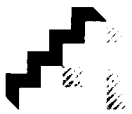

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2200 Jefferson Avenue
Toledo, Ohio 43624
(419) 251-0700
FAX: (419) 251-0722

September 26, 2006

Attention: CMS-1506-P
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

RE: Medication Therapy Management Services

Dear Sir or Madam:

Could you please provide additional guidance with regard to your statement,

"We have no need to distinguish medication therapy management services provided by a pharmacist in a hospital from medication therapy management services provided by other hospital staff, as the OPPS only makes payments for services provided incident to physicians' services."

In a recent CMS Q&A on the CMS website, CMS identifies the services that qualify as an "incident to." One of the requirements is that the physician must provide direct supervision by being present in the office suite to assist if necessary. However, from the CMS Medicare Benefit Policy Manual (Pub 100-02) Chapter 6, Hospital Services Covered Under Part B, Section 20.4 Outpatient Therapeutic Services, "the physician supervision requirement is generally assumed to be met where the services are performed on hospital premises." Would the services of a pharmacist fall under Section 20.4?

In regard to pharmacists employed in hospitals providing medication therapy management services, these services are provided similar to cardiac rehab. The primary care physician who has referred the patient to the hospital for services is not physically present at the hospital at the time medication therapy management services are rendered. In most cases, the referring physician is a physician in the Community and their only relationship with the hospital is that of being a member of the medical staff. One of the most common medication therapy management services provided by a pharmacist in a hospital is anticoagulation therapy. The patient may come to the hospital weekly to receive lab work and see the pharmacist. The pharmacist would call the referring physician to make recommendations regarding medication management, as necessary. Is supervision assumed because the service is provided in a hospital?

The physician medical director would not have direct contact with the patient but would be available for consultation with the pharmacist if necessary. The medical director would be responsible for setting policies and procedures, but would not see any patients and would often not be physically present in the hospital at the time services are rendered.

Would you please comment on how it would be appropriate to bill for this service? Would it be appropriate to bill this as a clinic visit in the range (99211- 99215)? Would the service be limited to billing under 99211 as a "nurse visit" type of service?

Comments on this service would be very much appreciated as hospitals that either have services such as this, or are considering such services, would appreciate knowing if these services are appropriately reimbursable. If these services, provided by a non-directly supervised pharmacist, are not reimbursable as provided, it is appropriate to notify providers of that and avoid the conflict that occurred with cardiac rehab.

"Visits"

In reviewing the "Guidelines Based on the Time Staff Spent with the Patient" and "Guidelines Based on Patient Complexity," CMS commented that these two models both have the "potential for upcoding and gaming." In fact for the Patient Complexity model, the words "significant potential for upcoding and gaming" are used. However, later in this same section, it is stated, "we are proposing that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with these codes."

Given all of that, if a hospital is using either of the two "Guidelines" above, may they continue to determine the visit levels based on this current methodology until CMS has implemented national guidelines? Does it matter if the distribution of codes does not result in "a normal curve?" Most facilities have a strong desire to be in compliance with CMS standards and appreciate clear guidance to avoid any potential fraud and abuse allegations in the future.

Sincerely,

R. Elizabeth Hickman

R. Elizabeth Hickman
Regional Director
Corporate Compliance

FRAZIER
HEALTHCARE VENTURES

49

Two Union Square
601 Union Street
Suite 3200
Seattle, WA 98101
P: 206-621-7200
F: 206-621-1848

September 22, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT
CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT
Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

Once again, I would like to thank you for the opportunity to comment on this year's proposed rule. Should you have any questions please do not hesitate to email me at Nathan@frazierhealthcare.com

Respectfully,

Nathan R. Every, M.D, MPH
General Partner
Frazier Healthcare Ventures

MHSACM, Inc.

