



106

Office of the CEO, President & Chairman of the Board
201 Technology Dr. • Irvine • California • 92618
Main Line: (949) 450-5400
Facsimile: (949) 450-5319
Website: www.endocare.com

VIA FEDERAL EXPRESS

November 2, 2006

Leslie V. Norwalk, Acting 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; Ambulatory Surgical Center Payment System and
CY 2008 Payment Rates

Dear Ms. Norwalk:

On behalf of Endocare, Inc., I am writing in response to the proposed rule governing the Medicare Ambulatory Surgical Center (ASC) Payment System and the ASC Payment Rates for CY 2008. This proposed rule was 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 has been on prostate cancer with the objective to dramatically improve men's health and quality of life. Endocare manufactures a total system required to perform cryosurgery and manufactures the *CryoProbes* (identified by HCPCS code C2618) used in the cryosurgery of the prostate procedure, the only procedure included in APC 674.

Proposed CY 2008 ASC Payment Rate for Cryosurgery of the Prostate

Our specific comments indicate that the proposed payment rate for prostate cryosurgery in the ASC setting is not adequate to cover the costs of the procedure. This is because the payment rates for procedures performed in ASCs are computed based on a discount of the rate set for hospital outpatient procedures—which, for reasons we will explain, are set too low for prostate cryosurgery procedures.

We think that this underpayment will restrict beneficiary access to this procedure in the ASC setting and create incentives for providers to choose better-paying, more-expensive cancer treatment options. In the case of prostate cryosurgery, we have previously submitted external data exhibiting the inadequacy of the hospital outpatient rate; CMS should use an alternative method to price this procedure when performed in ASCs.



Centers for Medicare & Medicaid Services

November 2, 2006

Page 2 of 4

1. The proposed 2008 payment rate for cryosurgery of the prostate procedures in an ASC setting is not sufficient to cover the cost of the procedure.

As we have documented in our previous submissions to CMS concerning hospital outpatient payment rates, an analysis of the costs hospitals incur to acquire the medical technologies used to provide the cryoablation procedure indicates that hospitals pay, on average, more than \$4,000 per case for CryoProbes and other cryoablation supplies. This data, copies of invoices and cancelled checks written by hospitals to Endocare, also indicates that, on average, the cost to a hospital to provide a cryoablation procedure is more than \$9,000; an amount much larger than the dollar figure (\$6,628) assigned, as a result of the payment methodology used by CMS to set hospital outpatient rates.

This underpayment is made much worse when the methodology specified in the proposed rule is used to price the prostate cryoablation procedure for the ASC setting. The proposed methodology results in a payment rate of only \$4,279.56, a rate that is not sufficient to cover the acquisition cost of the CryoProbes, temperature probes, and the urethral warmer used in prostate cryosurgery. The ASC still must incur costs associated with supplying argon and helium gases (approximately \$300-\$500), OR staff, recovery staff, pharmaceuticals, sterile supply items and/OR time.

2. The methodology CMS uses to establish the proposed 2008 ASC payment rate for cryosurgery of the prostate procedures is not appropriate for this procedure, and, if used, it will result in reduced beneficiary access to a minimally invasive treatment in a less intensive setting.

Physicians and ASC owners will not offer this minimally invasive treatment to Medicare patients if the payment rate does not approach covering the cost of supplies for the procedure. The proposed ASC payment rate for prostate cryosurgery procedures is not appropriate because this rate is predicated on a methodology that discounts the Medicare hospital outpatient payment rate, which itself does not cover hospital costs. There is no doubt that this inadequate rate will result in an access barrier to Medicare patients who desire to have a minimally invasive, clinically-effective procedure in the least intensive setting.

There are two reasons why the Medicare hospital outpatient payment rate is set too low for prostate cryosurgery procedures:

Centers for Medicare & Medicaid Services

November 2, 2006

Page 3 of 4

- *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.
 - *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, the APC where prostate cryosurgery is assigned.
3. *There will be cost and treatment consequences to the Medicare program if an adjustment is not made to the 2008 payment rate proposed for cryosurgery of the prostate procedures performed in ASC settings.*

If an appropriate reimbursement rate is not established for prostate cryoablation procedures performed in the least-intensive ASC setting, physicians will be forced to consider other treatments that are more costly to the Medicare program, either because the setting will be more intensive (e.g., inpatient or outpatient hospital for radical prostatectomy) or the treatment will be more costly (e.g., external beam radiation).

Though prostate cryosurgery is clinically equal (or even superior in certain cases) to other treatment alternatives, the cost to the Medicare program to treat prostate cancer patients with cryosurgery is much less than most other prostate cancer treatment alternatives. These alternative treatments for prostate cancer are up to three times more costly to the Medicare program (see Enclosure).

4. *CMS should make use of an alternative payment method for prostate cryosurgery procedures performed in the ASC setting, due to the documented inadequacies of the APC payment rate. CMS should permit direct billing of the acquisition costs of the technology used in this procedure (CryoProbes, temperature probes and urethral warmer) and establish a separate payment rate for the non-technology ASC facility costs that are incurred. If direct billing is not possible, CMS should hold harmless the device portion of the hospital outpatient APC rate for the procedure when calculating the rate for the ASC setting.*



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Centers for Medicare & Medicaid Services

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Page 4 of 4

We think that CMS should avoid using established hospital outpatient payment rates as a basis for setting ASC rates in situations where external data is available that places in doubt the accuracy of these rates. The newness of the prostate cryosurgery procedure, the irregularities associated with hospitals reporting the costs associated with this procedure, the difficulty in accounting for the number (and cost) of the CryoProbes used with this procedure lead us to recommend an alternative payment approach for prostate cryosurgery procedures performed in the ASC setting.

In closing, we sincerely request that CMS depart from the methodology it has proposed to price prostate cryosurgery procedures performed in ASCs. Instead of discounting a too low APC payment rate, CMS should allow for the direct billing by ASCs for the CryoProbes, temperature probes and urethral warmer supplies that are used, and establish a separate ASC payment rate for the non-technology ASC facility costs that are incurred. If CMS chooses not to take this approach, it should, at the very least, hold harmless the device portion of the hospital outpatient APC rate in calculating a final ASC payment rate for 2008.

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.

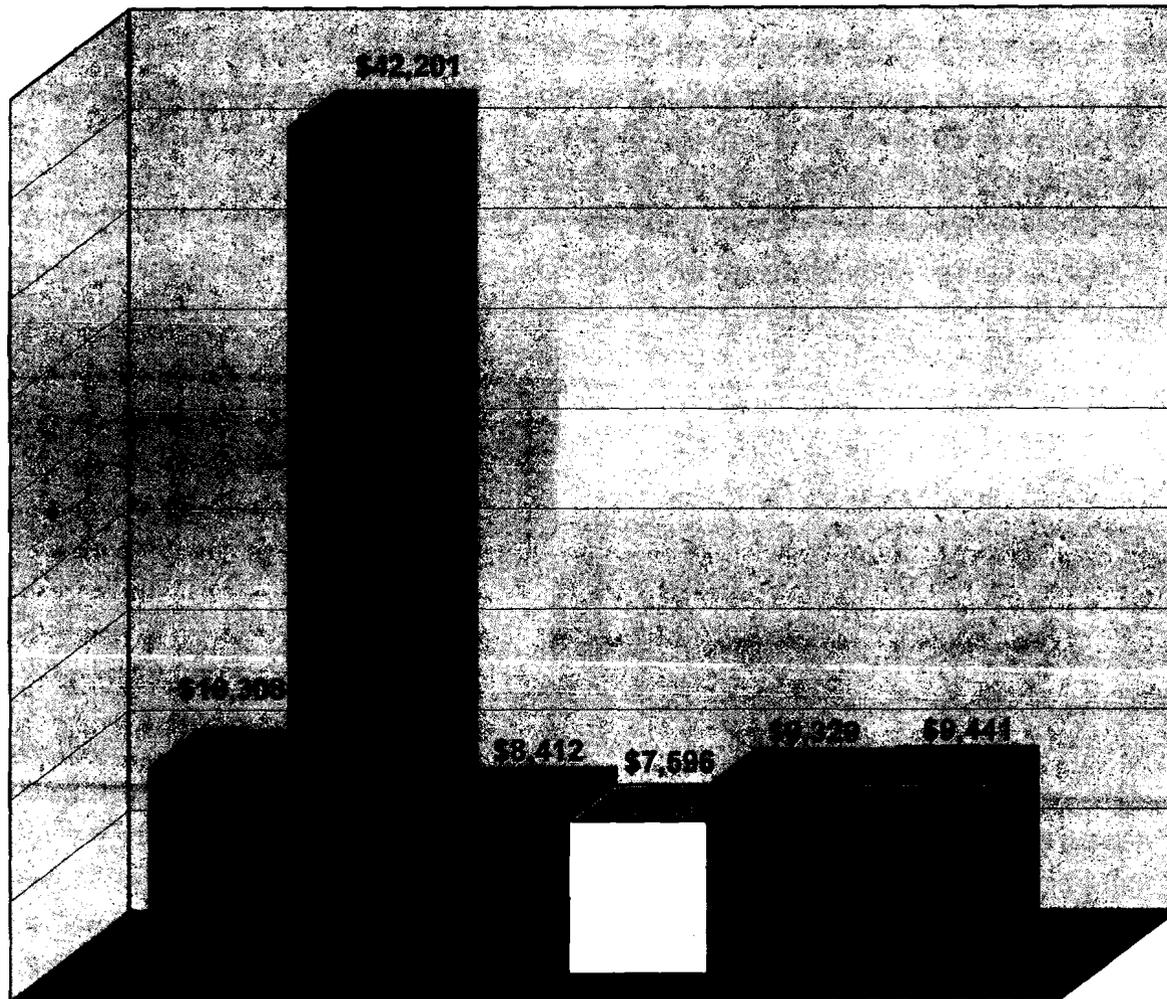
Sincerely,

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

Enclosures

CTD:res

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



- 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 Lupron (\$224.42)+ injection fee 90772 (\$18.57) = \$193.61 or \$242.99 = avg of \$218.30 x 3 months= \$654.90	APC 163 + radiation br. APC codes w/Palladium Seeds (C-1720) @ cost (assume \$4000)						
Brachytherapy w IMRT (Intensity Modulated Radiation Therapy)		\$2,478.99	\$654.90	\$7,811.71	\$10,945.60	\$1,984.70	\$12,910.30	\$29,290.83	\$42,201.13	0.75
Radiologist + Urologist	CPT 55879, 76000-26, 76965-26, 7718-26, 77290-26 (could select 77290-->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 Lupron (\$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		\$1,128.69	\$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 Lupron (\$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	2.70
Urologist	CPT 55840 prostatectomy, retropubic radical		Assume 3 months of TX = J9202 Zoladex (\$175.04) or J9217 Lupron (\$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	\$7,402.67	\$9,329.31	n/a		n/a	\$9,329.31	4.30
Urologist	CPT 55840 prostatectomy, retropubic radical		Assume 3 months of TX = J9202 Zoladex (\$175.04) or J9217 Lupron (\$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	2.00
Urologist	CPT 55866 laparoscopy surgical prostatectomy, retropubic radical, including nerve sparing		Assume 3 months of TX = J9202 Zoladex (\$175.04) or J9217 Lupron (\$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.

