryoablation supplies. This data also indicates that, on average, the cost to a hospital to provide a cryoablation procedure is more than $9,000.

The 2007 proposed payment to hospitals for the prostate cryoablation procedure is approximately $6,600. The average shortfall between hospitals' actual costs and payment by Medicare is $2,500 per case, with some hospitals relaying a loss of $4,000 per procedure.

Impact of Insufficient Payment. Many hospitals performing prostate cryoablation procedures absorbed these losses in the past due to the fact that the procedures were typically low volume and "under the radar screen" in terms of financial loss targets to the facility. More importantly, hospitals endured the losses in the early stage of instituting new prostate cryosurgery programs because they understood that CMS was in the very early stages of implementing its new prospective payment system for hospital outpatient services. They realized that many refinements in this payment system were being made, and they expected that issues associated with procedure underpayment (in APC 674 and in other areas) would eventually be resolved in a way that would result in a payment level that would cover their costs.

However, the issues that have led to underpayment for APC 674 have not been resolved. Although there has been a net growth in the number of hospitals offering prostate cryosurgery and the number of patients treated in the past few years as the Medicare hospital outpatient prospective payment system has been implemented, we expect that hospitals will be reluctant to establish new programs, to grow current programs, or even to continue programs where Medicare payment is not sufficient to cover costs.

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Despite good clinical results and patient satisfaction levels for prostate cryosurgery procedures, we understand that many hospitals are now making decisions regarding which new procedures they offer, based on established hospital outpatient payment levels set by Medicare. These hospitals have chosen not to absorb losses from any new technology procedure that they will offer. There have been instances where prostate cryosurgery has been considered in this way: the clinical value of the prostate cryosurgery procedure has been recognized, but a decision was made not to establish a cryosurgery program because of the anticipated losses due to the shortfall in payment associated with treating Medicare patients. It is only a matter of time before established hospital cryosurgery programs are cut back or dropped, due to the inadequate payment that exists, not their clinical efficacy.

Insufficient Medicare reimbursement rate for cryosurgery would be a severe blow to the adoption of this new procedural approach to prostate cancer particularly, at a time when it has begun to grow in acceptance with clinicians and patients. According to the American Urological Association patient website: "...results place cryoablation therapy between radical prostatectomy and radiotherapy in effectiveness... equivalent to other therapies for low-risk disease and possibly superior for moderate-and high-risk prostate cancer"[1]. If hospitals are not able to offer this procedure due to reimbursement concerns, it will result in diminished access for Medicare patients who desire to have a minimally invasive, clinically effective procedure that can be performed on an outpatient basis.

Medicare underpayment for prostate cryoablation procedures could also lead to more-expensive inpatient admissions. These alternative treatments for prostate cancer are up to three times more costly to the Medicare program and are not as clinically effective (see Attachment I for Cost Comparisons between prostate cancer treatments and Attachment II for Clinical Efficacy Comparisons between prostate cancer treatments).

In summary, we have the following comments and recommendations:

1. The proposed 2007 APC payment rate to hospitals for outpatient prostate cryosurgery procedures is not sufficient to cover the cost of the procedure. The 2007 proposed payment to hospitals for APC, 674 is approximately $6,600. The average shortfall between hospitals' actual costs and payment by Medicare is $2,500 per case, with some hospitals relaying a loss of $4,000 per procedure.

[1] See the American Urological Association patient website at:
http://urologyhealth.org/adult/index.cfm?cat=09&topic=42

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2. There will be undesirable cost and treatment consequences for the Medicare program and its beneficiaries if an adjustment is not made to the 2007 payment rate proposed for outpatient cryosurgery of the prostate procedures.
3. The current method CMS uses to set a payment rate for APC 674 is flawed due to errors in hospital reporting and charge compression. In its place, we suggest the following:
   a. External data on the actual costs hospitals incur in performing prostate cryosurgery procedures can and should be used to set appropriate rates.
   b. Hospital claims data that clearly does not reflect these costs should not be used in establishing a payment rate for APC 674. CMS should eliminate or adjust claims for prostate cryosurgery procedures in the 2005 Medicare data base in which costs for the CryoProbes are less than external data submitted in past years.
   c. CMS should utilize the charge compression analysis currently underway for Medicare Inpatient Billings (see attached article in Attachment III) to initiate a similar analysis for Medicare outpatient billings. Until CMS recognizes and incorporates modifications into the payment methodology for the phenomenon of charge compression, payments to hospitals for device-dependent procedures routinely will be underpaid resulting in potential access problems to new technology by Medicare patients.

Thank you for allowing us the opportunity to comment on this proposed rule. Please do not hesitate to contact me if you have questions or require additional information.

Sincerely,

Craig T. Davenport
Chief Executive Officer, President and
Chairman of the Board

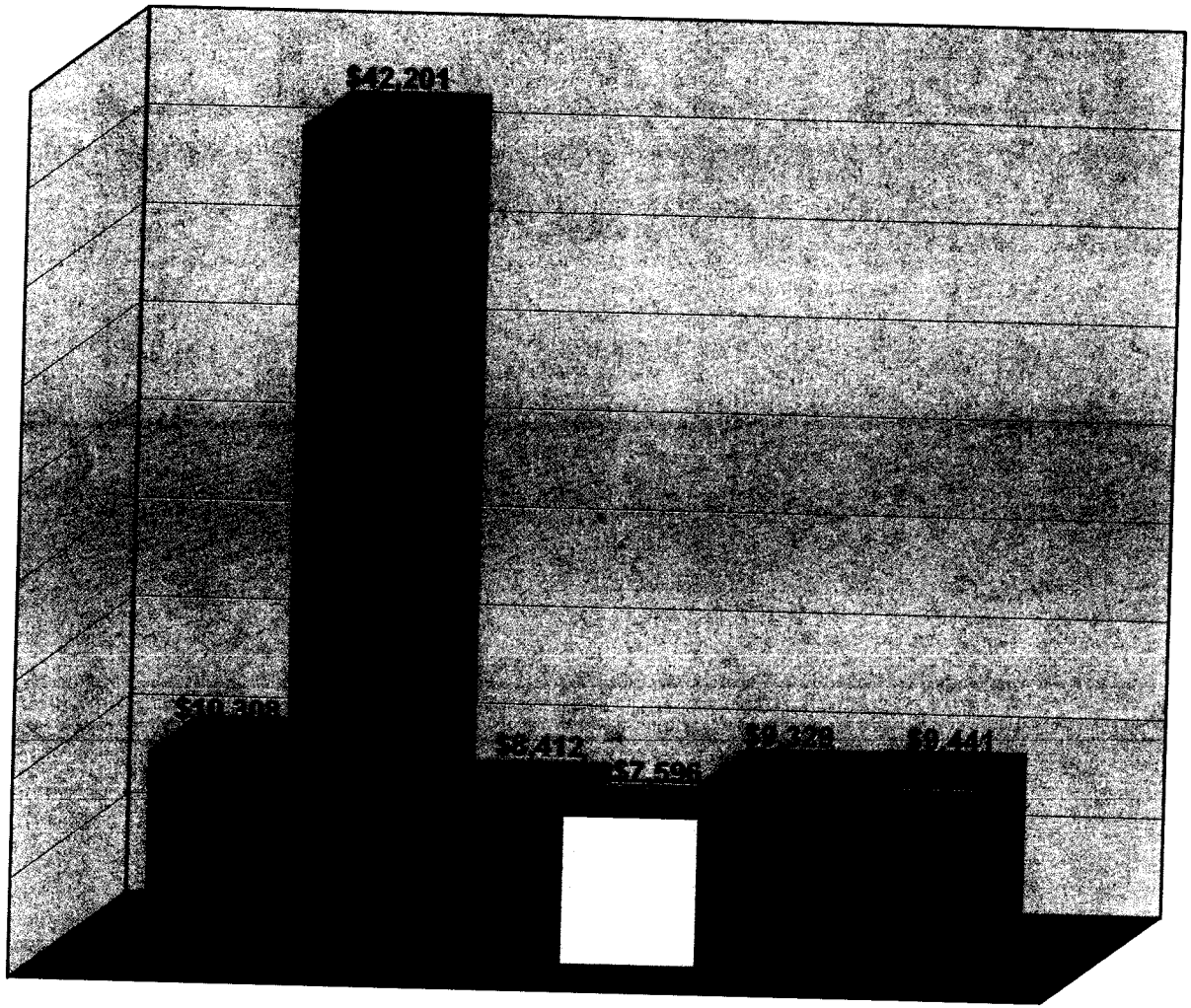
Enclosures:
Attachment I
Attachment II
Attachment III

CTD:res

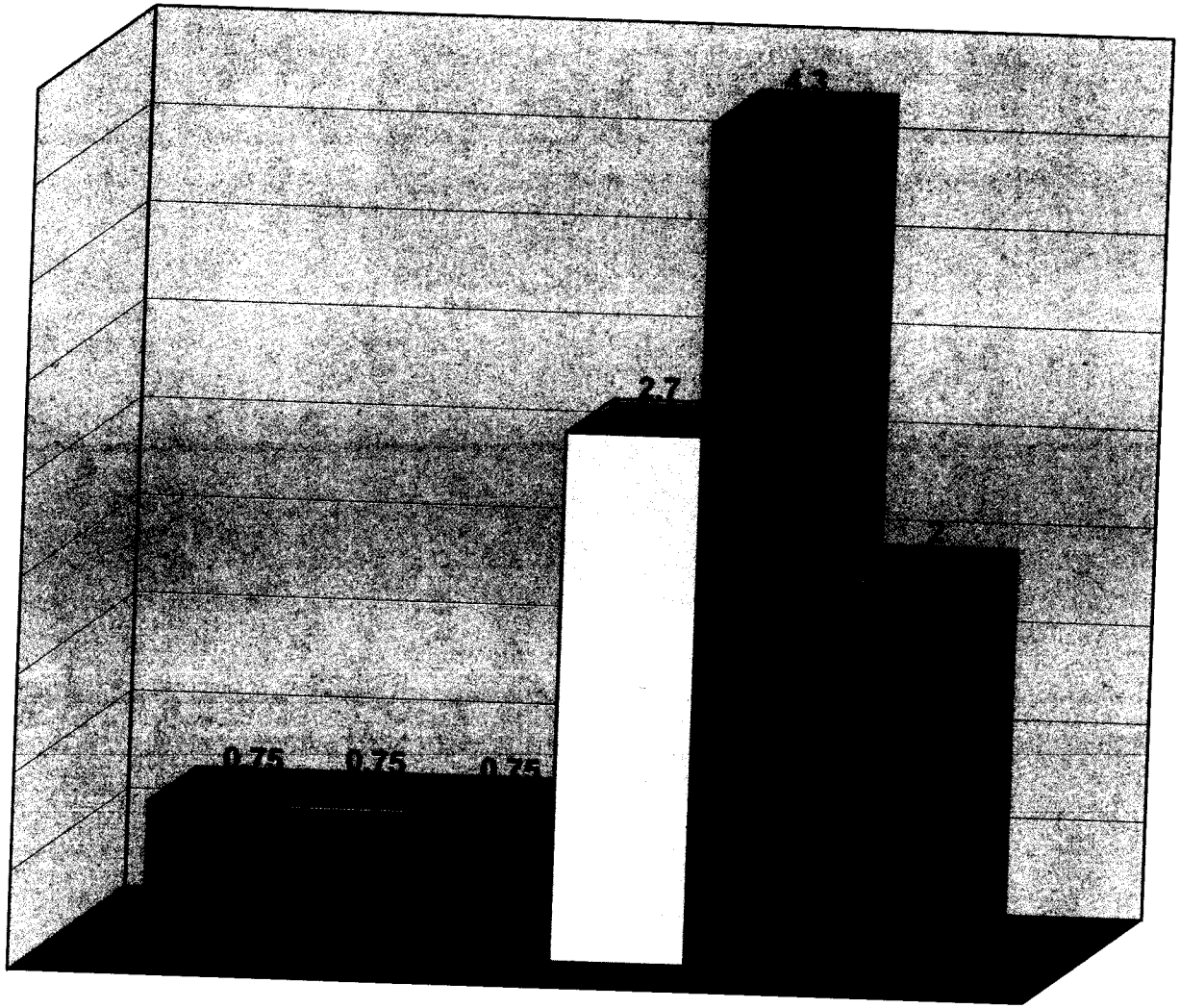
ATTACHMENT I

PROSTATE CANCER TREATMENT:
2006 EPISODE OF CARE COSTS FOR MEDICARE PATIENTS

Prostate Cancer Treatment: Episode of Care Costs
2006 Medicare Allowable CPT, APC and DRGs



ALOS By Prostate Cancer Treatment Type



- Brachytherapy
- Brachy w IMRT (X Beam)*
- Cryosurgery
- Rad Prostatectomy
- Rad Prostatectomy with cc
- Robotic "DaVinci" Radical Prostatectomy**

Medicare Payment to Treat Prostate Cancer on Per Case or "Episode of Care" Basis

Source: Medicare Allowable 2006 APC payments, DRG payments and CPT 2006 payments. ALOS from 2006 DRG sourcebook. (Ingenix, 2005)

