57

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September 12, 2007

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

RE: CMS-1392-P, Medicare Program; Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Mr. Weems:

On behalf of Endocare, Inc., I am writing in response to the Proposed Rule for the CY 2008 Medicare ambulatory surgical center (ASC) payment system, published in the *Federal Register* on August 2, 2007. This proposed regulation was published with the proposed rule updating the Medicare hospital outpatient prospective payment system for CY 2008.

Endocare is a medical device manufacturer focused on the development and distribution of minimally invasive technologies for tissue and tumor ablation treatments in patients diagnosed with cancer. 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 the medical devices necessary to perform cryosurgery, including the *cryoprobes* (identified by HCPCS code C-2618) used in prostate cryosurgery procedures. These surgical procedures (identified by CPT code 55873, *Cryoablate prostate*) are considered by CMS to be device-intensive, and they are the only procedures assigned to APC 0674 within the Medicare Hospital Outpatient Prospective Payment System (OPPS). Our comments in this letter address the payment rate assigned to prostate cryoablation procedures performed in the ASC setting.

Proposed CY 2008 ASC Payment Rate
CPT 55873, Cryoablate Prostate

For CY 2008, CMS proposes to put into place a new payment methodology for covered Ambulatory Surgery Center (ASC) procedures. This new methodology is based on APC relative payment weights established for the Medicare Hospital OPPS. CMS proposes to

calculate ASC payments by multiplying these payment weights by an ASC conversion factor ($41.40), which is 65 percent of the hospital OPPS conversion factor.

Transition Period

CMS also proposes a 4-year transition to the newly-established ASC rates for all services that appear on the CY 2007 ASC list of covered surgical procedures. This listing includes prostate cryoablation procedures, even though these procedures were not regularly billed as ASC procedures prior to CY 2007. As for procedures new to ASC payment for CY 2008 or later, CMS has stated that its policy is to make ASC payments based on the final methodology for the revised payment system, without a transition period.

Our understanding is that CMS, in establishing this transition period, was responding to public comments about the disruptions that might be caused by an abrupt drop in ASC payment rates. In these situations, a transition period would provide ASCs time to adapt to the revised payment rate, and it would help ensure that Medicare beneficiaries (and the physicians who treat them) would continue to have a choice in where these services are provided and paid under Medicare. We also understand that CMS would prefer the transition policy to apply both to procedures with decreased payments under the revised ASC payment system and to procedures with increased payments, so that ASCs could balance their case mix between procedures whose rates increase and procedures whose rates decrease.

We also appreciate that CMS has decided to make use of a special calculation to arrive at payment rates for device-intensive procedures (including prostate cryoablation) during the transition period (i.e., CMS does not subject the device payment portion of the total ASC payment to the transition policy). However, we believe that CMS should refine its transition policy for device-intensive surgical procedures that appear on the CY 2007 ASC list of covered procedures, but were not widely available in (or regularly offered by) ASCs to Medicare patients prior to 2007.

Endocare retained The Moran Company to analyze claims on the Medicare's Physician/Supplier Procedure Summary Master File to determine the extent to which prostate cryoablation procedures were performed in the ASC setting in 2005 and 2006. The Moran Company findings are included as an attachment to this comment letter (Attachment I). The Moran Company found that: **No Medicare claims were paid in 2005 for prostate cryoablation performed in an ASC setting, and only one claim was paid in 2006.**[1] This analysis confirms our understanding from a survey of our physician customers and industry resources that Medicare claims for prostate cryoablation were not paid on a regular basis for services provided in the ASC setting in 2005 or 2006.

[1] Excerpt from The Moran Company analysis, dated August 27, 2007 (see Attachment I):

If a service was not widely available in (or regularly offered by) ASCs, we assert there is not a need for a transition period. In fact, when a payment rate that is lower than the fully-implemented rate is set for procedures not regularly offered in the ASC setting, we believe that this policy will undercut the CMS goal in establishing the transition policy in the first place. The transition policy will only serve to delay adoption of the new procedure in the ASC setting, and it will restrict—rather than broaden—beneficiary and provider choice in selecting a site of care in which to receive a surgical procedure such as cryoablation of the prostate.

Table 1 (below) identifies the proposed CY 2008 ASC payment rates for procedures identified by CPT code 55873, Cryoablate Prostate, during the first year of transition to the revised ASC rates, as well as on a fully-implemented basis. There is a difference of $557 between the two rates. Given our experience in the marketplace, we see this lower payment due to the transition as a significant disincentive to offer this procedure in an ASC setting.

Table 1
Medicare ASC Payment in CY 2008

CPT Code	Description	1st Transition Year Payment	Fully Implemented Payment
55873	Cryoablate prostate	$6,201	$6,758

For these reasons, we propose that the ASC transition payments for prostate cryoablation procedures, identified by CPT 55873, be waived, and that the ASC payment for this procedure in CY 2008 be at the "Fully Implemented Payment" rate.

Impact of Not Waiving the Transition Payment

In our previous hospital OPPS comments, Endocare has emphasized that too low of a Medicare payment rate for prostate cryosurgery in any setting serves as a very real barrier to making this relatively-new treatment available to Medicare beneficiaries, despite its clinical and cost benefits when compared to other treatments[2]. It is also worth noting that Medicare underpayment for prostate cryoablation procedures could lead to more-expensive inpatient admissions or more costly alternative treatments for prostate cancer.

Please see Attachment II in which the most prevalent treatments for prostate cancer are compared in terms of Medicare "per patient episode of care case costs." The costs for several alternatives are up to three times more expensive to the Medicare program and are not clinically superior (see Attachment II for Cost Comparisons between prostate cancer treatments and Attachment III for Clinical Efficacy Comparisons between prostate cancer treatments).

[2] According to the American Urological Association patient website: "...results place cryoablation therapy between radical prostatectomy and radiotherapy in effectiveness....equivalent to other therapies for low-risk disease and possibly superior for moderate-and high-risk prostate cancer." See the American Urological Association patient website at http://urologyhealth.org/adult/index.cfm?cat=09&topic=42.

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In summary, we respectfully offer the following comments and recommendations:

1. CMS should refine its ASC transition policy for device-intensive surgical procedures, like prostate cryoablation (CPT 55873), that appear on the CY 2007 ASC list of covered procedures, but were not widely available in (or offered by) ASCs to Medicare patients prior to 2007. CMS policy should waive ASC transition payments in these situations. **The ASC payment for the prostate cryoablation procedure in CY 2008 should be at the "Fully Implemented Payment" rate, i.e., based on the final methodology for the revised payment system, without a transition period.**

2. Making use of the ASC transition policy in these situations will only serve to delay adoption of the new procedure in the ASC setting, and it will restrict—rather than broaden—beneficiary and provider choice in selecting a site of care in which to receive a surgical procedure.

3. There may be undesirable cost and treatment consequences for the Medicare program and its beneficiaries if the removal of the transition payment is not made to the CY 2008 ASC payment rate proposed for outpatient cryosurgery of the prostate procedures.

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We thank you for allowing us the opportunity to comment on this proposed rule. Should you or members of your staff have any questions or require additional information please do not hesitate to contact me.

Sincerely,

Craig T. Davenport

Craig T. Davenport
Chief Executive Officer
Chairman of the Board

Enclosures:

Attachment I- Moran Company Memorandum
Attachment II- Medicare Payment for Prostate Cancer Treatment: 2007
Attachment III- Clinical Efficacy Comparisons for Prostate Cancer Treatment

ATTACHMENT I

Moran Company Memorandum, August 27, 2007

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

Memorandum August 27, 2007

TO: Lisa Hayden, Galil and Mary Syiek, Endocare

FROM: Mary Jo Braid-Forbes and Marla Kugel, The Moran Company

SUBJECT: ASC volume for 55873

We counted the occurrences of 55873 in the 2005 Medicare Physician/ Supplier Procedure Summary Master File. There were 11 paid units billed with a Place of Service (POS) code of '24' which indicates ASC. However, none of these had a Specialty Code of '49', which would indicate an ASC facility claim. The 11 paid units appear to be claims for physician services where the physician has indicated the ASC is the place of service. There are no corresponding facility claims. It appears that the physician claims had an incorrect place of service code.

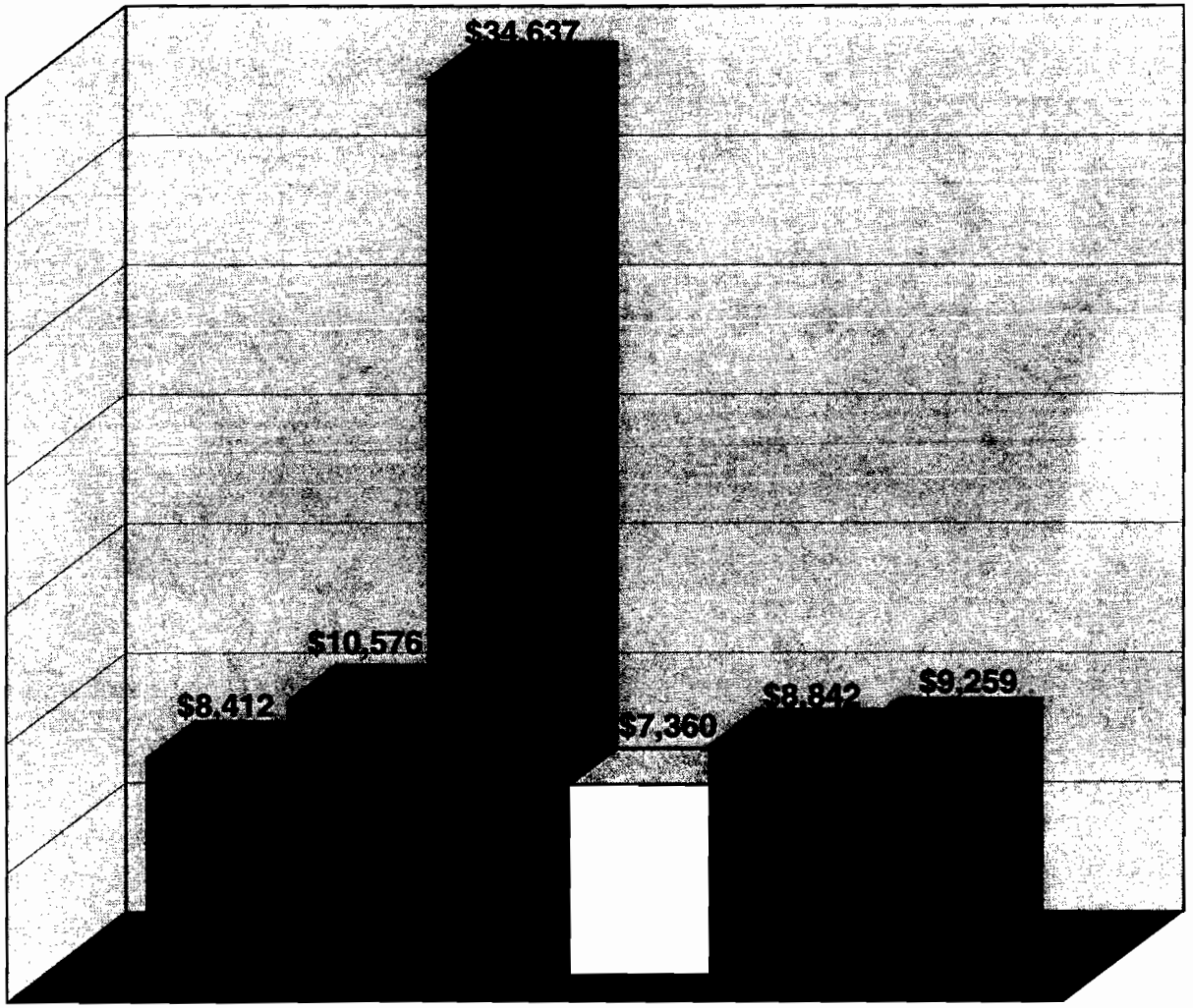
In the 2006 Medicare Physician / Supplier Procedure Summary Master File, there were 14 paid units of 55873 with Place of Service code '24.' Only 1 of these units was billed with Specialty Code '49', meaning it was an ASC facility claim. The other 13 paid units were physician services claims where the physician submitted the ASC as the place of service.

ATTACHMENT II

Medicare Payment for Prostate Cancer Treatment: 2007
Physician and Facility Reimbursement

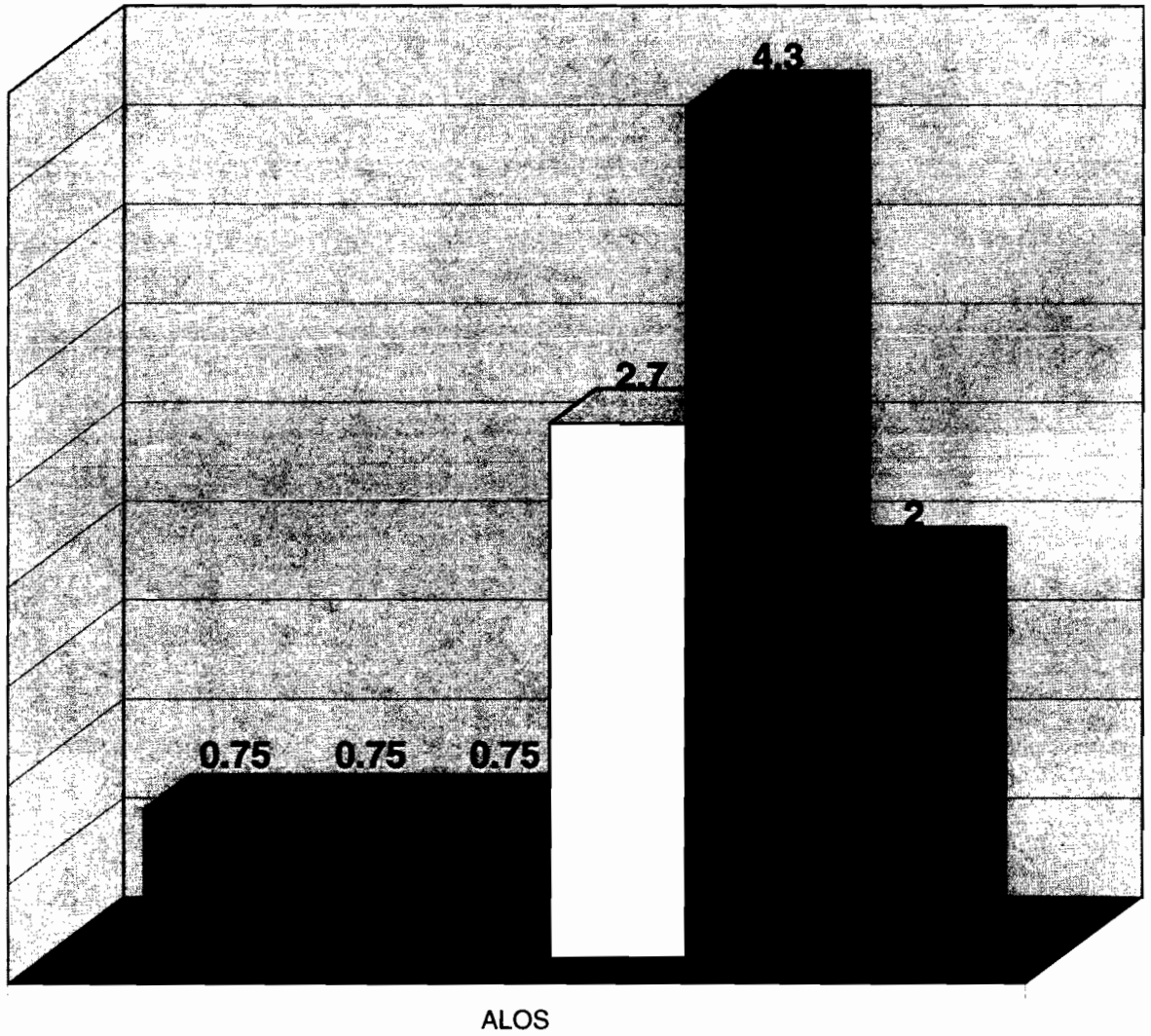
Medicare Payment for Prostate Cancer Treatment: 2007

Physician and Hospital Payments



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

Average Length of Stay



- Cryosurgery
- Brachytherapy
- Brachy w IMRT (X Beam)
- 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 2007 APC payments, DRG payments and CPT 2007 payments. ALOS from 2007 DRG sourcebook. (Ingenix, 2007)

			Physician	Hormone Therapy Prior to Treatment	Hospital	Total	Hormone Therapy After Brachy Treatment	Total II	IMRT Beam After Brachy Treatment	Total Episode of Care
Brachytherapy			**$1,668.25**	**$654.90**	**$8,253.00**	**$10,576.15**	n/a	**$10,576.15**	n/a	**$10,576.15**
Radiologist + Urologist CPT codes	CPT 55875, 77778,77290,77470,76000,76965,76950,77332,77790,77331		Urologist Portion= $729; Radiologist = $731	Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	APC 163 + radiation tx APC codes(651,305,299,272,268,303,304) w/Palladium Seeds (C-1720) @ cost (assume $2625)					
Brachytheray w IMRT (Intensity Modulated RadiationTherapy)			**$1,668.25**	**$654.90**	**$8,253.32**	**$10,576.47**	**$1,964.70**	**$12,541.17**	**$22,095.81**	**$34,636.98**
Radiologist + Urologist	CPT 55879, 76000-26, 76965-26, 7778-26, 77290-26 (could select 77280-->77295), 77262 for Treatment Planning, 77470-26 and 77418 for IMRT and 77301		Urologist portion = $729; Radiologist portion $731	Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	Same as above with additional APC 412 Rad Tx Delivery		Minimum of 9 months therapy; most with additional 12 months; some for years		See Description of Codes in Sample IMRT Costs	
Cryosurgery			**$1,128.59**	**$654.90**	**$6,628**	**$8,411.51**	n/a	**$8,411.51**	n/a	**$8,411.51**
Urologist	CPT 55873			Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	APC 674 (Procedure can be performed IP if patient condition warrants under 334 or 335)					
Rad Prostatectomy			**$1,271.84**	**$654.90**	**$5,433.60**	**$7,360.34**	n/a	**$7,360.34**	n/a	**$7,360.34**
Urologist	CPT 55840 prostatectomy, retropublic radical			Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	DRG 335 w/ 2.7 ALOS					
Rad Pros w CC			**$1,271.84**	**$654.90**	**$6,915.05**	**$8,841.79**	n/a		a	**$8,841.79**
Urologist	CPT 55840 prostatectomy, retropublic radical			Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	DRG 334 reimbursement w/ 4.3 ALOS					
Robotic or "DaVinci" Radical Prostatectomy			**$1,689.47**	**$654.90**	**$6,915.05**	**$9,259.42**	n/a		n/a	**$9,259.42**
Urologist	CPT 55866 laparoscopy surgical prostatectomy, retropublic radical, including nerve sparing			Assume 3 months of TX = J9202 Zoladex ($175.04) or J9217 Lupon ($224.42)+ injection fee 90772 ($18.57) = $193.61 or $242.99 = avg of $218.30 x 3 months= $654.90	DRG 334 reimbursement w/ 2.7 ALOS					

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

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

SAMPLE Brachytherapy and IMRT Therapy Costs

Special Note: The Brachytherapy "Episode of Care" total costs are underrepresented due to omission of many routine pre-treatment planning codes and post-treatment radiological scans.

units	payment	Physician Codes	Description	Physician Payment for IMRT (GLOBAL BILLING)	2007 Physician Payment Brachytherapy	Payment for Brachy WITH IMRT (OP Hospital)	OP Hospital APC	OP Hospital 2007 IMRT or Brachytherapy (rounded)	TOTAL	units	payment
40	$641.60	77418	**IMRT Daily Tx**	$25,664.00			412	$13,456.80		40	$336.42
1	$154.62	77263	Physician Tx Planning	$154.62		$154.62	n/a	$0.00			
1	$396.41	77290	Complex Simulation	$396.41		$75.42	305	$244.17			
1	$452.12	77470	Special Treatment Procedure	$452.12		$101.19	299	$361.67			
1	$1,755.41	77301	IMRT Treatment Plan	$1,755.41		$385.80	310	$848.76			
5	$79.96	77300	Basic Dosimetry	$399.80		$29.94 * 5 = $124.70	304	$483.60		5	$96.72
6	$181.15	77334	Immobilization / Shielding Devices	$1,086.90		6* $60.26 = $361.56	303	$1,085.40		6	$180.90
40	$77.69	76950	Ultrasound localization (tech only)	$3,107.60			268	$2,921.60		40	$73.04
5	$176.22	77427	Physician Weekly Management	$881.10		$881.10	n/a	$0.00			
6	$101.57	77336	Physics Weekly Consultation	$609.42		$609.42	n/a	$0.00			
					Subtotal	**$2,693.81**	**Subtotal**	**$19,402**			

55875	**Perc, needle insertion for brachytherapy**		$729.15	$729.15	163	$2,146.84	
76000-26	Flouroscopic exam		$7.96	$7.96	272	$79.34	
76965	Ultrasound guidance		$65.94	$65.94	268	$129.16	
77290-26	Set Radiation Therapy		$75.42	$75.42	305	$244.17	
77470-26	Special radiation treatment		$101.19	$101.19	299	$361.67	
76950	Ultrasound placement of RT fields		$28.04	$28.04	268	$73.04	
77331	Special Dosimetry		$41.69	$41.69	304	$97.00	
77332	Simple treatment device/Template		$26.53	$26.53	303	$181.00	
77778	Apply interstit rad compl		$541.93	$541.93	651	$1,035.50	
77790	Radiation handling		$50.40	$50.40			
		Subtotal	$1,668.25	$1,668.25	Subtotal	**$4,348**	
					Brachytherapy Seeds	**$3,906**	
TOTAL Physician		**$34,507.38**	**$1,668**	**$4,362**			**$8,253**
TOTAL Physician & Hospital		**$34,507.38** IMRT (global billing)	**$9,922** Brachytherapy in OP Hospital	**$32,017** Brachy & IMRT in OP Hospital			**$27,655**

Assume use of Palladium Seeds ($48.82/seeds x 80 seeds average treatment)

Total Hospital Brachytherapy Treatment

Total Hospital Brachy & IMRT Treatment

Source:Code Selection from Southern California High Volume Hospital Performing Brachytherapy and IMRT. Rates are OPPS Final Rule PPS rate for brachtherapy seeds; CPT and APC rate are 2007 Final Rule Medicare Payments.