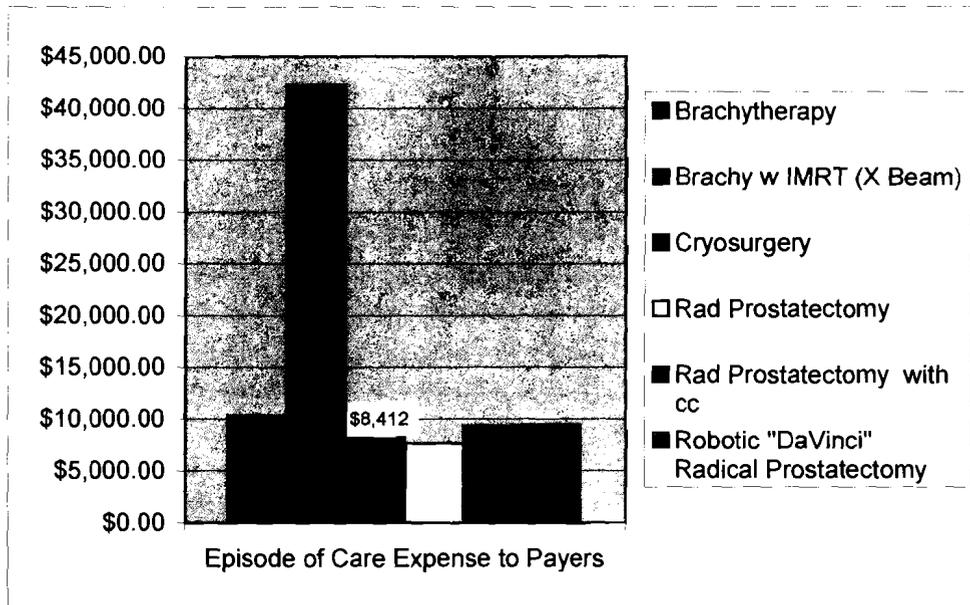
Note (2): Cost and Reimbursement for IMRT or X Beam based on sample coding provided by high volume facility in Southern California (5 x/wk x 6 wks). See details below.

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	Fluoroscopic 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
					\$7,493	\$7,812
						Palladium Seeds
						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

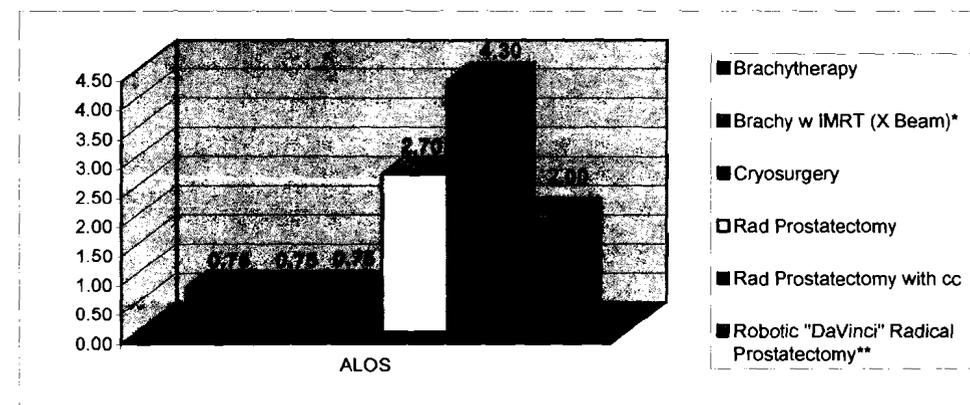
Prostate Cancer Treatment	Episode of Care Expense to Payers
Brachytherapy	\$10,307.96
Brachy w IMRT (X Beam)	\$42,201.13
Cryosurgery	\$8,411.51
Rad Prostatectomy	\$7,596.13
Rad Prostatectomy with cc	\$9,329.31
Robotic "DaVinci" Radical Prostatectomy	\$9,441.47



Prostate Cancer Treatment	ALOS
Brachytherapy	0.75
Brachy w IMRT (X Beam)*	0.75
Cryosurgery	0.75
Rad Prostatectomy	2.70
Rad Prostatectomy with cc	4.30
Robotic "DaVinci" Radical Prostatectomy**	2.00

*.75 OP Day for Brachytherapy followed by 5-6 weeks of radiation 5x/wk

** Specific ALOS not available; projected ALOS = 2.



107

October 31, 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: Ambulatory Surgical Center Payment System and CY 2008 Payment Rates [CMS-1506-P]

Dear Sir or Madam:

We are writing this letter in response to recent guidance documents regarding ASC reimbursement for CAT III CPT Codes. These comments are submitted by iScience Interventional, Inc., (iScience), a developer of novel diagnostic and minimally invasive devices intended for the treatment of ocular diseases. These include high-resolution imaging systems, and microcatheters designed for the interventional treatment of glaucoma and precise placement of drugs for the treatment of age-related macular degeneration.

We appreciate this 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, 2008.¹

We support CMS's proposed definition of the term "Surgical Procedure."² In particular, we are encouraged by CMS's proposal "to include within the scope of surgical procedures payable in an ASC certain services that are described by HCPCS alphanumeric codes (Level II HCPCS codes) or by CPT Category III codes which directly crosswalk to or are clinically similar to procedures in the CPT surgical range."³

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, 49,636, August 23, 2006).

² Id. at 49636.

³ Id.

In an earlier comment letter to CMS on the 2007 update to the ASC list, we urged 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. 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.

For the reasons discussed in our prior comment letter, these codes should be added to the ASC list for 2007. But independent of that request, 0176T and 0177T should be on the ASC list for 2008 because these codes satisfy the definition of a surgical procedure as described in the proposed rule. CPT 0176T and 0177T describe a new treatment for glaucoma called canaloplasty, which is similar to other ophthalmic outpatient procedures described in the CPT surgical range. In particular, canaloplasty is similar in several respects to trabeculectomy (CPT 66170), another procedure for glaucoma. A table comparing the individual steps of canaloplasty to trabeculectomy was included with the New Technology APC application submitted for canaloplasty.

For additional reasons it is important that these codes are on the ASC list, because relative to most other specialties, ophthalmologists do a high percentage of their cases in ASCs. In fact, most of the canaloplasty procedures performed thus far have been in ASCs. Patients are accustomed to the combination of a secure operating environment and the convenience that an ASC provides for eye surgery. Therefore, CPT codes 0176T and 0177T should be on the ASC list for 2008.

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 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 look forward to working with you on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "M. F. Nash", with a long horizontal flourish extending to the right.

Michael F. Nash
President/CEO
iScience Interventional, Inc.

HealthPark Surgery Center

108

1283 Jacaranda Boulevard • Venice, Florida 34292-4522
Phone: 941/497-5660 • Fax: 941/492-3942

November 1, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Norwalk:

I am the Administrator of Healthpark Surgery Center, a multi-specialty facility located in Venice, Florida. Our facility is one of three ASC's in the South County of Sarasota but the only one offering all twelve specialties, including G.I.

We are in our 12th year of operations and provided services to over 80,345 people, performing over 109,000 procedures.

Due to our physical location, basically in a community of retirees, we have always had a high Medicare patient volume ranging about 55-60 percent. These demographics have changed to 65-70 percent. This increase is indicative of the heavy influx of retiree's into our community, which shows no signs of slowing down. We are much more dependent upon and at the mercy of a reimbursement source in which we cannot control more so than most centers. Currently, we are in the midst of a "Medicare freeze" and struggling to cope with the rising costs of goods and services in order to maintain our quality of care and safety standards. Any changes in Medicare really impacts our business.

With great expectations we looked forward to the proposed reform to change the procedures list and reimbursement. We applaud and commend CMS for undertaking such a huge task but hoped the inclusionary ASC list would be abandoned, as it limits the access to our services as we view it in two ways. The physician's ability to select the site of service they feel is most clinically appropriate for their patients is limited as well as the Medicare patients are denied access to procedures many other patients currently receive in this setting. We strongly agree that MedPAC's recommendation of adaptation of the Outpatient Prospective Payment System. ASC's have certainly proven their ability of safely and cost efficiency performing the same scope of services provided in the hospital setting.



Accredited by

Accreditation Association for Ambulatory Health Care, Inc.

www.healthparksurgery.co

HealthPark Surgery Center

1283 Jacaranda Boulevard • Venice, Florida 34292-4522

Phone: 941/497-5660 • Fax: 941/492-3942

The criteria used to revise the Medicare list of procedures which may be formed ASC's are outdated and really don't serve the interest of the Medicare program nor its beneficiaries. Technological advances in medical systems and techniques as well as new generation drugs have decreased the system insults of general anesthesia. Nerve blocks and MAC's have curbed the long recovery periods of general anesthesia. Clinical pathways are also established to perform those procedures long thought to be only inpatient cases. Appropriate continuum of care is provided through nerve blocks, and pain pumps followed by home health nursing care.

There are several procedures that are appropriate additions to the ASC list and are strongly recommended for inclusion:

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)



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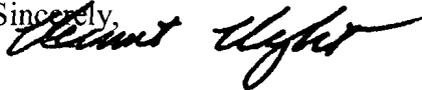
HealthPark Surgery Center

1283 Jacaranda Boulevard • Venice, Florida 34292-4522

Phone: 941/497-5660 • Fax: 941/492-3942

Thank you for allowing me to share in this very important process with its huge national impact. There is a niche for Ambulatory Surgery Centers in the Healthcare Delivery System their benefits are many and realized and greatly appreciated by our Medicare beneficiaries: ease of access from adjacent parking lots into our front door, convenient one-stop services, pre-procedure education and outcomes, needs assessment pre operatively, a safe environment and one on one nursing care, follow-up calls on everyone and quality performance indicators. Should you desire any further information please contact me at the following kermit@healthparksurgery.com or 941.492.3958.

Sincerely,



Kermit Knight, CASC
Administrator



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Accreditation Association for Ambulatory Health Care, Inc.

www.healthparksurgery.com

169

October 24, 2006

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
Hubert H. Humphrey Bldg.
Room 445-G
200 Independence Ave., SW
Washington, DC 20201



1096 Coathals Drive
Richland, WA 99352
Phone: (509) 943-7700

RE: Comments on Proposed Policies Affecting Ambulatory Surgery Centers (ASCs) for CY 2007

Dear Administrator McClellan:

The Tri-City Regional Surgery Center, located in Richland, Washington, is submitting comments on the proposed rule affecting ASC payment in 2007. We will submit separate comments on rules affecting ASC payment in 2008.

We applaud CMS for its decision to adjust the payment groups for CPT codes 19298 (from Group 1 to Group 9), 36475 – 36479 (from Group 3 to Group 9), 46947 (from Group 3 to Group 7), and 58565 (from Group 4 to Group 9).

We note the omission of CPT codes 19290 and 19291 from Addendum AA of the proposed rule as ASC list procedures for 2007. We believe that these procedures should remain as ASC list procedures for 2007.

We thank you for adding 14 procedures to the Medicare ASC list for 2007. This not only helps ASCs, but also helps Medicare beneficiaries by expanding their access to high quality and cost effective surgical services routinely performed in an ASC setting.

That said, we would like to see many more procedures that are safely and routinely performed in ASCs on non-Medicare beneficiaries added to the ASC list for 2007. We note that the revised ASC payment system proposed for 2008 will significantly expand the number of procedures which can be performed in an ASC.