		Physician	Hormone Therapy Prior to Treatment	Hospital	Total	Hormone Therapy After Brachy Treatment	Total II	X Beam After Brachy Treatment	Total Episode of Care	ALOS
Brachytherapy		**$2,160.17**	**$654.90**	**$7,492.89**	**$10,307.96**	n/a	**$10,307.96**	n/a	**$10,307.96**	**0.75**
Radiologist + Urologist CPT codes	CPT 55859, 76000-26, 76965-26, 77781-26 ($774.85), 77290-26 , 77470-26	Urologist Portion= $729; Radiologist = $1431.17	Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	APC 163 + radiation tx APC codes w/Palladium Seeds (C-1720) @ cost (assume $4000)						
Brachytherapy w IMRT (Intensity Modulated RadiationTherapy)		**$2,478.99**	**$654.90**	**$7,811.71**	**$10,945.60**	**$1,964.70**	**$12,910.30**	**$29,290.83**	**$42,201.13**	**0.75**
Radiologist + Urologist	CPT 55879, 76000-26, 76965-26, 7778-26, 77290-26 (could select 77280-->77295), 77262 for Treatment Planning, 77470-26 and 77418 for IMRT and 77301	Urologist portion = $729; Radiologist portion $1749.99	Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	Same as above with additional APC 412 Rad Tx Delivery		Minimum of 9 months therapy; most with additional 12 months; some for years		See Description of Codes in Sample IMRT Costs		
Cryosurgery		**$1,128.59**	**$654.90**	**$6,628**	**$8,411.51**	n/a	**$8,411.51**	n/a	**$8,411.51**	**0.75**
Urologist	CPT 55873		Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	APC 674 (Procedure can be performed IP if patient condition warrants under 334 or 335)						
Radical Prostatectomy		**$1,271.84**	**$654.90**	**$5,669.39**	**$7,596.13**	n/a	**$7,596.13**	n/a	**$7,596.13**	**2.7**
Urologist	CPT 55840 prostatectomy, retropublic radical		Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	DRG 335 w/ 2.7 ALOS						
Radical Prostatectomy wCC		**$1,271.84**	**$654.90**	**$7,402.57**	**$9,329.31**	n/a		n/a	**$9,329.31**	**4.3**
Urologist	CPT 55840 prostatectomy, retropublic radical		Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	DRG 334 reimbursement w/ 4.3 ALOS						
Robotic "DaVinci" Radical Prostatectomy		**$1,689.47**	**$654.90**	**$7,097.10**	**$9,441.47**	n/a		n/a	**$9,441.47**	**2**
Urologist	CPT 55866 laparoscopy surgical prostatectomy, retropublic radical, including nerve sparing		Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	DRG 334 reimbursement w/ 2.7 ALOS						

Note (1) : Clinical Protocols using hormone therapy obtained from surgeon urology practices in the Southwest, West, Midwest, Southeast and Northeast.

Note (2): Cost and Reimbursement for IMRT or X Beam based on sample coding provided by high volume facility in Southern California (5 x/wk x 6 wks). See details below.

SAMPLE Brachytherapy and IMRT/Xbeam Therapy Costs

Physician Codes	Description	2006 Physician Payment Brachytherapy	2006 Physician Payment for Brachy w/ IMRT	OP Hospital APC	2006 Brachytherapy	2006 Payment Brachy w/ Xbeam/IMRT	
55879	Perc, needle insertion for brachy	$729	$729	163	$1,999	$1,999	
76000-26	Flouroscopic exam	$9	$9	272	$79	$79	
76965-26	Echo guidance radiotherapy	$70	$70	268	$62	$62	
77781-26	apply interstit radiation course	$775	$775	313	$775	$775	
77290-26	Set Radiation Therapy	$234	$234	305	$234	$234	
77470-26	Special radiation treatment	$343	$343	299	$343	$343	
77418	Radiation tx delivery		$319	412		$319	
		$2,160	**$2,479**		**$3,493**	$3,812	
					$4,000	$4,000	**Palladium Seeds**
					$7,493	**$7,812**	**Total Brachytherapy Treatment**
77301	Radiotherapy dose plan		$325	310	1 treatment	$826	
					5x/wk x 6 weeks	$20,653	**Total IMRT Treatment**
TOTAL						**$29,291**	

Source: 2may, 2006 Southern California High Volume Hospital Performing Brachytherapy and IMRT

ATTACHMENT II

CLINICAL EFFICACY OF PROSTATE CRYOABLATION

CLINICAL EFFICACY OF PROSTATE CRYOABLATION

How does primary cryoablation compare to other prostate cancer treatments?

Attachment to CMS Comment Letter
2007 OPPS Proposed Rule
September 29, 2006

Efficacy

Comparison of ALL papers published 2000 – 2005

- Radical Prostatectomy
- Cryoablation
- Brachytherapy
- Beam radiation therapy
- IMRT

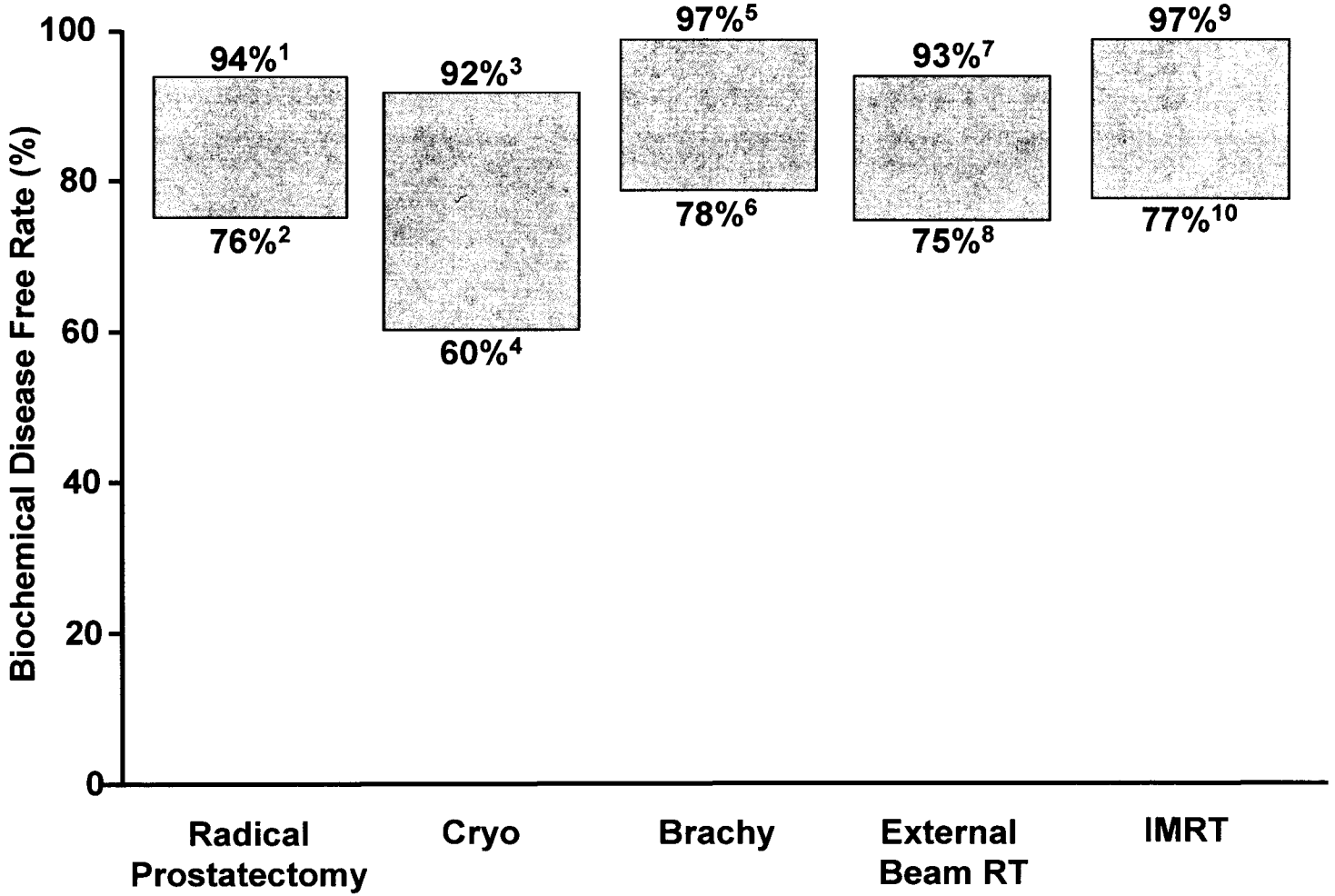
BDFS: biochemical disease free survivals compared

Methodology as utilized in Katz AE and Rewcastle JC. The current and potential role of cryoablation as a primary therapy for localized prostate cancer. *Current Oncology Reports* **5**(3) pp. 231–238 (2003)

Disease Classification / Risk Factors

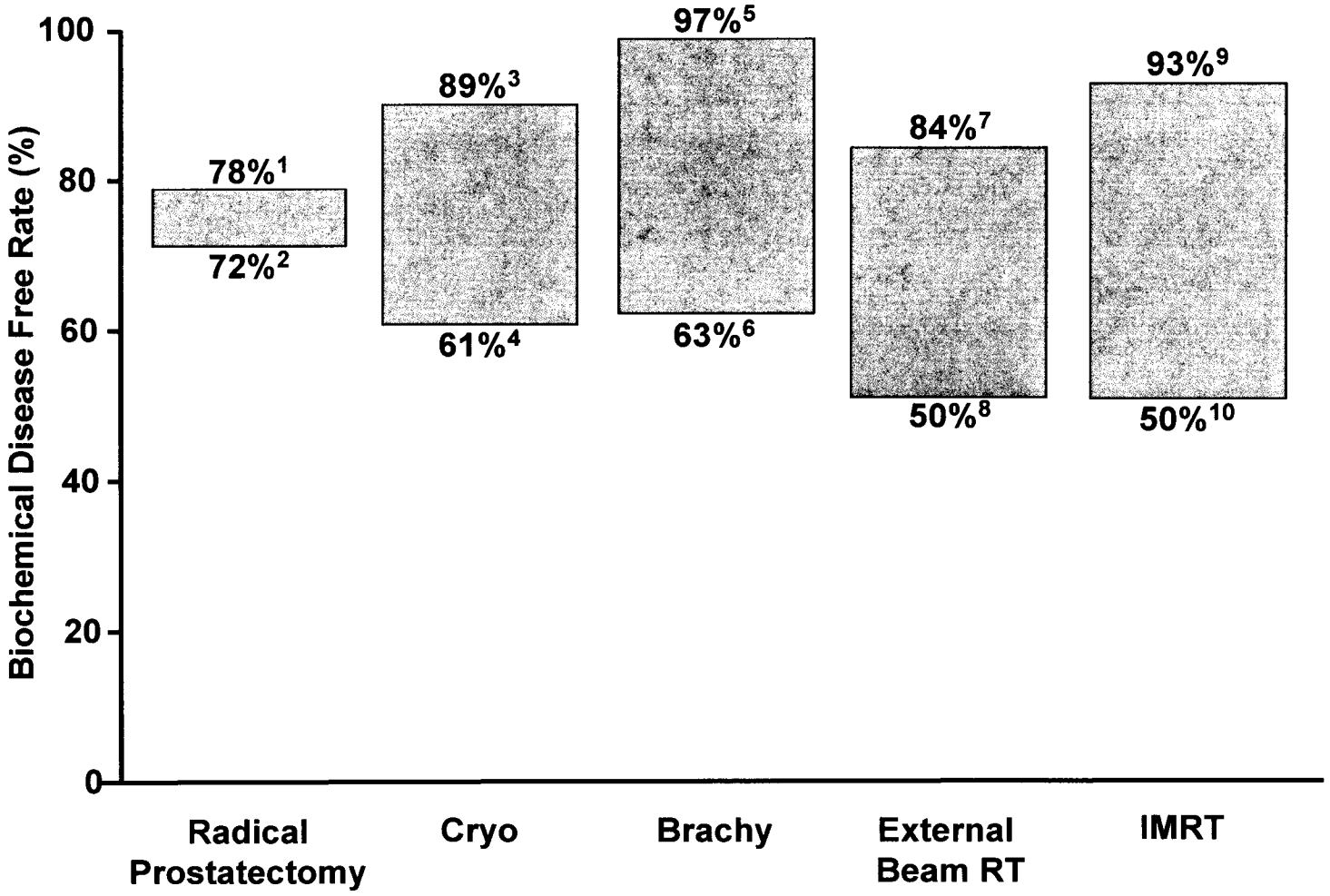
Risk Factors	PSA>10, GG>6, Stage>T2a
Low Risk	Patients having no risk factors
Moderate Risk	Patients having one risk factor
High Risk	Patients having two or more risk factors