Prostate Cancer Treatment	Episode of Care Payment
Cryosurgery	$8,411.51
Brachytherapy	$10,576.15
Brachy w IMRT (X Beam)	$34,636.98
Rad Prostatectomy	$7,360.34
Rad Prostatectomy with cc	$8,841.79
Robotic Davinci Radical Prostatectomy	$9,259.42

Prostate Cancer Treatment	ALOS
Cryosurgery	0.75
Brachytherapy	0.75
Brachy w IMRT (X Beam)	0.75
Rad Prostatectomy	2.7
Rad Prostatectomy with cc	4.3
Robotic Davinci Radical Prostatectomy	2

Professional/Physician Payment Source: Current Procedural Terminology (CPT® 2007 Professional Edition) is Copyright 2006 American Medical Association. All Rights Reserved.

Hospital Inpatient Payment Source: Diagnosis Related Groups (DRG) Numbers and Rates are released by CMS in a Federal Register Notice and are published by Ingenix (DRG Expert A comprehensive guidebook to the DRG classification system). ICD-9-CM: International Classification of Diseases, Ninth Revision, Clinical Modification. ICD Numbers are developed and maintained by the Federal Government and released by the U.S. Department of Health and Human Services. The codes are published on the Centers for Medicare and Medicaid (CMS) website and published by Ingenix (2007 ICD-9-CM Expert for Hospitals - Volumes 1, 2, & 3, is Copyright 2006. All Rights Reserved)Weblink:

http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/

Hospital Outpatient Payment Source (s): Ambulatory Payment Classification (APC) Numbers and Rates are developed and maintained by the Federal Government and published in a Federal Register Notice on November 24, 2006

42 CFR Parts 410, 46 et al.

Medicare Program - Revisions to Hospital Outpatient Prospective Payment System Rates and Calendar Year 2007 Payment Rates - Final Rule

67960 Federal Register/Vol. 71, No. 226/Friday, November 24, 2006/Rules and Regulations. WebLink:

http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1506fc.pdf

HCPCS: Healthcare Common Procedure Coding System Numbers and Rates are developed and maintained by the Federal Government and published on the Centers for Medicare and Medicaid (CMS) Website.

WebLink:

http://www.cms.hhs.gov/HCPCSReleaseCodeSets/25_HCPCS%20Release%20Information.asp#TopOfPage

ATTACHMENT III

Clinical Efficacy Comparisons for Prostate Cancer Treatments

Cryoablation as a primary therapy for localized prostate cancer

Efficacy

Comparison of ALL papers published from 2000 – 2005

Radical Prostatectomy

Cryoablation

Brachytherapy

Beam radiation therapy

IMRT

biochemical disease free survivals (as defined in the individual papers) are compared

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

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Sharkey J, Cantor A, Sole Z, Hutt W, Chovnick SD, Behar RJ, Perez R, Ofheguy J, Rabinowitz R. 103Pd brachytherapy versus radical prostatectomy in patients with clinically localized prostate cancer: a 12-year experience from a single group practice. Brachytherapy. 2005;4(1):34-44. Stokes SH. Comparison of biochemical disease-free survival of patients with localized carcinoma of the prostate undergoing radical prostatectomy, transperineal ultrasound-guided radioactive seed implantation, or definitive external beam irradiation. Ciezki JP, Klein EA, Angermeier K, Uchaker J, Chehade N, Altman A, Mahadevan A, Reddy CA. A retrospective comparison of androgen deprivation (AD) vs. no AD among low-risk and intermediate-risk prostate cancer patients treated with brachytherapy, external beam radiotherapy, or radical prostatectomy. Int J Radiat Oncol Biol Phys. 2004 Dec 1;60(5):1347-50. Kwok Y, DiBiase SJ, Amin PP, Naslund M, Sklar G, Jacobs SC. 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Risk-group stratification in patients undergoing permanent (125)I prostate brachytherapy as monotherapy. Int J Radiat Oncol Biol Phys. 2002 Jul 1;53(3):588-94. Merrick GS, Butler WM, Galbreath RW, Utt JH. Five-year biochemical outcome following permanent interstitial brachytherapy for clinical T1-T3 prostate cancer. Int J Radiat Oncol Biol Phys. 2001 Sep 1;51(1):41-8. Livsey JE, Cowan RA, Wylie JP, Swindell R, Read G, Khoo VS, Logue JP. Hypofractionated conformal radiotherapy in carcinoma of the prostate: five-year outcome analysis. Int J Radiat Oncol Biol Phys. 2003 Dec 1;57(5):1254-9. Ellis RJ, Vertocnik A, Sodee B, Zhou H, Kim L, Young B, Fu P, Colasso V, Spirnak JP, Dmochowski RR, Resnick MI. Combination conformal radiotherapy and radioimmunoguided transperineal 103Pd implantation for patients with intermediate and unfavorable risk prostate adenocarcinoma. Brachytherapy. 2003;2(4):215-22. Stock RG, Cesaretti JA, Kollmeier MA, Stone NN. 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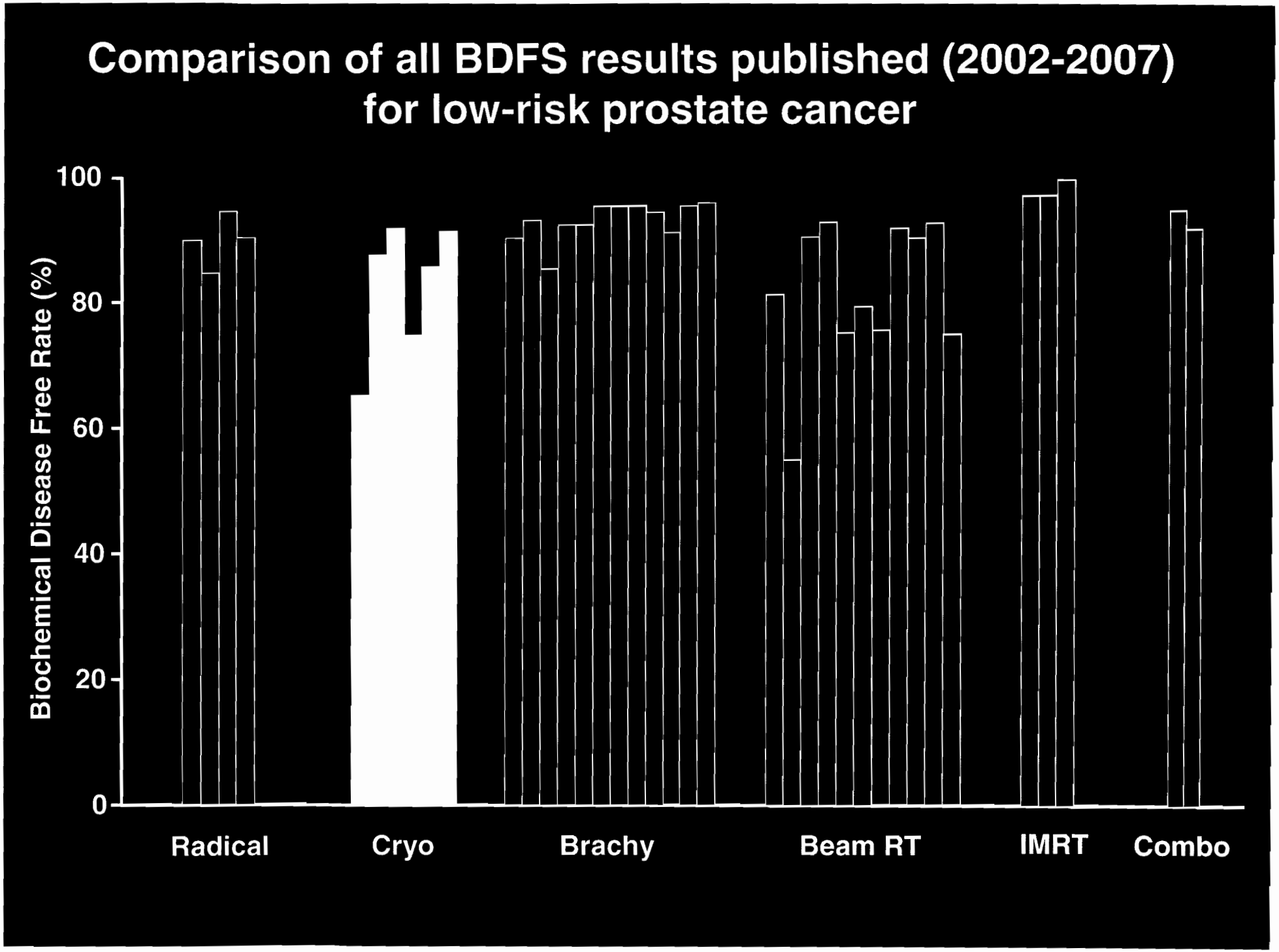
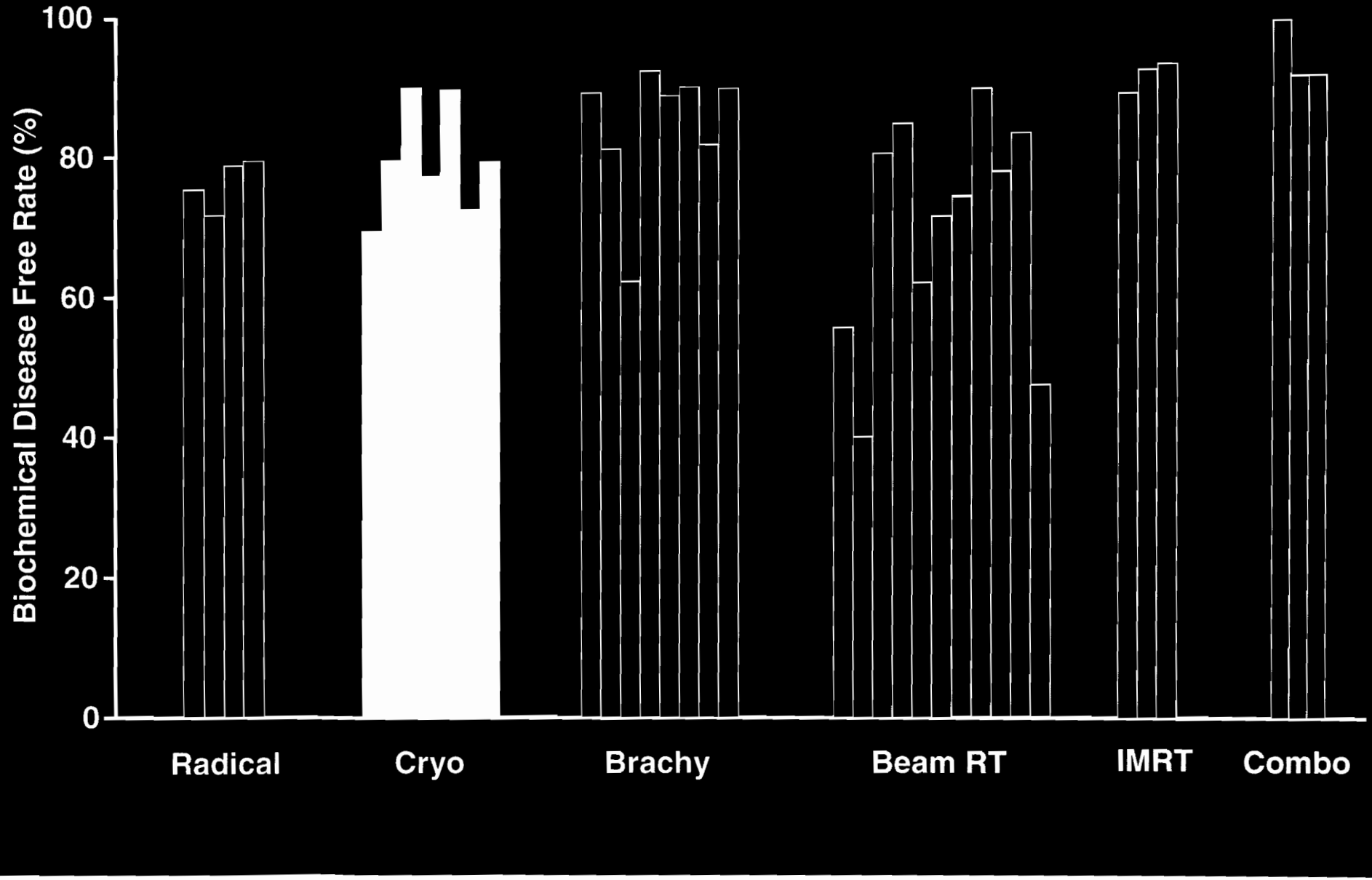
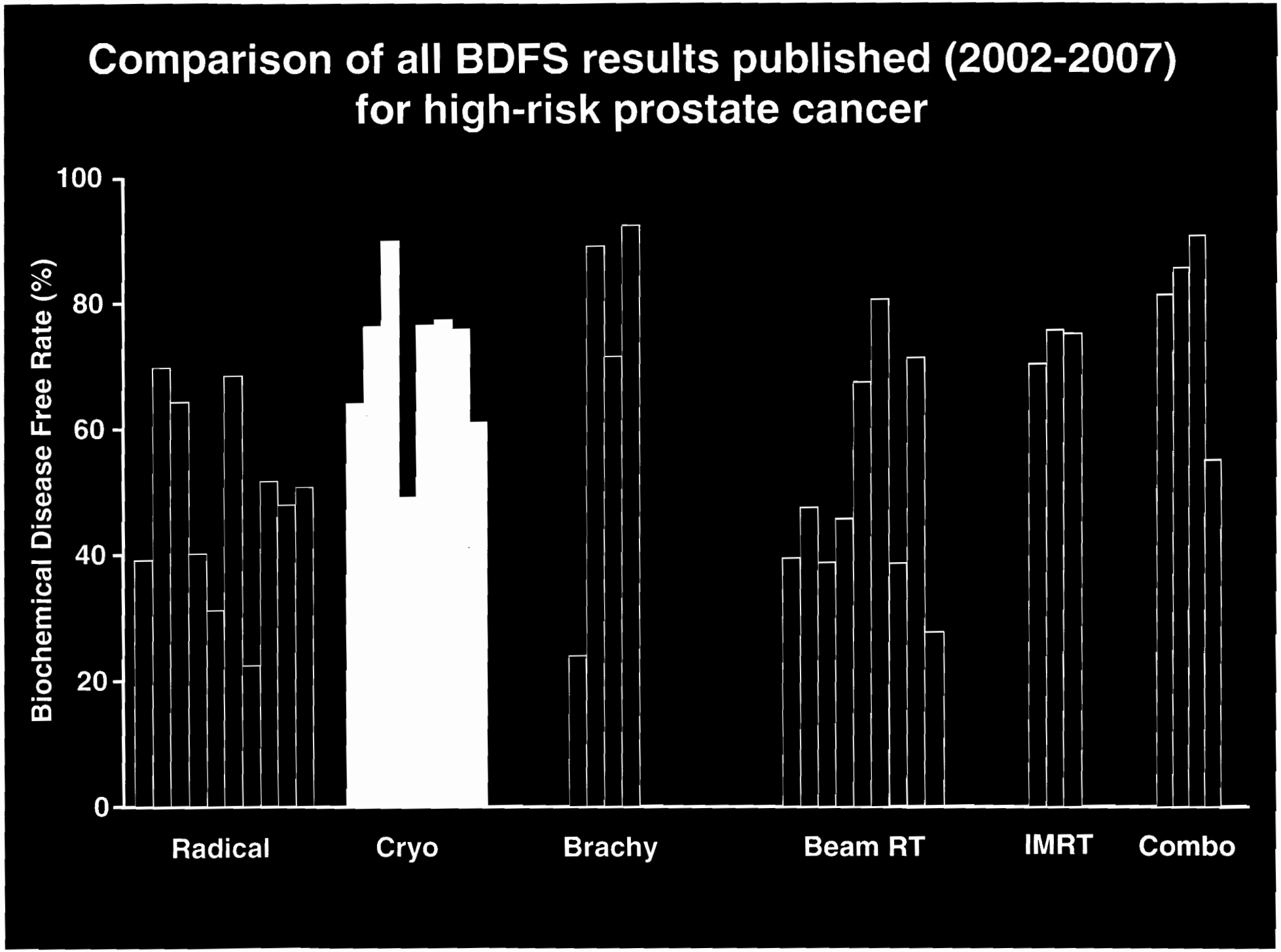
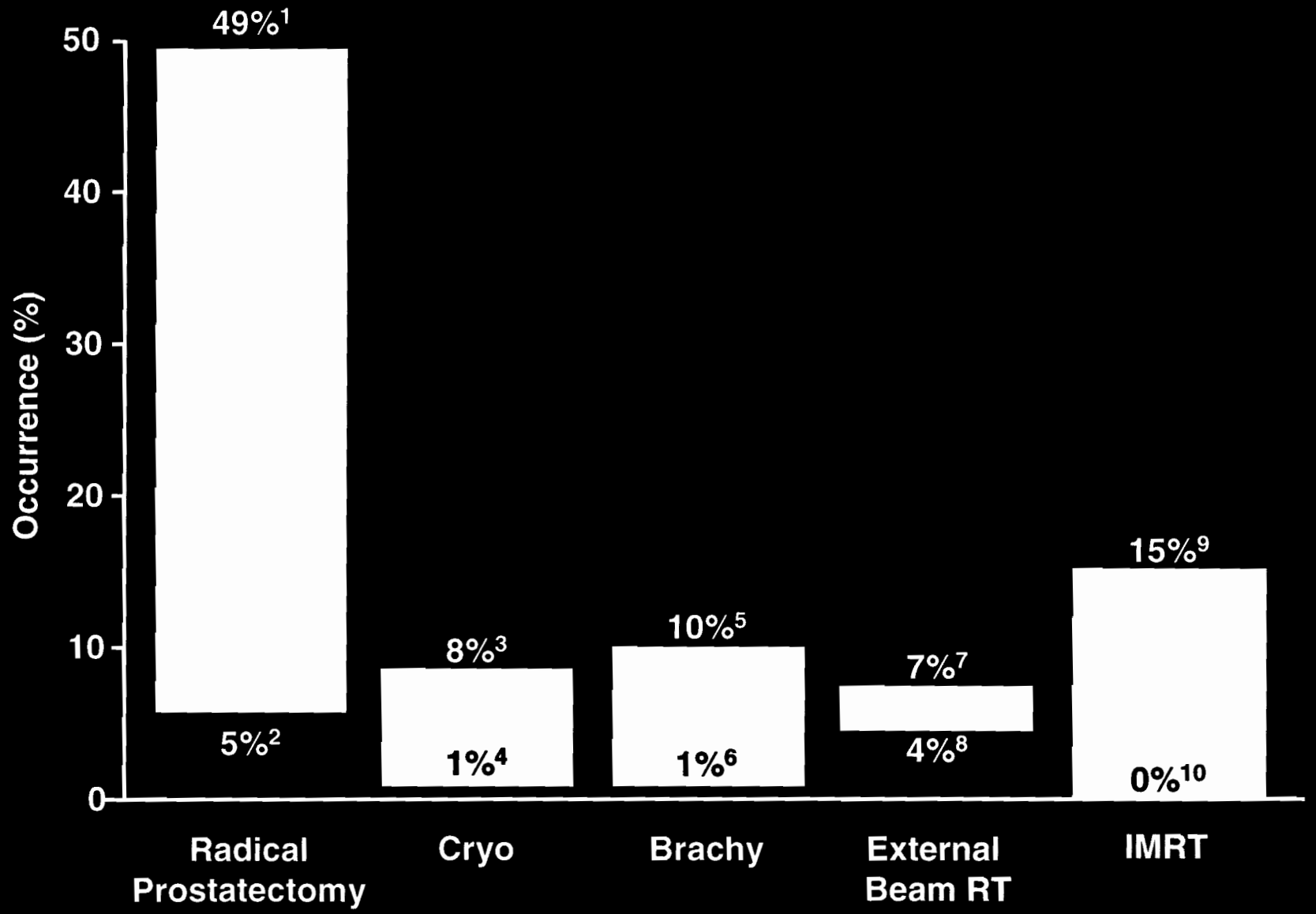