Given that a Federated Ambulatory Surgery Association (FASA) study recently showed that Medicare reimbursement to ASCs in 2005 was \$320 per procedure less, on average, than what Medicare paid to hospital outpatient departments for performing the same procedures, why should Medicare wait until 2008 to save such significant dollars? At very least, Medicare, in our opinion, should greatly expand the ASC list from the current 14 new codes by accelerating into 2007 many of the changes which are now slated for 2008.

Because of the case mix of procedures we do in our Surgery Center, the addition of certain procedures are more compelling to us than others, and would benefit local Medicare beneficiaries by giving them access to high-quality and cost-effective Surgery Center care. We therefore respectfully request that the following procedures be added to the ASC list for 2007:

CPT Code: Justification for Inclusion in 2007:

29866-29868 Clinically similar to 29800-29888 series of CPT codes, which are on ASC list. Typically require 45 minutes OR time and 1 hr recovery time. Major blood vessels are not affected, and most patients don't suffer significant blood loss.

43257 Clinically similar to other upper endoscopy procedures, and thus, this procedure meets the criteria for being on the ASC list. Proposed for ASC coverage in 2008—why delay it until then?

47562-47564 Technological advances in anesthesia and laparoscopes make this a safe and appropriate procedure for performance in an ASC. Currently proposed for ASC coverage in 2008—why delay potential Medicare savings until then?

G2089 We believe ASCs should be eligible for usage of this code as HOPDs are. This is an add-on procedure during knee arthroscopy.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink that reads "Francis Langston". The signature is written in a cursive style with a large, stylized "F" and "L".

Francis Langston
Executive Director
Tri-City Regional Surgery Center



October 30, 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: 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, SCHIP, and Mortality

Dear Sir or Madam:

These comments are submitted by Advanced Medical Optics (AMO), a global leader in the development, manufacturing, and marketing of medical devices for the eye. Among the products marketed by AMO is the Tecnis[®] foldable posterior chamber intraocular lens (IOL).

State of the art cataract surgery is instrumental in improving the productivity and quality of life of America's senior citizens. As the longevity of Americans continues to increase, cataract surgery becomes even more important in preserving high quality vision for all Americans. In fact, many Medicare beneficiaries first encounter the Medicare system in the course of having cataract surgery. It pleases us to know that the technological advances in cataract surgery instrumentation and IOLs have helped to make this encounter safer, more efficient, less painful, and continually better with respect to visual outcomes.

We appreciate this opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) on August 23, 2006, which proposes, among other changes, a new ASC payment system for 2008.¹ We support CMS's proposal to base ASC relative payment weights on APC groups and relative payment weights established under the OPSS. This is an important step toward site of service parity that will allow the doctor and patient to choose the best site of service for the patient's particular condition. We also think that

¹ See Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates, 71 Fed. Reg. 49506 (proposed August 23, 2006) (the Proposed Rule).

annual updates to the ASC payment system coincident with the annual update to the OPPS will streamline the update process and promote greater alignment and coordination between the OPPS and the ASC system. Our specific comments on the proposed ASC payment system follow.

I. **Budget Neutrality [ASC Conversion Factor]**

In its budget neutrality calculations, CMS has proposed to calculate the “aggregate amount for such services”² as the estimated payments for 2008 under the current ASC payment system based on only the estimated CY 2008 ASC volume for each CPT code on the current ASC list. We consider this approach to reflect an excessively narrow interpretation of the statutory language. It is likely that Congress intended “such services” to include not only services on the current ASC list, but also cases currently done in the HOPD but that will most likely move to the ASC because of the significant increases in ASC payment anticipated under the proposed new ASC payment system.

Furthermore, we challenge the assumption “that the net impact of migration of services currently on the ASC list is negligible.”³ For many procedures currently on the ASC list, the payment rates under the proposed ASC system will increase very dramatically from their existing payment group assignment. For example, orthopedic procedures described by codes 23615, 23660, 25515, 28406, 28705, 29805, 29805, 29806, 29850, 23450, 23530 will increase dramatically, in the range of 2 to 3 times the current ASC payments. Overall, the procedures currently on the ASC list that will experience a significant increase in payment outweigh the procedures that will experience a significant decrease, thereby effecting a significant net migration of cases from the HOPD to the ASC beginning in 2008. This effect should be accounted for in the budget neutrality calculations by including the estimated amount for these cases that are likely to migrate from the HOPD to the ASC in the “aggregate amount for such services” referenced above in the first paragraph of this section.

The budget neutrality and conversion factor calculation should take account of the payments for these services in the HOPD that are likely to contribute to this net migration from the HOPD to the ASC. CMS has already estimated the likely migration of services that will be new to the ASC list in 2008. To these estimates CMS should add a reasonable estimate of the percentage of cases for services currently on the ASC list that will likely migrate from the HOPD to the ASC in 2008. Therefore, the services that would be accounted for in the proposed conversion factor calculation⁴ should include not only projected ASC services but also HOPD and physician offices services (both existing ASC services and new services for 2008) that are likely to migrate in order to accurately reflect the overall “aggregate amount for such services” for budget neutrality purposes.

² See SSA § 1833(i)(2).

³ See 71 Fed. Reg. 49506, 49657.

⁴ See *Id.* At 49656.

We anticipate that our suggested approach would have the effect of increasing the ASC conversion factor from the proposed level of 62%. Others have suggested a conversion factor higher than 62%, including Senator Crapo, who proposed S. 1884 which included a suggested conversion factor of 75%. A similar bill was also introduced in the House of Representatives by Representative Herger, also calling for a 75% conversion factor. Both considered 75% to be fair and reasonable for the purposes of positive ASC reform. CMS should seriously consider whether a 62% conversion factor is sufficient to fully realize the potential of this monumental payment system reform.

We believe that our suggestions are consistent with the statutory language and Congressional intent. We also consider such an approach to be the most accurate and fair method of determining the "aggregate amount" mentioned in the statute so that the ASC conversion factor is not unduly burdened by the migration of services from the OPD to the ASC.

II. Annual Cost of Living Update

Beginning in calendar year 2010, CMS proposes to update the ASC conversion factor by the percentage increase in the CPI-U. While the recognition of the need for updates to guard against inflation demonstrates foresight on the part of the agency, CMS mentions an alternative update mechanism that may better serve the overall goals of the revised ASC payment system.

As CMS identifies, the hospital inpatient market basket percentage increase is used to update the OPPS conversion factor. As you know, this market basket percentage increase is the percentage increase that the cost of the mix of goods and services (based on the hospital inpatient operating costs) for the period at issue will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period. We believe that the market basket percentage increase better reflects the types goods and services that are usually consumed in an ASC as compared to the CPI-U, which is a more general index that may not as accurately reflect the inflation rate for health-related goods and services, which are frequently subject to higher inflation than most other consumer goods.

Furthermore, it would be consistent with CMS's goal of aligning the OPPS and the ASC payment system if the same factor (the market basket percentage increase) is used to update and inflation-adjust both payment systems according to the same factor. CMS should explore whether it has the flexibility to pursue this suggestion given the current statutory language and if not considering proposing to Congress that the statute be updated to allow for an annual ASC update according to the market basket index.

III. Need to accommodate new technology in the ASC

CMS has made many efforts to recognize new technology and accommodate the additional costs associated with the introduction of new technology into various sites of service, including hospital inpatient, hospital outpatient, and ASCs. The NTIOL program has been instrumental in providing access for Medicare beneficiaries to the most advanced new IOLs for cataract surgery, but it has been the only payment policy to explicitly recognize new technology in the ASC.

The new technology APC program and the outpatient pass-through program have fostered the development of new technology in the hospital outpatient department. While the NTIOL program will continue under the proposed new ASC payment system and new technology APCs will apply through the assignment of relative weights to new procedures, CMS should also allow for device pass through payments in the ASC through use of the appropriate C-code and relative weights for the APCs to which the C-codes map.

CMS states in the preamble of the proposed rule that “we are proposing to include within the scope of surgical procedures payable in an ASC certain services that are described by HCPCS alphanumeric codes (Level II HCPCS).” This could include C-codes that are used for pass-through devices. Allowing the pass-through C-codes to be billed when they are used in the ASC would allow for simultaneous adoption in the HOPD and the ASC for technologies that would otherwise be effectively confined to the HOPD until the cost of the pass-through device was incorporated into the APC for the procedure in which it is used.

With the allowance for pass-through devices in the ASC payment system, it should be well equipped to accommodate new technology so that Medicare beneficiaries will not have to choose a particular site of service because of the unavailability of new technology in other competing sites.

IV. “Hold harmless” concept for certain medical devices and medical specialty “carve-outs” are unfair and contrary to the goals of the revised ASC payment system

It is our understanding that certain special interests will suggest in their comments two proposals that would create special exceptions to the proposed ASC methodology, i.e., 1) that payments for certain relatively expensive medical devices be “held harmless” such that payments for these devices are carved out of the overall APC payment and not adjusted when a procedure is done in an ASC such that the payment in the OPSS and the ASC would be the same for such devices, and 2) certain medical specialties will request that they be granted some form of exception from the index, presumably to blunt or limit the effect of the new payment system of certain procedures that these specialties perform in high volume.

We believe that these proposed exceptions would amount to unfair giveaways to these interested parties and would also be inconsistent with the principles underlying the proposed new ASC payment system. The medical device “hold harmless” proposal is based on the false assumption that certain high cost implantable medical devices are fundamentally different than all of the other resources used in outpatient surgery. The OPSS already contains mechanisms to ensure that the costs of devices are properly accounted for with in device dependent APCs.

As you know, one of the basic tenets behind the ASC concept is that it is a less resource intensive site of service than hospital OPDs, i.e., that ASCs are more efficient than hospitals for many types of surgery. If certain cases involving expensive implantable medical devices require all of the resources in the OPD and therefore cannot be performed more efficiently or with less resources than in the OPD, then such procedures are probably best left for the hospital OPD. Otherwise, manufacturers of these devices need to compete like others and adjust to the ASC model of greater efficiency.

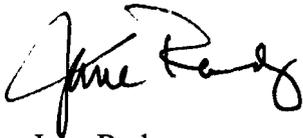
Regarding any suggested exceptions to the proposed ASC rates for certain medical subspecialties, their comment letters may include dire predictions of Medicare beneficiaries waiting too long for certain procedures or being denied access to certain procedures in the ASC. CMS does not need us to point out that such predictions are commonly exaggerated and that perhaps the difference between the current and the proposed ASC payments for specialties seeking an exception to the new system is more reflective of past overpayment than future underpayment.

CMS has repeatedly stated in various forums that “carve outs” of generally applicable payments policies to serve special interests are counter to both fairness and the administrative process. We hope that CMS will stand by this principle and apply the new ASC system, including the conversion index, fairly and consistently across the board.

V. Conclusion

We appreciate the monumental task of developing the new ASC payment system, and we commend CMS for taking the initiative and proposing the new system according to the timeline imposed by Congress. We are eager to work with the agency to ensure that Medicare beneficiaries obtain the best care in the site of service that the doctor and the patient think is best for the patient’s needs. We look forward to a continuing dialog with you on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Jane Rady". The signature is fluid and cursive, with a large initial "J" and "R".

Jane Rady
Corporate Vice President, Strategy and Corporate Development
Advanced Medical Optics

October 3, 2006

Mark McClellan, MD
CMS – Dept HHS
Attention: CMS-1506 and CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dr. Dr. McClellan:

I have recently been made aware of the CMS proposal to reduce the Medicare fee schedule and change the payment structure for facility fees at ambulatory surgery centers. The freestanding centers are an example of what is RIGHT with the medical system and I am concerned that changing the ambulatory surgery rules will seriously jeopardize their existence.