Range of all BDFS results published (2000-2005) for LOW-RISK prostate cancer



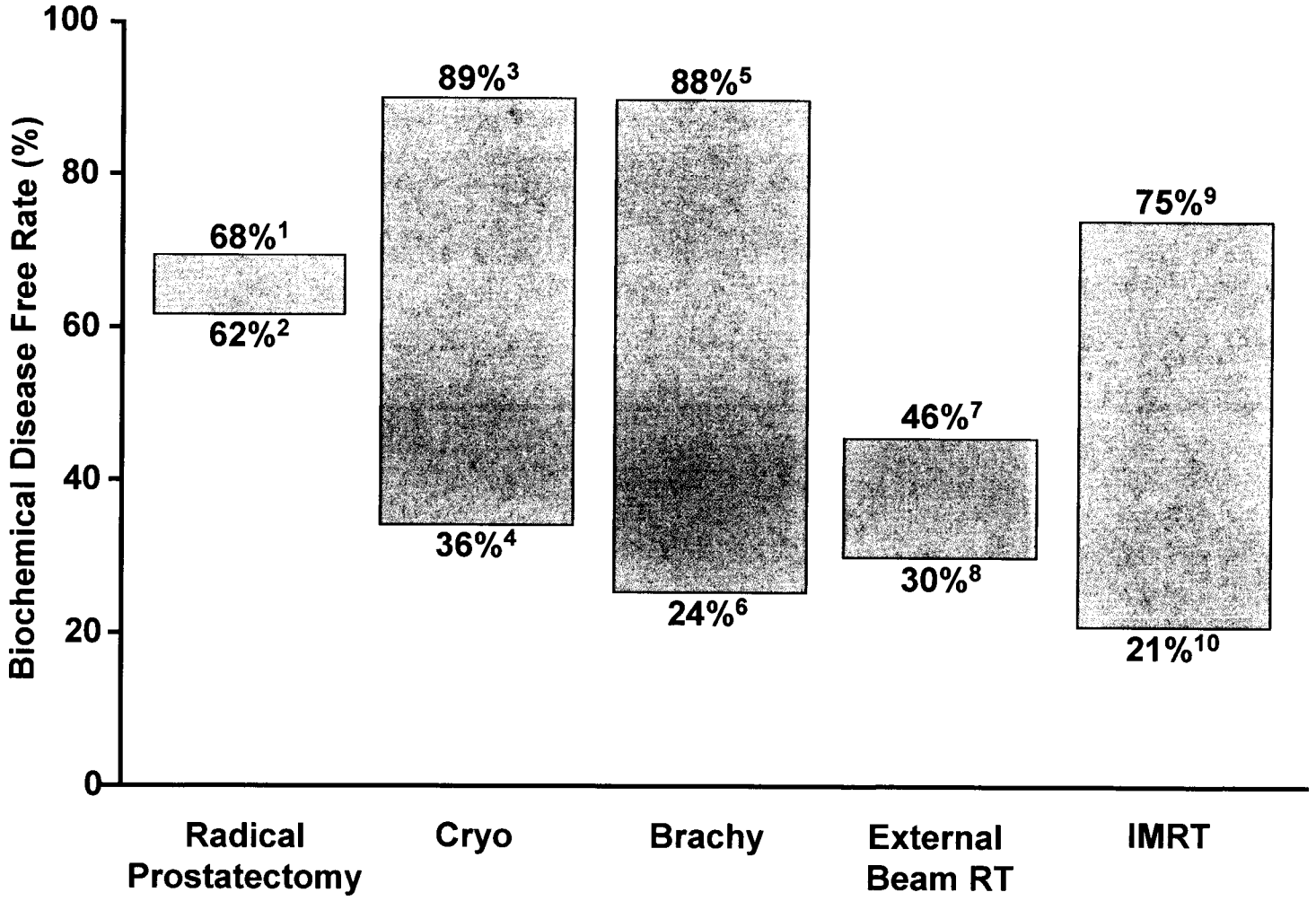
1. Sharkey et al, Brachytherapy. 2005;4(1):34-44; 2. Stokes, Int J Radiat Oncol Biol Phys. 2000 Apr 1;47(1):129-36; 3. Bahn et al, Urology. 2002 Aug;60(2 Suppl 1):3-11; 4. Long et al, Urology. 2001 Mar;57(3):518-23; 5. Merrick et al, Int J Radiat Oncol Biol Phys. 2001 Sep 1;51(1):41-8; 6. Stokes, Int J Radiat Oncol Biol Phys. 2000 Apr 1;47(1):129-36; 7. Ciezki et al, Int J Radiat Oncol Biol Phys. 2004 Dec 1;60(5):1347-50; 8. Kupelian et al, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):415-9; 9. Kupelian et al, Int J Radiat Oncol Biol Phys. 2005 Dec 1;63(5):1463-8; 10. Zelefsky et al, Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6.

Range of all BDFS results published (2000-2005) for MODERATE-RISK prostate cancer



1. Sharkey et al, Brachytherapy. 2005;4(1):34-44; 2. Ciezki et al, Int J Radiat Oncol Biol Phys. 2005 Dec 1;63(5):1463-8; 3. Bahn et al, Urology. 2002 Aug;60(2 Suppl 1):3-11; 4. Long et al, Urology. 2001 Mar;57(3):518-23; 5. Merrick et al, Int J Radiat Oncol Biol Phys. 2001 Sep 1;51(1):41-8; 6. Kwok et al, Int J Radiat Oncol Biol Phys. 2002 Jul 1;53(3):588-94; 7. Ciezki et al, Int J Radiat Oncol Biol Phys. 2004 Dec 1;60(5):1347-50; 8. Stokes, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):415-9; 9. Kupelian et al, Int J Radiat Oncol Biol Phys. 2005 Dec 1;63(5):1463-8; 10. Zelefsky et al, Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6.

Range of all BDFS results published (2000-2005) for HIGH-RISK prostate cancer



1. Grossfeld et al, J Urol. 2003 Jan;169(1):157-63; 2. Stokes, Int J Radiat Oncol Biol Phys. 2000 Apr 1;47(1):129-36; 3. Bahn et al, Urology. 2002 Aug;60(2 Suppl 1):3-11; 4. Long et al, Urology. 2001 Mar;57(3):518-23; 5. Sharkey et al, Brachytherapy. 2005;4(1):34-44; 6. Kwok et al, Int J Radiat Oncol Biol Phys. 2002 Jul 1;53(3):588-94; 7. Kupelian et al, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):415-9 ; 8. Stokes, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):415-9; 9. Kupelian et al, Int J Radiat Oncol Biol Phys. 2005 Dec 1;63(5):1463-8; 10. Zelefsky et al, Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6.

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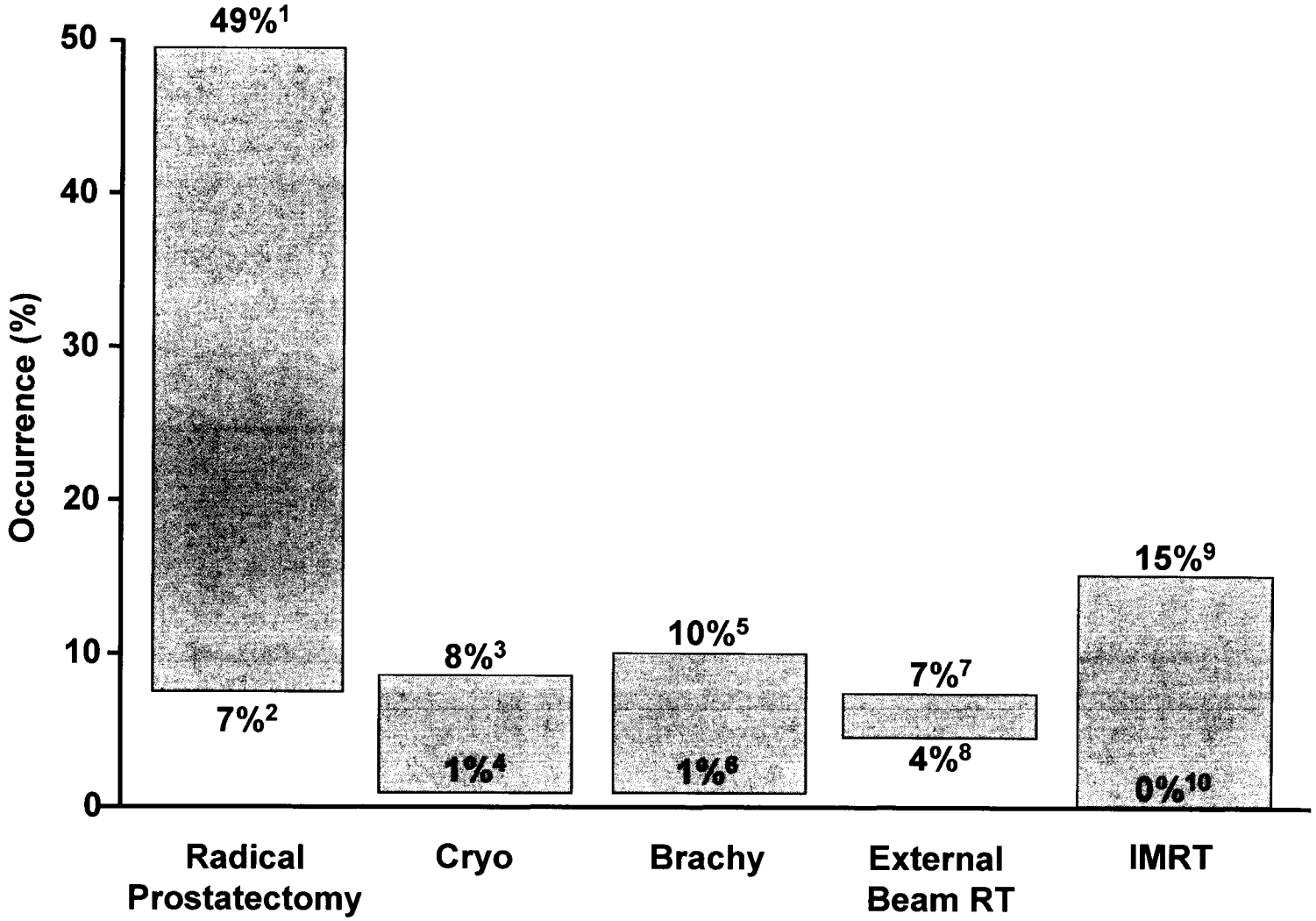
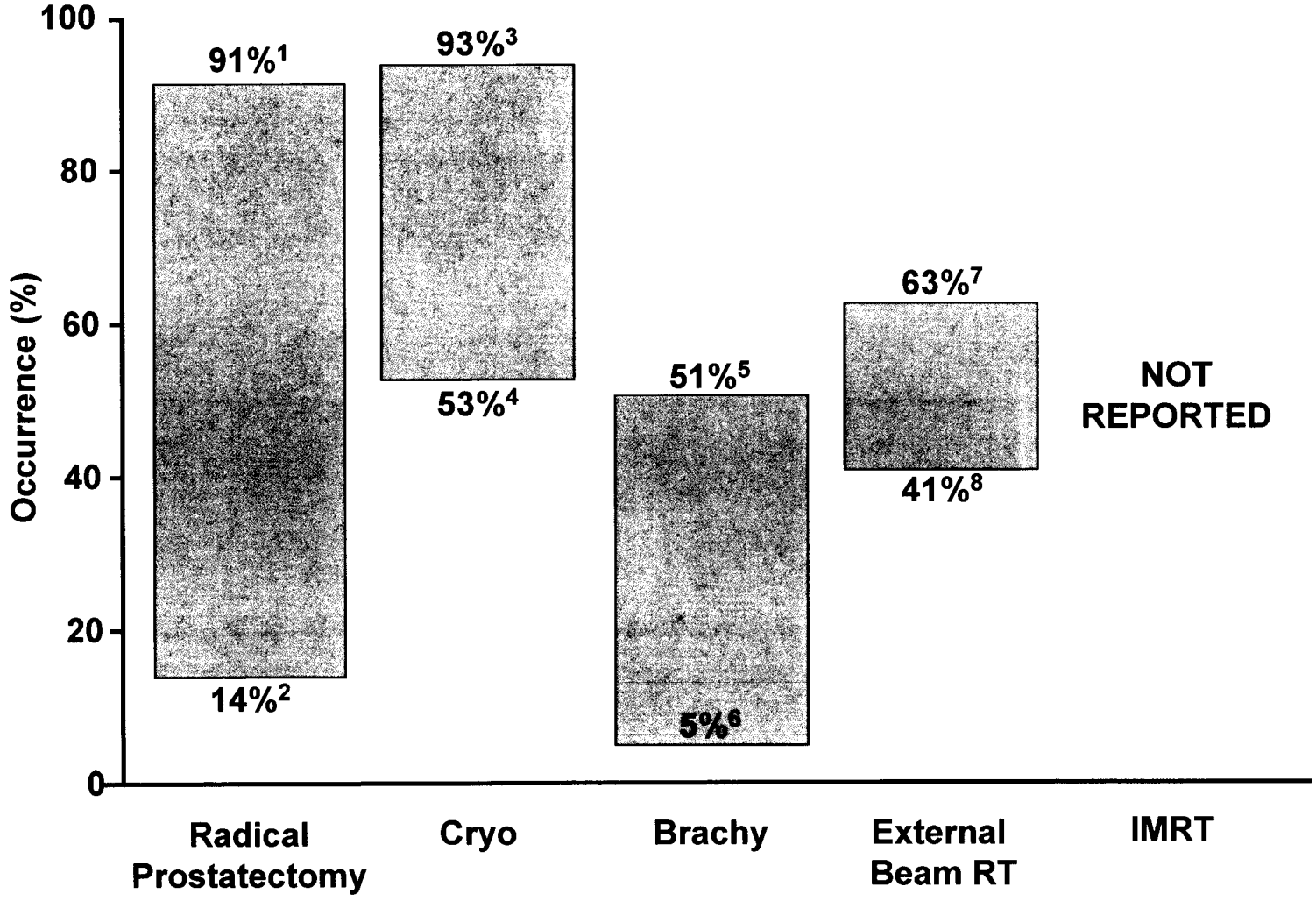
Range of published INCONTINENCE rates (2000-2005)



1. Steineck et al, N Engl J Med. 2002 Sep 12;347(11):790-6; 2. Walsh et al, J Urol. 2000 Jun;163(6):1802-7; 3. Long et al, Urology. 2001 Mar;57(3):518-23; 4. Donnelly et al, Urology. 2002 Oct;60(4):645-9; 5. Reis et al, Int Urol Nephrol. 2004;36(2):187-90; 6. Feigenberg et al, Int J Radiat Oncol Biol Phys. 2005 Jul 15;62(4):956-64; 7. Matalinska et al, J Clin Oncol. 2001 Mar 15;19(6):1619-28; 8. Potosky et al, J Natl Cancer Inst. 2000 Oct 4;92(19):1582-92; 9. Zelefsky et al, Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6; 10. Brabbins et al, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):400-8.