Comparison of all BDFS results published (2002-2007)
for low-risk prostate cancer
Biochemical Disease Free Rate (%)
100
80
60
40
20
0
Radical
Cryo
Brachy
Beam RT
IMRT
Combo

Comparison of all BDFS results published (2002-2007) for moderate-risk prostate cancer




Comparison of all BDFS results published (2002-2007)
for high-risk prostate cancer
Biochemical Disease Free Rate (%)
100
80
60
40
20
0
Radical
Cryo
Brachy
Beam RT
IMRT
Combo

Range of published incontinence rates (since 2000)



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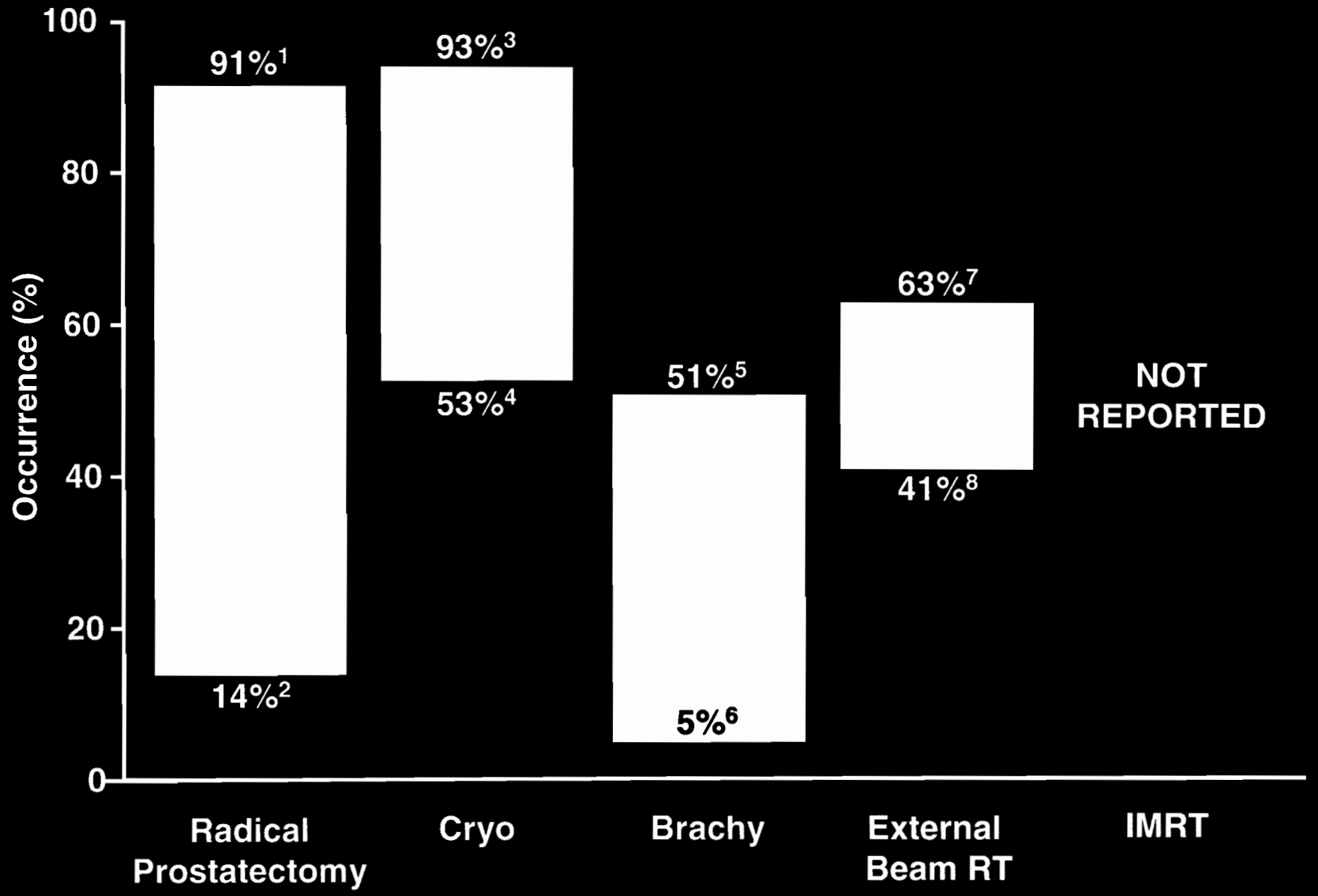
Range of published impotence rates (since 2000)



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Rectal Morbidity

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

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

Prospective trial of cryosurgical ablation of the prostate: five-year results.

Donnelly BJ, et al Urology. 2002 60(4): 645-9

Prospective non-randomized phase II trial with 76 patients

- 98.6% negative biopsy rate
- Biochemical disease free rate @ 5 years (PSA < 1.0 ng/ml):
  - 75 % low risk disease (n=13)
  - 89 % moderate risk disease (n=23)
  - 76 % high risk disease (n=40)
- Incontinence 1.3 %
- Fistula: 0 %
- Potency: intercourse with no assistance: 13%
  intercourse with pharmaceutical or device assistance: 34%

Targeted cryoablation of the prostate: 7-year outcomes in the primary treatment of prostate cancer.

Bahn DK, et al Urology. 2002 60(2 supp 1): 3-11

Retrospective analysis of 590 patients

- 87% negative biopsy rate
- Biochemical disease free rate @ 5 years (ASTRO):
  - 92 % low risk disease (n=94)
  - 89 % moderate risk disease (n=179)
  - 89 % high risk disease (n=317)
- Incontinence 4.3 %
- Fistula: <0.4 %
- Potency: 5.1%

Cryoablation of the Prostate.

Prepelica, Katz, et al Cancer. In press 2005 e-published March 05

High risk (PSA > 10 or Gl > 7) series of 65 patients

- 87.5% negative biopsy rate
- Biochemical disease free rate @ 6 years (ASTRO):
  - 83.3 %
- 100 % survival
- Incontinence 3.1 %
- Fistula: 0 %
- Potency: Not reported

9-year accrued clinical experience with targeted cryoablation in the treatment of clinically localized prosatate cancer.

Chinn et al, 15th International Prostate Cancer Update, Vail, CO, Feb 9-13, 2005

Retrospective review of 292 patients, 49 had 9 year f/u

- 93.8 % negative biopsy rate
- Disease free rate @ 9 years (PSA < 0.5 ng/ml & neg. Bx.):
  - 88 % low risk disease (n=17)
  - 74 % moderate risk disease (n=19)
  - 50 % high risk disease (n=12)
- Morbidities not reported

Cryoablation of the prostate: 10 year experience with 248 Cases

Derrick FC, et al 69th Annual Meeting of the South East Section of the AUA, Charleston SC, March 3-5, 2005

Retrospective analysis of 249 patients, 88 with 10 year f/u

- negative biopsy rate not reported
- Biochemical disease free rate @ 10 years
  - 74 % PSA < 1.0 ng/ml
  - 85 % PSA < 2.0 ng/ml
- Incontinence 10 %
- Fistula: < 0.5 %
- Potency: return of potency 10%
  some return of normal function: 50%

58

BIO

September 10, 2007

BY ELECTRONIC FILING AND OVERNIGHT MAIL

Hon. Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4–26–05,
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates (CMS-1392-P)

Dear Ms. Norwalk:

Bio-Tissue, Inc. ("Bio-Tissue") is pleased to submit the following comments to the above referenced proposed rule (the "Proposed Rule") appearing in the Federal Register at 72 Fed. Reg. 42628 (August 2, 2007).

Bio-Tissue is a bio-tech company specializing in the procurement and processing of high quality amnion-based tissue and cell products that provide healing and regeneration of ocular surface tissue including the cornea and the conjunctiva. Bio-Tissue's current products, AMNIOGRAFT® and PROKERA™, use cryopreserved human amniotic membrane tissue to treat ocular surface disease and damage, such as corneal defects/ulcers, tumors/scars, viral infections, leaking glaucoma blebs, chemical burns, high-risk corneal transplants, conjunctivochalasis, and many other conditions. Our comments to the Proposed Rule are limited to the payment status indicator assigned to amniotic membrane tissue.

Addendum B of the Proposed Rule will assign an "N" status indicator to V2790, the HCPCS Level II code assigned to human amniotic membrane tissue. Accordingly, payment of V2790 is bundled with its related procedure, CPT 65780, amniotic membrane transplant. For reasons discussed below, the bundling of V2790 results in a payment rate for CPT 65780 that does not cover the cost of the tissue supplied in the procedure. In order to continue to make this innovative tissue and treatment available, the payment rate must accurately reflect the cost of obtaining, processing and distributing the tissue, as well as performing the procedure.

We urge CMS to change the status indicator of V2790 in order to permit separate payment of amniotic membrane tissue. Alternatively, we ask that CMS create a separate APC for amniotic membrane transplantation that accurately reflects the cost of amniotic membrane tissue.

Preserved Human Amniotic Membrane Tissue

Amniotic membrane is the innermost lining of the placenta. The tissue is carefully processed and preserved using a specialized cryopreservation method. Since 2001, amniotic membrane has been recognized by the FDA for use in ocular surface wound repair and wound healing. The clinical efficacy of amniotic membrane transplantation for ocular surface reconstruction is well established in peer-reviewed scientific journals.

After transplantation on the ocular surface, cryopreserved amniotic membrane provides physical protection while simultaneously delivering therapeutic biologic actions that aid in ocular surface wound repair and wound healing. An ocular surface protected by amniotic membrane that has been properly processed and preserved is receiving FDA confirmed biologic actions which reduce inflammation, minimize scarring, facilitate epithelial wound healing, and aid in the migration of limbal stem cells.

Amniotic membrane provides a treatment option otherwise unavailable to ophthalmologist. It serves as a viable tissue replacement for the conjunctival for surgeries, like glaucoma surgery, in which the patient's conjunctiva is too brittle to properly close after surgery and there is no available tissue for an autograft.

Amniotic membrane, when properly processed and preserved, also acts as a therapeutic graft to help the eye's natural healing take place. The tissue's biologic actions are especially useful in indications like non-healing corneal defects in which amniotic membrane can be used to aid in corneal healing before the defect progresses and the patient needs a corneal transplant. Similarly, patients that have had corneal transplants and run the risk of rejecting the transplant can be treated with amniotic membrane to help save the transplanted cornea. Use of the tissue to avoid a corneal transplant or avoid a rejection of corneal transplant offer a significant treatment option to patients and dramatically decreases costs associated with additional corneal transplants.

Current Coding and Status Indicator

As recently as 2004 CMS added CPT 65780 to the list of procedures covered in an outpatient hospital setting. In a final rule issued November 24, 2006, CMS published its calendar year ("CY") 2007 payment rates for the hospital outpatient prospective payment system ("OPPS"). The final rule set the OPPS payment rate for CPT 65780 at $2,352.42 and bundled V2790 with CPT 65780. This represents the total Medicare payment for the transplantation procedure and the amniotic membrane tissue. In the Proposed Rule CMS again proposes to bundle V2790 with CPT 65780 by assigning an "N" status indicator to V2790. The Proposed Rule sets the CY 2008 OPPS payment rate for CPT 65780 at $2,438.93.

In order to determine the payment rate for CPT 65780, CMS assigned CPT 65780 to APC 244 "Corneal Transplant". The following seven CPT codes are grouped with APC 244:

HCPCS / CPT	Payment Rate	Single Frequency	Total Frequency	"True" Median Cost
65710 Corneal transplant	$2,438.93	608	933	$2,539.20
65730 Corneal transplant	$2,438.93	2033	3534	$2,433.19
65750 Corneal transplant	$2,438.93	170	429	$2,318.28

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65755 Corneal transplant	$2,438.93	1799	2848	$2,420.71
65780 Ocular surface reconstruction; amniotic membrane transplantation	$2,438.93	220	651	$2,125.02
65781 Ocular surface reconstruction; limbal stem cell allograft	$2,438.93	8	26	$1,899.50
65782 Ocular surface reconstruction; limbal conjunctival autograft	$2,438.93	12	30	$1,849.45

As the chart above indicates the same payment rate applies to each CPT code in APC 244. All procedures in APC 244 involve the tissue on the front of the eye and require a source tissue to complete the procedure. However, ***the source tissue is not bundled into the payment rate for every CPT code in APC 244, only amniotic membrane tissue.***

CPT codes 65710, 65730, 65750 and 65755 can bill for corneal tissue with a claim for HCPCS Code V2785 which has a special designation for separate payment in the OPPS environment. CPT 65781 can either bill for the corneal tissue using HCPCS Supply Code V2785 or bill a separate procedure for harvesting the tissue (CPT 68371 – Harvesting conjunctival allograft, living donor). CPT 65782 does not require a separate payment for tissue because the transplanted tissue is an autograft which would be taken from the same and there is no added cost of a tissue supplied by a third party.

Under OPPS, there are two HCPCS codes that are used to report services related to corneal tissue and amniotic membrane transplants:

Code Description	Status Indicator	Payment
V2785 corneal tissue, processing	"F"	Corneal tissue acquisition; paid at reasonable cost
V2790 amniotic membrane for surgical reconstruction	"N"	Items and Services Packaged into the APC rates; no separate payment

As required by status indicator "F", hospitals are paid separately (in addition to the APC rate) for costs associated with corneal tissue. Conversely, hospitals are not separately reimbursed for costs associated with processing amniotic membrane tissue for transplants.

We believe that because amniotic membrane transplant procedures are relatively new and because the costs for amniotic membrane tissue can vary widely (just as the costs vary widely for corneal tissue), that CMS may not have considered the inconsistency of assigning an "N" status indicator to HCPCS code V2790 when the bundled procedure is included in an APC where the vast majority of procedures are unbundled from their associated tissue. The cost of amniotic membrane tissue will never be accurately reflected in the APC payment rate because of the relatively low frequency of amniotic membrane transplant when compared to corneal transplant and the wide variance in cost of the tissue. The variance in cost is due to the necessity of offering different sized tissue to accommodate various treatments and patient requirements. Larger grafts result in fewer tissues from each placenta and, therefore, increase the cost of procuring the tissue.

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Maintaining the current "N" status indicator creates an improper financial incentive for hospitals to promote treatment using one type of "tissue" over another based on financial considerations rather than clinical indicators and efficacy. Hospitals and ambulatory surgery centers (ASCs) are invoiced and must pay for the costs associated with retrieving, processing and storing amniotic membrane tissue just as they pay for the costs associated with processing corneal tissue.

Bio-Tissue estimates that the processing fees (costs) associated with amniotic membrane tissue can range from approximately $600 to over a $1,000, depending on the size of the graft. These costs reflect the fact that processing amniotic membrane tissue for use on the ocular surface is a multi-step process that takes place over several months. Cryopreservation of human amniotic membrane tissue requires the following FDA reviewed processing steps:

1. Procurement of the tissue after scheduled cesarean section birth;
2. Serologically test the mother at the time of birth for transferable diseases;
3. Storage of the placenta in a -80° freezer until donor testing is complete and tissue is released for processing;
4. Aseptically dissect the amniotic membrane from the placenta;
5. Place tissue on carrier paper;
6. Manually cut the tissue on the carrier paper into sizes appropriate for use on ocular surfaces;
7. Package pre-cut tissue in validated storage medium and seal pouch;
8. Sterilize the outside of the validated inner pouch and place in the validated outer peel pouch;
9. Test cultures are taken from randomly selected pieces from each placenta processed to insure there was no contamination in processing and packaging;
10. Store tissue in -80° freezer until it is released for distribution; and
11. Ship tissue on dry ice via overnight carrier in validated shipping container to insure tissue integrity.

These steps add significant processing costs that are not reflected in the payment rate for the procedure. As noted in the first table above, the median cost of amniotic membrane transplantation is approximately the same as corneal transplant. Both procedures require similar preparation of the ocular surface, similar instruments and approximately the same amount of time in the procedure room and for patient recovery. Despite these similarities, corneal tissue is paid separately from a corneal transplant procedure while the payment rate remains the same as amniotic membrane transplantation.

Failure of Hospitals to Report Claims

Despite instruction that hospitals should report claims for bundled tissue, hospitals do not consistently report use of amniotic membrane tissue when used in a transplant procedure. CPT 65780 is the code associated with "ocular surface reconstruction; amniotic membrane transplantation." By definition amniotic membrane tissue is used in the procedure. Yet, claims data consistently shows that V2790 is dramatically under reported. The following claims are reported in the OPPS claims file:

OPPS Claim File	**Claims for CPT 65780**	**Claims for V2790**

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2004	437	50
2005	605	50
2006 (includes only claims filed by December 31, 2006)	646	91

Under reporting of the use of amniotic membrane tissue further aggravates the payment disparity by invalidating the methodology used to determine the tissue's median cost, as well as the overall payment rate for APC 244. The cost of procuring, processing, storing, and distributing amniotic membrane tissue is not reflected in the payment rate for CPT 65780.

We have reviewed claims data provided to us by The Moran Company for both CPT 65780 and V2790 during 2005 and 2006. The claims data reveals that in the vast majority of cases hospitals that purchased amniotic membrane tissue from Bio-Tissue did not submitted a claim for V2790 although they filed multiple claims for ocular surface reconstruction using amniotic membrane tissue. We have both the invoices and proof of payment for the tissue despite the fact that the hospital has not submitted a claim for the tissue to the Medicare program. In 2006 claims filed for human amniotic membrane tissue provided in the hospital outpatient setting equaled just over 14% of the claims filed for amniotic membrane transplant during the same time and in the same clinical location.

We believe that hospitals often fail to file a claim for V2790 because they are aware that the tissue is not separately payable. In some cases, we believe that coding personnel in the hospital consider it too much extra work to retrieve the invoice for the tissue from the accounts payable department in order to submit the claim. Whatever the cause, it is clear from the claims data that the cost of V2790 is not accurately attributed to the bundled payment rate for CPT 65780 under APC 244.

In order to correct payment of V2790 and continue to make amniotic tissue available to patients, we urge CMS to change the status indicator of V2790 in order to permit separate payment of amniotic membrane tissue. Alternatively, we ask that CMS create a separate APC for amniotic membrane transplantation that accurately reflects the cost of amniotic membrane tissue.

We sincerely appreciate the opportunity to submit these comments and recommendations. We are available and would be pleased to discuss these issues further with CMS.

Sincerely,

Amy Tseng

Amy Tseng, MBA
President

cc: Dana Burley, CMS
Pam West, CMS
Cherie McNett, Director of Health Policy, American Academy of Ophthalmology
Gail Daubert, Esq.
Paul Pitts, Esq.

The leader in ocular surface tissue therapies.

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59

EMORY-ADVENTIST HOSPITAL AT SMYRNA
OPERATED BY ADVENTIST HEALTH SYSTEM AS A JOINT VENTURE WITH EMORY HEALTHCARE

9-7-07

COMMENTS TO PROPOSED CHANGES FOR IMPLANTATION OF SPINAL NEUROSTIMULATORS

This letter will serve to highlight our viewpoint on CMS's proposal to essentially reduce reimbursement of rechargeable spinal neurostimulators by grouping them under the same APC as non-rechargeable neurostimulators.

We believe that this plan has not been adequately analyzed and thought out, and that the enactment of such a plan, would produce a number of unwelcome consequences that may not be expected.

The advent of rechargeable spinal neurostimulators has been a great asset to patients who require this technology due to persistent, chronic pain that does not respond to other treatment options. These patients can now have rechargeable technology which greatly increases the lifespan of the devices they have implanted.
The benefit to the patient is obvious and has resulted in the fact that most neurostimulators now implanted are of the rechargeable type. In fact, at our facility, non-rechargeable devices have almost been discontinued. We strive to provide the most appropriate treatment that our patient requires, and rechargeable devices definitely fill that niche.

By grouping these two types of devices under the same APC payment class, CMS will unwittingly create an incentive for facilities to abandon the newer, better, and more appropriate technologies in favor of the older, but more financially attractive option of the non-rechargeable neurostimulator. While a non-rechargeable unit may be indicated in some cases, the rechargeable device is the technology of choice for many others. A non-rechargeable unit currently costs our facility $11,023.00, while the rechargeable units cost $18,611.20 and $19,009.20 respectively. This is a minimum difference of $7588.20 between the two units. In a small facility of our size, this represents the financial feasibility of using the preferred technology. When the reimbursement of the new technology is reduced to this point, we would probably have to go with a more economical option with technological limitations.