I strongly encourage you to reject the CMS proposed changes to the ambulatory surgery rules in support of the freestanding centers. As a patient, I feel much more relaxed and “safe” in that environment. As a taxpayer, I would like to see support for a system that is successfully working – the freestanding centers.

Thank you for your time and attention to this matter.

Sincerely,



Mary Christiana
3338 S. Parkside Dr.
New Castle, Pa. 16105

margehris2@verizon.net

Centers for Medicare and Medicaid Services
Department of Health and Human Resources
Attention: CMS-4125-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Madam or Sirs,

Your agency is currently reviewing the reimbursement methodology for Ambulatory Surgery Centers (ASCs). This is a great opportunity for you to save the CMS system millions of dollars while continuing to provide Medicare beneficiaries with high quality surgical services. The ASC system has had its reimburse frozen for the past 6 years, during which the reimbursement gap between hospital-based outpatient surgery centers and free-standing ASCs has widened, threatening to deteriorate this excellent source of surgical services for many Medicare beneficiaries.

I realize that you need to operate within the requirement of budget neutrality. To this end, I urge you to examine the positive monetary result of allowing more surgeries to be performed in ASCs, where they can be performed in a more streamlined environment **(more convenient)(cheaper)** with much higher outcomes and much lower infection rates **(better)**. As surgeries migrate from the more expensive hospital departments to ASCs, the amount CMS will pay out in total reimbursements will decrease, resulting in not only budget neutrality, but a significant savings to CMS.

However, the new proposed payment rate of 62% of HOPD (hospital outpatient departments) is woefully inadequate to even cover our out-of-pocket costs to perform the surgeries. If passed, this amount would probably close many ASCs, including our own, which has provided surgical care to thousands of Medicare beneficiaries in a comfortable and efficient manner.

Our association urges you to accept the rate of 75% of the HOSD payment rate. Even at this rate, the CMS will save enormous amounts of money and allow ASCs to continue to provide needed services, such as cataracts removal, orthopedic and podiatric surgeries, and GI services.

Thank you for your consideration to this vital issue.

Most sincerely,



Joe Colbert, Administrator
HealthSouth North Coast Surgery Center



ROCKFORD GASTROENTEROLOGY ASSOCIATES, LTD.
ROCKFORD ENDOSCOPY CENTER

Roger L. Greenlaw MD
William N. Baskin, MD
James E. Frakes, MD
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John J. DeGude, MD
Aron J. Shields, MD
Kevin J. Peife, MD
Marcella A. Howard, APN

October 25, 2006

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

Re: Ambulatory Surgery Center Proposed Rule

Dear Administrator Norwalk:

Rockford Gastroenterology Associates, Ltd. is a fourteen physician single specialty gastroenterology practice located in Rockford, Illinois. We have been operating a Medicare certified ambulatory surgery center (ASC) since 1993. Our center has four endoscopy suites that served in excess of 11,000 patients in 2005. Over 3,800 of those patients were Medicare beneficiaries.

Given the number of Medicare patients that we serve, we have grave concerns about the proposed rule for reimbursement of ambulatory surgery services. The proposal as written describes reimbursement at 62% of hospital outpatient department (HOPD) rates, which results in significant financial repercussions for our endoscopy center. Estimates of the financial impact indicate that we will experience a reduction in reimbursement of at least \$450,000 annually. A loss of this magnitude would be devastating to our single specialty center. We have experienced significant cost increases in two areas that are beyond our control. Illinois has limited tort reform; therefore our malpractice insurance coverage has increased 55% to 79% per year in recent years. In addition, the nursing shortage has been a factor in our human resource costs rising 20% to 28% per year. We are simply not able to combine an increasing cost structure with reductions in reimbursement without looking for alternatives that will preserve our financial health.

Illinois Certificate of Need laws preclude us from adding other specialties that might offset the effect of this proposal on reimbursement for GI services. Therefore, if the payment system is implemented as outlined, we will be forced to look at controlling payer mix as a means of maintaining a positive bottom line. We have never turned patients away because of their insurance coverage or ability to pay. This is not a strategy that we take lightly, but it will become a necessity. If the proposed cuts are implemented, we will not be able to perform endoscopic procedures on Medicare

patients in our center. These patients will have to be referred to the hospitals for their procedures. Our physicians serve two hospitals in Rockford. These hospitals will not be able to accommodate the 3,800 Medicare patients that will be displaced if we take this approach.

Although we are located 90 miles west of Chicago, our primary service area is made up of three counties that are largely rural. There are only five other gastroenterologists serving the residents of these three counties. Because we are the largest group, the majority of GI services rendered to patients are provided by our physicians. The way we run our practice has a significant effect on GI services received by patients in this area. There is a shortage of gastroenterologists locally and nationally. Additionally, there is an increasing pool of patients as baby boomers grow older. Today our patients typically wait 6 to 8 weeks for non-emergent medical services. If we begin referring Medicare patients to the hospital for procedures, their capacity limitations will result in patients waiting 6 to 12 months at a minimum. Please understand that we do not relish treating Medicare patients differently than patients covered by private insurance, but we will have no other choice. Unfortunately, the result will be severely limited access for Medicare beneficiaries.

With increasing pressure on our financial performance, we may also find that we have to restrict services provided to patients with no health insurance. If we take this action, these patients will also be referred to local hospitals. Limited capacity will require that hospitals prioritize the order in which patients are served. This patient population tends to have more medical problems with higher acuity levels. These patients will need to be seen prior to Medicare patients who are waiting for elective services. Access for Medicare recipients will be further compromised.

Medicare introduced screening benefits for its high risk beneficiaries in 1997 and for average risk patients in 2000. These changes were the result of studies showing that treating cancer is more costly than detecting and preventing cancer. Taking steps that would restrict access to screening services seems to contradict your previous actions.

We understand that CMS is looking for ways to maintain fiscal solvency. The cost difference when services are shifted from the ambulatory surgery center to the hospital should be carefully considered. It is well known that hospitals receive higher reimbursement for the same services that we offer in our ASC. Increased costs will be borne by the Medicare program and its beneficiaries in the form of coinsurance payments. With a shift of patients to the hospital, it is not difficult to imagine that increases in claims paid to hospitals will far exceed savings that are expected as a result of reducing reimbursement to endoscopy centers. In 2005, the Federated Ambulatory Surgery Association engaged the Moran Company to conduct an ASC cost study. The study examined actual 2003 Medicare claims for surgical procedures, including GI endoscopy, payable in both ASCs and HOPDs, and repriced these claims according to the 2005 payment rules for each setting. The mean payment per claim in the ASC was only 64% of that in the HOPD. The study suggested that Medicare would save nearly \$1.6 billion in 2005 if eligible procedures performed in an HOPD were

performed in an ASC instead. Redirecting patients from ASCs to hospitals seems to be a flawed policy.

In summary, we believe that the proposed rule is detrimental to the Medicare program and its beneficiaries. Total expenditures to facilities for GI services will markedly increase, while fewer patients will receive life saving procedures as a result of barriers to access. To preserve patient access and continue Medicare savings, it is imperative that the proposal be modified to increase, not decrease facility fees to endoscopy centers.

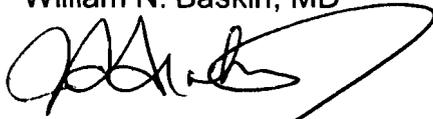
Sincerely,



Roger L. Greenlaw, MD



William N. Baskin, MD



James T. Frakes, MD



Donald E. Vidican, MD



S. Christopher Moore, MD



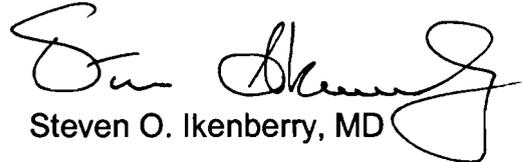
Mark T. Shiels, MD



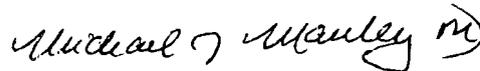
Arnold M. Rosen, MD



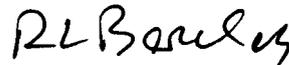
Joseph J. Vicari, MD



Steven O. Ikenberry, MD



Michael J. Manley, MD



Robert L. Barclay, MD



John J. DeGuide, MD



Aaron J. Shiels, MD



Kevin J. Peifer, MD

CC: Senator Richard Durbin
Senator Barack Obama
Congressman Donald Manzullo



**CENTENNIAL
SURGERY CENTER**

114

October 31, 2006

Leslie Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Proposed Rule For ASC Payment System

Dear Ms. Norwalk:

I am the Executive Director at Centennial Surgery Center located in Voorhees. We have been in business since 1999 and employ 50 staff. The physicians who use Centennial Surgery center provided 10,700 surgical procedures in 2005. We are a multispecialty center, and offer services in Gastroenterology, Urology, Orthopedics, Podiatry, General Surgery, Colon-Rectal Surgery, Plastic Surgery and Pain Management. We take care of people covered by private health insurance as well as many Medicare beneficiaries.

Centennial Surgery center is a high quality, cost effective alternative to the hospital. We play an important role in helping to hold down spending for medical care. Therefore, I was disturbed to learn that CMS is considering proposals to develop a new payment system that will cut our Medicare payments and make us less viable as a business entity than the HOPDs. A reduction of this size would make it more difficult to continue to provide services to our elderly patients. They would have to have their surgery done in the more expensive hospital outpatient department. These patients would have to pay much higher co-payments, and Medicare would pay more for the surgical care. With all the concern about higher medical costs, I don't think it makes much sense for Medicare to discourage the use of cost-effective providers like us.

In the last two years our liability insurance premiums have increased by 40 percent. Staff costs have increased by 30 percent and supply costs have increased by 6 percent. However, Medicare has provided us only limited inflation update since 1998. It is very hard for us to continue to absorb these higher costs. To assure Medicare beneficiaries

Centennial SurgUnit, LLC
502 Centennial Boulevard, Suite 1
Voorhees, New Jersey 08043-4537

Phone 856-874-0790



**CENTENNIAL
SURGERY CENTER**

access to ASCs, CMS should broadly interpret the budget neutrality provision enacted by Congress. 62% is simply not adequate.

The ASC list reform proposed by CMS is too limited. CMS should expand the ASC list of procedures to include any and all procedures that can be performed in an HOPD. CMS should exclude only those procedures that are on the inpatient only list.

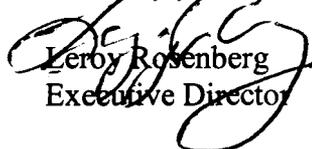
ASCs should be updated based on the hospital market basket because this more appropriately reflects inflation in providing surgical services than does the consumer price index. Also, the same relative weights should be used in ASCs and HOPDs.

On paper, a few of our rates may appear to be higher than the hospital rate, but that is very misleading. Our facility fee has to cover all the costs of our surgery, including radiology services. The hospital gets to bill separately for each of these as well as many other services. They also get to pass through the costs of new technology, but we cannot. By any standard, the hospital almost always gets paid much more for an operation than we do.

The services that Centennial Surgery Center provides to senior citizens represent one of the few health care bargains around. I urge you to oppose any cuts to our Medicare payments that could force these older patients back into the hospital outpatient department. Congress needs to encourage more cost-effective medicine, not less.