Range of published IMPOTENCE rates (2000-2005)



1. Matalinska et al, J Clin Oncol. 2001 Mar 15;19(6):1619-28; 2. Walsh et al, J Urol. 2000 Jun;163(6):1802-7; 3. Bahn et al, Urology. 2002 Aug;60(2 Suppl 1):3-11; 4. Donnelly et al, Urology. 2002 Oct;60(4):645-9; 5. Incrocci et al, Acta Oncol. 2005;44(7):673-8; 6. Incrocci et al, Acta Oncol. 2005;44(7):673-8; 7. Potosky et al, J Natl Cancer Inst. 2000 Oct 4;92(19):1582-92; 8. Matalinska et al, J Clin Oncol. 2001 Mar 15;19(6):1619-28; 9. Zelefsky et al, Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6; 10. Brabbins et al, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):400-8.

Quality of Life Following Cryoablation

- Badalament, 1999 (retrospective) 1 year post-op
  - ✓ n=223, 96% pt satisfaction – higher than any other therapy
- Robinson, 1999 (prospective) 1 year post-op
  - ✓ n=69, QOL assessed before *and* after cryo
  - ✓ return to baseline by 12 months for all domains except sexual function in all patients
- Robinson, 2002 (prospective) 3 year post-op

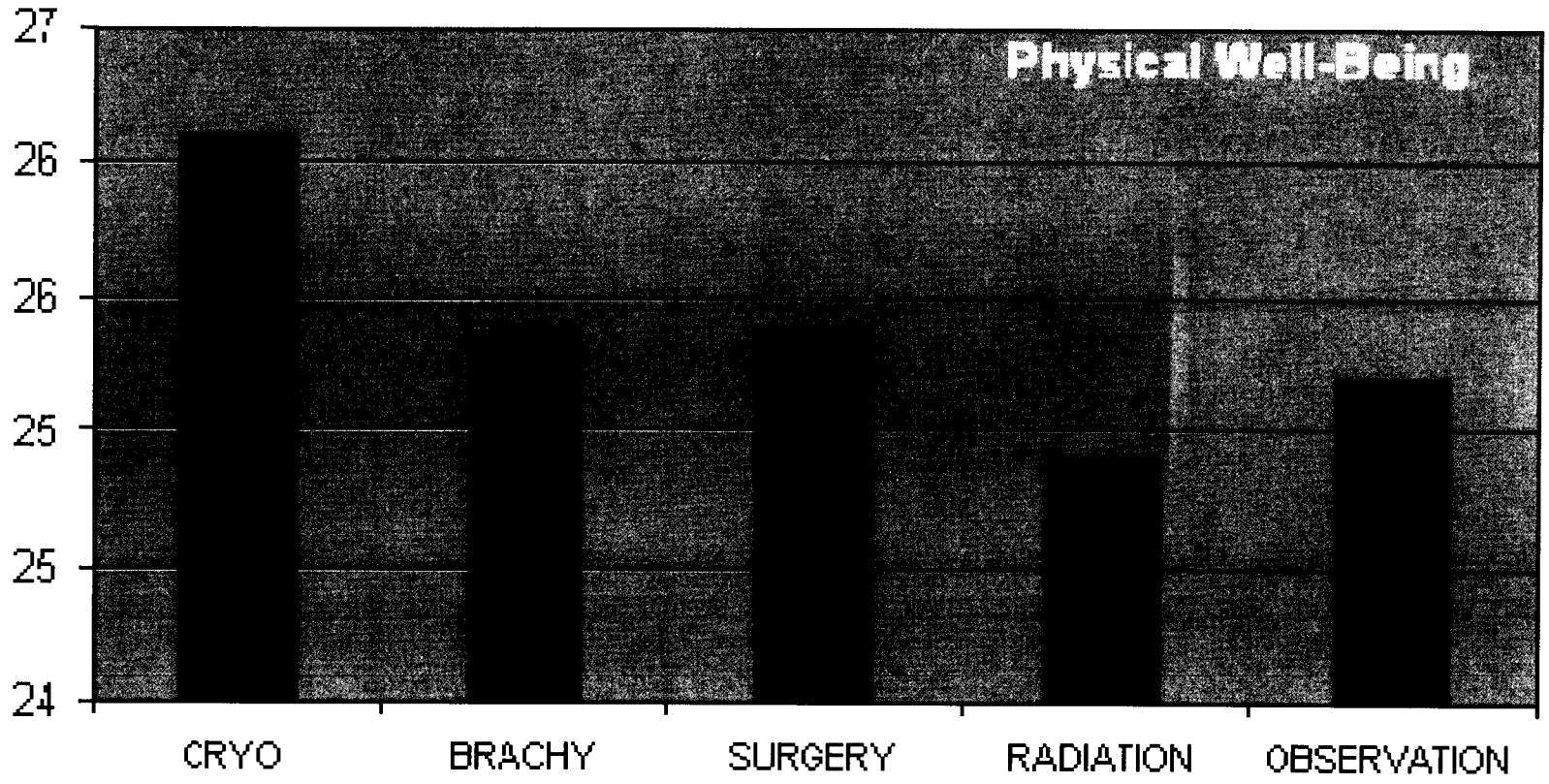
  Long term sexual function follow-up:
  - ✓ 13% full recovery of erectile function
  - ✓ 34% recovery sufficient for intercourse
  - ✓ No late onset morbidity

Rectal Morbidity

	Severe (fistula)	Moderate (bleeding, urgency, diarrhea)
Radical Prostatectomy	< 0.5%	1-19%
Cryoablation	< 0.5%	0%
Brachytherapy	< 0.5%	4-11%
Beam radiation		12-43%
IMRT		0-25%

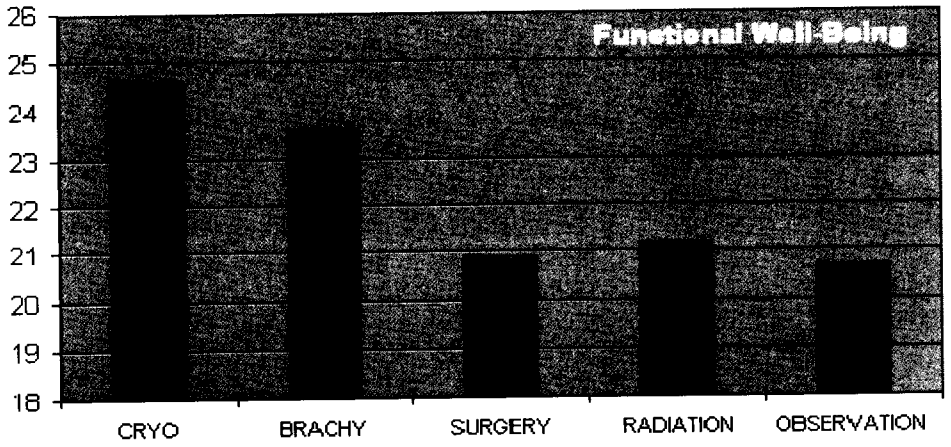
Shrader-Bogen Cancer 1997; Talcott J Clin Oncol 1998; Lim Urology 1995; Ragde Cancer 1997; Theodorescu Cancer 2000; Merrick Int J Radiat Oncol Biol Phys 1999; Merrick Int J Radiat Oncol Biol Phys 2000; Donnelly Urology 2002; Long Urology 2001; Zelefsky Radiother Oncol; Brabbins Int J Radiat Oncol Biol Phys. 2005.

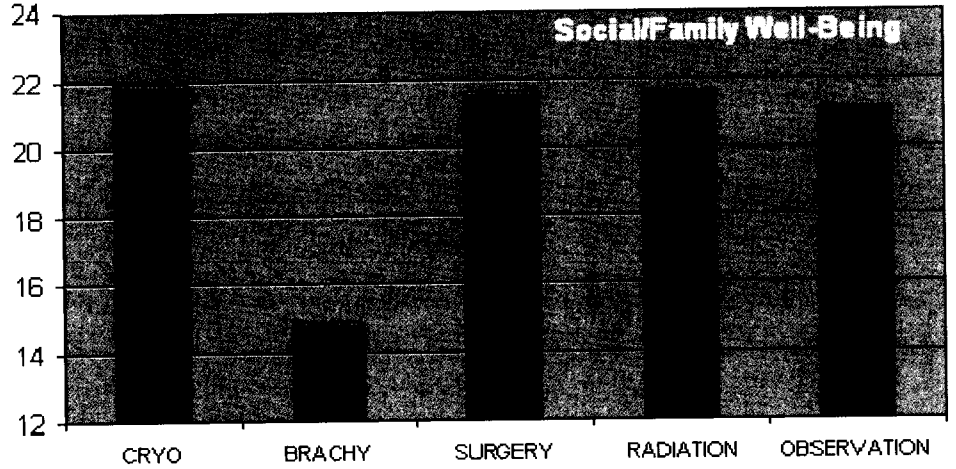
Quality of Life Following Cryoablation



Robinson, et al, UROLOGY, 2002

Quality of Life Following Cryoablation





Robinson, et al, UROLOGY, 2002

ATTACHMENT III

CMS'S PROPOSED APPROACH TO SET HOSPITAL INPATIENT PAYMENTS APPEARS PROMISING

GAO

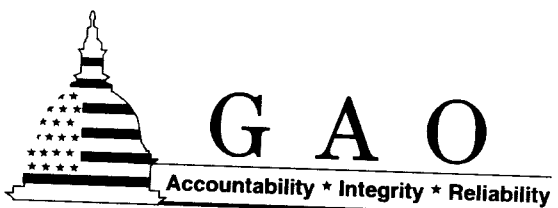
United States Government Accountability Office

Report to Congressional Committees

July 2006

MEDICARE

CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising



GAO-06-880

July 2006

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-06-880, a report to congressional committees

MEDICARE

CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising

Why GAO Did This Study

Under Medicare's inpatient prospective payment system (IPPS), hospitals generally receive fixed payments for hospital stays based on diagnosis-related groups (DRG), a system that classifies stays by patient diagnosis and procedures. CMS is required to at least annually update DRG payments to address changes in the cost of inpatient care. CMS uses charge-based weights to update these payments. Cost-based weights are used to set payments in the outpatient prospective payment system (OPPS). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required GAO to study IPPS payments in relation to costs. During the course of GAO's work, CMS proposed a new cost-based method for determining DRG weights. This report (1) examines the applicability of CMS's cost-based method—used for the OPPS—to weight DRGs in the IPPS and (2) evaluates whether CMS's proposed approach is an improvement over its OPPS method for setting cost-based weights. Using fiscal year 2002 cost reports and claims from 2001, 2002, and 2003 to examine the applicability of the OPPS method, GAO estimated costs for 1,025 IPPS hospitals whose Medicare cost reports most consistently reflected the total charges and number of Medicare stays that these hospitals reported on their claims. To evaluate CMS's proposed approach, GAO analyzed fiscal year 2003 cost reports and 2003 claims for 3,558 hospitals.

www.gao.gov/cgi-bin/getrpt?GAO-06-880.

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald, (202) 512-7101 or steinwald@gao.gov.

What GAO Found

If the OPPS method were applied to the IPPS, it could undermine the objective of better aligning DRG payment weights with actual costs. GAO estimated costs for 1,025 hospitals using CMS's cost-based OPPS weighting method to determine its applicability for weighting inpatient DRGs, and found that, for all but one of the 1,025 hospitals, GAO's application of CMS's OPPS method resulted in cost estimates for inpatient accommodation services that on average were 72 percent less than what the hospitals reported on their Medicare cost reports for these services. For 57 percent of the hospitals, GAO's application of CMS's OPPS method resulted in cost estimates for inpatient ancillary services that on average were 8 percent more than what the hospitals reported on their Medicare cost reports. For 22 percent of the hospitals, the application of CMS's OPPS method resulted in cost estimates for inpatient ancillary services that were on average 6 percent less than what the hospitals reported on their Medicare cost reports. These differences occur because the current OPPS weighting method does not address the variation in how hospitals allocate charges and costs in reporting Medicare services.

GAO found that CMS's proposed new approach to set payment weights for DRGs appears promising, and may result in improvements in setting cost-based weights compared with the OPPS method. CMS's proposed approach relies on grouping charges into 10 broad service groups, and converting those charges to cost-based weights by using national-average cost-to-charge ratios (CCR) that are derived from hospital data submitted to CMS. Use of national-average CCRs ameliorates the effects that variations in hospital charge and cost allocation decisions can have on DRG weights. GAO's analysis, using 2003 claims data and fiscal year 2003 cost report data for 3,558 IPPS hospitals, suggests that 6 of the service groups, which constitute a majority of Medicare inpatient charges, appear promising. GAO also found that wide ranges in the CCRs for 2 of the groups, the therapeutic services and operating room groups, raise concerns about their ability to better align payment with costs for those services. GAO did not have enough specific information to determine whether the remaining 2 groups are likely to capture the relevant cost-to-charge relationship for services in those groups.

In commenting on a draft of this report, CMS stated that it was pleased with GAO's findings. CMS also stated that it could not comment further because it is currently considering public comments in developing the fiscal year 2007 final rule for the IPPS payment rates. Hospital association reviewers agreed that cost estimation problems can result because of hospital reporting variation. However, they noted that because hospital reporting variation still affects the data CMS is proposing to use to set DRG weights, they were concerned with GAO's assessment that the CMS approach is promising. GAO believes the approach appears promising, in particular, because CMS proposes to use national-average CCRs to reduce the impact of individual hospital reporting practices.