We urge CMS to adopt a policy of grouping these neurostimulators into their own appropriate APC by creating a new APC group specifically for rechargeable spinal neurostimulators. This is the only way to obtain appropriate reimbursement for rechargeable units. This APC should be based on the actual facility cost of a rechargeable device so that facilities can continue to use the new beneficial technology.

Please do not limit our ability to continue to provide our patients with the best and most appropriate technology available and indicated in each case.

Sincerely,

Carol Hazen
Vice President of Finance

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COLLEGE OF MEDICINE, TULSA
DEPARTMENT OF GYNECOLOGY AND OBSTETRICS

September 11, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

As a practicing gynecologist I am pleased that the CMS has offered the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients. We believe that this technology has tremendous potential to improve health outcomes and the uterine fibroid application is only the first of many to come.

I welcome CMS' proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

1) Treatment objective is non-invasive tumor destruction
2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment
5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

However the payment rate for this procedure continues to be **far below** the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient centers to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 which more accurately reflects the clinical and economic resources utilized.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

J. Clark Bundren, M.D.
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Dir. Reproductive Endocrinology & Infertility

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61

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VIA Electronic Submission to http://www.cms.hhs.gov/eRulemaking

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

RE: CMS-1392-P: Proposed 2008 Changes to the Hospital Outpatient Payment System
Comments related to packaging of Intravascular Ultrasound

Dear Administrator:

I am an interventional cardiologist practicing at Rush University Medical Center for the past 18 years. I appreciate the opportunity to submit comments on the proposed changes to the Medicare Outpatient Payment System. My comments focus on CMS's proposal to package the costs of Intravascular Ultrasound (IVUS) and Functional Measurement (FM) into the payment rate for related procedures. Specifically, I disagree with CMS's proposal for the following reasons:

1. *Packaging of IVUS and/or FM would negatively affect my patients.* There are two reasons for this. First, packaging the cost of IVUS would mean that hospitals would have a financial incentive to reduce or discourage its use, despite its valuable clinical utility for certain patients and would ultimately inhibit access. Second, IVUS and FM allow a more definitive diagnosis and more accurate management of a patient's cardiovascular disease which reduces waste and future complications associated with interventions that could have been avoided with IVUS or FM. These procedures are indicated where angiography alone produces ambiguity with respect to the degree of narrowing, appropriate stent placement, and even the need for interventions in the first place (including bypass surgery). Maintaining separate payment for IVUS and FM will allow physicians to determine whether to employ these technologies only where clinically appropriate.

2. *IVUS (and FM) are low volume procedures with significant costs that are only performed with other cardiac cath procedures about 10% of the time.* The cost per-procedure (including time, staff, equipment/supplies) is about $2,000. Therefore, hospitals that do not utilize these technologies will be rewarded while hospitals that do will be forced to carry a disproportionate financial burden with respect to the use and

development of these procedures. This seems inconsistent with notions of encouraging quality healthcare services through payment policies.

3. *The proposed payment rates do not accurately reflect the costs associated with performing IVUS and/or FM.* CMS is only proposing to increase reimbursement for transcatheter placement of intracoronary stents by $300 and diagnostic cardiac catheterization by only $250; however, based on my experience, the actual total cost of performing IVUS is much greater (approximately $2,000 in many cases). Furthermore, CMS is proposing to decrease reimbursement for coronary angioplasty by $700. CMS should explain how it calculated these proposed package payment rates which appear inadequate to cover the cost of performing IVUS and FM in the majority of cases. This further underscores the points discussed above.

In conclusion, I believe that the routine clinical use of IVUS and FM should be encouraged rather than discouraged given how valuable they are to the therapeutic management of many patients' coronary artery disease. Therefore, to facilitate adoption and maintain patient access to this technology, CMS should continue to pay for IVUS and FM separately.

Please do not hesitate to contact me with any questions regarding any of these comments.

Yours sincerely,

Gary L Schaer MD

cc: Dr. William Rogers (Director, CMS Physicians' Regulatory Issues Team) (William.Rogers@cms.hhs.gov)

Dr. Carol Bazell (Director, CMS Division of Hospital Outpatient Care (carol.bazell@cms.hhs.gov)

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September 14, 2007

Kerry Weems
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P – Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Administrator Weems:

FASA is pleased to submit these comments on the proposed rule implementing the Medicare payment system for ambulatory surgical center (ASC) services for calendar year 2008. FASA is the nation's largest ASC organization, representing more than 2,200 ASCs, the professionals who provide care in such centers and the patients who receive high quality and cost-effective ASC services. FASA's members include all types of ASCs – small and large; for profit and non-profit; single specialty and multi-specialty; physician-owned, joint ventures between hospitals and physicians, joint ventures between physicians and management companies, and hospital-owned surgery centers.

We begin by commending and, on behalf of all of our members, thanking CMS for the careful consideration and tremendous effort that went into revising the ASC payment system over the past two years. FASA continues to support the agency's decision to base ASC payments on the ambulatory payment classification (APC) groups and relative weights established under the hospital outpatient prospective payment system (OPPS). Moreover, we appreciate that CMS has significantly modernized its view of what is payable in the ASC setting by adopting an "exclusionary" approach to determining what surgical procedures will be excluded from ASC payment for patient safety reasons or because they require an overnight stay, as opposed to the affirmative – and perpetually outdated – "ASC list" of covered procedures. We believe this new approach will promote more timely access for Medicare beneficiaries to advances in ambulatory surgical care.

We also are grateful that the final rule for the revised ASC payment system[1] included a number of important changes from last year's proposed rule that will expand the scope of covered ASC services and more closely align ASC and hospital outpatient department (HOPD) reimbursement. Especially noteworthy in this regard is the decision to adopt the same approach to covering ancillary services (like radiology services, implantable devices and drugs) in ASCs and HOPDs. We believe these changes will help physicians and patients in making direct comparisons on the basis of quality and price in choosing the most appropriate clinical site for their surgical needs. As a competitive alternative to hospitals, ASCs offer a number of benefits to consumers, including improved technology, a non-institutional, friendly environment, and more convenient locations, shorter wait times, and lower coinsurance than HOPDs.

That said, we also believe the revised ASC payment system falls short of promoting the kind of access and transparency that is needed to achieve the full competitive benefits of ASCs. In particular, we continue to have the following concerns with the revised ASC payment system:

- To better promote full transparency across sites of service, we believe it would be preferable to base payments to ASCs on a flat percentage of the payment for the same services established under the OPPS. Maintaining two separate payment systems that are sometimes consistent – and sometimes not – will impede Medicare beneficiaries' ability to understand their real costs in alternative settings and their ability to make direct comparisons between hospitals and ASCs. As President Bush articulated last year at a White House event on promoting transparency in the health care sector, Medicare beneficiaries need to be able to make such "apples to apples" comparisons.[2]

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[1] *Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008* (CMS-1517-F), 72 Fed. Reg. 42469 (Aug. 2, 2007).

[2] The following is an excerpt from the President's February 16, 2006 discussion at that event with Jerry Henderson, then the Administrator of the SurgiCenter of Baltimore and a FASA board member:

> THE PRESIDENT: Very good. And tell us, you know, the transparency issue – we had a little visit ahead of time, since it's not the first time I've seen her; she gave me a little hint about what she was going to talk about. Go ahead and share with people – small clinic, relatively small clinic, big hospital guy, small clinic person.
>
> MS. HENDERSON: I think the ambulatory surgery centers offer a good, low cost alternative for outpatient surgery for patients. And what we do, I think we do a very good job of offering transparency for the patients because we think it's important that they have the information that they need, both for quality, safety and price. And so for our patients we offer information on our website about our payment policies, we give them a brochure about our patient payment policies. Then we also call the insurance companies and make sure that they have their coverage and how much that insurance company is going to pay. And then we call our patients and we tell them, okay, your insurance is going to cover this amount and you're going to be responsible for this other amount. But it's really difficult for patients to make those comparisons on price because the payment systems are outdated and ambulatory surgery centers are not paid on the same type of a payment system as the hospital. And it would be a lot more transparent for the patient if they had a system that was paid on the same type of a system.
>
> THE PRESIDENT: Yes, apples to apples.
>
> MS. HENDERSON: Apples to apples, and then they could make those comparisons. We give them information, but I'm not sure that they can get that same information across the health care system.

- Paying ASCs 65 percent of OPPS rates results in reimbursement that is simply too low for far too many ASCs, and will likely force the migration of many procedures to the more expensive hospital setting and create access barriers and higher coinsurance obligations for Medicare beneficiaries. We strongly urge CMS to reconsider how the new payment system is likely to affect a shift in procedures between ASCs, HOPDs and physician offices, and whether such migration supports a higher ASC conversion factor that actually will promote beneficiary access to ASC services, rather than reduce it. Absent additional adjustments to the proposed payment rates, we are concerned that certain individual procedures or classes of surgical services will not be viable in the ASC setting.

- We are disappointed that the revised payment system caps payment to ASCs for procedures that are performed more than 50 percent of the time in physician offices at the lower physician fee schedule rates. Such an arbitrary cap is inappropriate, particularly since it is not applicable to identical procedures performed in HOPDs.

- We disagree with CMS's decision to use the CPI-U, rather than the hospital market basket index, to determine annual inflation updates for ASCs. ASCs are affected by the same inflationary costs as hospitals, such as hiring nurses and purchasing medical devices, which are unrelated to general consumer price increases.

- CMS did not go far enough in eliminating the use of specific ASC list criteria that have proven to be barriers to Medicare coverage of the full scope of services that ASCs are capable of safely performing. CMS should use only safety and the lack of need for an overnight stay as the criteria to determine what procedures are reimbursable in the ASC setting. Any other criteria risk becoming quickly outdated with advances in medical technology.

- Even more troubling is the fact that after establishing specific safety criteria, CMS then excludes procedures from payment without providing any information to the public regarding which criteria apply in any given case.[3] Without knowing the specific reasons why procedures are excluded from ASC payment, the affected public is denied a meaningful opportunity to comment on the agency's proposals.

In adopting the final ASC payment system rule for 2008, we urge CMS to reconsider its approach on these issues to ensure that Medicare (i) covers the full scope of services that ASCs are capable of performing safely and efficiently, and (ii) pays reasonable and adequate rates, so that ASCs actually are encouraged and able to expand their provision of services to Medicare beneficiaries, thereby lowering costs for the program and for beneficiaries and enhancing the Medicare benefit by improving access to a treatment setting preferred by an ever-growing number of patients.

[3] For example, while 13 procedures are proposed for removal from the "inpatient only" list for calendar year 2008, only three are proposed for payment in ASCs and no explanation is offered for why the other 10 procedures should not be covered.

With those goals in mind, our comments on specific aspects of the 2008 ASC payment system proposed rule follow.

1. Covered Surgical Procedures (Section XVI.C.1.a)

We support CMS's decision to adopt MedPAC's recommendation from 2004 to replace the current "inclusive" list of ASC-covered procedures with an "exclusionary" list of procedures that would not be covered in ASCs based on two clinical criteria: (i) beneficiary safety; and (ii) the need for an overnight stay. We agree that existing site-of-service volume and operating and recovery time limits are no longer clinically relevant, and that an exclusionary list reflects the best approach to balancing the need to protect beneficiary safety with the desire to increase beneficiary access to ASCs. We also support the agency's decisions to abandon any artificial numerical thresholds on utilization, such as the provision in last year's proposed rule that would have excluded procedures from ASC payment solely because they were performed 80 percent or more of the time on an inpatient basis, and to extend ASC coverage to five additional procedures (CPT codes 25931, 33240, 33249, 50580, and 58805) for calendar year 2008. We agree that these procedures may be safely performed in ASCs without an overnight stay.

We are concerned, however, that the proposed rule implements the MedPAC recommendation too narrowly, and thus continues to exclude many procedures that can be safely and appropriately performed in ASCs. In particular, we recommend that CMS reconsider its approaches to (i) using detailed safety criteria to determine what procedures should be excluded from ASC payment, (ii) denying payment for any unlisted procedures, and (iii) defining overnight stay in a way that conflicts with state laws that permit overnight recovery in ASCs. We address each of these issues in turn, and also identify in Appendix A of these comments additional procedures proposed for exclusion from payment that currently are safely performed in ASCs without an overnight stay.

A. Safety Criteria

CMS applies three criteria to determine which procedures to exclude from payment under OPPS as inpatient procedures: (i) the nature of the procedure; (ii) the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged; and (iii) the underlying physical condition of the patient. While these are generally similar to the safety criteria that CMS proposes to continue using for ASCs (i.e., extensive blood loss, major or prolonged invasion of body cavities, etc.), we see no inherit safety differences between ASCs and HOPDs to justify the use of different safety criteria. Indeed, a recent study by RAND Health commissioned by MedPAC looked at adverse events for cataract surgery and colonoscopies performed in ASCs and HOPDs and concluded that the rates of adverse outcomes were "very low" in both settings, "so that the magnitudes of significant differences between settings are quite small."[4] Moreover, our experience has been that the general exclusions retained at Section 416.166(c) of the proposed rule are applied as proxies for safety and as a basis for excluding

[4] *Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings*, a study conducted by staff from RAND Health for the Medicare Payment Advisory Commission (October 2006) at 48.

procedures from the ASC list which may be unsafe for some patients, but not for all or even most Medicare beneficiaries. Unless a procedure is inherently unsafe to perform on an outpatient basis – and thus a candidate for the OPPS inpatient list – we believe physicians are in the best position to determine the appropriate site-of-service based on the individual needs of their patients.

With that in mind, we recommend that CMS apply uniform safety criteria to ASCs and HOPDs. We also suggest that the agency develop a reasonable process for gathering and evaluating reliable information about the safety of performing surgical procedures in ASC and HOPD settings as a basis for making informed decisions about the relative safety of the two sites-of-service. This process should include additional studies like the RAND/MedPAC study. It also should include a requirement that if CMS proposes a procedure for exclusion from ASC coverage (other than procedures on the inpatient list), the agency must specify the clinical basis for exclusion, with the data it relied on and supporting arguments, and then provide the industry with an opportunity to respond with its own data, arguments and medical experts with ASC experience. **As a general rule, a procedure should not be excluded from ASC coverage if it can be safely performed in an outpatient surgical setting pursuant to reasonable and generally accepted patient selection criteria, which are best applied by physicians applying their medical judgment, rather than CMS erring on the side of exclusion.**

B. Unlisted Procedures

Because of concerns about the potential for safety risks when procedures that are reported with unlisted procedure codes (i.e., "catch-all" codes that do not contain a specific description of the procedure being billed), CMS also proposes to prohibit any payment for unlisted CPT codes under the new ASC payment system. We see no rational basis for assuming that the safety risks associated with the performance of unlisted procedures in ASCs is greater than the risk in HOPDs, which may receive payment for unlisted CPT codes at the discretion of the Medicare carriers. Moreover, it seems unnecessary to eliminate the entire unlisted procedure code payment mechanism on the chance that it conceivably could be used to report procedures that may not be appropriate for the ASC setting. Certainly, there are other, more effective safeguards against the performance of unsafe procedures, including licensure, certification, tort liability and the Medicare Quality Improvement Organization (QIO) Program. There also does not appear to be any safety risk with unlisted CPT codes within a range of procedures that are all covered services, such as CPT 58579 (Unlisted hysteroscopy procedure). **Therefore, at a minimum, when all the specific codes in a given section of CPT are eligible for payment under the revised ASC payment system, the associated unlisted code should be eligible for payment as well.**

C. Overnight Stays

In adopting midnight as the defining measure of an overnight stay, the final rule implements a payment standard that is at odds with a number of states that have expanded the concept of "ambulatory" surgery over the past 20 years by permitting ASCs to perform procedures

involving stays of up to 23 or 24 hours.[5] We are more concerned, however, by plans to extend this midnight standard to the ASC conditions for coverage ("CfC") n a way that apparently would prohibit Medicare-certified ASCs from performing *any* procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, *even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed.*

More specifically, in the August 31, 2007 CfC proposed rule, an ASC is defined as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay" – a newly-defined term that picks up on the payment system's concept of active monitoring beyond midnight, "regardless of whether it is provided in the ASC."[6] While we intend to submit extensive comments on the CfC proposed rule, it should be noted that this particular proposal seems to reflect a radical departure from longstanding Medicare policy, which currently defines an ASC, in accordance with Section 1833(i)(1)(A) of the Social Security Act,[7] as an entity that operates for the purpose of providing surgical services to patients not requiring "hospitalization." *See* 42 C.F.R. § 416.2. By defining an ASC by reference to hospitalization, rather than overnight stay, the current CfC rules allow overnight stays for non-Medicare patients, either in the ASC itself or in a licensed or certified recovery care that is distinct from the ASC and not a hospital, where such recovery care is permitted under state law. In reliance on the current policy, ASCs throughout the country have invested significant time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule.

Studies have shown non-hospital recovery care is safe and desirable to patients and health care professionals.[8] Thus, there is no apparent reason for the substantial harm and disruption that would occur from overriding state licensure laws through a new CfC definition of ASC that would prohibit non-hospital recovery care for non-Medicare patients, even though such care is permitted in several states.

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[5] We are aware of at least 14 states that permit ASCs to retain patients for up to 23 or 24 hours of overnight recovery care: Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah. A number of states also permit stays beyond 24 hours in separately licensed or certified recovery care units.

[6] 72 Fed Reg. 50469, 50471-72 (Aug. 31, 2007).

[7] Specifically, Section 1833(i)(1)(A) provides that the Secretary shall provide Medicare coverage for "those surgical procedures...performed on an inpatient *in a hospital* but which also can be performed safely on an ambulatory basis in an ambulatory surgical center" (emphasis supplied). In other words, the Medicare statute envisions ASCs as a surgical alternative for patients *not requiring hospitalization*, which is how ASCs have been defined since Medicare coverage was first established for ASC services in 1982. *See* 42 C.F.R.§ 416.2.

[8] For example, a study released in 2000 by the California Office of Statewide Health Planning and Development, titled *Postsurgical Recovery Care Demonstration Project Report 2000*, concluded that recovery care is safe for patients and that "there was substantial interest [among] both patients and professional staff in short-stay recovery periods, pleasant surroundings, home-like settings, and hotel-like services."

2. Office-Based Procedures (Section XVI.C.1.c (2))

In an attempt to mitigate potentially inappropriate migration of services from physician offices to ASCs, the proposed rule provides that payment for services added to the ASC list in 2008 that are primarily performed in physician offices would be capped at the physician fee schedule non-facility practice expense rate. No such limitation is applied to payments under the OPPS, presumably because CMS recognizes that if these procedures are being performed in a hospital setting, it is because the physician has decided that a more capable and resource-intensive setting (e.g., more nursing staff, a sterile operating room, more advanced equipment and/or closer supervision of the patient) is necessary to meet that particular patient's clinical needs, or because it makes sense to combine the office-based procedure with another procedure and perform them at the same time.

These very same considerations also drive site-of-service selection for ASCs. Indeed, patient safety and convenience are far more important to site-of-service selection than Medicare reimbursement policy. Physicians seek to provide services in the most convenient setting that is medically appropriate, consistent with adequate reimbursement. Physicians who have acquired the equipment and personnel to perform procedures in their office want to continue providing services in their office. This seems to be borne out by CMS's own analysis of site-of-service utilization data. As was noted in the 2005 ASC list final rule, the rate of performance in ASCs of the office-based procedures originally proposed for deletion in 2005 was relatively stable over the preceding 10 years.[9] In other words, the inclusion of these procedures on the ASC list did not induce substantial shifts in sites of service, which suggests that site-of-service selection is being driven by clinical need and convenience, not financial considerations.

Regardless of the payment rate, our members do not anticipate measurably increased performance of office-based procedures in ASCs under the new payment system. Indeed, if payment is capped at the physician rates, we expect that many ASCs will simply refuse to perform these procedures. As a result, if a physician believes that a higher level of care is needed, those cases would, by necessity, be performed in the higher-cost HOPD setting. Thus, although we appreciate the rationale for the proposed payment cap for office-based procedures, we do not believe it reflects good payment policy, since it may have the effect of limiting the ability of physicians and Medicare beneficiaries to choose the most appropriate site-of-service based on patient need. **If CMS nevertheless believes that a cap on payment for office-based procedures is necessary, then the same rationale would seem to support a cap on HOPD payments for office-based procedures.**

In addition, it appears that a number of procedures identified as office-based in the proposed rule, in fact, were not performed more than 50 percent of the time in physician offices in 2006 or at the time the were designated as office-based in the ASC payment system final rule (which relied on 2005 claims data). Lists of those procedures are provided as Appendix B and Appendix C to these comments.

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[9] 70 Fed. Reg. 23689, 23696 (May 4, 2005).

3. Transition to Revised ASC Payment Rates (Section XVI.C.1.c (5))

We appreciate CMS's decision to increase the phase-in to the new payment system from two to four years. The longer transition will assist ASCs that are disproportionately affected negatively by the revised payment system, especially certain types of single-specialty ASCs.