251 West Central Street, Suite 21, Natick, Massachusetts 01760 (508) 647-8385 / Fax (508) 647-8311

Elizabeth Funk, *President/CEO* Ellen Attaliades, MA, *Chairman*

September 20, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1506-P: Proposed Changes to Hospital Outpatient 2007 Rates

Dear Dr. McClellan:

Thank you for the opportunity to submit comments on the *CMS-1506-P: Proposed Changes to Hospital Outpatient 2007 Rates.* I am writing in regard to the proposed rate reduction for Partial Hospitalization services (APC 0033). MHSACM is a statewide association representing more than 100 community-based mental health and substance abuse providers and we adamantly oppose the proposed 14 percent rate reduction for Partial Hospitalization services. This reduction, when combined with the rate reduction instituted last year, would be devastating and severely hinder access to needed services. The rate methodology used by CMS to calculate rates for this service is flawed and we respectfully request that CMS suspend the proposed rate reduction and institute a process by which to review its rate setting methodology.

CMS Rate Computation

CMS states that per diem costs were computed by summarizing the line item costs on each bill and dividing by the number of days on the bills. This calculation methodology can severely dilute the rate and penalize providers.

- Partial Hospital programs are only paid their per diem rate when three or more qualified services are delivered within a day of service. Our Partial Hospital providers, however, are encouraged by their fiscal intermediary to submit all service days on claims, even when the patient receives less than three (3) services on a given day. Programs must report these days to be able to meet the 57 percent attendance threshold necessary to avoid potential delays in the claims payment. If only one or two services are included as a cost and the day is divided into the aggregate data, the cost per day is significantly diluted.

- Even days that meet the three or more services delivered criteria, but only have three services delivered to a client, can dilute the cost factors in the rate calculations. Days where three or fewer services are delivered can occur frequently when providing treatment to people with severe mental illnesses.

- CMS has reduced certain providers' cost for purposes of deriving the rate based on its observation that "costs for settled cost reports were considerably lower than costs from 'as submitted' cost reports" (68 Fed. Reg. 48012). While this CMS observation is true, it fails to include in the providers' costs those costs that were denied and removed from the "as submitted" cost reports, but then reversed on appeal to the Provider Reimbursement Review Board (PRRB) and subsequently settled pursuant to the PRRB's mediation program, or otherwise settled between the provider and the intermediary.

During the relevant years at issue, providers of Partial Hospitalization services incurred particularly significant cost report denials but also experienced favorable outcomes on appeal. Because the CMS analysis did not take all the allowable costs into consideration, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs that were subsequently allowed.

Recommendations

- MHSACM respectfully requests that CMS not implement the *Proposed Changes to Hospital Outpatient PPS 2007 Rates* for Partial Hospitalization services and leave the current rate in place until such time that a Task Force is established and develops a new rate methodology that captures all relevant data and reflects the actual costs to providers to deliver these services.

- MHSACM recommends that the members of a new Rate Setting Task Force be composed of CMS staff and a diverse group of stakeholders that include front-line providers of Partial Hospital services. The Task Force should also include representatives from national organizations including the National Council for Community Behavioral Healthcare (NCCBH), National Association of Psychiatric Health Systems (NAPHS) and American Association of Behavioral Healthcare (AABH).

Community-based Partial Hospitalization services are a vital component of the continuum of mental health care in Massachusetts. They are a proven, cost-effective model of care for clients who remain at high risk for admission to more costly inpatient services. These programs provide intensive clinical treatment to clients who otherwise would not be able to function in the community.

In *Grading the States: A Report on the National Health Care System for People with Serious Mental Illness* (National Alliance for the Mentally Ill, 2006), Massachusetts is criticized for the lack of access to community-based services because the system is "grossly underfunded." We need to maintain and expand the services we have and increase access to community-based treatment, not decimate access though rate reductions.

Thank you again for the opportunity to submit comments. If you would like to discuss our recommendations further, please contact me at 508-647-8385.