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Abbreviations

AAMC	Association of American Medical Colleges
AHA	American Hospital Association
APC	ambulatory payment classification
CCR	cost-to-charge ratio
CMS	Centers for Medicare & Medicaid Services
COPD	chronic obstructive pulmonary disease
DRG	diagnosis-related groups
HCRIS	Healthcare Cost Reporting Information System
HHS	Department of Health and Human Services
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
IPPS	inpatient prospective payment system
MedPAC	Medicare Payment Advisory Commission
MEDPAR	Medicare Provider Analysis and Review
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
OPPS	outpatient prospective payment system

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At $119.4 billion, spending for hospital inpatient services accounted for over a third of total Medicare spending in fiscal year 2005. Most of these dollars were spent on care provided to Medicare beneficiaries by the approximately 4,000 acute care hospitals that bill Medicare under its inpatient prospective payment system (IPPS). Under this payment system, a hospital generally receives a fixed, predetermined payment amount for a hospital stay.[1] IPPS rates are based on diagnosis-related groups (DRG), a system that classifies inpatient stays by patient diagnosis and the procedures they receive. Each DRG has a numeric weight, which signifies the average costliness of stays assigned to that DRG relative to the average costliness of other inpatient stays. The Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) is required by statute to update DRG weights at least annually to address the changes in the cost of inpatient care. As a result of the DRG updates, changes occur annually in the payments hospitals receive for inpatient stays.

Because CMS does not have a direct measure of the cost of a hospital stay, it uses the charge information hospitals include on their Medicare claims to adjust the DRG weights. The weights that are developed from charge data are referred to as charge-based weights. Health policy analysts have had long-standing concerns about the use of charge data to set DRG weights.[2] They contend that charges are not a good proxy for costs, in large part, because of the variation in hospitals' charge-setting practices.

[1]Throughout this report, we use the term stay to represent a patient's hospitalization, which CMS and hospitals refer to as a discharge for data-reporting purposes.

[2]See Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Variation and Innovation in Medicare* (Washington, D.C.: June 2003); MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* (Washington, D.C.: March 2005). MedPAC advises the Congress on issues affecting the Medicare program. See also J. Newhouse, et al., "Predicting Hospital Accounting Costs," *Health Care Financing Review*, vol. 11, no. 1 (1989); and Kurt F. Price, "Pricing Medicare's Diagnosis Related Groups: Charges versus Estimated Costs," *Health Care Financing Review*, vol. 11, no. 1 (1989).

A hospital sets a charge for a service that is generally above the cost of the service. The difference between the charge and cost is referred to as a mark-up. Not all services are marked up by the same percentage; mark-ups for services may be influenced by several factors, including level of competition in the local market, service utilization, and insurers' purchasing arrangements. If all services were marked up over costs by an identical percentage, charges would represent the relative costliness of services perfectly. However, because variations in mark-up percentages vary across services and across hospitals, weights based on charges can overvalue some services and undervalue others and compromise the accuracy of DRG payment amounts.

Recognizing the problem involved in using charges to determine DRG weights, the Medicare Payment Advisory Commission (MedPAC) recommended in 2005 that CMS use a cost-based rather than charge-based method to weight the DRGs in the IPPS.[3] A cost-based method entails estimating the costs of hospital services for each DRG. Basing weights on cost estimates is intended to better align payments with hospitals' costs compared with the current charge-based method.

CMS currently uses cost-based weights to determine relative costliness for outpatient services provided to Medicare beneficiaries under its hospital outpatient prospective payment system (OPPS).[4] However, in its notice of proposed rulemaking for the fiscal year 2006 IPPS rates, CMS noted that, without further analysis, it was uncertain whether using the current OPPS cost estimation method would better align payments with costs for inpatient DRGs.[5]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required us to conduct a study of the appropriateness of Medicare's IPPS payments in relation to costs.[6] In light of MedPAC's recommendation that CMS adopt a cost-based weighting method, we evaluated CMS's concern about using the OPPS cost-based method to set DRG weights. During the course of our work, CMS published a notice of

[3]MedPAC, *Report to the Congress: Physician-Owned Specialty Hospitals* (Washington D.C.: March 2005).

[4]*See* 42 U.S.C. § 1395l(t)(2)(C).

[5]70 *Fed. Reg.* 23,306, 23,455 (May 4, 2005).

[6]Pub. L. No. 108-173, § 501(c), 117 Stat. 2066, 2290.

proposed rulemaking describing its intent to use a new cost-based approach to adjust the DRG weights beginning in fiscal year 2007.[7] We discussed these developments with the committees of jurisdiction, and this report examines (1) the applicability of CMS's cost-based method—used to set weights in OPPS—to weight DRGs in the IPPS and (2) whether CMS's proposed approach for the IPPS is an improvement over its OPPS method for setting cost-based weights.

To examine the applicability of CMS's OPPS cost-based method to weight DRGs in the IPPS, we reviewed CMS instructions to hospitals on billing Medicare for services provided, and CMS instructions to hospitals for filing Medicare cost reports—these cost reports are submitted annually to CMS by hospitals and contain aggregate information on charges for services and the actual costs of providing those services to all patients, as well as information on total charges and estimates of costs for services provided to Medicare beneficiaries. We used the Medicare Provider Analysis and Review (MEDPAR)—a CMS database that compiles and maintains hospitals' Medicare claims—to analyze hospital claims. For 3,660 hospitals paid under Medicare IPPS in fiscal year 2002, we compared Medicare cost reports and claims for services delivered. We identified 1,025 IPPS hospitals whose Medicare cost reports most consistently reflected the total charges and number of Medicare stays that these hospitals reported on their claims.[8] Using each hospital's fiscal year 2002 claims and Medicare cost report data for the 1,025 hospitals, we applied the OPPS cost estimation method to estimate Medicare costs for each hospital separately. CMS uses a single method to match cost information from the cost reports to charge information from the claims, and applies this method uniformly to all hospitals to estimate costs. Costs are estimated by using hospital-specific cost-to-charge ratios (CCR) derived from each hospital's respective Medicare cost report. A CCR is a ratio that describes the cost and charge relationship for similar services, such as pharmacy or laboratory, or for all services provided in a hospital. Similar to CMS, we developed a single method to match costs to charges, applied this method uniformly to all hospitals, and used hospital-specific CCRs to

[7]71 *Fed. Reg.* 23,996, 24,006-24,011 (April 25, 2006). By August 1, 2006, after evaluating comments on its notice of proposed rulemaking, CMS expects to publish a final rule describing its decision on the use of cost-based weights.

[8]We excluded hospitals from our analysis if the total Medicare charges and number of stays from their cost reports and claims data did not match within .3 percent.

estimate a hospital's costs.[9] For each hospital, we aggregated cost estimates for accommodation and ancillary services separately.[10] We then compared these aggregate estimates to what each hospital reported as its total Medicare costs for these services for fiscal year 2002 to determine the extent to which our cost estimates matched what each hospital reported on its Medicare cost report. We interviewed representatives from CMS, and fiscal intermediaries (claims administration contractors for CMS that process hospital claims). In addition, we spoke with representatives of the American Hospital Association (AHA) and the Association of American Medical Colleges (AAMC) about general hospital IPPS issues in October 2004. Our results are not generalizable to hospitals whose total charges and hospital stays from their Medicare cost reports and claims data did not match within .3 percent in fiscal year 2002.

To address whether CMS's proposed approach for the IPPS is an improvement over its OPPS method of setting cost-based weights, we first identified potential problems in applying the OPPS method to the IPPS. If our cost estimates did not match what hospitals reported on their cost reports, we compared how charges were categorized on the claims relative to how they were categorized on the cost report. On the basis of this analysis, we then determined whether CMS's proposed approach would better capture measures of cost. In particular, CMS's approach entails grouping charges from hospitals' claims into 10 broad service groups.[11] CMS uses these service groups as a basis to create cost-based weights by using national-average CCRs to eliminate charge mark-ups for each service group. In examining the proposed approach, we reviewed CMS's April 2006 notice of proposed rulemaking and analyzed 2003 Medicare claims and fiscal year 2003 Medicare cost reports for 3,558 IPPS hospitals to evaluate the national-average CCRs.[12] We determined the data to be

[9]Because the data sources that CMS uses to set payment rates are different for the IPPS and OPPS and because certain IPPS services are not provided in the OPPS, we needed to develop a mapping method to match cost information from the cost report to IPPS charge information from the claims. For more detail on our mapping method, see our scope and methodology in app. I.

[10]Accommodation services include room and board and nursing services. Ancillary services include all other services associated with an inpatient stay, for example, drugs and diagnostic services.

[11]The 10 proposed service groups are routine, intensive, drugs, supplies & equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services.

[12]We did not examine the extent to which the OPPS method measures relative costliness for outpatient services.

sufficiently reliable for the purposes of this report. (For more detail on our scope and methodology, see app. I.) We performed this work from June 2004 through July 2006 in accordance with generally accepted government auditing standards.

Results in Brief

If the OPPS method were applied to the IPPS, it could undermine the objective of better aligning DRG payment weights with costs. When we estimated fiscal year 2002 costs using CMS's cost-based OPPS weighting method to determine its applicability for weighting inpatient DRGs, we found that, for all but one of the 1,025 hospitals in our analysis, our application of CMS's OPPS method resulted in cost estimates for inpatient accommodation services that on average were 72 percent less than what the hospitals reported on their Medicare cost reports for these services. For 57 percent of the hospitals, our application of CMS's OPPS method resulted in cost estimates for inpatient ancillary services that on average were 8 percent more than what the hospitals reported on their Medicare cost reports.[13] For 22 percent of the hospitals, our application of CMS's OPPS method resulted in cost estimates for inpatient ancillary services that were on average 6 percent less than what the hospitals reported on their Medicare cost reports. These differences resulted from our application of CMS's single approach to mapping hospital-specific cost center CCRs to revenue center charges. Cost differences result because this method does not address the variation in how hospitals allocate their charges and costs.

CMS is proposing a new cost-based approach to set payment weights for inpatient DRGs that appears promising, and may result in improvements in setting cost-based weights compared with the OPPS method. The proposal involves grouping charges into 10 broad service groups. The charges for each of the 10 service groups are converted to cost-based weights by using national-average CCRs that correspond to each of the service groups. This approach ameliorates the problems we observed with the OPPS method because the approach does not require the application of hospital-specific CCRs. When CMS applies hospital-specific CCRs to match charges to costs for all hospitals, it may not capture the relevant cost-to-charge

[13]The 8 percent is based on estimates from 1,020 hospitals. This estimate excludes ancillary cost estimates for 5 hospitals from our sample of 1,025 because they were extreme outliers. When we included data from these hospitals in our aggregate cost estimates, the resulting ancillary cost estimates for the 1,025 were overestimated on average by 222 percent relative to what all the hospitals reported.

relationships for services. Using national-average CCRs in the proposed approach is intended to reduce the impact that variations in hospital charge and cost allocation decisions can have on the DRG weights. Six of the service groups, which constitute a majority of Medicare inpatient charges, appear promising because their CCRs are relatively consistent with one another within a service group and are likely to capture the relevant cost-to-charge relationship for the services included in these groups. An additional 2 groups contain cost center CCRs that range widely within their respective groups and, therefore, raise concerns about their ability to better align payment with costs for services in those groups. While the remaining 2 groups also include cost center CCRs that vary widely, due to the limitations of the MEDPAR data, we did not have enough specific information to determine whether the 2 remaining service groups are likely to capture the relevant cost-to-charge relationship for the services included in those groups.

In commenting on a draft of this report, CMS stated that it was pleased with our findings. CMS also stated that it could not comment further because it is currently considering public comments in developing the fiscal year 2007 final rule for the IPPS payment rates. Hospital association reviewers agreed that cost estimation problems can result because of hospital reporting variation. However, they noted that because hospital reporting variation still affects the data CMS is proposing to use to set DRG weights, they were concerned with our assessment that the CMS approach is promising. We believe the approach appears promising, in particular, because CMS proposes to use national-average CCRs to reduce the impact of individual hospital reporting practices.

Background

To set payment weights for inpatient and outpatient services, CMS has two sources of data: claims, which are bills hospitals submit to CMS upon a Medicare beneficiary's discharge to receive payment for inpatient and outpatient services rendered to Medicare beneficiaries, and Medicare cost reports, which are statements that hospitals submit annually to CMS identifying, by service category, the charges and costs for services rendered to all patients, not just Medicare beneficiaries. Charge-based weights, derived from claims data, are used to measure the relative costliness of stays assigned to DRGs in the hospital inpatient setting. Cost-based weights, derived from claims and Medicare cost report information, are used to measure the relative costliness of ambulatory payment classification (APC) groups in the outpatient setting. APCs in the OPPS are analogous to DRGs in the IPPS.

Claims and Medicare Cost Reports Are the Data Sources Available to Set Payment Weights for IPPS and OPPS Services

Hospitals submit claims upon a beneficiary's discharge to CMS identifying charges for services delivered to a Medicare beneficiary. These charges are billed by categories of service—for example, anesthesiology, cardiology, radiology—and these categories are referred to as revenue centers. A revenue center represents a revenue-generating department or unit within a hospital. By associating a revenue center with each service billed on a claim, a hospital can track its charges for services associated with that department.

In addition to keeping track of its charges for services by department or unit, a hospital tracks the costs associated with these departments. Hospitals submit this information annually to CMS on their Medicare cost reports. These reports contain hospitals' actual total costs and costs by department for all patients. The costs are reported in broad categories called cost centers. Similar to revenue centers, pharmacy, supplies, cardiology, and emergency room are also examples of cost centers, based on departments common to many hospitals.

CMS requires hospitals to report total charge and cost data for all patients by cost center. Although CMS does not require a one-to-one match between cost centers and revenue centers, it requires that a hospital report its list of revenue centers that are contained in each of its cost centers. Neither the cost nor the charge data reported in cost centers are broken down by individual items and services delivered by hospital stay, or DRG. Revenue center charges are accumulated from all claims for all patients and reported in total in associated cost centers on the Medicare cost report. The relationship between revenue centers and cost centers is subject to individual hospital discretion in how they accumulate charges and costs and is therefore variable across hospitals. Table 1 describes the information included on claims and on Medicare cost reports.