We urge the agency to monitor the migration of procedures involving certain implantable devices from HOPDs during the four transition years, and consider accelerating the transition period for these procedures if warranted. In particular, FASA has concerns about the effect of the transition on two specific categories of procedures involving devices.

First, there are a number of procedures currently performed in ASCs that receive separate and additional payment for implantable devices, but which have not been designated by CMS as device-intensive procedures in the new payment system. During the first years of the transition, as the rates are phased in using a blend of ASC payments that do not include device costs, the payment for these types of procedures may not adequately cover the costs for the procedure and the cost of the implants. CMS also may want to consider reducing the threshold for identifying procedures to be paid as device-intensive if services that could migrate to the ASC setting remain in HOPDs. In these cases, the cost of the device may be less than 50 percent of the APC rate, but more than what ASCs can afford under the discounted conversion factor. Two examples follow:

- The first is CPT 66180, commonly known as a glaucoma drainage implant (using Baerveldt, Molteno, or Ahmed shunts), which was performed 40 percent of the time (almost 2,750 times) in ASC settings in 2005. For the most acute glaucoma patients facing irreversible vision damage, the standard trabeculectomy procedure performed to move fluid out of the eye and relieve pressure may not be an option, or may have been tried and failed. For these patients, inserting a shunt to relieve intraocular pressure is necessary. For some of these high-risk patients there may be other medical indications, such as anatomic anomalies or scarring, for shunt placement. Under the new ASC payment system, the shunt used in these cases no longer will be separately paid under the DMEPOS fee schedule. However, CMS has not included CPT 66180 on the list of device-intensive procedures. On average, the typical shunt device costs approximately $650 and the pericardial graft tissue used to cover the tube shunt is an additional $255, for a total device cost of around $905. Previously, the ASC facility payment for this service was $717, plus DME payment for the devices of approximately $964, for a total payment around $1,681, which is adequate to cover costs at the typical facility. By contrast, the total expected payment in the ASC for code 66180 in 2008 is only $941.

- Another example is CPT 57288, repair bladder defect, which is included in a device-dependent APC (202) under OPPS, but not classified as device-intensive under the revised ASC payment system. The proposed payment for the first year of the transition is $985.14. The cost of the sling alone (Johnson & Johnson, Gynecare TVT Secur™) is $1,095.00, which exceeds the proposed reimbursement.

A second category of procedure that should be monitored by CMS during the transition period is one that has been added to the ASC list in the recent past, but has been virtually never performed since its addition because of an inadequate payment associated with it. A procedure in this category is CPT 55873, prostate cryosurgery. This procedure was added to the list of ASC procedures in July 2005 and, because of the associated device costs, has rarely been performed in ASCs for Medicare beneficiaries due to the cost of the device, for which ASCs have been unsuccessful in receiving separate payment. In 2005, according to physician claims, this procedure was performed 11 times in an ASC and in 2006 only once. A transition payment policy for a procedure that is virtually never performed because of inadequate payment does not make sense. Such procedures may need to be treated in the same manner as procedures added to the ASC list in 2008 and subsequent years. Again, CMS should closely monitor these types of procedures and adjust payment policies if appropriate.

In sum, if one major purpose of the new ASC payment system is to promote greater access to ASCs, it will be imperative for CMS to closely monitor the effect of the four year transition on procedures for which separate payment for implants is currently made to ASCs and for procedures that are virtually never performed because the rate is insufficient to cover the included implant. FASA suspects that the speed with which these types of procedures migrate could be significantly delayed if payment levels during the early years of the transition are inadequate. As a result, these services will continue to be provided primarily in the more expensive hospital setting. FASA believes that the number of procedures that fall into these categories is small and that any adjustment in the payment policies for them would not adversely affect average rates for other procedures, even in the context of maintaining budget neutrality.

4. Covered Ancillary Services (Section XVI.C.2)

Perhaps no change from the 2006 ASC payment system proposed rule is more important than the decision to maintain consistent payment and packaging policies across ASC and HOPD settings for covered ancillary services integral to the performance of covered surgical procedures. Indeed, failure to align the payment bundles for ancillary radiology services, brachytherapy sources, drugs, biologicals, and implantable devices would have completely undermined the validity of using the OPPS as the basis for a revised ASC payment system. As we noted above, however, we do have some concern that discounting payments to ASCs for implantable devices, in particular, does not recognize that the costs for these services do not vary significantly between the ASC and HOPD settings.

We also appreciate that CMS recognized the need to amend the "Stark" physician self-referral regulations to permit the provision of the full-scope of covered ancillary services in physician-owned ASCs, including radiology services and drugs for which separate payment will be made under the revised ASC payment system. Since the vast majority of ASCs have physician owners who use the facilities as extensions of their office practices, and because the proposed Stark exceptions would apply only to ancillary services and items integrally related to covered surgical procedures, we agree that the proposed exceptions are necessary for effective operation of the new ASC payment system and do not present any risk of program or patient abuse.

5. Proposed Calculation of the ASC Conversion Factor and ASC Payment Rates (Section XVI.L)

We are particularly concerned that inadequate payment rates under the revised system for certain services will present major obstacles to Medicare beneficiary access to ASCs. We fully appreciate the fact that CMS is required to work within the restraints of budget neutrality imposed by Congress in the Medicare Modernization Act of 2003 (MMA). As recently as 2003, however, ASC payments were at 86.5 percent of HOPD payments under OPPS.[10] Moreover, pursuant to the MMA, the GAO conducted a study of 2004 claims data – which the MMA requires be taken into account in establishing the revised ASC payment system – and found that the median costs for procedures performed in ASCs was 84 percent of the median APC costs for the same procedures under the OPPS (when weighted by Medicare volume).[11] In the intervening years, ASC rates were cut by Congress in MMA and frozen at the reduced levels through 2009, while HOPDs have received annual hospital market basket updates. Largely as a result of the MMA's multi-year payment rate freeze, CMS proposes a revised ASC payment system for 2008 with an estimated conversion factor at 65 percent of the OPPS conversion factor.

We believe that substantial payment reductions under the revised payment system for certain high-volume ASC procedures will lead inevitably to large numbers of those procedures being shifted to higher cost hospital settings, thus increasing expenditures for both Medicare beneficiaries and the government. We also thought that one of the primary goals for the new payment system was to eliminate artificial incentives in the current payment system for outpatient surgical services which are driving site-of-service selection.[12] A 35 percent differential in ASC and hospital payment rates would seem to perpetuate, rather than diminish, the incentives for the use of higher cost settings. Indeed, as long as these kinds of payment disparities persist, market pressures will tend to favor the growth of hospitals and impair the ability of ASCs to serve as a fully-effective competitive counterbalance to more costly hospital-based surgery.

In assessing the capability of ASCs to absorb the kinds of payment cuts envisioned in the proposed rule, two factors warrant particular consideration:

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[10] This 86.5 percent figure is based on an analysis performed by CMS and provided to FASA in August 2003. The CMS analysis used a strict interpretation of budget neutrality and applied 2002 ASC volume data and 2003 ASC and HOPD payment rates to the then-current list of ASC covered procedures.

[11] *Medicare Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System*, GAO-07-86 (Nov. 30, 2006).

[12] Administrator McClellan discussed the elimination of these kinds of incentives in testimony before the Health Subcommittee of the House Energy and Commerce Committee in May 2005. Specifically, in his discussion of the disparity of payment systems for ASCs and hospital outpatient departments, Dr. McClellan indicated that "CMS is currently planning to reform the ASC fee schedule to diminish the divergence in payment levels that create artificial incentives for the creation of small orthopedic or surgical hospitals." *Hearings on Specialty Hospitals Before the Health Subcommittee of the House Energy and Commerce Committee* (May 12, 2005).

- *First, most ASCs are small businesses.* According to FASA's 2007 ASC Employee Salary & Benefit Survey, 61 percent have 20 or fewer employees. Small businesses generally have less capability to absorb sudden decreases in payment of the sort contemplated in the proposed rule.

- *Second, a significant percentage of ASCs are single-specialty* (42 percent according to FASA's 2007 ASC Employee Salary & Benefit Survey). Increases in payment rates on certain procedures may allow some ASCs to make up for losses on other procedures. Single-specialty ASCs will have a limited ability to do so, however. Thus, we are convinced that many ASCs will be unable to absorb these cuts and will discontinue providing procedures slated for major payment reductions if the new ASC system is implemented as proposed. The impact on Medicare beneficiary access to gastroenterology procedures now commonly performed in ASCs may be particularly profound. While CMS suggests that specialty ASCs negatively impacted by the new payment system should seek to diversify their mix of procedures, that is far easier said than done, and is neither an easy nor short-term solution. Indeed, diversification may be impossible to achieve in states with certificate of need restrictions or in health professional shortage areas (HPSAs) lacking any physicians, let alone a diverse mix of surgeons and other specialists that ASCs can draw on to offset losses from the new Medicare payment system.

In short, setting ASC payment rates too low has the potential to deny Medicare beneficiaries choices and increase their out-of-pocket costs, as well as increase overall expenditures for the Medicare program as procedures are shifted to more costly hospital settings. **Thus, CMS should seek to set the payment rate at a reasonable and fair level to promote optimum access to ASCs.** Simply put, we do not believe that 65 percent of HOPD rates is either reasonable or fair to ASCs. Nor is it sufficient to prevent services from shifting to hospitals and reduced access to ASCs for certain services.

FASA is supportive of legislation pending in Congress (H.R. 1823) that would set ASC payment rates at 75 percent of HOPD payments. Under this legislation, Medicare would save at least 25 cents on every dollar spent relative to HOPD prices. We believe 75 percent is a reasonable level of savings and that CMS should seek to use this as the optimum payment rate for ASCs. Even this rate would result in payments to ASCs significantly lower than what they received relative to HOPDs just a few years ago.

Given these realities, we believe CMS needs to reconsider how the new payment system is likely to affect a shift in procedures between ASCs, HOPDs and physician offices, and whether such migration supports a higher ASC conversion factor that actually will promote beneficiary access to ASC services, rather than reduce it. In particular, we disagree with the conclusion that the net budget effect of migration into and out of ASCs for procedures currently on the ASC list will be negligible. This conclusion does not give adequate weight to the preference of physicians to perform procedures in ASCs and the likelihood that expansion of the list of ASC-covered procedures will allow thousands of procedures currently performed in HOPDs to migrate to

ASCs at a savings to the government and to beneficiaries. Moreover, ASC payment rates for some services have been grossly inadequate. As a result, these services are infrequently performed in ASCs even though their clinical characteristics make them appropriate for this setting.

In comments submitted on last year's proposed rule, FASA joined with the other members of the ASC Coalition and commissioned The Lewin Group to conduct numerous studies on how changes in payment under a revised ASC payment system were likely to impact facility and physician behaviors. The Lewin Group and the Coalition constructed a series of impact models which produced comparable results supporting budget neutrality with an ASC conversion factor of up to 73 percent of OPPS rates. **We continue to believe that the assumptions underlying these models are sound, and urge CMS to reconsider using them to revise the payment rates in the final ASC payment rule for 2008.**

6. Updating the ASC Conversion Factor (Section XVI.L.4.b)

The primary inflationary pressures on ASCs are the same as those facing hospitals – namely, intense competition for nurses, rapidly rising medical device costs, and a growing need to adapt new health information technology. Accordingly, we believe the hospital market basket unquestionably is a more appropriate basis for annual ASC updates than the CPI-U, which is a measure of general consumer inflation that is not used for any other Medicare payment system. Certainly, CMS recognizes that health care inflation continues to outstrip inflation in the general economy. The following table reveals that over the past five years, the average annual difference between the hospital market basket and the CPI-U proposed for use with ASCs has been 0.8 percent:

TABLE 1

COMPARISON OF HOSPITAL MARKET BASKET TO CPI-U (2002-2006)

Year	Hospital Market Basket	CPI-U	Difference
2002	3.3	1.6	-1.7
2003	3.5	2.3	-1.2
2004	3.4	2.7	-0.7
2005	3.3	3.4	+0.1
2006	3.7	3.2	-0.5
Average	**3.44**	**2.64**	**-0.8**

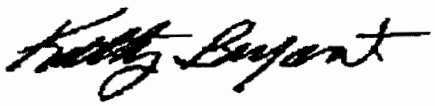
Both CBO and OMB project that this differential between CPI-U and the hospital market basket will persist for the foreseeable future.

It is the fact that ASCs have the same kinds of cost considerations as HOPDs which justifies linking the new ASC payment system to the OPPS relative payment weights and APC groups in the first place. Once that link is established, we see no sound policy basis for providing different inflation updates to ASCs and HOPDs. Indeed, we are concerned that over time, the cumulative effect of applying differing annual updates to ASCs and HOPDs will further exacerbate the already substantial disparity in payment rates contemplated in the proposed rule and create additional incentives for the creation and expansion of hospitals, rather than more cost-effective ASCs. **Therefore, since CMS acknowledges that it has "flexibility under the statute to employ a different update mechanism,"[13] we urge CMS to update ASC payments using the hospital market basket once the MMA freeze on ASC payment rates expires.**

* * *

Thank you for your consideration of our comments. We look forward to continuing to work with CMS on improving the revised payment system for ASCs.

Sincerely,



Kathy J. Bryant
President

[13] 72 Fed. Reg. 42627, 42778 (Aug. 2, 2007).

APPENDIX A

1. Procedures for Addition to the ASC List for 2008

CPT	Description	FASA Comments
22526 22527	Percutaneous intradiscal electrothermal annuloplasty (IDET or IDEA)	These are minimally invasive surgical procedures for the treatment of discogenic lumbar pain. These procedures are commonly performed in the outpatient setting, with discharge on the day of the procedure. Following placement of a local anesthetic and administration of sedation, an introducer is placed through a small incision and fluoroscopically guided to the affected lumbar disc. An electrothermal catheter is passed through the introducer and positioned in the annulus. Electrothermal energy is applied via the catheter for a period of 15 to 20 minutes. These procedures are clinically similar to 0062T/0063T, which are included in Addendum AA for ASC coverage.
29866 29867 29868	Knee arthroscopy with autograft implantation or meniscal transplantation	These knee arthroscopy procedures were added as CPT codes in 2005 and are clinically similar to the 29800-29888 series of codes, which are on the ASC list. They typically require approximately 45 minutes of operating time and do not require an overnight stay.
35470	Transluminal balloon angioplasty	This procedure is safe to perform in the ASC and does not require an overnight stay. It involves peripheral vessels, takes approximately one hour and does not require overnight recovery. It is similar to, but less invasive than, 37205 and 37206, which CMS added to the ASC list in 2005.
35493	Transluminal peripheral artherectomy	This procedure involves peripheral vessels and is safe to perform in an outpatient setting. The procedure typically takes approximately one hour to complete and does not require an overnight stay.
63030 63035 63042 63047	Low back disk surgery	While Medicare patients primarily have lower back disc surgery performed on an inpatient basis, a growing number of non-Medicare patients (and some Medicare patients who choose to pay out of pocket) are having these procedures performed in ASCs, often using endoscopically-assisted approaches. The procedures are non-emergent, do not involve a major or prolonged invasion of a body cavity and do not involve major blood loss. In ASC settings, these procedures involve 60 to 90 minutes of operating room time and do not require an overnight stay.
64448 64449	Injection of anesthetic agent (nerve block) for	These procedures are already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS

CPT	Description	FASA Comments
	femoral nerve or lumbar plexus, with continuous infusion by catheter	should make these procedures available to Medicare beneficiaries as they often are performed in conjunction with other pain management procedures. By denying Medicare coverage for these procedures, CMS creates an obstacle to their efficient performance with other procedures in ASCs.
0088T	Submucosal radiofrequency volume reduction of the tongue base, or somnoplasty	This is a commonly performed outpatient procedure for the treatment of obstructive sleep apnea or upper airway resistance syndrome. The radiofrequency probe is inserted into the tongue muscle and then heated, producing tissue injury that, after healing, reduces the volume of the tongue. Patients typically receive local anesthesia. Procedure time is less than 45 minutes and patients are discharged home on the day of the procedure. The procedure is clinically similar to, though less invasive than, excisional procedures involving the tongue described by CPTs 41110 and 41113, both of which will be covered in the ASC setting.
0135T	Percutaneous cryosurgery of renal tumors	This procedure is a minimally invasive treatment option for patients with small cortical renal tumors. The procedure requires general or regional anesthesia. Ultrasound or other guidance modalities are used to guide placement of the cryoablation needles and thermal sensors. Following completion of two freeze thaw cycles, the patient is monitored in recovery and discharged on the day of the procedure. This procedure is clinically similar to CPT 50592, Percutaneous radiofrequency ablation of renal tumor(s), which is included in Addendum AA for coverage in the ASC setting.
0137T	Prostate saturation biopsy	Prostate saturation biopsy is typically performed in an outpatient setting using intravenous sedation. This procedure involves taking a greater number of prostate biopsies than have traditionally been taken during one procedure. The patient is discharged on the same day. This procedure is clinically similar to CPTs 55700 and 55705 describing prostate biopsy, which are currently covered in the ASC setting.
0170T	Anal fistula repair with a biodegradable porcine small intestinal mucosal plug	This procedure is an outpatient surgical procedure that can be performed under general, spinal or local anesthesia. Following identification of the internal and external fistula tract openings, the plug is pulled into the tract using suture ligatures and subsequently sutured in place. Patients are discharged home on the day of the procedure. The procedure is clinically similar to CPT 46706, Repair of anal fistula with fibrin glue, which currently on the ASC list of covered procedures.

CPT	Description	FASA Comments
0184T	Transanal endoscopic resection of a rectal tumor	This Category III CPT code will be implemented on January 1, 2008. Transanal endoscopic microsurgery is a minimally invasive procedure for the excision of precancerous lesions or early cancers of the rectum. This procedure can be performed on an outpatient basis, with discharge on the same day. It is clinically similar to CPT 45170, Excision of rectal tumor, which is currently on the ASC list of covered procedures.
0186T	Suprachoroidal drug delivery	This Category III CPT code will be implemented on January 1, 2008. A microcannula is introduced into the suprachoroidal space and used as a means to deliver drugs to the macula, optic nerve and posterior pole. This in an outpatient procedure and patients are discharged on the same day. The procedure is clinically similar to CPTs 67027 and 67028 (describing intravitreal drug delivery), which are both included in Addendum AA for ASC coverage in CY 2008.

2. Surgical Services Packaged into SI "Q" Radiologic Services under OPPS

We remain concerned about the impact of existing OPPS packaging policies on selected services that meet CMS's definition of ASC surgical services (CPTs 10000-69999). Procedures such as diskography have both an injection component and a radiographic component. In CPT, the injection portion of the service is described by a code in the surgical range (in this example, 62290 or 62291), while the radiographic portion of the service is described by a code in the radiology range (in this example, 72285 and 72295). Under OPPS, the injection portion of the procedure is packaged into the radiographic portion of the procedure. As a result, only CPT codes 72285 and 72295 are payable. In this proposed rule, CMS has outlined expanded OPPS packaging policies that would further affect the payment of these services. As proposed, the radiologic services in question would be packaged into the APC payment for other associated independent services, and would no longer be separately payable when performed with other services under OPPS. CMS has recognized that these imaging guidance and radiologic supervision and interpretation services are occasionally performed independently. Accordingly, a new status indicator, "Q", has been devised that would allow OPPS payment when these radiologic services are the only ones reported on the claim.

ASCs should also have the opportunity to receive separate reimbursement for one of these services when it is the only service reported on the claim. Applying this policy to both payment systems acknowledges that a surgical service has in fact been performed and allows payment for services rendered. We propose CMS implement status indicator "Q" (or an equivalent) to allow separate ASC payment of services similarly designated under OPPS, if performed in isolation.

Of particular interest in this table are CPT codes 19290 and 19291, which have been covered ASC services for many years and have been paid by CMS as separately identifiable services. These services have been packaged into CPT codes 77031 and 77032 under OPPS. Under the newly proposed policies, CMS has not assigned a status indicator "Q" to CPTs 77031 or 77032, but rather a status indicator "N". We believe this is an error that should be corrected, as these services are occasionally performed as the sole service.