Please feel free to contact me if you would like to have more information about Centennial Surgery Center. Thank you.

Sincerely yours,



Leroy Rosenberg
Executive Director

cc: FASA
1012 Cameron Street
Alexandria, VA 22314

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502 Centennial Boulevard, Suite 1
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Phone 856-874-0790



11/06 - CMS
11/06 - 11:53

November 6, 2006

Leslie Norwalk Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P2 (The Ambulatory Surgical Center Payment System and CY2008 Payment Rates)

Dear Acting Administrator Norwalk:

DaVita¹ is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed changes to the Ambulatory Surgery Center payment methodology for FY 2008. DaVita is a leading kidney care provider serving patients with high-quality specialized prevention and treatment services, spanning 42 states and the District of Columbia. The DaVita network includes more than 1,250 outpatient facilities as well as acute inpatient units in over 750 hospitals. RMS Lifeline, a subsidiary of DaVita, provides management services to physician outpatient offices that provide vascular access repair and maintenance procedures exclusively to hemodialysis patients. There are presently 29 operating RMS-Lifeline managed centers throughout the country.

We are pleased that CMS recognizes the importance of expanding the types of procedures performed in the ASC setting to include those related to the repair and maintenance of AV fistula and grafts, as evidenced by the inclusion of G0392 and G0393 in the November 1, 2006 Final Rule for the Hospital Outpatient Prospective Payment System (OPPS). We encourage CMS to continue to allow the full range of vascular access-related procedures to be performed in an ASC, by including these new G-codes in the Revised ASC Payment for CY 2008 and beyond.

Our main points pertaining to the CY 2008 proposal are the following:

- As we noted in our CY 2007 Update to the ASC Covered Procedure List comments submitted on October 10, 2006, we believe CMS should support the Fistula First initiative by permitting a full range of vascular access repair and maintenance procedures to be performed in the ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

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



- CMS should ensure that the vascular access procedures incorporated into the CY 2007 procedures list may also be performed in the ASC setting in CY 2008 and beyond. In order to ensure this, we request that the Agency revise the ASC exclusion criteria to align more closely with the Medicare Payment Advisory Commission (MedPAC) recommendation.
- We strongly urge CMS to reassess the migration assumptions embedded in the new CY2008 revised ASC payment methodology. At a reimbursement rate of 62% of the OPPOS rate, we believe there will be very little, if any, migration into the ASC setting.

I. ASC Payable Procedures (Exclusion Criteria):

CMS, in its revised FY 2008 ASC payment system, proposes to include all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay. We strongly endorse this practice. Since the agency first began the process of developing criteria for determining which codes are appropriately performed in ASCs in 1987, CMS has often reexamined its policies as technology improves and practice patterns change. CMS also considers evidence about whether procedures are safe to perform in ambulatory settings. In the Final Rule for the Hospital Outpatient Prospective Payment System (OPPOS) released on November 1, 2006, CMS reconsidered its proposal to add CPT codes 37205 and 37206 to the list of approved procedures, stating "it would be in the best interests of Medicare beneficiaries to continue to deny payment for them in ASC facilities." We are requesting the Agency reconsider these codes for the FY 2008 ASC Payment system, as there is strong evidence of their safety and efficacy. In addition, both codes meet the MedPac recommended criteria as neither "poses a significant safety risk" nor "require an overnight stay."

- Similar to the new G codes (G0392 and G0393) created specifically for hemodialysis vascular access, we urge CMS to create similar codes for stent procedures performed for hemodialysis vascular access care in the ASC setting.
- The inclusion of these CPT codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access repair and maintenance procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting. Despite the initiative, (which we fully support), which was introduced in 2004 to encourage the use of fistulae, the rate remains significantly less than the targeted rate of 66% by 2009.
- In the OPPOS Final Rule,² you rescinded these codes stating, "they are virtually never performed in a physicians office, require > 4hours of recovery and almost require an overnight stay." RMS Lifeline's strong clinical record suggest otherwise. We have successfully performed these procedures in our Lifeline centers, while ensuring a high level of patient safety.
- Lastly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting, as it provide them with a more efficient and accessible option to ensure that their life-saving access is properly maintained. RMS Lifeline's monthly patient satisfaction survey shows that historically, 91% of rated their experience at RMS Lifeline managed centers as either very good or excellent.

² 71 Fed. Reg. at 49636.



Incorporating a full-range of vascular access procedures into the ASC setting will result in important savings to the Medicare program (approximately \$1.25 billion over 10 years).³ In 1999, Dr. Allan Collins and his colleagues found that shifting vascular access-related procedures from the inpatient to the outpatient setting resulted in savings of more than \$9,000 per event/procedure. They concluded that: “significant savings on [vascular access (VA)] procedures for hemodialysis patients can be achieved if an appropriate infrastructure and incentives are provided to encourage this site of care. Creative reimbursement systems for VA should be considered to encourage more cost-effective delivery of uncomplicated VA interventions.”⁴ Although Dr. Collin’s conclusions were based upon comparisons between inpatient and outpatient settings, DaVita believes that based upon CMS reimbursement policy, the ASC setting would provide the lowest cost opportunities for performing these procedures while also ensuring a high level of patient safety.

2. ASC Reimbursement Rates

We support CMS’ proposal to replace the current ASC system with one based on the OPPS procedure groups (APCs) and relative weights, so that ASC rates are more aligned with surgical procedures provided in hospital outpatient departments. Such alignments would make payments more accurate and promote higher quality and value in outpatient care. We are concerned, however, with CMS’ proposal that ASCs be paid based upon a methodology that results in ASCs being paid no more than 62 percent of the HOPD rates in 2008 and even less in 2009.

Although the 62 percent payment rate, as well as the expanded ASC coverage policy, will make it possible to provide some services in ASCs that are now commonly provided in hospital outpatient departments, this payment rate represents a sharp reduction for a number of services that are already being frequently provided in ASCs and may result in ASC centers closing altogether. As such, we encourage CMS to reconsider its assumptions about utilization rates under the new payment system and work to achieve the highest possible level of comparability between the ASC and OPPS rates. These adjustments will minimize any unintended adverse impact on patient access to care and physician ability to choose appropriate sites of service for patient care.

A. Migration Assumptions/Budget Neutrality: We understand that the Medicare Modernization Act of 2003 (MMA) dictates that changes to the ASC payment system must be made in a budget neutral manner (*interpreted by CMS to mean the Agency spends the same amount on ASC services under the revised system that it would have spent without the changes*). However, we believe that the assumptions used to arrive at the payment rate of 62% of the OPPS rate should be re-examined. To achieve the policy goals set forth above, we believe it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following the implementation of the new payment system. Otherwise, if budget neutrality is applied only to ASC

³Judy Xanthopoulos, “Analysis of Section 101: Modification of Physician Surgical Reimbursement for Dialysis Access Procedures to Align Incentives for Cost and Quality” (2005). Available upon request.

⁴Allan J. Collins, James Ebben, Shu Chen, & Jennie Z. Ma, “Cost-Effectiveness in Inpatient and Outpatient Vascular Access Services” Minneapolis Medical Research Foundation, University of Minnesota, Twin Cities, University of Tennessee, Memphis (1999). Presentation available upon request.



services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the viability of ASCs serving as an effective competitive alternative site of service and will likely have a negative impact on beneficiary access to care.

B. ASC Payment for Office-Based Procedures: CMS proposes to allow payment of an ASC facility fee for office based procedures that have been historically excluded from the ASC list because the agency agrees with commenters that these procedures do not pose a significant safety risk and do not require an overnight stay. However, CMS has concerns that allowing office based procedures to be performed in an ASC may provide incentives for physicians to convert their offices into ASCs or to move office based procedures to the ASC setting. We believe that for a given procedure, physicians should be able to determine the site of service that is most appropriate given the patient's specific condition. Although physicians may be able to perform a particular procedure in his/her office, some patients are sicker or more frail and may require the additional infrastructure and safeguards that an ASC can provide to help ensure safe and effective outcomes. For this patient population, physicians are NOT likely to perform procedures in their office, and will therefore elect the more expensive hospital setting, yielding greater costs to the Medicare program while neglecting physician and patient choice. We believe the best policy is to allow physicians to select the site of service they believe is most clinically appropriate for their patients.

4. ASC Packaging

CMS has proposed to model the ASC payment methodology on the OPPS payment system. In stark contrast, the OPPS/APC provides for pass-through (C Codes) of certain technology costs. The proposed rule upholds the practice of bundling the payment for direct and indirect costs incurred by the facility to perform the procedure into a single ASC facility. We question why the new ASC payment system (which is modeled after the OPPS system), would not provide the same reimbursement for supplies as the APC system does. As proposed, this payment structure will not facilitate the achievement of Secretary Leavitt's and CMS' goal of ASC reform, as it does not afford ASCs the reimbursement equity as currently allowed in the hospitals and outpatient departments. Further, we understand that the Office of Inspector General has concerns regarding place of service coding, as between ASCs and HOPDs, because of the differences in Medicare payment based on site of service and plans to devote audit resources to monitoring in this area.⁵

In closing, Congress has given the Department of Health and Human Services (HHS) broad authority to develop a new Medicare payment system for ambulatory surgical centers (ASCs). HHS and CMS should use this opportunity to achieve cost savings for the Medicare program; more closely align payments across

⁵ See OIG 2007 Work Plan at 11.5[1] Leveling the payment and coverage playing field by eliminating [or reducing] the payment and coverage disparity between the sites of service with respect to identical clinical services would eliminate the need for concern and audit scrutiny in this area allowing CMS and the OIG to focus on other threats to program integrity rather than monitoring potential problems caused by the structure of payment mechanisms created by CMS.⁵



the different sites of service for outpatient surgery; and provide patients and physicians with options in which to choose the appropriate setting while maintaining optimal patient outcomes.

DaVita appreciates the opportunity to comment on these important policy proposals. We sincerely hope that CMS will consider our comments and incorporate our suggestions into the Final Rule. Please feel free to contact Stephanie Dyson at (202) 457-0417 if you have any questions regarding these comments. We look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to treatment in the appropriate sites of service.

Sincerely,

Charles J. McAllister, M.D., FACP
Chief Medical Officer
DaVita

Gerald Beathard, M.D.
VP, Provider Development
RMS Lifeline, Inc.

cc: Kent Thiry, Mayor and CEO, DaVita
Eric Berger, Senior Vice President, DaVita
LeAnne Zumwalt, Vice-President, DaVita
Stephanie Dyson, Director Public Policy, DaVita



116

Fresenius Medical Care

November 6, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4125-P, Proposed Rule to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Ms. Norwalk:

US Vascular Access Holdings, LLC (USVA), a division of Fresenius Medical Care North America, is pleased to submit these comments to the above referenced Proposed Rule that was published in the *Federal Register* on August 23, 2006, and which will revise the ASC payment system effective January 1, 2008. USVA's primary business is to create and maintain vascular access for patients with end stage renal disease (ESRD) who require frequent hemodialysis treatments.

USVA is pleased to learn that CMS has approved and created new procedure codes for arteriovenous (AV) fistulas and grafts (G0392, G0393) in the ASC setting, effective January 2007. This change supports the CMS Fistula First national quality improvement initiative, with the goals that primary AV fistulas should be created in at least 50% of all new patients requiring hemodialysis, with a long-range goal of maintaining fistulas in 40% of eligible patients who remain on dialysis. The creation of ASCs that specialize in vascular access for ESRD patients is an additional step in furtherance of this goal.