Table 1: Hospital Information Included on Claims and Medicare Cost Reports Submitted to CMS

Information	Claims[a]	Medicare cost report[b]
Charges	Lists charges for each service provided	Includes hospital's total charges and charges aggregated by cost center for (1) all patients and (2) Medicare beneficiaries
Costs	None	Includes hospital's total costs aggregated by cost center for all patients and hospital's estimates of the share of costs accounted for by Medicare beneficiaries
Categories of services	Revenue centers	Cost centers
Submitted to CMS	Upon a beneficiary's discharge	Annually

Source: GAO analysis of information contained on claims and Medicare cost reports.

[a]A claim contains billed charges for services provided during an inpatient stay.

[b]A Medicare cost report contains an annual summary of a hospital's total costs and charges.

Hospitals vary in the number of cost centers and revenue centers they use, and their decisions in allocating costs and charges to cost centers are driven typically by the hospitals' own internal accounting systems and organizational structure. For example, if a hospital does not have a separate department for anesthesia services, it may allocate its charges for anesthesia to the Medicare cost report's cost center for operating room.

Though hospitals report their total charges and total costs for all patients, as well as total costs and charges by cost center, they do not separately track the costs of services delivered by payer source. However, in reporting to CMS, each hospital must include in its Medicare cost report total charges for all patients, total charges for Medicare beneficiaries, and an estimate of the share of the hospital's costs for services delivered to Medicare beneficiaries, in total and by cost center.

Charge-Based Weights Are Used to Measure Relative Costliness of Inpatient DRGs

To determine the costliness of one inpatient DRG compared with others, CMS uses charge data from claims. Generally, the charges on a claim are for accommodation and ancillary services. Accommodation services include room and board and nursing services. These services are classified as either routine or intensive care, based on the level of intensity of the nursing services required. Ancillary services include all other services

associated with an inpatient stay; for example, drugs and diagnostic services.[14]

Charges for accommodation and ancillary services have been used to weight DRGs since 1986. In general, the average charge for each DRG is divided by the average charge for all DRGs to produce a weight. The resulting weights are multiplied by a base payment rate to determine payment for each DRG.[15]

Charges have long been considered a problem in setting relative weights for inpatient hospital services because the method assumes a consistent relationship between the charge set for an item or service and its cost to the hospital. A recent MedPAC-sponsored report on hospitals' charge-setting practices attributes the wide variation in the relationship between costs and charges to hospital-specific factors—such as mission, location, and payer mix—and charge mark-up decisions.[16]

Cost-Based Weights Are Used to Measure Relative Costliness of Outpatient APCs

Unlike IPPS, which uses charges to set payment weights for DRGs, CMS uses cost-based weights in the OPPS to measure the costliness of one APC relative to the others. Because neither the claims nor the Medicare cost reports include the costs for individual items or services, these costs must be estimated by CMS in order to calculate payment weights. As a first step, CMS obtains hospital charge data on each outpatient service from the claims. It calculates each hospital's cost for each service by multiplying the charge amount for each service by the CCR that is computed from each hospital's cost report, generally on a cost center-specific basis. The application of a CCR to a charge is designed to remove the mark-up from each charge in order to identify the cost of the item or service. For example, to estimate the cost of a radiology service, CMS multiplies the charge associated with a hospital's radiology revenue center on each claim by the radiology cost center CCR for that hospital. CMS uses these estimated costs to develop payment weights for each APC.

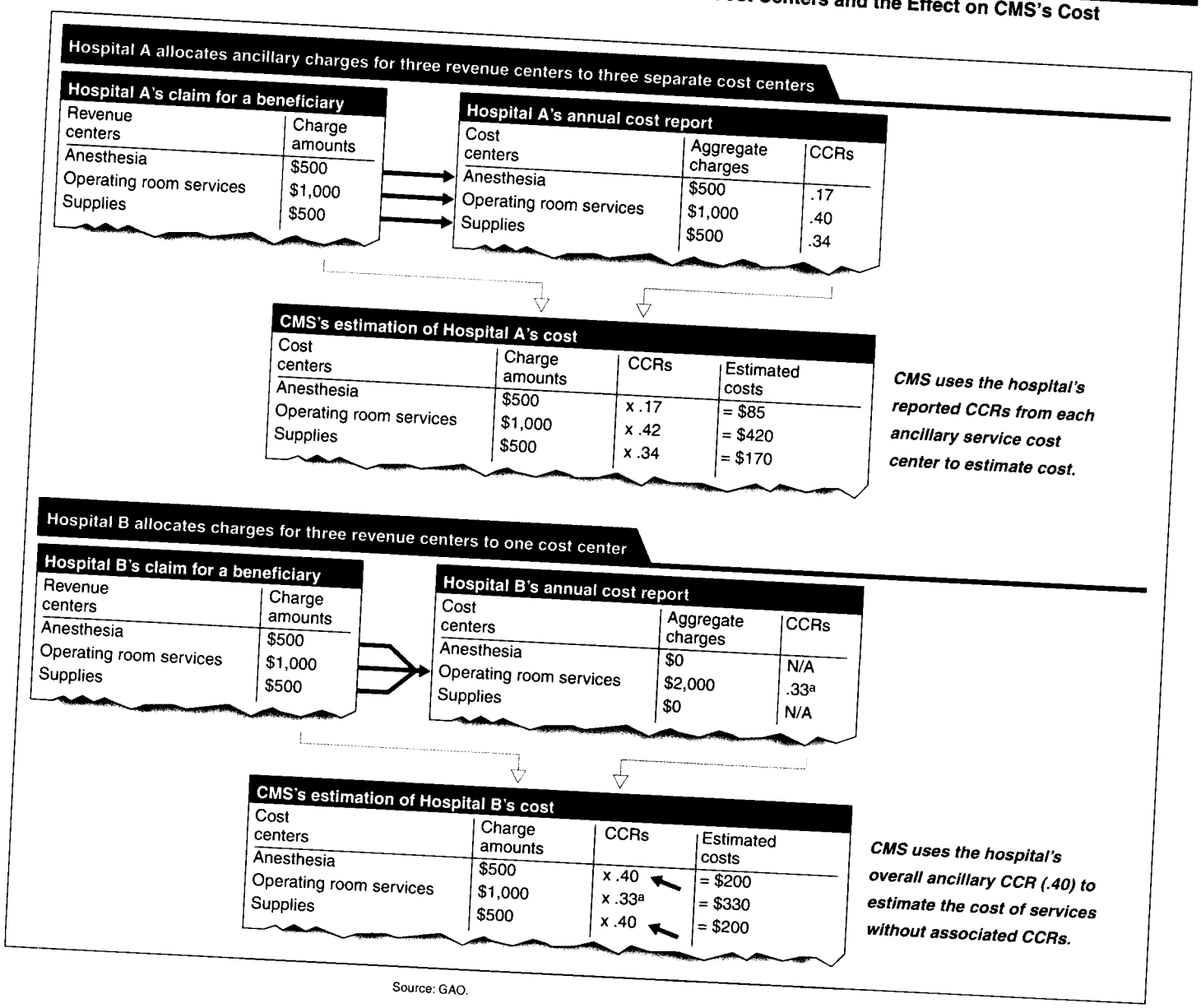
[14]Payment for physician services is not included in the DRG payment to hospitals. Physicians are paid by Medicare under a separate fee schedule.

[15]The base payment rate is a standardized amount, which is divided into labor and nonlabor-related shares.

[16]The Lewin Group, *A Study of Hospital Charge Setting Practices* (Falls Church, Va.: 2005).

Hospitals vary in how they allocate revenue center charges to cost centers on their Medicare cost reports. When estimating costs for purposes of weighting APCs, however, CMS uses its own system of mapping the hospitals' revenue center charges to cost center CCRs in order to convert the charges to an estimate of cost. This can be problematic since hospitals may allocate their revenue centers to cost centers in a different manner from CMS. For example, as illustrated in figure 1, some hospitals allocate charges from the same revenue center to separate cost centers; others allocate charges from several revenue centers to a single cost center. CMS's use of a single method in mapping charges to costs and then applying that method across all hospitals for purposes of cost estimation does not recognize the differences in hospital allocation decisions when estimating costs. As a result, some service costs are systematically overestimated and some are underestimated.

Figure 1: How Hospitals Can Allocate Charges from Revenue Centers to Cost Centers and the Effect on CMS's Cost Estimates



Source: GAO.

Note: For illustrative purposes, these hospitals' total charges reflect charges for only one patient. Hospitals' Medicare cost reports would normally contain all charges for all services delivered during a fiscal year.

[a]The CCR computed for Hospital B's operating room services is a weighted average reflecting the costs and charges for all three of the services reported on the Medicare cost report.

The services represented in figure 1 are ancillary services typical to many hospitals. Hospital A reports charges in all three cost centers, and reports CCRs for these cost centers. Hospital B does not use separate cost centers for anesthesia and supplies; therefore, it does not report any charges in its cost centers for anesthesia and supplies. As a result, Hospital B does not report CCRs for these services specifically. To estimate the cost for these services without an associated CCR, the current OPPS cost-based weighting method uses, or defaults to, the hospital's overall ancillary CCR—which is the ratio of a hospital's total ancillary costs to its total ancillary charges. Therefore, in the case of Hospital B, CMS's single mapping approach defaults to Hospital B's overall ancillary CCR to estimate a cost for its anesthesia and supply charges. To the extent that the hospital's overall ancillary CCR is an inaccurate measure of the cost-to-charge relationship for those services, the costs of those services will be overestimated or underestimated. If these cost estimates are used to set relative weights, payment amounts for the services can be inappropriate.

CMS asserts that the application of CCRs to Medicare charges is a fundamental principle of cost reimbursement and has been in effect for many years. Because CMS does not have any other financial information from hospitals except each hospital's claims and Medicare cost report, it views the use of CCRs as the most straightforward way to estimate costs from charges.[17]

Applying the OPPS Weighting Method to IPPS Could Undermine the Objective of Better Aligning DRG Payment Weights with Costs

When we used CMS's cost-based OPPS weighting method to determine its applicability for weighting inpatient DRGs, we found that, for the majority of hospitals in our analysis, our estimates of aggregate costs for Medicare stays were on average more than what the hospitals reported on their cost reports for ancillary services. In addition, our estimates for accommodation services were on average less than what the hospitals reported on their cost reports for the Medicare services associated with these stays. These differences resulted from CMS's single approach to mapping hospital-specific cost center CCRs to revenue center charges. Cost differences result because the CMS method does not address the variations in how hospitals allocate charges and costs. Using such cost estimates to set DRG weights in the IPPS would undermine the goal of better aligning payment with costs.

[17]*See* 70 *Fed. Reg.* at 23,455 (May 4, 2005).

We estimated costs using the OPPS method for each hospital stay and aggregated the accommodation and ancillary cost estimates for each of the 1,025 hospitals in our analysis. We compared our aggregate accommodation and ancillary cost estimates to the accommodation and ancillary costs each hospital reported on its Medicare cost report. For all but one of the hospitals in our analysis, our application of CMS's OPPS method resulted in cost estimates for inpatient accommodation services that were on average 72 percent less than what the hospitals reported on their Medicare cost reports for these services. For 57 percent of the hospitals, our application of CMS's OPPS method resulted in cost estimates for inpatient ancillary services that were on average 8 percent more than what the hospitals reported on their Medicare cost reports.[18] For 22 percent of the hospitals, our application of CMS's OPPS method resulted in cost estimates for inpatient ancillary services that were on average 6 percent less than what the hospitals reported on their Medicare cost reports.

The differences between our aggregate estimates using the OPPS method and hospitals reported costs indicate that a single approach to mapping cost center CCRs to revenue center charges is problematic because CCRs are applied to certain charges that do not capture the cost-to-charge relationship for those charges. For example, approximately 18 percent of the hospitals in our analysis did not allocate their charges for anesthesia services to their Medicare cost report's anesthesia cost center and thus did not report a CCR for that cost center.[19] In applying the CMS OPPS method to estimate the cost of anesthesia services for these hospitals, we multiplied each hospital's anesthesia charge included on the hospital's claims by each hospital's overall ancillary CCR. Although we could not measure the precise effect of using a default CCR for these services, our information on average CCRs was instructive. That is, the average overall ancillary CCR for the 1,025 hospitals in our analysis was .34 and for the hospitals that reported costs and charges in the anesthesia cost center, the

[18]The 8 percent is based on estimates from 1,020 hospitals. This estimate excludes ancillary cost estimates for 5 hospitals from our sample of 1,025 because they were extreme outliers. When we included data from these hospitals in our aggregate cost estimates, the resulting ancillary cost estimates for the 1,025 were overestimated on average by 222 percent relative to what all the hospitals reported.

[19]This hospital allocation practice—billing for services and allocating the charges to a different cost center service type—occurred to varying degrees for all ancillary cost centers.

average anesthesia CCR was .16.[20] The difference between the two CCRs suggests that using each hospital's overall ancillary CCRs to estimate its anesthesia costs produced an estimate that, on average, overvalued these services at the individual hospital level and contributed to the differences between the aggregated ancillary cost estimates we calculated and what hospitals reported to CMS as their ancillary costs. The extent of the problem for cost estimation depends upon the frequency with which the overall ancillary CCR is used in place of a specific cost center CCR.

Cost estimation problems can also result when hospitals report two distinct service types, with different mark-ups, in one cost center. Specifically, about 9 percent of the hospitals in our analysis reported charges for intensive care services in a cost center other than intensive care. For example, some of these hospitals may have reported intensive care charges with routine service charges in the routine cost center. In fiscal year 2002, hospitals' average CCR for intensive care services for the 1,025 hospitals in our analysis was .81 compared with the average CCR for routine services of .96. Such combining into one cost center results in a weighted average CCR that may undervalue routine services and overvalue intensive care services. These estimates can systematically influence DRGs that have a disproportionate amount of either intensive care or routine services.