Surgical Services Packaged into SI "Q" Radiologic Services under OPPS		
Surgical Code(s)	**Corresponding CPT Code(s) for Radiologic Service**	**Descriptor of Payable Radiologic Service Code**
68850	70170	X-ray exam of tear duct
21116	70332	X-ray exam of jaw joint
31708	70373	Contrast x-ray of larynx
42550	70390	X-ray exam of salivary duct
31708, 31710, 31715	71040-60	Contrast x-ray of bronchi
62284	72240-70	Contrast x-ray of spine
62291	72285	Diskography, cervical or thoracic
62290	72295	Diskography, lumbar
23350	73040	Contrast x-ray of shoulder
24220	73085	Contrast x-ray of elbow
25246	73115	Contrast x-ray of wrist
27093, 27095	73525	Contrast x-ray of hip
27370	73580	Contrast x-ray of knee joint
27648	73615	Contrast x-ray of ankle
49400	74190	X-ray exam of peritoneum
47505	74305	X-ray bile ducts/pancreas
47500	74320	Contrast x-ray of bile ducts
50394, 50684, 50690	74425	Contrast x-ray, urinary tract
51600, 51605	74430	Contrast x-ray, bladder
55300	74440	X-ray, male genital tract
54230	74445	X-ray exam of penis
51610	74450	X-ray, urethra/bladder
51600	74455	X-ray, urethra/bladder
58340	74740	Hysterosalpingography
38790	75801-07	Lymph vessel x-ray
49427	75809	Nonvascular shunt, x-ray
38200	75810	Vein x-ray, spleen/liver
36481	75885-87	Vein x-ray, liver
20501, 49424	76080	X-ray exam of fistula
19290, 19291	77031	Stereotactic guidance breast biopsy or needle
19290, 19291	77032	Mammographic guidance, placement breast needle
19030	77053, 77054	X-ray of mammary duct

APPENDIX B

PROCEDURES PROPOSED FOR DESIGNATION AS OFFICE-BASED BUT NOT PERFORMED MORE THAN 50% OF TIME IN PHYSICIAN OFFICES IN 2006

HCPCS	Short Description	Final Rule Indicator	Proposed Rule Indicator	CY 2006 OPPS Units	CY 2006 MPFS In Office Allowed Services	Total Volume	% Physician Office
24640	Treat elbow dislocation	G2	P3	51	18	69	26.09%
26641	Treat thumb dislocation	G2	P2	66	29	95	30.53%
26670	Treat hand dislocation	G2	P2	72	29	101	28.71%
26700	Treat knuckle dislocation	G2	P2	522	106	628	16.88%
26775	Treat finger dislocation	G2	P3	264	217	481	45.11%
28630	Treat toe dislocation	G2	P3	100	95	195	48.72%
28660	Treat toe dislocation	G2	P2	295	159	454	35.02%
29505	Application, long leg splint	G2	P3	19,482	1,106	20,588	5.37%
29515	Application lower leg splint	G2	P3	56,482	17,910	74,392	24.08%
36469	Injection(s), spider veins	G2	R2	3	1	4	25.00%
46505	Chemodenervation anal musc	G2	P3	163	37	200	18.50%
64447	Nblock inj fem, single	G2	R2	1381	950	2,331	40.76%

APPENDIX C

PROCEDURES NOT PERFORMED MORE THAN 50% OF TIME IN PHYSICIAN OFFICES WHEN DESIGNATED AS OFFICE-BASED IN THE FINAL RULE

CPT	Short Description	CY 2005 OPPS units	CY 2005 MPFS in office allowed services	Total Volume	% Physician Office
0046T	Cath lavage, mammary duct(s)	3	1	4	25.00%
0047T	Cath lavage, mammary duct(s)	0	0	0	--
11950	Therapy for contour defects	39	32	71	45.07%
11951	Therapy for contour defects	43	10	53	18.87%
11952	Therapy for contour defects	19	6	25	24.00%
11954	Therapy for contour defects	196	34	230	14.78%
11976	Removal of contraceptive cap	31	11	42	26.19%
12001	Repair superficial wound(s)	132984	36471	169455	21.52%
12002	Repair superficial wound(s)	98727	23901	122628	19.49%
12004	Repair superficial wound(s)	14338	2748	17086	16.08%
12011	Repair superficial wound(s)	70950	9485	80435	11.79%
12013	Repair superficial wound(s)	39628	4734	44362	10.67%
12014	Repair superficial wound(s)	5222	548	5770	9.50%
15340	Apply cult skin substitute	15359	6617	21976	30.11%
15783	Abrasion treatment of skin	86	25	111	22.52%
15786	Abrasion, lesion, single	472	373	845	44.14%
15787	Abrasion, lesions, add-on	155	54	209	25.84%
26010	Drainage of finger abscess	1975	1790	3765	47.54%
29010	Application of body cast	3	2	5	40.00%
29049	Application of figure eight	22	14	36	38.89%
29055	Application of shoulder cast	27	21	48	43.75%
29058	Application of shoulder cast	118	43	161	26.71%
29086	Apply finger cast	580	228	808	28.22%
29105	Apply long arm splint	18280	9569	27849	34.36%
29125	Apply forearm splint	120178	32832	153010	21.46%
29126	Apply forearm splint	6623	702	7325	9.58%
29130	Application of finger splint	26636	8515	35151	24.22%
29131	Application of finger splint	1534	459	1993	23.03%
29240	Strapping of shoulder	17263	6576	23839	27.59%
29260	Strapping of elbow or wrist	6187	5690	11877	47.91%
29358	Apply long leg cast brace	146	91	237	38.40%

CPT	Short Description	CY 2005 OPPS units	CY 2005 MPFS in office allowed services	Total Volume	% Physician Office
29530	Strapping of knee	18662	13284	31946	41.58%
29700	Removal/revision of cast	3525	2380	5905	40.30%
29710	Removal/revision of cast	17	4	21	19.05%
29715	Removal/revision of cast	12	2	14	14.29%
30901	Control of nosebleed	67943	60188	128131	46.97%
36430	Blood transfusion service	477254	15877	493131	3.22%
36440	Bl push transfuse, 2 yr or <	24	7	31	22.58%
36450	Bl exchange/transfuse, nb	59	30	89	33.71%
36468	Injection(s), spider veins	68	42	110	38.18%
36550	Declot vascular device	12215	11617	23832	48.75%
36598	Inj w/fluor, eval cv device	6388	3343	9731	34.35%
38242	Lymphocyte infuse transplant	37	8	45	17.78%
41820	Excision, gum, each quadrant	376	1	377	0.27%
41822	Excision of gum lesion	27	14	41	34.15%
41823	Excision of gum lesion	95	41	136	30.15%
41830	Removal of gum tissue	218	107	325	32.92%
41850	Treatment of gum lesion	26	4	30	13.33%
41872	Repair gum	422	0	422	0.00%
41874	Repair tooth socket	4473	573	5046	11.36%
46606	Anoscopy and biopsy	876	619	1495	41.40%
46910	Destruction, anal lesion(s)	531	340	871	39.04%
46945	Ligation of hemorrhoids	1108	1068	2176	49.08%
51702	Insert temp bladder cath	1211839	145409	1357248	10.71%
53025	Incision of urethra	0	0	0	--
55450	Ligation of sperm duct	8	5	13	38.46%
55870	Electroejaculation	16	4	20	20.00%
55876	Place rt device/marker, pros	1293	245	1538	15.93%
58345	Reopen fallopian tube	5	3	8	37.50%
58356	Endometrial cryoablation	21	16	37	43.24%
59001	Amniocentesis, therapeutic	8	4	12	33.33%
59015	Chorion biopsy	18	9	27	33.33%
59020	Fetal contract stress test	357	9	366	2.46%
59025	Fetal non-stress test	11562	5260	16822	31.27%
60100	Biopsy of thyroid	12967	7236	20203	35.82%
63615	Remove lesion of spinal cord	4	2	6	33.33%
64402	Nblock inj, facial	1312	874	2186	39.98%
67208	Treatment of retinal lesion	454	374	828	45.17%

(603)

Intacs CORNEAL IMPLANTS

AlphaCor™ ARTIFICIAL CORNEA

September 14, 2007

Kerry N. Weems
Acting Administrator
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P

Dear Mr. Weems:

Addition Technology, Inc. ("ATI") would like to thank you for the opportunity to comment on Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System ("OPPS") and CY 2008 Payment Rates" (the "Proposed Rule") published in the *Federal Register* on August 2, 2007.[1] As requested, we have keyed our comments to the relevant issue identifiers in the Proposed Rule.

At the outset we wish to commend and thank the members of the hospital outpatient prospective payment system team with whom we have been working. Throughout this process we have felt that these individuals have given their time and attention to the problematic circumstances surrounding integrated keratoprosthesis (CPT Code 65770). We also would like to thank you for the proposed payment increase to $5,290.37 for performing this procedure. This payment rate will help mitigate the financial loss incurred by hospitals when they offer AlphaCor to their patients.

Unlike hospital outpatient departments, ambulatory surgical centers ("ASCs") are facing a drastic cut in payment for the procedure. Under the standard ASC methodology, for 2008, the proposed unadjusted payment rate is only $1605.93 for both the procedure and device because the cost of the device will be packaged into the payment rate for the procedure.

We are deeply concerned that CMS' proposal to reimburse ASC at a payment rate of $1,605.93 for performing an integrated keratoprosthesis will impair Medicare beneficiaries access to this last resort treatment in the ASC setting. Accordingly, we recommend that CMS designate integrated keratoprosthesis (CPT Code 65770) as a device intensive procedure to ensure that this procedure is appropriately paid in the ASC setting.

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[1] 72 *Fed. Reg.*42626 (Aug. 2, 2007).

ADDITION TECHNOLOGY, INC.
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OPPS: DEVICE-DEPENDENT APCS
ASC IMPACT

I. CMS SHOULD ENSURE THAT MEDICARE BENEFICIARIES CONTINUE TO HAVE ACCESS TO INTEGRATED KERATOPROSTHESIS

A. Integrated keratoprosthesis is a last resort treatment option for a limited patient population

AlphaCor™ was cleared by the FDA in 2002 and designed replace a scarred or diseased native cornea. It is the only technology available today that is a flexible, bio-integratable, one piece synthetic cornea made of poly-HEMA, with a 7.0 mm diameter. While the majority of Medicare beneficiaries are successfully treated with a standard corneal transplant procedure, keratoprosthesis implantation using AlphaCor provides a critical treatment option for those patients who are not candidates for a corneal transplant procedure. Keratoprosthesis is a last resort procedure for those patients with corneal opacity not suitable for standard penetrating keratoplasty with donor tissue, who have rejected donor tissue or where adjunctive measures required to prevent graft rejection are medically contraindicated. Left untreated, these Medicare beneficiaries likely will become blind.

B. Severe payment disparity in the ASC setting will exist in 2008

We are deeply concerned that access through ASCs will become essentially non-existent in 2008 if integrated keratoprosthesis is not treated as a device intensive procedure. In 2006, only approximately 80 procedures using AlphaCor were performed.[2] ASCs are an important site of service for this procedure. In 2006, approximately 75% of the integrated keratoprosthesis procedures performed in the United States were performed in the ASC. We fear that ASCs will find it financially impossible to continue to offer the procedure at this grossly inadequate payment rate resulting in fewer provider options for Medicare beneficiaries.

ASCs are facing a drastic cut in payment in 2008. In 2007, ASCs received two payments when they performed integrated keratoprosthesis: (1) an (unadjusted) ASC facility rate of approximately $995 for the procedure and (2) a payment for the cost of the device itself. The manufacturer cost of the AlphaCor device is $6,950 (excluding shipping costs). Under the standard ASC methodology, for 2008, the proposed unadjusted payment rate is only $1605.93 for both the procedure and device because the cost of the device will be packaged into the payment rate for the procedure. This reimbursement rate is clearly inadequate when it does not even cover the cost of the device, which is approximately $7,000. ASCs will no longer perform the procedure if the payment rate is insufficient to cover their costs resulting in limited patient access to integrated keratoprosthesis.

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[2] This number includes all public and private payors, not just Medicare beneficiaries. The number of procedures performed remains constant each year. In 2005, only 78 procedures using AlphaCor were performed.

II. CMS SHOULD DESIGNATE CPT CODE 65770 AS A DEVICE-INTENSIVE PROCEDURE

We believe that CPT Code 65770 meets the criteria for a device-intensive procedure in the ASC setting. CMS created an exception to the standard ASC methodology for device-intensive procedures because it recognized that the standard ASC methodology (bundling the cost of the device with the procedure) may result in inadequate payment for device-intensive procedures.[3] Payment for device intensive procedures is the sum of: (1) the cost of the device portion (which is the OPPS unadjusted national rate multiplied by the device offset percentage calculated by CMS) and (2) the payment for the service portion (which is reduced by the applicable conversion factor). It is only the service portion of the OPPS rate that is reduced by 67%, not the device portion. Device-intensive procedure criteria are set forth in 42 CFR §416.171:

1. The procedure must be a device-dependent APC under OPPS. Device-dependent APCs are procedures that usually, but not always, require a device to be implanted or used to perform the procedure and

2. The APC must have a device cost of greater than 50% of the median cost of the APC. CMS calculates the device cost used by applying a device offset percentage (which it calculates based on claims data) to the median cost.

A. APC 0293 should be designated as a device-dependent APC

APC 0293 (Level V Anterior Segment Eye Procedures) meets the criteria for a device-dependent APC. This APC consists of only one procedure, integrated keratoprosthesis. Device-dependent APCs consist of procedures that usually, but not always, require a device to be implanted or used to perform the procedure. Integrated keratoprosthesis always requires the implantation of an artificial cornea. CMS recognized that the procedure requires a device to be implanted when it assigned that device edits to the CPT Code 65770:[4]

> Where there are device HCPCS codes for all possible devices that could be used to perform a procedure that always requires a device and the APC is designated a device-dependent APC, we have commonly instituted device edits that prevent payment of claims that do not include both the procedure and an acceptable device code. In that way, hospitals become aware of the proper coding requirements, and we can be confident that our procedure claims include charges for the necessary devices so we can establish appropriate payment rates for those procedures. . . .After carefully considering the comments received, we are adopting our proposal without modification to assign CPT code 65770 to APC 0293, with

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[3] 72 *Fed. Reg.* 42628, 42504 (Aug. 2, 2007).
[4] 71 *Fed. Reg.* 67960, 68053-54 (Nov. 24, 2006).

a median cost of $3,177.05 for CY 2007. We are also assigning a procedure-to-device edit for CPT code 65770 with APC 0293.

We believe that it is reasonable for CMS to designate APC 0293 as the device dependent APC. It is the only APC listed in the January 2007 device edit file that is not listed as a device-dependent APC in the Proposed Rule, except for two categories of APCs. The first category consists of APCs that CMS is proposing will be deleted from the list of device-dependent APCs due to migration of HCPCS codes to other APCs. The other category of APCs consists of a mix of procedures, some of which do not require devices to perform the procedure and do not have a device edit. These categories are distinguishable because they do not, or will no longer, meet the device-dependent APC criteria.

Based on the fact that APC 0293 consists entirely of one procedure, integrated keratoprosthesis, that always requires the use of a device to perform the procedure (as evidenced by the assignment of the device edit), the procedure satisfies the first prong of the device intensive procedure test.

B. The device costs of APC 0293 is likely greater than 50% of the median costs of the APC

We believe that the device offset for APC 0293 will likely be greater than 50% of the median costs of the APC. We used the prices the carriers have established in their fee schedules for the device code L8609 (artificial cornea) to develop an estimate for the device offset percentage. Based on our estimate, the device costs likely will represent more than 50% of the median costs of the APC.

	Estimated Median Cost Percentage
OPPS CY 2008 median cost for APC 0293[5]	$5,224.94
Manufacturer cost of the AlphaCor device	$6,950 (excluding shipping costs)
Carrier DMEPOS Schedule Fee for the device L8609 (artificial cornea)	Range of $4,900 to $6,530
Estimate Device Cost Percentage of APC 0293 (using the lowest carrier price)	**94% (based on the lowest carrier payment)**

Based on our estimate, we suspect that the median cost files for APC 0293 will indicate that the device offset percentage is greater than 50% and the second prong of device-intensive procedure

[5] We obtained the median cost from the median cost files for services payable under the Hospital OPPS in calendar year 2008. The data are based on claims for hospital outpatient services provided January 1, 2006 through December 31, 2006.

will also be met. We respectfully ask that CMS review the median cost files to determine whether the 50% threshold would be satisfied for APC 0293.

We believe that CPT Code 65770 meets the device intensive procedure criteria. Accordingly, we recommend that CMS designate integrated keratoprosthesis (CPT Code 65770) as a device intensive procedure to ensure that this procedure is appropriately paid in the ASC setting. We request that CMS assign APC 0293 to a device-dependent APC and assign payment indicator "H8".

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ATI would again like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We urge CMS to designate integrated keratoprosthesis as a device-intensive procedure to ensure that ASCs are adequately reimbursed for providing keratoprosthesis and that Medicare beneficiaries continue to have access to this innovative, last resort treatment option.

Sincerely,

William Flynn
President & CEO

US Oncology

64

RECEIVED - CMS

2007 SEP 14 P 2:52

September 14, 2007

HAND DELIVERED

Kerry N. Weems
Acting Administrator
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P

Dear Mr. Weems:

US Oncology[1] would like to thank you for the opportunity to comment on Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates" (the "Proposed Rule") published in the *Federal Register* on August 2, 2007.[2] As requested, we have keyed our comments to the relevant issue identifiers in the Proposed Rule.

OPPS: Specified Covered Outpatient Drugs

CMS should follow the Ambulatory Payment Classification (APC) Panel's March and September 2007 recommendations to maintain payment levels for specified covered outpatient drugs at Average Sales Price (ASP) plus 6% in 2008

US Oncology urges CMS to rescind its proposal to reduce payment for specified covered outpatient drugs (SCODs) from the 2007 rate of ASP + 6% to ASP + 5% in 2008. This proposal flies in the face of the Ambulatory Payment Classification (APC) Panel's recent recommendations to maintain reimbursement for all separately payable drugs under the hospital outpatient prospective payment system (HOPPS), including separately payable SCODs, at the

[1] US Oncology, headquartered in Houston, Texas, is one of the nation's largest caner treatment and research networks. US Oncology provides extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced treatments and technologies, build integrated community-based cancer care centers, improve their therapeutic drug management programs and participate in many of the new cancer-related clinical research studies. US Oncology also provides a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting. US Oncology is affiliated with 1,122 physicians operating in 442 locations, including 90 radiation oncology facilities, in 38 states.
[2] 72 *Fed. Reg.*42626 (Aug. 2, 2007).

reimbursement rate set under the Physician Fee Schedule, which is ASP + 6%.[3] The reimbursement cut for SCODs detailed in the Proposed Rule is particularly disturbing given that CMS appears to have concluded payment for pharmacy overhead costs associated with the procurement, storage, and handling of SCODs will continue to be packaged into the reduced payment rate for the drugs in 2008.[4]

Physician practices in the US Oncology network face significant financial difficulties under the current ASP + 6% reimbursement system. In part, payment pressure continues because Congress has yet to rectify fundamental flaws in the ASP system that stand in the way of using the ASP metric to accurately match drug reimbursement with the acquisition costs of healthcare providers. Customary prompt pay discounts extended to wholesalers still must be deducted from ASP when manufacturers sell their products through traditional or specialty distributors despite the fact that those discounts are not passed on to physicians or hospitals. At a time of rapidly rising drugs costs, ASP continues to understate costs at the time of purchase because the two-quarter lag built into the data collection process that supports CMS' publication of the quarterly ASP values that determine payments to physician offices and hospital outpatient departments. Further, ASP-based payments fail to recognize state and local taxes that must be paid in some jurisdictions even though the taxes, including sales taxes, cannot be passed though to customers, as they normally are, if those customers are Medicare beneficiaries because of the rules that limit physicians and hospitals charges for items and services to the Medicare allowable amount.[5] Bad debt contributes significantly to drug underpayments as well. Given these realities, we are convinced hospital-based infusion centers will be particularly hard-pressed if reimbursement for SCODs is reduced to ASP + 5%.

The APC Panel heard testimony at its August 26, 2006 meeting which showed the ASP + 6% Medicare HOPPS payment rate applicable to SCODs failed to cover the cost of many of the separately payable outpatient prescription drugs on a typical hospital's formulary.[6] The APC Panel also heard testimony that the proposed reduction in payment would make it even more difficult for hospitals to offer chemotherapy and related cancer care, which could result in fewer provider options for Medicare beneficiaries. A 2006 survey conducted by the Association of Community Cancer Centers (ACCC) in response to CMS' proposal to reduce Medicare payments for separately billable drugs to ASP + 5% in calendar 2007 confirmed the APC Panel testimony. The survey found that payment rate would be insufficient to cover costs associated with five of the eight common oncology therapies evaluated.[7]

This story is no different this year. Based on testimony heard at its March and September 2007 meetings, the APC Panel again recommended that CMS continue paying for hospital infusion

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[3] Advisory Panel on Ambulatory Payment Classification Groups, "March 7-9 2007 Mtg, Agenda, Rpt," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

[4] 72 *Fed. Reg.* at 42735.

[5] *See* 42 C.F.R. § 424.55(b)(1) for the rules limiting charges by participating physicians and non-participating physicians who take assignment, 42 U.S.C. § 1848(g) for charge limitations facing non-participating physicians, and 42 C.F.R. § § 489.20(a) and 489.30(b) for the rules limiting hospital outpatient charges.

[6] Advisory Panel on Ambulatory Payment Classification Groups, "August 23-34 Mtg, Agenda & Report," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

[7] "Preliminary Results from ACCC's Survey on Hospital Outpatient Department Reimbursement Levels" available at http://www.accc-cancer.org/media/media_hopdsurvey06.asp.