Sincerely,

Elizabeth Funk
President/CEO and
Chair, Board of Directors
National Council for Community Behavioral Healthcare

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University Health Care

NEUROLOGY CLINIC – MSI LAB

Michael E. Funke, M.D., Ph.D.
University of Utah
Magnetic Source Imaging
729 Arapeen Drive
Salt Lake City, UT 84108

September 25, 2006

To Whom It May Concern:

It has recently come to our attention that CMS just published the new Proposed Rules for 2007 which included MEG reimbursement (see pp. 160-165). Of concern is that these rules are based on both incomplete and inaccurate claims data for CPT codes 95965, 95966 and 95967. It is our understanding that CMS has a total of 23 claims for 95965 with a minimum charge of $400 and a maximum charge of $4000. However, we are aware that none of the University of Utah's Medicare (CPT 95965) claims were included in the supposed CMS "total" database for the year 2005. Therefore, our concern is that there must be other missing, yet crucial data that would change the newly proposed reimbursement levels.

Please find enclosed the University of Utah's 2005 Medicare claim's data for your review (nine claims total for 95965). Accordingly, we respectfully request that these claims, which were submitted to and paid for by Medicare, be considered in the final rule making.

Sincerely,

Michael Funke

Michael E. Funke, M.D., Ph.D.
Program Director, Magnetic Source Imaging
University of Utah Health Care

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2			3 PATIENT CONTROL NO. [redacted]						4 TYPE OF BILL 131	
	5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV'D	8 N/C'D	9 C/I'D	10 L/R'D	11			
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b												B	b
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		b						b
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	42 REV CD	43 DESCRIPTION	44 HCPCS/RATES	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
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	50 PAYER		51 PROVIDER NO.	52 REL. IND.	53 ASSIGN. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56	
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B	MEDICAID	D11	876000525088	Y	Y	91200			B
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	58 INSURED'S NAME	59 P REL	60 CERT. SSN. HIC. ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO.	
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	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION	
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67 PRIN. DIAG. CD	68 CODE	69 CODE	OTHER DIAG. CODES 70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM. DIAG. CD	77 E-CODE	78
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79 P C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
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	84 REMARKS	85 PROVIDER REPRESENTATIVE	86 DATE
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UB-92 HCFA-1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2	3 PATIENT CONTROL NO [redacted]	4 TYPE OF BILL 131

5 FED TAX NO	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N-C D	9 C-I D	10 L-R D	11
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13 PATIENT ADDRESS [redacted]

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b												B
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38 MEDICARE
127 S 500 E STE 400
SALT LAKE CITY UT 84102

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	42 REV CD	43 DESCRIPTION	44 HCPCS/RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
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	50 PAYER	51 PROVIDER NO	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST AMOUNT DUE	56
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B	MEDICAID OF UT PCP	876000525088	Y	Y	94 37		
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57 DUE FROM PATIENT ... >

	58 INSURED'S NAME	59 P REL	60 CERT -SSN - HIC - ID NO	61 GROUP NAME	62 INSURANCE GROUP NO
A	[redacted]	18	[redacted]		
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	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
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67 PRIN DIAG CD	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E CODE	78
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79 P C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
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82 ATTENDING PHYS. ID 95-312149-1205
G94368 CONSTANTINO TAW

83 OTHER PHYS. ID

OTHER PHYS. ID

84 REMARKS

85 PROVIDER REPRESENTATIVE

86 DATE 08/16/06

UB-92 HCFA-1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

APPROVED OMB NO. 0938-0279

1	2	3 PATIENT CONTROL NO.	4 TYPE OF BILL
UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891		[redacted]	131

5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N/C D	9 C/I D	10 L/R D.	11
876000525W	030205	030205					529457204

12 PATIENT NAME	13 PATIENT ADDRESS
[redacted]	[redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO.	CONDITION CODES 24	25	26	27	28	29	30	31
[redacted]	[redacted]	S	030205	13		1	23	01	7406333	G0	G0						

	32 CODE	32 OCCURRENCE DATE	33 CODE	33 OCCURRENCE DATE	34 CODE	34 OCCURRENCE DATE	35 CODE	35 OCCURRENCE DATE	36 CODE	36 OCCURRENCE SPAN FROM	THROUGH	37	
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38	39 CODE	39 VALUE CODES AMOUNT	40 CODE	40 VALUE CODES AMOUNT	41 CODE	41 VALUE CODES AMOUNT	
MEDICARE 127 S 500 E STE 400 SALT LAKE CITY UT 84102	a						a
	b						b
	c						c
	d						d