CMS's Proposed Cost-Based Approach for IPPS May Result in Improvements over the OPPS Cost-Based Method

CMS is proposing an approach to set payment weights for inpatient DRGs that appears promising, and may result in improvements in setting cost-based weights compared with the OPPS method. The proposal involves grouping charges into 10 broad service groups. The charges for each of the 10 service groups are converted to cost-based weights by using national-average CCRs that correspond to each of the service groups. This approach ameliorates the problems we observed with the OPPS method because it does not require the application of hospital-specific CCRs, which, using CMS's single method to match charges to cost, may not capture the relevant cost-to-charge relationships for services. Using national-average CCRs is intended to reduce the impact that variations in

[20]The average mark-up for overall ancillary services was 194 percent of the cost, and for anesthesia services the average mark-up was 525 percent. These mark-ups were in addition to the cost and result in a charge that is almost three times and six times the cost of services for all ancillary and anesthesia services, respectively. For example, a hospital's cost for an anesthesia service was $16. The hospital applied a mark-up of $84, which is 525 percent of $16, resulting in a charge of $100.

hospital charge and cost allocation decisions can have on the DRG weights. Six of the service groups, which constitute a majority of Medicare inpatient charges, appear promising because their CCRs are relatively consistent within a service group and are likely to capture the relevant cost-to-charge relationship for the services included in these groups. An additional 2 groups contain cost center CCRs that range widely within their respective groups and, therefore, raise concerns about their ability to better align payment with costs for services in those groups. Finally, due to the limitations of the MEDPAR data, we did not have enough information to determine whether the 2 remaining service groups are likely to capture the relevant cost-to-charge relationship for the services included in those groups.

National-Average CCRs Intended to Reduce Impact on IPPS Weights of Variation in Hospital Charge and Cost Allocation Decisions

Under its proposed approach for the IPPS, CMS takes several steps to create cost-based weights for each DRG. The approach entails grouping charges from hospital's claims into 10 broad service groups.[21] (See table 2.) CMS uses these service groups as a basis to create charge-based weights by standardizing the charges in each group to remove differences due to hospital-specific characteristics. To standardize the charges, CMS calculates an average charge for each hospital for each of the 10 proposed service groups. CMS then divides each individual hospital's charge for each service by that hospital's average charge for the service group. Ultimately, these standardized charges for all hospitals are aggregated by DRG and the average charge for each DRG is divided by the national-average charge for all cases. This yields 10 standardized, national charge-based weights that correspond to each service group for each DRG. In order to convert these charge-based weights to cost-based weights, charge mark-ups must be removed. To accomplish this, CMS calculates 10 national-average CCRs for each of the 10 broad service groups using hospitals' Medicare cost report data. CMS then uses these CCRs to convert the national charge-based weights to cost-based weights.[22] The 10 cost-based weights for each DRG are summed to produce one final weight for each DRG.

[21]In this report, we use the term service group to describe CMS's proposed groups. In its *Federal Register* notice, CMS refers to these groups as cost centers.

[22]It is possible that a particular DRG may have a zero value for one or more of the 10 service groups. This can occur if hospitals do not provide particular services as part of a DRG.

Table 2: CMS's Proposed Service Groups

CMS's proposed service group	Revenue centers from claims used to calculate relative charge weights[a]	Cost centers from Medicare cost report used to calculate national-average CCRs
Routine	Private room Semi-private room Ward	Adults & pediatrics
Intensive	Intensive care Coronary care	Intensive care unit Coronary care unit Burn intensive care unit Surgical intensive care unit Other special care unit
Drugs	Pharmacy	Drugs charged to patients Intravenous therapy
Supplies & Equipment	Medical/surgical supply Durable medical equipment Used durable medical equipment	Medical supplies charged to patients Durable medical equipment rented Durable medical equipment sold
Therapeutic Services	Physical therapy Occupational therapy Speech therapy Inhalation therapy	Physical therapy Occupational therapy Speech pathology Respiratory therapy
Operating Room	Operating room Anesthesia	Operating room Recovery room Delivery and labor room Anesthesiology
Cardiology	Cardiology	Electrocardiology Electroencephalography
Laboratory	Laboratory	Laboratory Provider-based physician clinical laboratory service
Radiology	Radiology Magnetic resonance imaging (MRI) Lithotripsy	Radiology-diagnostic Radiology-therapeutic Radioisotope
Other Services	Ambulance Blood Blood administration Outpatient services Emergency room Clinic visit End-stage renal disease (ESRD) Other services	Ambulance Whole blood and packed red blood cells Blood storing, processing, and transporting Other outpatient services Ambulatory surgical center (Non-distinct part) Emergency Clinic Home program dialysis Renal dialysis Other ancillary

Source: GAO analysis and 71 *Fed. Reg.* 23,996, 24,009-24,010 (April 25, 2006).

[a]Data for the revenue centers are from the CMS MEDPAR file. MEDPAR pools revenue centers into broad revenue center categories and reports total charges by these categories. The revenue centers from MEDPAR are not a one-to-one match with cost centers from the Medicare cost reports.

The proposed approach, which entails using national-average CCRs rather than individual hospital CCRs, is intended to reduce the impact that variations in hospital charge and cost allocation decisions can have on DRG weights. Specifically, the national-average CCRs, in conjunction with standardized charge-based weights, are more likely than the OPPS method that entails using hospital-specific CCRs to capture the relevant cost-to-charge relationships for the services in each group. In principle, the national-average CCRs are applied to a group of services with similar charge mark-ups. Similarly, the national-average CCRs will be influenced by the most commonly used hospital allocation practices among hospitals and are, therefore, less likely to be influenced by atypical hospital allocation practices. Furthermore, because a national-average CCR is established for each service group, the proposed approach eliminates the need to use, or default to, a hospital's overall CCR when a particular cost center CCR is not reported. For these reasons, CMS's proposed approach to establishing cost-based weights for the purpose of better aligning payments with costs for DRGs appears promising.

Service Group Approach Appears Promising but Some Concerns Exist

Because CMS's broad service group approach is integral to improved payment accuracy, and because CMS is currently considering refinements to the service groups for the fiscal year 2007 IPPS payments, we examined the 10 proposed service groups and their associated national-average CCRs.[23] For 6 of the proposed service groups, which constitute a majority of Medicare inpatient charges, the national-average CCRs appear promising, and are likely to capture the relevant cost-to-charge relationships for the services included in these groups. An additional 2 groups contain cost center CCRs that range widely within their respective groups, and therefore, raise concerns about their ability to better align payment with costs for services in those groups. Due to the limitations of the MEDPAR data, we did not have enough information to determine whether the 2 remaining service groups are likely to capture the relevant cost-to-charge relationship for the services included in the groups.

[23]CMS's proposed service groups are based on its analysis of cost report and claims data. Each group includes revenue center charges that, in total for the group, represent at least 5 percent of all Medicare charges for inpatient hospital services. The groups also include cost centers that, CMS asserts, are consistent with general hospital accounting definitions. To analyze the cost centers within the service groups, we used fiscal year 2003 Medicare cost report data for 3,558 hospitals paid under the IPPS in order to conform to the same time period as the analysis CMS conducted for its April 2006 notice of proposed rulemaking.

Six of the groups, which constitute approximately 63 percent of total Medicare inpatient charges in 2003, appear promising since they either contain cost center CCRs that are relatively consistent with one another within a group, or contain individual cost center CCRs that vary from the national-average CCRs, but the charges associated with those services constitute a small percentage of total Medicare inpatient charges. For example, one of these six groups—radiology—includes three cost center CCRs that are relatively consistent with the radiology national-average CCR, with a range of 7 percentage points between the highest and lowest CCR for these three cost centers. This grouping produces a national-average CCR that will not be unduly influenced by any one cost center CCR included in the average. The other service groups that appear promising include cardiology, routine, drugs, supplies & equipment, and other services.[24]

While six of the service groups that constitute a majority of Medicare inpatient charges appear promising, two other groups, therapeutic services and operating room, raise concerns because they contain cost center CCRs that vary widely and involve services that can be linked to high-volume DRGs. The national-average CCR for these service groups may not capture the appropriate cost-to-charge relationships for certain services in those groups and could undermine the goal of better aligning payments with costs for those services. Table 3 illustrates this problem for one of the groups, therapeutic services, where the difference between the lowest and highest cost center CCR is 26 percentage points. The cost center CCR for respiratory therapy is substantially lower than the other cost center CCRs included in this group.[25] Respiratory therapy is used to treat respiratory diseases classified under DRG 088—chronic obstructive pulmonary disease (COPD)[26]—Medicare's fourth most frequently billed DRG. In 2003, hospitals billed Medicare approximately $1.4 billion for respiratory therapy services provided under DRG 088. This amount accounted for 17 percent of the total ancillary service charges and 11 percent of the total charges for DRG 088, which were $12 billion. The

[24]The supplies & equipment and other services groups include cost center CCRs that range widely from the national-average CCR for their groups; however, the charges associated with those services constitute approximately 1 percent of total Medicare charges and, therefore, are not likely to have an impact on the DRG weights that include those services.

[25]Respiratory therapy is also referred to as inhalation therapy.

[26]COPD refers to chronic lung disorders that result in blocked air flow in the lungs. The two main COPD disorders are emphysema and chronic bronchitis, the most common causes of respiratory failure.

other therapy services in the group accounted for approximately 1 percent of the DRG's total charges.

Table 3: Proposed Therapeutic Services Group: Cost Centers and CCRs

Cost centers included in the therapeutic services group	GAO-calculated cost center CCRs	CMS-proposed national-average CCR for therapeutic services group
Physical therapy	.52	.35
Occupational therapy	.44	
Speech pathology	.53	
Respiratory therapy	.27	

Source: GAO analysis based on fiscal year 2003 Medicare cost report data and 71 *Fed. Reg.* 24,021 (April 25, 2006).

Our analysis of hospitals' fiscal year 2003 Medicare cost report data showed that, on average, for the 3,558 hospitals paid under the IPPS that we reviewed, the CCR for respiratory therapy is .27. The use of the national-average CCR would result in a weight that would undervalue physical, occupational, and speech therapy services. Conversely, the use of the national-average CCR in this instance would result in an estimate that overvalues respiratory therapy services. Because these services account for 17 percent of all ancillary charges for DRG 088, the application of the national-average CCR will result in a weight that would be based on an overstated cost estimate. This is a problem because the overstated cost estimate for this service is a significant portion of a high-volume DRG.

Similarly, the operating room service group may not capture the appropriate cost-to-charge relationships for certain services. The services contained within this group can be linked to DRGs that involve surgery, and those DRGs constitute almost half of the number of IPPS DRGs. The group contains CCRs for operating room and anesthesia, which are .38 and .17, respectively. CMS's proposed national-average CCR for this service group is .37. The use of the national-average CCR would result in a weight that would overvalue anesthesia services. In its comment on the CMS proposed approach, MedPAC noted problems with the therapeutic services and the operating room service groups.[27]

[27]MedPAC correspondence to CMS, June 12, 2006.

Finally, the remaining two groups—intensive and laboratory—include cost center CCRs that also vary widely. However, using the MEDPAR data that CMS uses to construct the IPPS rates, we could not assess the charges associated with those services because they cannot be separately identified. Without such information, we could not determine the volume of specific services provided under these groups and, therefore, we could not assess the potential impact on the DRG weights.

Concluding Observations

Policy analysts have for decades suggested that replacing charge-based with cost-based weights would improve the accuracy of the weights to measure relative costliness for hospital inpatient DRGs. Our findings suggest that the CMS approach of using national-average CCRs to develop cost-based weights for inpatient DRGs appears promising because it addresses the concerns associated with charges that are currently used to weight DRGs. The proposed approach improves the OPPS method of estimating costs because the OPPS uses a single method to map hospital-specific CCRs to charges. That method does not reflect the effects that variation in hospital charge and cost allocation decisions can have on the DRG weights.

The national-average CCRs for the service groups are critical to the goal of better aligning payments with costs for DRGs. As CMS is considering refining its service group categories, we note that two of the groups, therapeutic services and operating room, contain cost center CCRs that range widely and raise concerns about its ability to better align payment with costs for services in those groups. This issue notwithstanding, we found that most of the proposed service groups, which represent a majority of the Medicare inpatient charges, are likely to capture the relevant cost-to-charge relationship for the services included in these groups.

Agency and External Reviewer Comments and Our Evaluation

We received written comments on a draft of this report from CMS (see app. II). We also received oral comments from representatives from two hospital associations, the AHA and the AAMC.

CMS Comments

In commenting on a draft of this report, CMS stated that it was pleased with our findings. CMS also stated that it could not comment further because it is currently considering public comments in developing the fiscal year 2007 final rule for the IPPS payment rates.

Hospital Association Comments and Our Evaluation

Representatives from both AHA and AAMC acknowledged the problems inherent in matching charges from claims to cost information on hospitals' cost reports due to the differences in the ways in which hospitals report these data. The AHA representatives specifically noted that the problems with cost estimation due to hospital reporting variation we describe in this report parallels what AHA has found in its own analysis. AHA representatives also agreed that the differences in which hospitals allocate their charges and costs, and the cost estimates that result, could potentially affect DRG relative weights.

AHA representatives stated, however, that we should more prominently discuss the issues of using cost report data to set the relative weights. Specifically, they stated that we should better emphasize that CMS's proposed national-average CCRs are based on cost report data that could still present problems as a result of hospital reporting variation.