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centers at ASP + 6%.[8] The APC Panel again heard testimony at its September 2007 meeting that the current Medicare payment of ASP + 6% is insufficient to cover the acquisition costs (much less the handling costs) for approximately 59% of the separately payable drugs on many hospital formularies. This is not surprising, because drug costs have continued to rise and the flawed nature of the ASP metric has not been remedied over the past year. Given that the current rate is inadequate, the APC Panel again recommended that CMS maintain reimbursement at ASP + 6% to avoid placing hospitals under even greater financial strain.

We are particularly troubled by CMS' continued insistence that ASP + 5% is adequate to cover both hospitals' drug costs and their pharmacy handling costs as well. Under the Medicare Prescription Drug, Improvement and Modernization Act,[9] the Medicare Payment Advisory Committee (MedPAC) was directed to study the cost of pharmacy services in hospital outpatient departments. MedPAC concluded "[h]ospitals appear to incur nontrivial costs in handling separately paid drugs and radiopharmaceuitcals. Thus, as the outpatient PPS moves toward reimbursing hospitals for drugs at their acquisition cost, it should also provide some payment for handling costs."[10] Physicians who furnish chemotherapy in their offices face essentially the same handling costs as hospitals when they management and administer chemotherapy in their offices, and those costs certainly are not covered by drug payments at ASP + 6%.

MedPAC cited studies showing that hospital pharmacy services overhead costs make up 26-33% of pharmacy departments' direct costs, with the rest of the costs attributable to the acquisition cost of drugs.[11] MedPAC also noted that hospitals do not have precise information about the magnitude of their pharmacy expenses and are not likely to have included all of these costs into their charges for drugs.[12] If true, it is clear payment at ASP + 5%, or for that matter ASP + 6%, is inadequate to cover both drug costs and pharmacy handling costs, regardless of the site of service where chemotherapy is administered. A 2005 study commissioned by the National Patient Advocate Foundation and funded through donations from 42 organizations, including other non-profit entities invested in patient access issues, found the average handling cost for each dose of chemotherapy administered was $36.03 plus the costs of drugs.[13] This study assessed handling costs associated with chemotherapy furnished in both physician office practices and hospital outpatient departments at academic medical centers.

CMS indicated in the preamble to "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates"[14] (HOPPS Proposed Rule) its

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[8] Advisory Panel on Ambulatory Payment Classification Groups, "March 7-9 2007 Mtg, Agenda, Rpt," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

[9] Pub. L. 108-173 (Dec. 8, 2003).

[10] MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program," Chapter 6, p 142 (June 2005), available at http://www.medpac.gov/publications/congressional_reports/June05_Titlepg_Insidecov_Acknow.pdf.

[11] *Id.* p 140.

[12] *Id.*

[13] Gary Oderda, University of Utah Pharmacotherapy Outcomes Research Center, "Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices" (Feb. 8, 2005), prepared for the National Patient Advocate Foundation and the Global Access Project, available at http://www.npaf.org/pdf/gap/utah_study.pdf.

[14] 70 Fed. Reg.42675 (July 25, 2005) as corrected at www.cms.hhs.gov/providers/hopps/2006p/1501p.asp.

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intention to exercise its discretionary authority under Social Security Act §1833(t)(14)(E)(ii)[15] to provide an overhead adjustment of 2% of ASP to cover the cost of pharmacy services whenever a separately billable drug is reimbursed. As a result, hospital outpatient departments would have been paid a combined ASP + 8% in 2006 to cover pharmacy handling and drug acquisition costs had the proposal been finalized. Implicit in MedPAC's recommendations and CMS's proposal to include a pharmacy services adjustment under the 2006 HOPPS Proposed Rule is the recognition that pharmaceutical management and handling costs are linked to the nature of the drug products handled and to the complexities of drug protocol management, not to the setting in which they are handled.

We know from our own experience acting as the buying agent for the oncology practices in the US Oncology network that many cancer drugs currently viewed as the standard of care are not available to hospitals, physicians or any other retail class of trade at discounted prices. We know too that flaws in the ASP system prevent our affiliated practices from buying certain chemotherapy products at prices at or below the ASP + 6% reimbursement rate they receive when they administer the drug to a Medicare beneficiary. We also understand the costs incurred by our affiliated practices to inventory, manage, admix, and safely use chemotherapy agents that often require refrigeration, have short shelf-lives both before and after admixture, and require special handling precautions (gloves, goggles, gowns and laminar flow hoods) because they are toxic or even carcinogenic. We appreciate the work that pharmacists, nurses and physicians must do to determine drug interactions and contraindications, manage drug toxicity, and verify therapy appropriateness and dosing before and during the administration of chemotherapy to patients. Additional costs are associated with negotiating wholesaler contracts, building information systems to deal with drug management issues, and disposing of unused drug products that typically are considered hazardous waste in accordance with all applicable regulations. We know the Proposed Rule's insistence that ASP + 5% would be sufficient to cover these costs as well as drug acquisition costs is unsupportable in the physician-office context and we have every reason to believe it is unsupportable in the hospital-outpatient context as well.

The APC Panel agrees with our conclusion. After the Panel heard testimony at its March 7-8 2007 meeting, it recommended that CMS implement a three-phase plan to establish payment for pharmacy overhead costs incurred by hospitals.[16] The Panel again recommended at its September 2007 meeting that CMS follow this plan that provides for reimbursement for pharmacy-related costs while allowing CMS to collect data for use in setting future rates with minimal administrative burdens for hospitals. Under the first phase, CMS would define three pharmacy overhead categories based on the complexity of drug handling, set flat fee payments to compensate hospitals for each level of handling and begin paying for the services in 2008 under New Technology APCs. Under the second phase, CMS would solicit outside survey data on pharmacy resource utilization and handling costs. Finally, under the third phase, after hospitals

[15] Social Security Act §1833(t)(14)(E)(i) requires a MedPAC report to CMS on adjustments to APC payments of separately billable drugs under HOPPS. Social Security Act §1833(t)(14)(E)(ii) states "The Secretary *may* adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i) (emphasis added).

[16] Advisory Panel on Ambulatory Payment Classification Groups, "March 7-9 2007 Mtg, Agenda, Rpt," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

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have had time to develop and implement appropriate systems for capturing accurate data, reimbursement for the pharmacy handling APCs could be realigned to reflect cost report data. We strongly encourage CMS to follow the advice of its own APC advisory panel and to move forward expeditiously to implement payments for pharmacy handling fees.

Last year when CMS proposed paying for separately payable drugs at ASP + 5% in calendar year 2007[17], we opposed that change on beneficiary access grounds. We noted in our comments that reducing drug payments to this level likely would make what was already a difficult financial situation for many hospitals even worse, possibly to the point of seriously compromising beneficiary access.[18] We suggested some hospitals, particularly those in rural areas where costs typically run higher or those that serve as safety net providers, simply would not be able to continue offering outpatient chemotherapy services. Others might have to limit the availability of certain more innovative and costly cancer treatment on their formularies. Still others might be forced to respond to the cost pressures by offering certain therapies only on an inpatient basis, a "solution" that not only deprives patients of care in the most clinically appropriate, patient-friendly setting but also one that increases costs to the healthcare system as a whole.

We noted Mark Miller, Executive Director of the MedPAC, in testimony before the House Ways and Means Subcommittee on Health on July 13, 2006, stated that many oncology practices had stopped treating Medicare beneficiaries since the change to an ASP-based reimbursement methodology.[19] As a result, the number of Medicare beneficiaries transferred to hospital outpatient departments increased in 2005.[20] We also cited a research study prepared by the Duke Clinical Research Institute that observed some apparent dislocations in access in rural areas and among Medicare beneficiaries without supplemental insurance, including an increase in inpatient treatment.[21]

The APC Panel also heard testimony at its September 2007 meeting expressing concern that, if CMS' proposal is finalized, the different payment rates for physician offices and hospitals may influence the site of care for Medicare beneficiaries. This concern contributed, in part, to the APC Panel's recommendation to maintain reimbursement at ASP +6%.

Our experience with the insufficient reimbursement oncologists can face under an ASP + 6% payment system forces us to question the appropriateness of reducing reimbursement for separately payable SCODs to ASP + 5% under the HOPPS. For these reasons, we strongly urge

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[17] Last year, CMS proposed to reduce payment to ASP + 5% based on its data analysis. Its analysis indicated that the mean unit costs based on the hospital claims data to set the payment rates for separately payable drugs would be equivalent to basing their payment rates, on average, at ASP+5 %. 71 *Fed. Reg.* 49504, 49585 (Aug. 23, 2006).

[18] Please see attached as Appendix A for our comment letter on the HOPPS proposed rule for calendar year 2007.

[19] "Medicare Part B Drugs and Oncology: Testimony before the Subcommittee on Health Committee on Ways and Means U.S. House of Representatives (July 13, 2006) (Statement of Mark E. Miller, PhD, Executive Director, Medicare payment Advisory Commission), available at http://www.medpac.gov/publications/congressional_testimony/071306_Testimony_Part%20B_oncology.pdf.

[20] *Id.*

[21] Joelle Friedman et al., Duke Clinical Research Institute, Duke University Medical Center, "The Medicare Modernization Act and Changes in Reimbursement for Outpatient chemotherapy: Do Patients Perceive Changes in Access to Care?" (Sept. 15, 2006), prepared for the National Patient Advocate Foundation and the Global Access Project, available at http://www.npaf.org/pdf/gap/sept_2006/duke.pdf .

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CMS to follow the APC panel's recommendations and maintain payments to hospital outpatient departments for SCODs at ASP + 6% in 2008.

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In closing and on behalf of US Oncology and our nationwide network of cancer care specialists, thank you for this opportunity to provide our comments on Proposed Rule CMS-1392-P. As you know, we are grateful for the opportunity to engage in substantive discussions and continue to extend our open invitation for CMS staff to make site visits to any of our offices, and we continue to stand ready should you have any questions about the issues, concerns, suggestions and data analyses discussed above.

Sincerely,

Dan Cohen
Senior Vice President
Government Relations & Public Policy

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APPENDIX A

US Oncology

65

October 9, 2006

HAND DELIVERED

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

Re: **CMS-1506-P**

Dear Dr. McClellan:

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

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

OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[7] *Id.*

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New Technology APCs

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

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

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

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

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

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

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

Sincerely,

Dan Cohen
Senior Vice President
Government Relations & Public Policy

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(66)

A National Network for Healthcare Reform

RECEIVED - CMS

2007 SEP 14 P 2:56

September 14, 2007

HAND DELIVERED

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P

Dear Mr. Weems:

The National Patient Advocate Foundation ("NPAF") would like to thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates" (the "Proposed Rule") published in the *Federal Register* on August 2, 2007.[1] As requested, we have keyed our comments to the relevant issue identifiers in the Proposed Rule. We hope CMS finds our recommendations helpful as it finalizes the outpatient prospective payment system rates for 2008.

NPAF is a non-profit organization dedicated to improving access to healthcare services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling and case management and co-payment relief services from our companion organization, the Patient Advocate Foundation ("PAF"), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. In fiscal year July 1, 2006 – June 30, 2007, PAF was contacted by over 6.2 million patients requesting information and/or direct professional intervention in the resolution of access disputes. Of that number, 24.6% were Medicare beneficiaries and 78% were individuals dealing with a diagnosis of cancer.

OPPS: Specified Covered Outpatient Drugs

NPAF Urges CMS to Follow the Ambulatory Payment Classification ("APC") Panel's Recommendation to Maintain Payment Levels for Specified Covered Outpatient Drugs ("SCODs") at Average Sales Price ("ASP") Plus 6%

NPAF urges CMS to rescind its proposal to reduce payment for SCODs from the 2007 rate of ASP + 6% to ASP + 5% in 2008. This proposal is contrary to the APC Panel's March and September 2007 recommendations to maintain reimbursement for all separately payable drugs under the hospital outpatient prospective payment system ("HOPPS"), including separately payable SCODs, at the ASP +

[1] 72 *Fed. Reg.*42626 (Aug. 2, 2007).

6% reimbursement rate currently applicable for drugs furnished in both hospital infusion centers and physician offices.[2]

NPAF is quite troubled by the site-of-service distinction in Medicare drug reimbursement rates that would be created under the Proposed Rule. It is our understanding that many new, innovative prescription drugs that have become the standard of care for patients with cancer or with other chronic or life-threatening diseases are not offered to retail customers, whether they be hospitals or physician practices, under discount arrangements. Certainly, for those SCODs that fall into this category, there would seem to be no justification for setting hospital reimbursement at ASP + 5%, particularly under a methodology that purportedly packages payments for pharmacy overhead costs with drug costs,[3] when physicians who pay the same price for the drugs are reimbursed at ASP + 6%. Furthermore, flaws associated with ASP as a reimbursement metric, erroneous assumptions about hospital pharmacy costs and how they are compensated, and evolving concerns about beneficiary access coupled with CMS' failure to account for certain new operational drug-associated costs facing hospitals next year argue strongly for maintaining ASP + 6% reimbursement for other SCODs as well.

Our conversations with providers and with other advocacy groups serving the cancer community suggest hospitals and physician practices alike are often financially squeezed under the current ASP + 6% reimbursement system. A recent report by the Health and Human Services Office of Inspector General ("OIG") surveyed twelve oncology practices of various sizes across the United States in part to assess the practices' ability to purchase infused or injected anti-cancer drugs at prices at or below ASP + 6%.[4] Despite the OIG's conclusion that "nine of the twelve practices reviewed could generally purchase drugs . . . for the treatment of cancer patients at or below the MMA-established reimbursement . . . ,"[5] we note this means that fully one-fourth of the practices could not. Further, based on the detailed data presented in the report, it appears when the OIG says three-fourths of the practices were "generally" able to buy drugs at ASP + 6% or less, it means only that those practices did not loose money on more than half of their drug purchases. In reality, half of the practices surveyed lost money on 30% or more of the drugs they needed for their patients. Because we know that reimbursement and patient access are inextricably linked, we find these statistics disconcerting and we are concerned about the physician choice and care access implications of the findings for Medicare beneficiaries newly diagnosed with cancer.

We suspect payment pressures facing hospitals and physician practices to continue, in part because Congress has yet to rectify fundamental flaws in the ASP system that stand in the way of using the ASP metric to match drug reimbursement accurately with the acquisition costs healthcare providers incur in the marketplace. Manufacturers that sell their products through traditional distributors must deduct customary prompt pay discounts extended to wholesalers from ASP. This requirement flies in the face of Congress' implicit recognition, in the change to the definition of Average Manufacturer Price ("AMP") included in the Deficit Reduction Act of 2005 ("DRA"),[6] that wholesalers rely on these payments to bolster their margins and/or to account for shipping and handling costs associated with drug delivery and rarely, if ever, pass such discounts on to physicians or hospitals.

ASP also may understate costs at the time of purchase because of the two-quarter lag built into the data collection process that supports CMS' publication of the quarterly ASP values that determine drug payment rates to hospital infusion centers and physician practices. Further, ASP-based payments fail to recognize state and local sales taxes that must be paid in some jurisdictions even though the taxes cannot be passed though to customers, as sales taxes normally are, if those customers are Medicare beneficiaries because of the rules that limit charges for items and services to the Medicare allowable

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[2] Advisory Panel on Ambulatory Payment Classification Groups, "March 7-9 2007 Mtg, Agenda, Rpt," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

[3] 72 *Fed. Reg.* at 42735.

[4] *Review of Selected Physician Practices' Procedures for Tracking Drug Administration Costs and Ability to Purchase Cancer Drugs at or Below Medicare Reimbursement Rate,* A-09-05-00066) (July 27, 2007), available at http://www.oig.hhs.gov/oas/reports/region9/90500066.htm.

[5] *Id.* at p 6.

[6] Pub. L. 109-071 (Feb. 8, 2005) (§ 6001(c)(1)(B) excludes customary prompt pay discounts extended to wholesalers from the calculation of AMP).

amount for most physicians and hospitals.[7] Unfortunately, bad debt contributes significantly to drug underpayments as well, particularly in the physician office setting where no Medicare payments are made to offset beneficiaries' failure to meet their co-pay obligations. Even in the hospital outpatient setting, bad debt can be significant since Medicare only reimburses hospitals for 70% of their bad debt and then only after reasonable collection efforts have been made. Given these realities – realities that all are recognized in a recent Medicare Payment Advisory Committee ("MedPAC") report to Congress [8] – we are convinced hospital outpatient departments will be quite hard-pressed if reimbursement for SCODs is further reduced to ASP + 5%. The result would be to reduce services to seniors to balance the loss.

Last year, the APC Panel heard testimony at its August 26, 2006 meeting which showed that the ASP + 6% Medicare HOPPS payment rate then applicable to SCODs failed to cover the cost of many of the separately payable outpatient prescription drugs on a typical hospital's formulary.[9] Furthermore, a 2006 survey conducted by the Association of Community Cancer Centers ("ACCC") in response to CMS' proposal to reduce Medicare payments for separately billable drugs to ASP + 5% in 2007 found that hospital outpatient payment rates would be insufficient to cover costs associated with five of the eight common oncology therapies evaluated.[10]

This story is no different this year. Based on testimony heard at its March and September 2007 meetings, the APC Panel again recommended that CMS continue paying hospital infusion centers at ASP + 6% for all separately payable drugs.[11] The APC Panel again heard testimony at its September 2007 meeting that the current Medicare payment of ASP + 6% is insufficient to cover the acquisition costs (much less the handling costs) for approximately 59% of the separately payable drugs on many hospital formularies. This is not surprisingly, since drug costs have continued to rise and the flawed nature of the ASP metric has not been remedied over the past year. Given that the current rate is inadequate, the APC Panel again recommended that CMS maintain reimbursement at ASP + 6% to avoid placing hospitals under even greater financial strain.

We are concerned some hospitals, particularly those in rural areas where costs typically run higher or those that serve as safety net providers, simply will not be able to continue offering outpatient chemotherapy services under the Proposed Rule. Others may have to limit the availability of certain more innovative and costly cancer treatments on their formularies. Still others may be forced to offer certain therapies only on an inpatient basis.

Although a baseline study of 2004 Medicare claims data by Duke University Institute of Research entitled, *"The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?,"* coupled with a Web-based convenience survey of Medicare beneficiaries in early 2005 found no statistically significant differences in time to treatment or site of treatment for Medicare beneficiaries with cancer before the Medicare Prescription Drug, Improvement and Modernization Act of 1003 ("MMA")[12] and in the first year (2004) of the MMA's implementation, it did note some apparent dislocations in access in rural areas and among Medicare beneficiaries without supplemental insurance, including an increase in inpatient treatment. The report recommended interpreting these findings with caution, however, because the relevant beneficiary subgroups were too small to permit the covariate adjustments needed

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[7] *See* 42 C.F.R. § 424.55(b)(1) for the rules limiting charges by participating physicians and non-participating physicians who take assignment, 42 U.S.C. § 1848(g) for charge limitations facing non-participating physicians, and 42 C.F.R. § § 489.20(a) and 489.30(b) for the rules limiting hospital outpatient charges.

[8] MedPAC, "Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs," p 6 (Jan. 2007 2005), available at http://www.medpac.gov/publications/congressional_reports/Jan07_PartB_mandated_report.pdf.

[9] Advisory Panel on Ambulatory Payment Classification Groups, "August 23-34 Mtg, Agenda & Report," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

[10] "Preliminary Results from ACCC's Survey on Hospital Outpatient Department Reimbursement Levels" available at http://www.accc-cancer.org/media/media_hopdsurvey06.asp.

[11] *Supra* note 2.

[12] Pub. L. 108-173 (Aug. 26, 2003).

to determine whether the findings reflected baseline differences between the pre-MMA and post-MMA cohorts.[13]

In testimony to the House Ways and Means Subcommittee on Health on July 13, 2006, Mark Miller, Executive Director of the MedPAC, stated that, based on data gathered in 2005, it appears many oncology practices have stopped treating Medicare beneficiaries.[14] As a result, the number of Medicare beneficiaries transferred to hospital outpatient departments increased in 2005.[15] A second MedPAC study, released in January 2007, drew similar conclusions about dislocations in access from an evaluation of 2006 data intended to assess the impact of the MMA on oncologists, urologists, rheumatologists, and specialists in the treatment of infectious diseases.[16]

The APC Panel also heard testimony at its September 2007 meeting expressing concern that, if CMS' proposal is finalized, the different payment rates for physician offices and hospitals may influence the site of care for Medicare beneficiaries. This concern contributed, in part, to the APC Panel's recommendation to maintain reimbursement at ASP +6%.