Consequently, USVA is concerned about the methodology CMS has employed to convert OPPS payment into ASC payment at a 62% rate. The data upon which this conversion factor has been based is twenty years old and bears little, if any, relationship to today's actual costs for performing surgical procedures. In the event that ASC payments are inadequate to cover costs for certain procedures, it is likely that those procedures will be moved to the more costly hospital outpatient setting. Of even greater concern, should it become financially impractical to perform certain procedures in the ASC setting, such as vascular access for ESRD beneficiaries on hemodialysis, access to these critical procedures may be compromised for this vulnerable patient group.

Vascular access procedures commonly require both surgical and radiology elements. Therefore, USVA believes the revised ASC payment system should allow an ASC to bill for radiology procedures under the ASC's provider number. Currently, the ASC payment system requires an ASC to obtain a separate Independent Diagnostic Testing Facility (IDTF) provider number in order to bill for radiology procedures. ASCs should be separately paid under the ASC



Fresenius Medical Care

payment system for radiology procedures that are necessary and directly related to vascular procedures, without a requirement to bill these diagnostic procedures as an independent diagnostic testing facility (IDTF).

USVA is concerned not only about which procedures are reimbursed, but also about reimbursement for items and services that are directly related to a vascular procedure. For example, a procedure commonly performed in an ASC by interventional nephrologists on patients with end stage renal disease is the tunneled insertion of a central venous catheter, CPT code 36558. This procedure is generally performed on ESRD patients to either establish an emergency vascular access to maintain access for hemodialysis treatments when AV fistulas or grafts are revised to correct lesions or other complications, or when newly created AV fistulas or grafts require a maturation or healing period. Currently ASCs are reimbursed for the cost of the central venous catheter (\$325). Under the proposed 2008 payment system, the catheter would be "packaged" into the facility fee, and would not be paid separately. ASCs do not generally receive the same product volume discounts that large volume hospitals are offered and can ill afford to absorb the costs of such items. As a result of the proposed revised 2008 ASC payment system, it may become financially impractical for ASCs to continue performing procedure code 36558, which will lead to such procedures shifting to the more costly hospital outpatient setting.

Finally, it is important that ASCs receive an annual update similar to the market basket updates granted to hospitals. ASCs are generally smaller entities than hospital based outpatient surgical settings, and may be disproportionately impacted by the inability to remain competitive in this market.

Your consideration of these issues is greatly appreciated.

Sincerely,

Cathleen O'Keefe, RN, JD
Vice President - Regulatory and Government Affairs
Products and Hospital Group
Fresenius Medical Care North America
(800) 662-1237 x 4560



November 3, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Ms. Norwalk:

These comments are submitted on behalf of ONCURA,¹ a leading manufacturer of state-of-the-art medical products and systems that employ novel hypothermic surgical technologies to destroy cancerous tissues. Our products include cryoablation systems, which offer highly effective and minimally invasive therapies for prostate and kidney cancer.

We appreciate the opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services ("CMS") on August 23, 2006, in the *Federal Register* which proposes a revised payment system for ASC (Ambulatory Surgical Center) facility services furnished in connection with a surgical procedure beginning January 1, 2008.

We wish to comment on the following specific codes related to cryotherapy:

CPT 55873 - Cryoablation of the Prostate

We set forth more detailed comments below.

* * *

¹ ONCURA was created in July 2003 by the merger of Amersham's brachytherapy business with Galil Medical Ltd's urology business.

ONCURA commends CMS on its efforts to develop a new ambulatory surgical center (ASC) payment system for implementation in 2008 as mandated by the Medicare Modernization Act of 2003 (MMA). In general, ONCURA supports the CMS proposal to align the new ASC payment system with the hospital outpatient prospective payment system (HOPPS). Although we understand the need to create a payment system that is budget neutral, the differential between the HOPPS rates and the proposed ASC rates exceed what we believe to be reasonable. Further, ONCURA remains concerned about the hospital claims data used to determine current HOPPS payment rates and the basis for ASC payment rates beginning in 2008.

I. CPT 55873 - CRYOABLATION OF THE PROSTATE

In summary, we believe **the final 2007 HOPPS payment of \$6685.05 for cryosurgical ablation of the prostate (CPT 55873, APC 674) does not accurately reflect the costs incurred by hospitals in administering this procedure.** The payment for this procedure has continued to be inadequate since the inception of HOPPS as a result of flawed claims data that does not accurately reflect or capture the full costs related to this procedure on the UB-92 claims. Actual hospital acquisition cost data has been provided to the agency by manufacturers on a number of occasions to demonstrate that the actual amount hospitals pay for the cryoablation probe devices alone is well over \$4000. per procedure. CMS has categorized prostate cryoablation as a device dependant procedure. Oncura is prepared to submit actual invoices again that CMS could use to match specifically to the providers' claims that were used for rate setting purposes. Since the proposed ASC payment rates are based on a percentage of the Hospital Outpatient Payments, the payment for prostate cryoablation in the ASC setting will continue to prohibit ASC providers from offering this service as further explained below.

We also note that when prostate cryoablation was added to the list of ASC approved procedures, the procedure was assigned to payment group 9. To date, there have not been any prostate cryoablation procedures performed on Medicare beneficiaries in the ASC setting due to the inadequate payment amount that is currently assigned \$1339.00. While an ASC is clearly an appropriate place of service for prostate cryoablation procedures, ASC's simply can not afford to perform the procedure. The proposed 2008 50/50 transition rate of \$2809.28 and the proposed 2008 full rate of \$4279.56 will not begin to cover the cost of the cryoablation procedure and therefore Medicare beneficiaries will not have access to this procedure in the ASC setting.

II. BACKGROUND ON CRYOSURGERY OF THE PROSTATE

A. Importance of Cryosurgery in Treatment of Prostate Cancer

In the United States, prostate cancer is the most common cancer seen in men and the second most common cause of male cancer deaths, and it is disproportionately more prevalent within the Medicare population. Cryotherapy systems are designed to treat prostate cancer by destroying cancerous tissue through the application of extreme cold temperatures delivered by cryoablation probes.² The number of probes used for a given procedure can range from 5 to as many as 20, depending on the particular case and the type of cryotherapy system used.

Recurrent and residual disease after initial therapy for prostate cancer is fairly common, with rates ranging from 25 percent to 85 percent depending on the initial therapy and disease type. Local recurrence of prostate cancer presents a difficult challenge, because there are limited therapeutic options: additional radiation rarely is an option due to the limits on cumulative doses, hormonal therapy is not curative, and salvage prostatectomy has limited efficacy.

² These probes are inserted through the perineum into the prostate. Argon gas circulating through the probes generates very low temperatures causing the formation of ice, which destroys targeted cancer cells.

Cryosurgery is highly effective in treating prostate cancer, and it is essentially one of the only treatment methods currently available for radiation-failure prostate cancer cases.³ Moreover, patients are demanding initial treatment options for prostate cancer that are minimally invasive.

B. Effect of Innovations on Clinical Outcomes and Cost of Procedure

One of the most important technological advancements in this mode of treatment has been the development of smaller and more advanced probes, which enable the application of cryoablation with far more precision. Specifically, these increasingly sophisticated probes allow the physician to target cancerous tissue without causing damage to surrounding healthy tissue. This substantially reduces the likelihood of serious complications often consequent to prostate cancer therapy -- such as incontinence -- which avoids needless patient pain and suffering and reduces Medicare costs. In addition to decreasing complications, technological developments in cryotherapy systems have enabled this therapy to often be administered in hospital outpatient facilities, which produces savings for Medicare and allows patients to go home shortly after the procedure has been performed.

III. CURRENT OPPTS PAYMENT FOR PROSTATE CRYOABLATION IS BASED ON INACCURATE CLAIMS DATA

We are convinced that the current 2006 HOPPS payment of \$6628.02 for APC 674 is based on flawed claims data that understates the actual costs incurred by hospitals in administering this procedure. Oncura contracted with The Moran Company⁴ to analyze the 2005 claims data set provided by CMS. Clearly, the median cost reflected in the claims data continues to under reflect the actual cost of the procedure. Deriving ASC payments for procedures which are predominantly device cost dependant and taking a percentage of the HOPPS rate will restrict access to this procedure in an ASC setting.

Inaccurate Charge Reporting for Cryosurgery of the Prostate

Manufacturers are not permitted to suggest how hospitals should establish their charges and so the educational efforts with the hospitals has been very challenging. Under such circumstances, it is not surprising that the claims data compiled from reported hospital charges do not provide an accurate picture of the total cost of performing cryosurgery of the prostate.

The 2005 claims data set analysis provided to us by The Moran Company clearly shows that many hospitals have failed to submit claims to CMS for prostate cryosurgery that properly reflect the costs of supplies -- especially the cost of the cryoablation probes. The majority of the claims used to set the payment rates grossly understate the actual costs that the provider pays for the devices. Oncura's reimbursement group has had a significant number of discussions with our customers since the device dependant procedure edit was put in place in April of 2005. While we knew that a significant problem existed, it has been an astounding experience to see the number of hospitals that had claims returned because hospitals were not accounting for the cryoablation devices on the claims. When attempting to educate many of hospitals, the standard response that we have gotten is that they just want to get the C-Code on the claim so it passes through the edits and they get paid for the procedure. This respondent is typically

³ The importance of cryosurgery in treating prostate cancer is evidenced by two separate national Medicare coverage decisions issued by CMS in 1999 and 2001. Cryosurgery is safe, effective, and medically necessary and appropriate in certain patient populations -- specifically, those patients with stages T1-T3 prostate cancer. It has demonstrated effectiveness through an absolute analysis and a comparative analysis. Its results are comparable to brachytherapy (involving implantation of a radioactive seed) and external beam radiation.

⁴ The Moran Company is an independent health care research and consulting firm.

not someone who is in the finance or administration area of the hospital who would understand the impact of the claims data on rate setting and/or someone who is concerned about the charges on the claim accurately reflecting the cost of the device. Rather, the person coding the claims is usually a patient accounting claims clerk who is reviewing the denied claims and is responsible for resubmitting the claim. A standard response that we hear from our hospital clients is: "the payment for the device is bundled into the procedure so our main concern is to get the C-Code on the claim and get the claim processed and paid." They also tell us that they do not believe that they are able to establish charges based on the CCR methodology and that the standard sliding scale approach that they have used to set charges historically has worked well

As a result, because we know how much hospitals pay for the cryoablation devices, we believe the current and proposed payment level causes hospitals to incur substantial losses when administering this therapy. We continue to have hospitals stopping this program based on the inadequate payments they receive. We believe that deriving ASC payments in the future based on 62% of the hospitals costs will result in ASC's never performing this procedure in that setting.

In the past, we have noted through analysis provided to the agency that hospitals frequently submit claims for this procedure that do not contain charges for probes in numbers sufficient to enable the procedure to be performed. While the claim edits put in place for the procedure have prohibited the claims from being processed without the device code, the challenge of appropriate charges being submitted on the claims remains a significant issue. Under such circumstances, it is not surprising that the claims data compiled from reported hospital charges do not provide an accurate picture of the total cost of performing cryosurgery of the prostate.