As we stated in the draft report, the only data sources available to CMS to set the DRG weights are hospital Medicare cost report and claims. Medicare cost report data reflect hospital reporting variation because CMS allows hospitals the flexibility to report charges and costs in a manner that is consistent with each hospital's accounting system and organizational structure. Our conclusion that the proposed approach appears promising is based on our assessment that, given that cost report and claims are the only data available, CMS's approach in using these data to set DRG weights, that is, using national-average CCRs with standardized charge-based weights, can ameliorate the effects of differences in hospital reporting.

Representatives from both organizations also were concerned about the overall message of the report that the CMS approach appears promising. The AHA representatives stated that although the proposed approach could address some issues associated with using cost report data, they also noted that we did not test the validity of the proposed approach. The AAMC representatives also questioned our overall message given some of the concerns we noted in the report with the national service groups. In particular, AAMC stated that although we found that the service groups accounting for 63 percent of total inpatient charges appear promising, they believed that the remaining 37 percent was a substantial percentage.

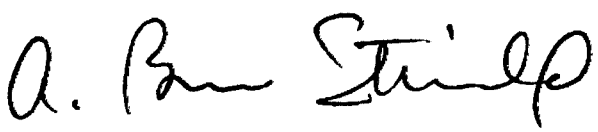
Testing the validity of CMS's proposed approach was beyond the scope of our work. However, we believe that the report presents a balanced view of the CMS approach, given our findings on hospital reporting variation and its effects on cost estimation. As noted in the draft report, we found that

6 of the 10 service groups that represent 63 percent of Medicare inpatient charges are promising because the cost center CCRs within each service group are relatively consistent. As a result, the proposed national-average CCRs for these 6 groups are likely to capture the relevant cost-to-charge relationships for the services within these groups. However, we also noted in the draft report that we have concerns about the ability of 2 of the service groups to better align payment with costs, and that we did not have enough information to evaluate the 2 remaining service groups.

Additionally, we received technical comments from the two associations, which we incorporated as appropriate.

We are sending a copy of this report to the Administrator of CMS. We will also provide copies to others on request. The report is available online at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions, please contact me at (202) 512-7101 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.



A. Bruce Steinwald
Director, Health Care

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Appendix I: Scope and Methodology

This appendix identifies data sources used for our analyses and summarizes our methods.

Data Sources

We used data from Medicare Provider Analysis and Review (MEDPAR)—the Centers for Medicare & Medicaid Services' (CMS) database for compiling and maintaining hospitals' Medicare claims—from 2001, 2002, and 2003. A MEDPAR record represents one distinct stay, and contains patient and hospital identifiers and diagnosis and procedure codes based on the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). CMS uses MEDPAR for rate-setting purposes under the inpatient hospital prospective payment system (IPPS).

We also used fiscal year 2002 and 2003 hospital Medicare cost report data that individual hospitals are required to submit annually to Medicare as compiled in CMS's Healthcare Cost Reporting Information System (HCRIS) database. HCRIS is constructed by CMS based on the Medicare cost reports submitted to the fiscal intermediaries. Each hospital defines its own fiscal year—the only requirement is that the beginning date of the hospital fiscal year must fall within the federal fiscal year (October 1 through September 30). There is a time lag of up to 2 years before the data are complete for all hospitals.

Hospitals report total costs and total charges by cost center on their Medicare cost reports. They have the discretion to use as many or as few cost centers on the cost report as they choose. Beyond the more general cost centers, hospitals have the ability to report more detailed information, referred to as subscripts, for specific services. For example, a hospital may report data for the cardiology cost center, and additional data for a subscript of cardiology, called cardiac catheterization. In the HCRIS database, the cost center data reflect the sum of the subscripted data. This level of detail is similar to the manner in which service-level data are available in the MEDPAR file.

To assess the reliability of the MEDPAR and HCRIS data, we reviewed existing documentation related to the data quality control procedures and electronically tested the data to identify obvious problems with accuracy. We determined that the data were sufficiently reliable for the purposes of this report. Further, because we chose to estimate costs using only those hospitals that most consistently reported charges and stays between their claims and their Medicare cost report, we could then assess the validity of our cost estimates relative to the aggregate Medicare costs these hospitals reported on their Medicare cost reports. Because our cost estimation

analysis was conducted on a subset of hospitals in fiscal year 2002, the results are not generalizable to the hospitals in fiscal year 2002 whose total charges and number of stays from their Medicare cost reports and claims did not match within .3 percent.

Methods

To examine the applicability of CMS's current cost-based method used to set weights in the outpatient prospective payment system (OPPS) to weight diagnosis-related groups (DRG) in the inpatient prospective payment system (IPPS), we first identified 3,660 short-term, acute hospitals that were paid under IPPS and submitted fiscal year 2002 data to CMS. A hospital's fiscal year 2002 could start anytime from October 1, 2001, through September 30, 2002. As a result, the cost reports contain charges and estimated costs for services provided to Medicare beneficiaries in 2001, 2002, and 2003. For this reason, we used MEDPAR and Medicare cost reports to match claims from 2001, 2002 and 2003 to each hospital's fiscal year 2002 Medicare cost report. Using approximately 12 million MEDPAR records and HCRIS data from 3,660 hospitals, we aggregated charges and stays from the MEDPAR claims file for each hospital in our universe. We compared the aggregate charges and stays from MEDPAR with the charges and number of stays reported on each hospital's Medicare cost report. We used fiscal year 2002 data because these were the most recent, complete Medicare cost report data available when we began our analysis in October 2004.

From this analysis, we identified 1,025 hospitals whose Medicare cost report charges and number of stays matched within .3 percent. We looked at the distribution of hospitals matching aggregate charges and stays ranging from .1 percent to 1 percent as reported in Medicare cost reports and claims. We chose .3 percent (1,025 hospitals), because it represented over a quarter of the total IPPS hospitals and included at least 25 hospitals for each hospital type (e.g., teaching, urban, for-profit). The 1,025 hospitals have a distribution across types of hospitals similar to the population of IPPS hospitals. We assumed these 1,025 hospitals had the most consistent cost information available to perform our cost analysis.

To estimate costs for inpatient services for each of the 1,025 hospitals, we applied the cost estimation method that CMS uses in the outpatient hospital setting; that is, we used individual cost center CCRs based on each hospital's Medicare cost report data to convert charges to costs. Similar to what CMS does for estimating costs for outpatient services, we developed a mapping method to match revenue centers to cost centers to determine which CCR to use to estimate costs for the 1,025 hospitals

included in our analysis. For example, we mapped the radiology revenue center charges to the radiology cost center. In cases where revenue centers and cost centers did not directly correspond, we used the hospital's overall ancillary CCR to estimate costs, with the following exceptions. If a hospital billed for speech, occupational or physical therapy charges, but did not include a matching cost center on its cost report for those services, we used another therapy cost center CCR to estimate costs. For example, if a hospital billed for physical therapy but did not have a matching cost center, we used the speech therapy cost center CCR. In addition, if a hospital's cost report did not include a DME cost center but the claims showed DME revenue center charges, we applied the hospital's overall supply CCR to estimate costs.

We multiplied the cost center CCR from the hospital Medicare cost report to each charge for each claim. Subsequently, for each of the 1,025 hospitals we summed our cost estimates for accommodation and ancillary services separately and then compared these aggregate cost estimates to what hospitals reported as their costs for these services on their Medicare cost reports. From this analysis, we calculated the percentage of hospitals where our estimates were, on average, either more or less than what the hospitals reported for ancillary and accommodation services separately. After comparing our cost estimates to what the hospitals reported on their Medicare cost report, we examined hospital reporting methods, that is, we identified the cost centers to which hospitals reported their charges and compared these charges to how hospitals reported these services on their claims. For example, while a hospital may record $1,500 in physical therapy charges on its claims, it may record these physical therapy charges in the occupational therapy cost center on its cost report. This practice is in keeping with the discretion CMS affords hospitals in how they accumulate and report charges and costs.

To examine whether CMS's proposed approach for the IPPS is an improvement over its OPPS method for setting cost-based weights, we estimated costs for fiscal year 2002 using the OPPS method, and reviewed CMS's April 2006 notice of proposed rulemaking.[1] In particular, we identified potential problems in applying the OPPS cost-based method to the IPPS and determined whether CMS's proposed approach would ameliorate those problems. We evaluated CMS's proposal to use national-

[1]We did not examine the extent to which the OPPS method measures relative costliness for outpatient services.

average CCRs to derive cost-based weights. We used data from 3,558 hospitals paid under the IPPS that submitted a fiscal year 2003 Medicare cost report. We used fiscal year 2003 Medicare cost reports in order to conform to the same time period as the analysis CMS conducted for its April 2006 notice of proposed rulemaking. We calculated CCRs for each of the cost centers that are included in CMS's 10 proposed service groups.[2] We determined whether the service groups appear promising based on the extent to which cost center CCRs contained within each group varied. Additionally, using 2003 claims data, we analyzed the proportion of service group charges to determine whether the service groups appear promising in capturing cost-to-charge relationships for the respective services in each group.

[2]The 10 proposed service groups are routine, intensive, drugs, supplies & equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services.

Appendix II: Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs

200 Independence Avenue SW
Washington, DC 20201

DATE: JUL 18 2006

TO: A. Bruce Steinwald
Director, Health Care
U.S. Government Accountability Office

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Government Accountability Office's (GAO) Draft Report: "MEDICARE: CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising" (GAO-06-880)

Thank you for the opportunity to review and comment on the GAO's draft report entitled "MEDICARE: CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising." We appreciate GAO's efforts to analyze potential improvements to the relative weighting methodology used for the Hospital Inpatient Prospective Payment System (IPPS). As GAO stated in the report, "policy analysts have for decades suggested that replacing charge-based with cost-based weights would improve the accuracy of the weights to measure relative costliness for hospital inpatient DRGs." The Centers for Medicare & Medicaid Services (CMS) is pleased that GAO's findings suggest our approach of using the national average cost-to-charge ratios to develop cost-based weight for inpatient diagnosis-related groups (DRGs) appears promising because it addresses the concerns associated with charges that are currently used to weight DRGs. As stated by the GAO, use of national-average cost-to-charge ratios ameliorates the effects that variations in hospital charge and cost allocation decisions can have on DRG weights.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, required GAO to study IPPS payments in relation to costs. During the course of GAO's work, CMS proposed a hospital-specific cost weighting methodology for determining the DRG weights. GAO examined the applicability of CMS' method for developing cost weights under the Outpatient Prospective Payment System (OPPS) to the hospital-specific cost weights proposed for the IPPS.

The fiscal year (FY) 2007 IPPS proposed rule was made available on April 12, 2006. The comment period on the proposed rule ended on June 12, 2006, and CMS is carefully evaluating the public comments we received. At this time, we are not commenting further on the GAO's analysis because we are considering these issues for the FY 2007 IPPS final rule that we expect to make available on August 1, 2006.

Once again, thank you for your analysis of this issue and the opportunity to review your report.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

A. Bruce Steinwald, (202) 512-7101 or steinwalda@gao.gov

Acknowledgments

In addition to the contact above, Maria Martino, Assistant Director, Shamonda Braithwaite, Melanie Anne Egorin, Hannah Fein, Nora Hoban, Julian Klazkin, Daniel Lee, and Eric Wedum made key contributions to this report.

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Specialists in Gastroenterology

Leonard Weinstock, MD
Erik Thyssen, MD
Janet Todorczuk, MD
Steve Fern, DO

September 21, 2006

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
Mailstop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Reduction in Endoscopic Reimbursement

To Whom It May Concern:

In reviewing the government's proposal to finally implement the proposed reimbursement rate changes that the 1998 Balance Budget Act enacted I am quite disturbed and perplexed. The proposed rate of reimbursement for GI procedures (62% of hospital reimbursement rates) is completely unacceptable. How can any ambulatory center make enough money to pay its overhead and provide excellent quality of care at that rate? This is completely unfair. While I understand that hospitals are not as efficient as ambulatory centers there is still a certain amount of overhead that must be paid for. Why would the government reward hospitals with larger reimbursements for the same exact procedure when they are traditionally very inefficient? Isn't that the hospitals' issue? Why are the citizens of this country, whether through the government or through their own pocket book, being forced to pay for the hospitals' inefficiency?

Insurance companies are currently offering gastroenterologists a larger professional fee if the procedures are conducted in the ambulatory care setting rather than the more expensive hospital setting, but this action on the part of the federal government will have the exact opposite effect. This reimbursement will force ambulatory care centers out of business and drive ambulatory GI procedures back to a hospital setting thus creating more expense to the government rather than less. Driving these procedures back to a hospital setting will also increase the inefficiency of the hospital and thus drive the cost of care back up.

The domino effect will continue as traditionally private insurance companies will demand lower reimbursement rates following the government's lead for their patients as well. Historically the federal government has seen the benefits of ambulatory care for the citizens of this great country and has promoted it. I don't understand this change of heart on the part of the government. This is prohibiting the growth of ambulatory care rather

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than promoting it to the citizens as a very cost effective method of providing quality health care.

On a last note, there is the elderly to consider. Medicare requires that its patients pay a 20% co-pay for all care. If you drive these procedures back to a hospital setting the cost will be greater not only to the government but also to the elderly of this country as their co-pay will be higher. Forcing the healthcare industry to be more efficient is great for the citizens of this country, but forcing the ambulatory care industry out of business isn't.

Hospitals across this country are continually trying to hoodwink the government that they are losing money, but if you look closely at their balance sheets even the religious not-for-profit hospitals are doing financially well. The only hospitals having financial issues are either not run efficiently or have a large indigent population that they serve. Possibly the government would be wiser to pursue better laws about providing indigent care to the citizens of this country and not try to "take care of the world" by providing free care to illegal aliens.

Sincerely,

Leonard Weinstock, MD

Erik Thyssen, MD

Janet Todorczuk, MD

Steven Fern, DO