Patients and their families served by hospitals struggling with the proposed reimbursement cuts could be left with no or limited service options in their communities if the hospitals are forced to trim standard-of-care therapies from their formularies or shut their outpatient infusion centers. Further, if the "solution" to the cost pressures that could result in 2008 under SCOD payments at ASP + 5% involves putting more Medicare beneficiaries in inpatient beds for chemotherapy, the drug payment cuts would not only deprive those patients of care in the most clinically appropriate, patient-friendly setting but, perversely enough, also would increase costs to the healthcare system as a whole. We also are deeply concerned about how the proposed cuts in drug reimbursement might impact hospitals' ability to participate in clinical trials since a recent 2006 baseline study funded by the Global Access Project entitled, *"Baseline Study of Patient Accrual Onto Publicly Sponsored U.S. Cancer Clinical Trial?"* suggest such changes in reimbursement policy could have a negative impact on cancer trial enrollment.[17]

In summary, we urge CMS to take the advice of its own APC advisory panel to heart and to maintain reimbursement for SCODs at ASP + 6% for 2008. We fear the patient access concerns raised by the MedPAC report and the Duke study will become a reality in 2008 should the proposed cuts in payment go into effect.

NPAF Urges CMS to Adopt the APC Panel's Recommendation to Establish Separate Payments for Pharmacy Overhead Costs

Given the flaws associated with ASP as a measure of provider acquisition costs, we are troubled by CMS' continued insistence that ASP-based payments for SCODs at or below ASP + 6% are adequate to cover hospitals' pharmacy handling costs as well as their drug costs. In our view, available data suggest just the opposite. For example, a 2005 study commissioned by the National Patient Advocate Foundation and funded through donations from 42 organizations, including other non-profit entities invested in fostering patient access, entitled "*Documentation of Pharmacy Cost in the Preparation of Common Chemotherapy Infusions in Academic and Community-Based Oncology Practices*" found the

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[13] *The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?*, Kevin A Schulman *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Sept. 15, 2006), funded by The Global Access Project. For complete study, visit www.npaf.org .

[14] Medicare Part B Drugs and Oncology: *Testimony before the Subcommittee on Health Committee on Ways and Means U.S. House of Representatives* (July 13, 2006) (Statement of Mark E. Miller, PhD, Executive Director, Medicare Payment Advisory Commission), available at http://waysandmeans.house.gov/hearings.asp?formmode=view&id=5110.

[15] *Id.*

[16] *Supra* note 8.

[17] *"Baseline Study of Patient Accrual Onto Publicly Sponsored U.S. Cancer Clinical Trial?"*, Robert L. Comis, M.D., John Crowley, Ph.D *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Feb. 1, 2006), funded by The Global Access Project. For complete study, visit www.npaf.org

average cost per dose of chemotherapy administration was $36.03 plus the costs of drugs.[18] This study assessed drug handling costs associated with chemotherapy furnished in both physician office practices and hospital outpatient departments at academic medical centers.

Findings from a 2005 MedPAC study of the cost of pharmacy services in hospital outpatient departments are similar. MedPAC concluded "[h]ospitals appear to incur nontrivial costs in handling separately paid drugs and radiopharmaceuitcals. Thus, as the outpatient PPS moves toward reimbursing hospitals for drugs at their acquisition cost, it should also provide some payment for handling costs."[19] MedPAC cited studies showing that hospital pharmacy services overhead costs make up 26% to 33% of pharmacy departments' direct costs, with the rest of the costs attributed to the acquisition cost of drugs.[20] MedPAC also noted that hospitals do not have precise information about the magnitude of their pharmacy expenses and are not likely to have included all of these costs in their charges for drugs.[21] Based on the MedPAC report's estimate of pharmacy overhead costs (i.e., 26-33% of direct costs) and assuming ASP is actually equal to a hospital's drug costs, a packaged outpatient payment rate of well in excess of ASP + 6% would be needed to compensate hospitals fully for both the entire spectrum of drugs they administer in their outpatient departments and the handling costs they incur in conjunction with those drugs. From our perspective, these data raise serious questions about the adequacy of current SCOD reimbursement levels as a packaged drug/drug handling payment. The data certainly contradict the appropriateness of further reducing hospital outpatient department payments for SCODs to ASP + 5% in 2008.

The APC Panel agrees with our conclusion. After the Panel heard testimony at its March 7-8 2007 meeting, it recommended that CMS implement a three-phase plan to establish payment for pharmacy overhead costs incurred by hospitals.[22] Under the first phase, CMS would define three pharmacy overhead categories based on the complexity of drug handling, set flat fee payments to compensate hospitals for each level of handling and begin paying for the services in 2008 under New Technology APCs. Under the second phase, CMS would solicit outside survey data on pharmacy resource utilization and handling costs. Finally, under the third phase, after hospitals have had time to develop and implement appropriate systems for capturing accurate data, reimbursement for the pharmacy handling APCs could be realigned to reflect cost report data. We strongly encourage CMS to follow the advice of its own APC advisory panel and to move forward expeditiously to implement payments for pharmacy handling fees.

Although we appreciate the importance of gathering data to define appropriate payment levels for pharmacy handling services, our concerns about the inadequacy of the proposed reimbursement rates for SCODs in 2008 are exacerbated by the un-reimbursed costs hospitals will have to bear this year and next to implement two new drug-related reporting requirements. If the Proposed Rule is finalized without change, in 2008 hospitals will be required to report pharmacy overhead charges associated with outpatient drug administration on an un-coded revenue line on each drug claim. Charges would have to be reported for all drugs and biologicals (except radiopharmaceuticals) irrespective of the item's packaged or separately payable status. CMS made no attempt to quantify the costs or the administrative burden that would be associated with this new billing requirement in the Proposed Rule's Impact Analysis. It does acknowledge, however, that when it proposed establishing specific HCPCS codes for hospitals to report pharmacy overhead for CY 2006, commenters expressed significant concerns about the billing system modifications that would be required.[23] Apparently, those concerns contributed, at least in part, to CMS' decision not to go forward with that proposal to years

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[18] Gary Oderda, University of Utah Pharmacotherapy Outcomes Research Center, "Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices" (Feb. 8, 2005), prepared for the National Patient Advocate Foundation and the Global Access Project, available at http://www.npaf.org/pdf/gap/utah_study.pdf.

[19] MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program," Chapter 6, p 142 (June 2005), available at http://www.medpac.gov/publications/congressional_reports/June05_Titlepg_Insidecov_Acknow.pdf.

[20] *Id.* p 140.

[21] *Id.*

[22] Advisory Panel on Ambulatory Payment Classification Groups, "March 7-9 2007 Mtg, Agenda, Rpt," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

[23] 72 *Fed. Reg.* at 42736.

ago. A review of the 2006 Hospital Outpatient Prospective System Final Rule[24] suggests some hospitals do not have sophisticated enough cost accounting systems to permit them to determine the amount attributable to pharmacy handling costs without great difficulty. Commenters also pointed out the questionable reliability of data gathered from claims when the relevant data element has no immediate reimbursement impact.[25] They raised questions about CMS' ability to use the reported data to set appropriate drug handling fees at the individual drug level.

The concerns expressed in 2006 seem equally pertinent in the context of the 2008 Proposed Rule given CMS' current plan to use reported charges to package drug handling costs with drug administration APCs beginning in 2010. To do that, CMS will have to apply an average pharmacy department cost-to-charge-ratio ("CCR") to billed charges to determine the drug handling costs for various drug administration APCs. This methodology ignores the fact that CCRs were never intended to determine cost at the specific procedure level. It will likely lead to the packaging of pharmacy handling costs that are skewed by the phenomenon of charge compression, leaving the more complex and expensive drug administration APCs, like the chemotherapy administration codes, underpaid because of leakage to the APCs for less complex, less costly services. It also is unclear to us how usable the reported data will be since the Proposed Rule would allow hospitals "the flexibility to decide whether they reported a pharmacy overhead charge per drug or per episode of drug administration services."[26]

In addition to shouldering the burden of assessing and reporting pharmacy costs, hospital outpatient departments are or will soon be grappling with implementation issues associated with Medicaid claims for separately payable outpatient prescription drugs under DRA § 6002 and its implementing regulations recently published in the *Federal Register*.[27] The new law obligates hospital outpatient departments to report the NDC number of each single-source or innovator multiple-source separately payable drug they administer on the claim so that State Medicaid programs can capture the data and charge pharmaceutical manufacturers Medicaid drug rebates on the units administered. States that are not collecting this information from hospitals as of January 1, 2007 are at risk of losing federal financial participation for their Medicaid drug costs unless they have applied for an implementation waiver. Presumably most will do so since there currently is no space on the paper or electronic version of the standard claims forms used by hospitals that can accept the required NDC number. The obligation to report NDC numbers will expand on January 1, 2008 to encompass the top 20 multiple source drugs identified each year by CMS, based on the prior year's Medicaid expenditures. CMS acknowledges in the preamble to the Medicaid Program Prescription Drug Final Rule that it understands the requirement carries "operational difficulties" and "that some hospitals . . . will require systems modifications and changes in dispensing and billing procedures in order to comply with the billing requirement."[28] Adequate reimbursement for drugs and drug handling costs is essential to support the costs of these changes. Without it hospitals will either pass costs or reduce services to patients who receive low reimbursement.

OPPS: DRUG ADMINISTRATION

NPAF Urges CMS to Adopt the APC Panel's Recommendation to Pay Separately for Concurrent Infusion Therapy

NPAF applauds CMS for implementing the full set of APCs for drug administration services for 2007. We commend CMS for proposing to increase payments for drug administration services anywhere from 1.6% to 12.2% in 2008. Although we recognize the differences in the methodologies that underlie the physician fee schedule and the HOPPS, as we discussed in the comments we filed earlier this month on CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008,"[29] it is imperative that CMS take steps to ensure that physicians also are adequately compensated for the cost inflation associated with the drug administration services. Otherwise, there could be a growing economic push on the part of community-based oncologists to

[24] 70 *Fed. Reg.* 68515 (Nov. 10, 2005).
[25] 70 *Fed. Reg.* at 68662.
[26] 72 *Fed. Reg.* at 42735.
[27] 72 *Fed. Reg.* 39141, 39244 (July 17, 2007) (codifying 42 C.F.R. § 447.520).
[28] 72 *Fed. Reg.* at 29220.
[29] 72 *Fed. Reg.* 38120 (July 12, 2007).

refer the 80% of Medicare beneficiaries who receive chemotherapy in physicians' office to hospitals for infusion services. Such a result would be costly for Medicare. It would also be costly for beneficiaries, both financially and emotionally.

To make hospital outpatient payments for drug administration more consistent with the realities of cancer care, NPAF would like to encourage CMS to go even further and take steps to ensure outpatient departments will be paid appropriately when a patient receives concurrent infusion therapy. To that end, we recommend that CMS accept the recommendation the APC Panel made at its March 6-7, 2007 meeting and pay separately for CPT 90768, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)*, at the same rate CMS has set for CPT 90767, *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (list separately in addition to code for primary procedure)*.[30] We believe implementing this recommendation would be an important step towards ensuring that Medicare beneficiaries continue to have access to complex chemotherapy treatments in the hospital outpatient setting. It also is consistent with a basic promise of the MMA – the promise that Medicare reimbursement rates will accurately match the costs associated with both the drug and the drug administration services with the costs physicians and providers incur for furnishing each component of care.

OPPS: PAYMENT FOR THERAPEUTIC RADIOPHARMACEUTICALS

NPAF Urges CMS to Ensure that Payment for Therapeutic Radiopharmaceuticals Is Adequate to Cover Incurred Costs

NPAF is concerned that hospitals will stop providing radiopharmaceutical therapy to Medicare beneficiaries if the payment rate for these innovative products is not adequate to cover all their costs. CMS is proposing to continue separate payment for therapeutic radiopharmaceuticals that have a mean per day cost of more than $60, with the payment rate for each product set based on the mean unit cost as reported in 2006 claims data. We worry that the proposed approach would perpetuate the severe underpayments that plague therapeutic radiopharmaceuticals under the 2007 HOPPS. We understand that the radiopharmaceutical APCs do not capture all the handling and transportation costs incurred by hospitals to acquire these drugs and handle them safely. We urge CMS to ensure that the payment rate for 2008 adequately reimburses hospitals for their costs so that Medicare beneficiaries will continue to have access to these therapeutic alternatives for treating certain cancer including concerns of relapse. For patients, treatment alternatives after relapse are often extremely limited. Those approved drugs will be of great benefit to Medicare patients dealing with relapse.

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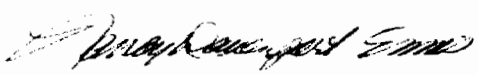
NPAF would again like to thank CMS for the opportunity to submit formal comments on the 2008 Hospital Outpatient Prospective Payment System Proposed Rule. We strive to make dialogue with the agency about payment policies give voice to the concerns of Medicare beneficiaries dealing daily with the burdens of a chronic, debilitating or life-threatening disease. We would be happy to discuss our comments with you if you have any questions about our recommendations for improving Medicare beneficiaries' access to cancer care.

Respectfully submitted,



Nancy Davenport-Ennis
President and Chief Executive Officer

[30] Advisory Panel on Ambulatory Payment Classification Groups, "March 7-9 2007 Mtg, Agenda, Rpt," available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

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ASC Quality Collaboration

September 14, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P; Quality Data

Dear Acting Administrator Weems:

On behalf of the ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring that ASC quality data is appropriately developed and reported, please accept the following comments regarding CMS-1392-P, Section XVII. Reporting Quality Data for Annual Payment Rate Updates as it pertains to ambulatory surgical centers (ASCs). Early in 2006, the ASC Quality Collaboration came together to initiate the process of developing standardized ASC quality measures. The organization's stakeholders include ASC corporations, ASC associations, professional societies, accrediting bodies and government entities. We are pleased that Section 109 of the Tax Relief and Health Care Act of 2006 (TRHCA) will afford ASCs the opportunity to share standardized quality indicators with CMS and the public.

We appreciate the consideration CMS demonstrated in its decision to introduce quality measures for ASC reporting beginning January 1, 2009. With the implementation of the revised ASC payment system in 2008, the ASC community will face a significant transition and we are pleased additional requirements will not be introduced simultaneously. The current absence of any nationally endorsed ASC quality measures designed for public reporting and accountability would have been a further barrier to implementation in 2008. However, we anticipate ASC quality measures will be endorsed by the National Quality Forum by the end of the year and will be available for implementation in 2009.

I. Quality Measures for Outpatient Surgery

The quality of facility services for outpatient surgery is most appropriately evaluated by measures specifically designed to assess processes or outcomes of care germane to the specific services rendered by facilities that provide ambulatory surgical services. It is crucial that measures selected for the evaluation of facility quality reflect processes or outcomes of care that are attributable to and reasonably the responsibility of the facility itself -- its staff, the equipment, the environment of care offered to its patients, and its roles in the delivery of patient care.

When the ASC Quality Collaboration was formed, our clinicians undertook a detailed evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. Though several existing measures addressed surgical care, none had been developed specifically for the ambulatory surgical center setting. In fact, many of these measures are specific to procedures that are either uncommonly performed in outpatient facilities, or not performed at all for Medicare beneficiaries in the outpatient surgical setting. Other measures expressly exclude patients with a stay of less than 24 hours, effectively eliminating the entire ASC patient population. Still other measures focus on processes of care that are specific responsibilities of physicians, such as the selection and ordering of antibiotics.

Finding no measures designed for public reporting and accountability specific to facilities performing outpatient surgery, the ASC Quality Collaboration developed a number of facility-level measures of ASC quality. These measures were based on those already commonly used by the ASC community for internal quality assessment and external benchmarking. After refining these standardized measures, the ASC Quality Collaboration piloted them in a sample of twenty ASCs and was able to confirm their feasibility and usability. To date, these measures have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement and have recently been open to public and NQF member comment. We anticipate that final action on these measures could be taken as early as November 2007.

Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure which evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (PQRI #20 and PQRI #21) developed to evaluate physician performance in this area. Please see Attachment A for detailed information on the five outpatient surgical facility-specific quality measures.

The prophylactic antibiotic timing measure also addresses the statutory requirement under TRHCA for evaluation of medication errors. In their recent *MEDMARX® Data Report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005*, the U.S. Pharmacopeia detailed the various types of medication errors in outpatient surgery, one of which was "wrong time." The report specifically recommended "[d]eveloping strategies to ensure that medications, especially antimicrobial agents, are administered at the correct time."

As of this writing, we are not aware of any other measures specifically addressing facility quality in the delivery of outpatient surgical services that have either been nationally endorsed for public reporting and accountability or are in the process of evaluation for endorsement. Therefore, we strongly recommend CMS consider these five facility-specific measures for ASC reporting if they are endorsed by the NQF.

One of the principles that guided the ASC Quality Collaboration was harmonization – the idea that the measures developed through our efforts should be applicable to all facilities offering ambulatory surgery, allowing comparison of quality across sites of service. The ASC measures currently under consideration for endorsement by the NQF are appropriate for other outpatient surgical settings, effectively addressing the need to harmonize quality measures whenever possible.

II. ASC Data Collection

To date, CMS has implemented a number of quality reporting systems that employ a variety of methods to collect patient-level quality data. Most of these systems require that data be submitted electronically to a repository. As proposed in this rule, hospital outpatient departments would adopt the same methodology currently used by hospitals for inpatient reporting. That process requires abstraction of clinical data based on chart review, followed by compilation and submission in specific XML format to an approved data submission vendor. This vendor then transmits the data to the QIO Clinical Warehouse.

On the other hand, under the Physician's Quality Reporting Initiative (PQRI), physicians report patient-level quality data using administrative claims. Using either HCPCS Level II G codes or AMA Category II CPT codes adopted specifically for quality reporting, the physician is able to submit quality data in conjunction with codes for services rendered on the CMS-1500. Given the administrative burden of medical record extraction, physicians are likely to continue using a claims-based approach to quality reporting in the future.

We have carefully evaluated these alternative approaches, taking into account the characteristics and resources of the typical ASC. Though there is significant variability, CMS data indicates a median of two operating/procedure rooms per facility (mean = 2.5). FASA's 2006 ASC Salary & Benefits Survey shows that the majority (62.2%) of ASCs have 20 or fewer total full time equivalents, including both clinical and non-clinical staff. It is unusual for an ASC to have a medical records department staffed with multiple individuals.

Our evaluation of alternative reporting methodologies has focused on their complexity, staff resources needed for implementation, requirements for hardware and software, training requirements, and additional expenses, particularly related to contracting with data submission vendors. In all these areas, we find the administrative claims data approach to be the most practical, feasible and economical solution for ASCs.

The administrative and financial burden of reporting quality measures should be fully considered. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72 Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

Further, ASCs will continue submitting their Medicare claims using the CMS-1500 at least through 2008. Therefore, ASCs are in a position to report quality data in the same manner as physicians, which will allow CMS to leverage the processes it has already developed under

PQRI. If ASCs move to the UB-04 in the future (a change we support), these codes can continue to be reported on the new form and comparisons made across multiple years remain feasible.

We request CMS work with ASC leaders to develop HCPCS Level II G codes that would allow facility-level quality measures to be reported using a claims-based approach. Reporting data on the claim form using HCPCS codes is achievable across ambulatory settings and can be accommodated on both the CMS-1500 and the UB-04.

III. Publication of Quality Data Collected

The demand for more publicly available health care information is being driven by federal and some state actions and by employers in an effort to control escalating health insurance costs and improve quality. Generally these transparency oriented efforts are motivated by a desire to provide consumers with information they can use in a meaningful way to improve their health and lower the cost of their care. As the health insurance industry moves to more consumer driven health care through Health Savings Accounts (HSAs), Health Reimbursement Accounts (HRAs) and Flexible Spending Accounts (FSAs), access to cost and quality information will become even more important to consumers. The ASC Quality Collaboration supports the development of transparency regarding health care information and welcomes a fair presentation of ASC cost and quality information to assist consumers in making decisions.

The success of transparency efforts is closely linked to how effectively information is shared with the public. A data reporting infrastructure should allow patients and payers to compare quality across Medicare's payment silos when a service or procedure can be delivered in multiple ambulatory settings.

Consumers should be able to access quality and cost information on websites that are organized to allow easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date, and clearly presented. Specifically, web-based presentation of quality and cost data should address or incorporate the following principles.

1) Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations.

2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its public presentation.

3) There should be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented.

4) In addition to reporting quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

We request more detailed consideration and expanded description on this vital matter from CMS in future rulemaking.

IV. Summary of Recommendations

The ASC Quality Collaboration fully supports public reporting of facility-level quality measures that evaluate outcomes or processes of care specific to the facility services rendered in the outpatient surgical setting. CMS should adopt measures of quality for public reporting and accountability that have been developed specifically for application in the outpatient surgical facility.

CMS should implement a claims-based reporting system for ASCs, similar to the quality reporting system the agency has implemented for physicians. Such a system would allow patient-level data collection without undue financial and administrative burden.

Presentation of quality data deserves careful consideration to achieve the most effective communication of information. At a minimum, the method CMS selects for sharing data should allow interested parties to directly compare measures of outpatient surgical facility services across facility types.

Thank you for considering these comments. I would be happy to assist with questions or provide additional information at your request.

Sincerely,

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