	42 REV. CD.	43 DESCRIPTION	44 HCPCS/RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
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	50 PAYER	51 PROVIDER NO	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56	
A	MEDICARE MED	460009	Y	Y	961980			A
B	HEALTHY U MEDICAID UHN	2364	Y	Y	91200			B
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57 DUE FROM PATIENT -->

	58 INSURED'S NAME	59 P REL	60 CERT. SSN HIC ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO.	
A	[redacted]	18	[redacted]			A
B	[redacted]	18	[redacted]			B
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	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION	
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67 PRIN. DIAG. CD.	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM. DIAG. CD.	77 E CODE	78
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79 P.C.	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
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	82 ATTENDING PHYS ID	95-312149-1205	
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	83 OTHER PHYS ID		
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			08/16/06

UB-92 HCFA-1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2	3 PATIENT CONTROL NO [redacted]	4 TYPE OF BILL 131

5 FED TAX NO.	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N-C D	9 C I D	10 L-R D	11
876000525W	033005	033005					501060750

12 PATIENT NAME [redacted]

13 PATIENT ADDRESS [redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO	CONDITION CODES 24	25	26	27	28	29	30	31
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38 MEDICARE
127 S 500 E STE 400
SALT LAKE CITY UT 84102

	39 CODE	VALUE CODES AMOUNT	40 CODE	VALUE CODES AMOUNT	41 CODE	VALUE CODES AMOUNT
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B	BENESIGHT BTF	876000525	Y	Y	9200		
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57 DUE FROM PATIENT -->

	58 INSURED'S NAME	59 P REL	60 CERT. SSN HIC ID NO	61 GROUP NAME	62 INSURANCE GROUP NO
A	[redacted]	18	[redacted]	[redacted]	[redacted]
B	[redacted]	43	[redacted]		
C					

	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
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67 PRIN DIAG CD	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E CODE	78
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	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE

82 ATTENDING PHYS. ID 751579231205 a
D26534 MATSUO FUMISUKE b

83 OTHER PHYS. ID a
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OTHER PHYS. ID a
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84 REMARKS a b c d

85 PROVIDER REPRESENTATIVE

86 DATE 08/16/06

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

UB 92 HCFA 1450

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2	3 PATIENT CONTROL NO [redacted]	4 TYPE OF BILL 131							
5 FED TAX NO	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N:C D	9 C I D	10 L R D	11			
876000525W	042705	042705					529929057			

12 PATIENT NAME [redacted]

13 PATIENT ADDRESS [redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO	CONDITION CODES 24	25	26	27	28	29	30	31
[redacted]	[redacted]	D	042705	14		1	23	01	6372254								

	32 CODE	32 OCCURRENCE DATE	33 CODE	33 OCCURRENCE DATE	34 CODE	34 OCCURRENCE DATE	35 CODE	35 OCCURRENCE DATE	36 CODE	36 OCCURRENCE SPAN FROM	THROUGH	37
a												A
b												B
												C

38 MEDICARE
127 S 500 E STE 400
SALT LAKE CITY UT 84102

	39 CODE	39 VALUE CODES AMOUNT	40 CODE	40 VALUE CODES AMOUNT	41 CODE	41 VALUE CODES AMOUNT
a						
b						
c						
d						

	42 REV CD	43 DESCRIPTION	44 HCPCS/RATES	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON COVERED CHARGES	49
1	0740	EEG	95965	042705	01	10531 80		
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23	001	TOTAL CHARGES				10531 80		

	50 PAYER	51 PROVIDER NO	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST AMOUNT DUE	56
A	MEDICARE MED	460009	Y	Y	961980		
B	MEDICAID OF OR D09	032383	Y	Y	912 00		
C							

57 DUE FROM PATIENT -->

	58 INSURED'S NAME	59 P REL	60 CERT. SSN. HIC. ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO
A	[redacted]	18	[redacted]		
B	[redacted]	18	[redacted]		
C					