We also believe that this apparent self-defeating behavior of hospitals, i.e., not claiming the full charges for each case resulting in an underpaying APC, is due to a fundamental disconnect between the hospital personnel doing the claims coding and the hospital personnel who actually understand the Medicare HOPPS. We have tried to bridge this disconnect through educational efforts but are somewhat limited by the willingness of certain hospital personnel to get sufficiently motivated to correctly complete hospital claims and by the fraud and abuse laws and rules that cultivate an overly-cautious approach in manufacturer-hospital relations.

Problem with Application of Cost-to-Charge Ratio to High-Cost Devices

As we have noted in the past, we believe CMS's methodology results in charge compression, particularly for the higher cost devices which contributes to inadequate payment rates for prostate cryosurgery. As stated above, our hospital clients generally do not use a single formula to establish device charges, but rather typically use a sliding scale, whereby a lower markup is applied to relatively high-cost devices, such as cryoablation probes. When CMS applies a cost-to-charge ratio, however, it fails to take into account this sliding-scale approach to establishing device charges. Thus, applying the cost-to-charge ratio to the charges for cryoablation probes used for prostate cryosurgery produces an overstated markup for the device, and results in cost finding that understates the actual cost of the device to hospitals. This methodology harms high cost device dependant procedures.

Applying the CCR when hospitals do not use the CCR factor to establish their markup on items is illogical. We are encouraged that CMS has contracted an outside group to study the charge compression phenomena for the IPPS and hope that valuable information can be gleaned from this study and applied to future payment methodologies for the ASC payment system and OPSS which also results in payments that are grossly understated.

Inability to Report Charges for Supplies

An additional problem with charge reporting for prostate cryosurgery is the inability of hospitals to report charges for a number of supplies without specific codes used in connection with the procedure. There are several supply items that are required to perform prostate cryoablation and are unlikely to be used or stocked by the hospital for any other procedure. These supplies -- such as urethral warming catheters, temperature sensor probes, and

argon/helium gas (6,000 psi) -- are not insignificant costs to the hospitals. All are required in order to perform prostate cryosurgery safely and effectively. While the hospitals may have the ability to report such supplies under a supply revenue code, of the UB-92 claim forms that we have reviewed, we do not believe these supply costs are adequately reflected in the claims data. Again, the administrative burden to create and maintain supply charge master items that are not separately reimbursed or described by HCPCS codes results in many supply items being left off the UB-92 claim forms.

RECOMMENDATION FOR APC 674 – PROSTATE CRYOABLATION

The proposed 2008 50/50 transition rate of \$2809.28 and the proposed 2008 full rate of \$4279.56 will not begin to cover the cost of the cryoablation procedure and therefore Medicare beneficiaries will not have access to this procedure in the ASC setting. Since the proposed payments were derived from HOPPS claims data, We suggest that CMS take the most conservative approach in limiting the claims data set to claims with the appropriate device code (C2618) and apply a minimum charge threshold amount based on the external data provided by the manufacturers accompanied by the provider table analysis from The Moran Company. In doing so, we believe that an adequate number of claims could be used for rate setting purposes.⁵ As an alternative, CMS could depart from the methodology it has proposed to price prostate cryosurgery procedures performed in ASCs. Instead of discounting a too low APC payment rate, CMS should allow for the direct billing by ASCs for the cryoablation probes, temperature sensor probes, and urethral warmer supplies that are used, and establish a separate ASC payment rate for the non-technology ASC facility costs that are incurred. If CMS chooses not to take this approach, it should, at the very least, hold harmless the device portion of the hospital outpatient APC rate in calculating a final ASC payment rate for 2008.

Basing payments on this defined claims data set would enable the agency to be confident that the payments for prostate cryoablation reasonably relate more directly to the costs incurred to perform cryoablation of the prostate. This relationship between payment and cost is critical to prevent Medicare ASC payment policy from hindering the adoption of this emerging and groundbreaking therapy in this setting.

Additionally, there are a number of high volume procedures that CMS proposes to pay in the ASC setting in 2008 that are safely performed in a physician's office (i.e. office-based procedures). We believe that the affect of adding these office-based procedures to the ASC would result in a lower than reasonable payment rate for all procedures performed in an ASC. Therefore, we strongly encourage CMS to re-evaluate its criteria for procedures paid in an ASC and also ensure that an adequate number of accurate hospital claims are utilized to set appropriate ASC payment rates.

IV. ASC Conversion Factor

For 2008, CMS estimates a budget neutral ASC conversion factor of \$39.688. CMS currently estimates that the revised ASC rates would be 62 percent of the corresponding HOPPS payment rates effective January 1, 2008.

ONCURA is greatly concerned that the proposed conversion factor will result in insufficient payment to ASCs for their services across the board. Paying for procedures performed in the ASC setting at 62 percent of the hospital outpatient payment rate is too low to ensure Medicare beneficiary access to surgical services in the ASC setting particularly in the case of device dependant procedures.

⁵ As mentioned above, the \$6000. charge threshold assumes a very conservative total device cost of \$4000 multiplied by a conservative mark up factor of 1.5, which would assume a CCR of 0.665. If we were to use the average CCR established by CMS of 0.420, the assumed markup factor would have increased to 2.38 and the threshold charge to \$9500, based on the minimum \$4000 cost of the device. Using the more conservative limiting charge of \$6000 and the higher CCR/minimal markup factor of 1.5 allows CMS to use a representative number of claims and results in a median of \$7635.

Device dependant procedures such as prostate cryoablation if performed in an ASC setting involve the use of expensive medical devices (i.e. cryoablation probes, temperature sensor probes, warming catheter). When the cost of the devices alone exceed the proposed CMS payment rate for the surgery, ASCs have a strong financial disincentive to perform the procedure and typically will not offer it. The 2008 conversion factor as proposed will result in Medicare beneficiaries not having access to prostate cryoablation in the ASC setting.

Surgical procedures performed in the ASC are efficient and cost-effective. CMS should examine the consequences of the new ASC payment system on all sites of care and adopt alternative methodologies to determine the conversion factor.

For this reason, we urge CMS to depart from the methodology it has proposed to price prostate cryosurgery procedures performed in ASCs. Instead of discounting a too low APC payment rate, CMS should allow for the direct billing by ASCs for the cryoablation probes, temperature sensor probes, and urethral warmer supplies that are used, and establish a separate ASC payment rate for the non-technology ASC facility costs that are incurred. If CMS chooses not to take this approach, it should, at the very least, hold harmless the device portion of the hospital outpatient APC rate in calculating a final ASC payment rate for 2008.

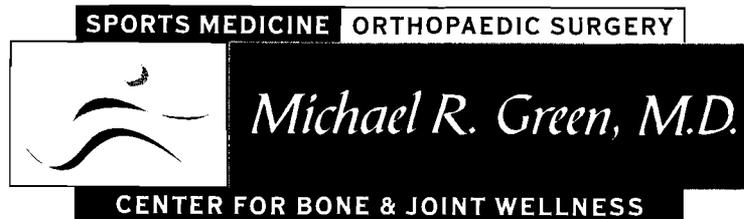
CONCLUSION

ONCURA appreciates the opportunity to submit comments on the Proposed Rule for ASC's in 2008, and we are eager to provide CMS with any information or clarification that would enable the agency to ensure Medicare beneficiaries continued access to cryosurgery of the prostate. We recognize that a new payment system as complex as the proposed ASC payment system will encounter challenges for specific types of services, including cryotherapy. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me or you may also contact Lisa Hayden at (703) 948-7685.

Sincerely,

James McGlone

James McGlone
President/CEO Oncura



118

American Board of Orthopaedic Surgery • Arthroscopy Assoc. of North America
American Academy of Orthopaedics • American College of Surgeons

October 31, 2006

Leslie V. Norwalk, Esquire, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

RE: CMS-1506-G-Medicare Program:
The Ambulatory Surgical Center Payment System
CY 2008 payment rates.

Dear Ms. Norwalk:

I am writing as a concerned surgeon in the Southern Utah area. I currently practice orthopedic surgery in St. George.

We have several out-patient surgical facilities (ASC's) in this area. Each of these allow myself and other surgeons to provide excellent, efficient, high quality care to Medicare patients, at a costs far less to medicare than similar services at a hospital (HOPD).

Unfortunately due to the current reimbursement of Medicare to ASC's, we are unable to provide these services to a plethora of otherwise appropriate patients.

In many situations the care provided to Medicare recipients is far superior in quality, efficiency, and all other aspects to the only other available inpatient facility (HOPD). We as surgeons would like to be able to offer the ASC option to a wider variety of patients. Unfortunately this is not possible because Medicare currently reimburse ASC's at rates lower than it does for surgery at HOPD's.

Page 2

RE: CMS-1506-G-Medicare Program:
The Ambulatory Surgical Center Payment System
CY 2008 payment rates.

In many situations ASC's are unable to bill Medicare for necessary equipment such as screws, pins, suture anchors, etc. while the HOPD's are. In many situations the cost of these implants exceeds what Medicare allows for the complete surgical package at ASC's.

I am asking you for the benefit of my patients, to please make sure that Medicare changes the rules in such a way to allow ASC's to be reimbursed on par with HOPD's for similar surgical procedures.

This will allow patients access to "better, more timely superior care but also much more economic care." (It will save medicare and the patients money).

Sincerely,

A handwritten signature in black ink, appearing to read "Michael R. Green". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Michael R. Green, M.D.

MRG/ms

October 31, 2006

Centers of Medicare and Medicaid Services
Department of Health and Human Resources
Attention: CMS-4125-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD. 21244-1850

I am submitting this letter in reference to CMS-4125-P. Please accept this as my public comments on the proposed changes in reimbursement for care and service provided to Medicare and Medicaid recipients.

My name is Karl Klungreseter and I am the Administrator of Surgicare of Hawaii, a freestanding Ambulatory Surgery Center (ASC) in Honolulu, HI. At present we are the only freestanding, multi-specialty ASC on the island of O'ahu. We provide surgical and procedural services to approximately 300 patients a month. On average we provide service for 70 to 80 Medicare/Medicaid patients per month. When we are the site of choice for the Medicare/Medicaid patients, we are providing them with high-quality and less expensive care in a convenient setting for both them and their provider and saving the patient and CMS a significant amount of money.

While the Medicare Modernization Act requires that ASC's be transitioned to a new payment system by 2008, action without due and deliberate review may cause more harm than good. Looking at budget neutrality in relation to a single site of service fails to address the true impact to all sites of service that can and do provide the services to these patients. CMS must examine the impact of the proposed changes on all sites of service this decision will impact, not just the ASC. With the proposed changes we will see migration of patients from one site of service setting to another and it is CMS's responsibility to take all this into account when reviewing this proposal. Please take a closer look at all Medicare/Medicaid spending for all outpatient procedures in all settings and seek to understand the impact across all settings, not just a narrow portion of the outpatient setting such as the ASC.