	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
A		3		
B		3		
C				

67 PRIN DIAG CD	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E-CODE	78
34541											

79 P C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
9						
	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE

82 ATTENDING PHYS ID 95-312149-1205 a
G94368 CONSTANTINO TAW b

83 OTHER PHYS. ID a
b

OTHER PHYS ID a
OTH000 UNKNOWN DOCTOR b

84 REMARKS a b c d

85 PROVIDER REPRESENTATIVE 86 DATE 08/16/06

UB 92 HCFA 1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2	3 PATIENT CONTROL NO [redacted]	4 TYPE OF BILL 131

5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N/C D	9 C I D	10 L R D	11
876000525W	092105	092105					571798524

12 PATIENT NAME [redacted]

13 PATIENT ADDRESS [redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO.	CONDITION CODES 24	25	26	27	28	29	30	31
[redacted]	[redacted]	M	092105	12		1	23	01	9388927	09							

32 CODE	OCCURRENCE DATE	33 CODE	OCCURRENCE DATE	34 CODE	OCCURRENCE DATE	35 CODE	OCCURRENCE DATE	36 CODE	OCCURRENCE SPAN FROM	THROUGH	37
a										007100	A
b											B
											C

38 MEDICARE
127 S 500 E STE 400
SALT LAKE CITY UT 84102

	39 CODE	VALUE CODES AMOUNT	40 CODE	VALUE CODES AMOUNT	41 CODE	VALUE CODES AMOUNT
a						
b						
c						
d						

	42 REV CD.	43 DESCRIPTION	44 HCPCS/RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0370	ANESTHESIA	99142	092105	01	70 40		
2	0710	RECOVERY ROOM		092105	01	45 80		
3	0740	EEG	95965	092105	01	10531 80		
4								
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11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23	001	TOTAL CHARGES				10648 00		

	50 PAYER	51 PROVIDER NO.	52 REL. ASG.	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56
A	MEDICARE MED	460009	Y	Y	973600		
B	MOLINA MEDICAID TRAD D81	876000525W	Y	Y	9120		
C							

57 DUE FROM PATIENT ... >

	58 INSURED'S NAME	59 P REL	60 CERT. SSN · HIC · ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO.
A	[redacted]	18	[redacted]		
B	[redacted]	18	[redacted]		
C					

	63 TREATMENT AUTHORIZATION CODES	64 ISC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
A		3		
B		3		
C				

67 PRIN DIAG CD	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E CODE	78
34541											

79 P C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
9						
	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE

82 ATTENDING PHYS ID 95-312149-1205 a
G94368 CONSTANTINO TAW b

83 OTHER PHYS ID a
b

OTHER PHYS. ID a
b

84 REMARKS a b c d

85 PROVIDER REPRESENTATIVE 86 DATE 08/16/06

UB-92 HCFA-1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2		3 PATIENT CONTROL NO [redacted]							4 TYPE OF BILL 131
	5 FED. TAX NO	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N.C.D.	9 C.I.D	10 L.R.D.	11		
	876000525W	092805	092805					528061923		

12 PATIENT NAME [redacted]

13 PATIENT ADDRESS [redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO.	CONDITION CODES 24	25	26	27	28	29	30	31
[redacted]	[redacted]	X	092805	08		1	23	01	6826663								

	32 OCCURRENCE CODE	DATE	33 CODE	DATE	34 CODE	DATE	35 CODE	DATE	36 OCCURRENCE SPAN CODE	FROM	THROUGH	37
a											007129	A
b												B
												C

38 MEDICARE
127 S 500 E STE 400
SALT LAKE CITY UT 84102

	39 VALUE CODES CODE	AMOUNT	40 VALUE CODES CODE	AMOUNT	41 VALUE CODES CODE	AMOUNT
a						
b						
c						
d						

	42 REV. CD	43 DESCRIPTION	44 HCPCS/RATES	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0370	ANESTHESIA	99142	092805	01	7040		
2	0710	RECOVERY ROOM		092805	01	4580		
3	0740	EEG	95965	092805	01	10531 80		
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22								
23	001	TOTAL CHARGES				10648 00		