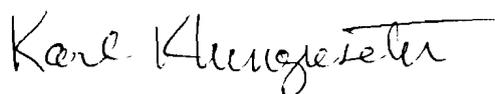
Another area of concern for me is the site of service access and discrimination that is fostered in the present list of approved procedures used to determine which procedures or services can be provided to Medicare/Medicaid recipients. The practice of medicine should be left up to the physicians. The decision to

perform any surgery or procedure in any setting should be dictated by the practice of medicine, choosing the most appropriate site of service based on the best interest, needs and desire of the patient and not based on compliance with a list of approved procedures that is only applicable to one segment of the population at large. CMS is forcing a decision based on medical insurance coverage by Medicare/Medicaid rather than what is most appropriate for the patient. When a patient is denied equal access to the same procedures, in the same settings as any other patient based on their coverage you are in fact discriminating against the same patient you are seeking to serve. Because of coverage exclusions for procedures routinely performed in the ASC setting for patients with alternative coverage, Medicare/Medicaid patients are forced to seek service in facilities with higher prices and greater inconvenience. Adoption of a truly exclusionary list for ASC services is a much more effective way to afford the patient increased choices, money saving opportunities and the ability to rely on the clinical judgment of the provider.

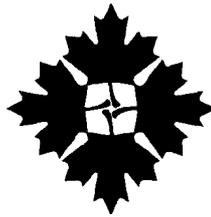
In closing let me also state that while all providers of health care services face the same challenges such as staffing with qualified care givers, the costs of materials used in the provision of care or the costs of operations (such as utilities, rent or equipment) we are also equally effected by the same inflationary pressures. By requiring one segment of the health care industry to be held to the CPI as their measure of inflation while allowing another segment to be measured by a completely different and more market specific measurement (the hospital market basket update) the potential disparity of payment for the same procedures will grow without any evidence that different payment rates are warranted.

I strongly urge that CMS look closely at the true impact of this proposal. That consideration is made for the need to treat Hospital Outpatient Departments (HOPD's) the same as ASC's in all aspects as we serve the same population.

I thank you for your time and consideration of my comments.



Karl Klungreseter, RN, BSN
Administrator



Continental
Wound Center, LLC
Where wounds heal™

120

November 1, 2006.

Leslie V. Norwalk, Esq,
Acting Administrator,
Center for Medicare & Medicaid,
Department of Health and Human Services,
Attention: CMS 1506-P
Mailstop C4-26-05
7500 Security Blvd,
Baltimore, MD 21244-1850

Dear Administrator Norwalk,

I am writing to express my serious concerns regarding your proposed reorganization of ASC services in general, and also as they will affect my own practice in particular.

I currently practice specialized wound management and hyperbaric medicine in a free-standing ASC environment. My partner and I had this specialized center constructed specifically for the care of these chronic patients. We opened in March 2006. Our fiscal proformas were built around the current CMS schedule.

I also hold an appointment as Adjunct Professor in the College of Business, Southeast Missouri State University where I teach MBA students about health care system design, quality management, and related topics. (The views expressed in this document are not endorsed by the University)

I have also been VPMA of one of our two regional hospital medical centers, and have experience in the British Health service, the Canadian system, Kaiser Permanente NW HMO and in private practice. In addition to my MD, I also hold a Masters degree in Health Administration, part of which was earned at RAND's Health Policy Department, Santa Monica, California under the supervision of Dr Robert Brook.

Acute care hospitals by their very nature are risky places for all patients. The only ethical justification for placing patients in this setting is if they require therapies that cannot be delivered in less risky environments. The acute care setting is not user friendly. Care systems designed for complex inpatients often are maladapted to less complex patients.

Resource consumption, both fixed and variable, for hospital patients is almost always significantly higher than for the equivalent service delivered outside the hospital. Part of this increase is due to the high risk environment and attendant complications, and the need for the complicated care systems required by the very ill. However, these expensive systems are often misapplied to all patients, regardless of their severity. Fixed costs are also higher for similar reasons.

I believe that CMS must continue to subscribe to high ethical and resource conserving principles. If so, then CMS ought to be encouraging the ASC care model and disincenting the more expensive hospital model for those large numbers of patients suited to ASC care. This is as true ethically as it is for reasons of fiscal responsibility.

Recent proposals do not appear to fulfill these principles, and in some cases such as our own Wound Management program they appear to be doing the opposite.

As you know, ASCs are expensive to construct, maintain, and operate. Revenues must cover these costs, and replacement costs both for structure and equipment are an additional concern. Specialized clinical staff are increasingly in short supply, which increases their wage and benefit demands. The ever-increasing regulatory burden is also a cost factor.

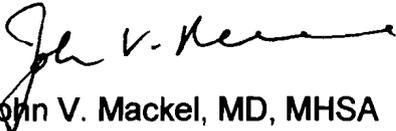
The overall cost reduction proposed by CMS is much too low. If we are to continue to move patients from the unnecessary acute-care hospital environment, we need to encourage ASC use, and not discourage it. I recognize that the approved ASC procedure list has been expanded, but expansion of money-losing customers is not a survival strategy for any business, especially one as complex as modern health care. We need to re-examine the budget neutrality question again with a view to increasing overall reimbursement to a more appropriate level. Our professional organizations have made reasonable suggestions as to the levels needed.

Scope of services is another related issue. As noted above, it makes little clinical or fiscal sense to have the identical services delivered in a riskier and more expensive environment. The vast majority of hospital outpatient services do not need to be there. They are delivered just as well, and cheaper, in community-based setting such as ASCs. We therefore need your support to approve for ASC care the vast majority of hospital OPD services, and to remunerate them at a reasonable level.

Remuneration needs to be calculated based on the hospital basket of services. The normal consumer price index is calculated on items such as foodstuffs that have little or no relevance to the costs of complex health care. Relative weights are a similar problem. OPDs and ASCs provide the same services and should be treated the same. Paying a hospital more for services that should not be delivered there is not a success strategy for CMS, for providers, or for taxpayers. Alignment of ASC and OPD remuneration makes sense, will move patients in the right direction and will help accommodate the large increase in Medicare enrollees that we all face. It will also help your budget.

I hope you will give these views your serious consideration. I have also included a separate discussion of the particular problems created by the CMS proposal that we face in our own specialty of Wound Management.

Thank you for your attention.



John V. Mackel, MD, MHSA
President,
Continental Wound Center.

c. Senator Kit Bond

Senator Jim Talent

Congresswoman Joanne Emerson.

Wound Management—an Emerging Medical Specialty.

In this review we use the word "Wound" as it is commonly used. Technically, a "Wound" is a condition only caused by trauma, with all others being "Ulcers". Here, we mean to include all etiologies in the same word.

Chronic wounds have existed for many years, and have been the poor relation of organized medical care for most of that time. In recent years, there has been increasing interest in these problems, because of increased ability to cure many of these patients. Measuring the true medical and social costs of amputation has also been a factor.

As the population ages, with many more obese diabetics and vascular patients, a steady increase in the numbers of wound patients is likely to continue for the foreseeable future.

Current Wound Programs are mostly located in acute care hospitals. These programs are usually joint ventures with for-profit non-clinical management companies who focus on hyperbaric therapy for reimbursement reasons. Also, for reasons that are unclear, a hyperbaric facility fee can only be reimbursed if the unit is functionally part of a hospital department, whether geographically in-house or not. HBO therapy has no inherent risk that would require in-hospital location, in contrast to tests such as Cardiac Stress Testing or Diagnostic Catheterization that are widely available in the community setting.

Our new Ambulatory Surgery Center is specifically designed to meet the needs of wound patients, who are often disabled, elderly or otherwise "mobility-challenged". There is no reason for a hospital to be in control of Wound Healing programs. Hence our unit is free-standing, without a hospital involvement. This has a number of advantages for patients and for payors, both clinically and operationally.

Our medical director, Dr. L. Holmes, is the only physician in our region (and one of only seven in the entire State of Missouri) to hold Board Certification in Hyperbaric Medicine, and also has recently attempted the Certified Wound Specialist examinations of the American Academy of Wound Management (results pending).

We believe that our focused specialist approach to the management of chronic wounds results in a superior experience for the patient and family, with excellent heal rates and excellent patient satisfaction, both of which we measure. It also results in optimal resource consumption by our patients.

Most wounds heal. When they do not, there has to be one or more additional problems. The task of the physician is to make a full and complete diagnosis of these underlying problems, and then to choose the best management approach.

In our program, patients are managed as follows:

First, there is an extensive interview with nursing staff who electronically document all pertinent data regarding both the patient and the wound, including photographs and measurements of the wound. Next, the physician reviews this information, and obtains a further history and physical examination. The findings and suggested plan of care are then discussed with the patient and family.

Second, the necessity for regular and aggressive wound debridement is central to healing. Dead and dying tissue contains chemical and biologic inhibitors of the healing process, resulting in the chronic pattern seen microscopically. Correctly performed debridement converts this chronic wound pattern to the acute pattern needed for healing. 80% of our patients require this procedure, which is completed by the team of MD and RN in the on-site OR.

Third, the prepared wound surface often requires highly specialized and complex dressings. These complex dressings are applied immediately following the debridement, in the presence of patient and family. Because we see patients only once weekly, they require focused instruction in the application of these complex dressings. They may have to change these dressings twice or three times daily. If not carefully instructed by the RN staff, then the expected healing will be slower (more expensive) or not occur at all (still more expensive).

To summarize, all of our patients, at every visit, need a comprehensive nursing assessment, 80% need a debridement, and all patients need careful, detailed education by the RN staff to ensure they can manage their dressing changes. Nonprescription complex dressings (the majority) are provided at no charge to the patient. 20% of our patients also need HBO therapy in addition.

This entire program is solely remunerated by the debridement fee, currently \$416.00. CMS proposes to change this to \$160.00 on January 1, 007, and then to \$100.00 in 2008. This makes the program unsustainable.

In contrast, the acute care hospital receives an outpatient visit fee for every patient, plus a much higher debridement fee based on an outpatient surgery charge, plus a facility fee for HBO treatments.

It should be evident from the above that specialist wound care, when properly performed, is an expensive process in time, staff expertise, materials and equipment. However, inexpert care is even more expensive, because it results in more prolonged courses of treatment, more treatment failures with consequent major surgeries, and possibly less stringent patient selection for expensive and prolonged HBO therapy. All of these elements are readily measurable by paying agencies. Most expensive of all is inexpert care delivered in a high-cost environment such as an acute care hospital.

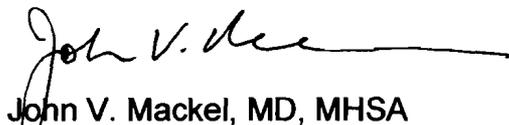
The recent proposals by CMS regarding ASC remuneration of our principal use Code 11042 have caused us great concern. This code is a Dermatology code, since Wound Management has no group of codes that relate specifically to it. As is often the case, when a code is "stretched" to fit a service that is markedly different from the average, it becomes increasingly unsuited to meet the needs. This is the case here. Most dermatologic service billed under this code are of lower complexity, do not need the extensive pre and post debridement assessment and education processes that we provide, do not require the complex wound dressings whose costs are not remunerated at all, and include no HBO therapy whatever.

In terms of acute care hospital services, they are unnecessary for this chronic population, are 100% remunerated as outpatient visits, have additional debridement fees based on outpatient OR levels, and have additional HBO facility fees, all for services that at best are identical.

We believe that as a general principle, CMS ought to remunerate hospitals for what they alone can do, and reduce or eliminate hospital fees for those conditions such as chronic wound management and HBO that are readily and more easily performed in community-based facilities such as our own.

At very least, CMS ought to maintain our principal fee codes at the same level as is currently the case. This will prevent the movement of patients from a more appropriate facility that is less expensive into the acute care hospital environment that is neither.

I would be pleased to discuss these and related issues further with you or with any of your colleagues.



John V. Mackel, MD, MHSA
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