	50 PAYER	51 PROVIDER NO.	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56
A	MEDICARE MED	460009	Y	Y	973600		
B	HEALTHY U MEDICAID UHN	2364	Y	Y	9120		
C							

57 DUE FROM PATIENT -->

	58 INSURED'S NAME	59 P REL	60 CERT. SSN HIC ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO.
A	[redacted]	18	[redacted]		
B	[redacted]	18	[redacted]		
C					

	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
A		3		
B		3		
C				

67 PRIN DIAG CD	68 CODE	69 CODE	70 CODE	OTHER DIAG CODES 71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E CODE	78
34541											

79 P.C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
9						
	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE

82 ATTENDING PHYS ID 95-312149-1205
G94368 CONSTANTINO TAW

83 OTHER PHYS ID

OTHER PHYS. ID

84 REMARKS

85 PROVIDER REPRESENTATIVE

86 DATE 08/16/06

UB 92 HCFA 1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2		3 PATIENT CONTROL NO [redacted]						4 TYPE OF BILL 131
5 FED. TAX NO	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV'D	8 N-C'D	9 C-I'D	10 L-R'D	11		
876000525W	121405	121405					528657782		

12 PATIENT NAME	13 PATIENT ADDRESS
[redacted]	[redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO	CONDITION CODES 24	25	26	27	28	29	30	31
[redacted]	[redacted]	M	121405	08		1	23	01	12067229								

	32 CODE	32 OCCURRENCE DATE	33 CODE	33 OCCURRENCE DATE	34 CODE	34 OCCURRENCE DATE	35 CODE	35 OCCURRENCE DATE	36 CODE	36 OCCURRENCE SPAN FROM	THROUGH	37
a											000009	A
b												B
38												C

38	39 CODE	39 VALUE CODES AMOUNT	40 CODE	40 VALUE CODES AMOUNT	41 CODE	41 VALUE CODES AMOUNT
MEDICARE 127 S 500 E STE 400 SALT LAKE CITY UT 84102	a					
	b					
	c					
	d					

	42 REV CD	43 DESCRIPTION	44 HCPCS/RATES	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON COVERED CHARGES	49
1	0370	ANESTHESIA	99142	121405	01	7040		
2	0710	RECOVERY ROOM		121405	01	4580		
3	0740	EEG	95965	121405	01	10531 80		
4								
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9								
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12								
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15								
16								
17								
18								
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20								
21								
22								
23	001	TOTAL CHARGES				10648 00		

	50 PAYER	51 PROVIDER NO	52 REL IND	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56
A	MEDICARE MED	460009	Y	Y	973600		
B	HEALTHY U MEDICAID UHN	2364	Y	Y	9120		
C							

57	DUE FROM PATIENT --->

	58 INSURED'S NAME	59 P.REL	60 CERT. SSN HIC ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO.
A	[redacted]	18	[redacted]		
B	[redacted]	18	[redacted]		
C					

	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
A		9	WALMART	
B		3		
C				

67 PRIN DIAG CD	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E CODE	78
34541											

79 P C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
9						
	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE

	82 ATTENDING PHYS ID	95-312149-1205
a	G94368	CONSTANTINO TAW
b		
a	83 OTHER PHYS ID	
b		
a	OTHER PHYS ID	
b		

	84 REMARKS
a	
b	
c	
d	

85 PROVIDER REPRESENTATIVE	86 DATE
	08/16/06

UB 92 HCFA-1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

APPROVED OMB NO. 0938-0279

UNIVERSITY OF UTAH HOSPIT PO BOX 510721 SALT LAKE CITY, UT 84151 (801)297-4891	2	3 PATIENT CONTROL NO [redacted]	4 TYPE OF BILL 131

5 FED TAX NO	6 STATEMENT COVERS PERIOD FROM	THROUGH	7 COV D	8 N-C D	9 C I D	10 L R D	11
876000525W	020905	020905					528370305

12 PATIENT NAME [redacted]

13 PATIENT ADDRESS [redacted]

14 BIRTHDATE	15 SEX	16 MS	ADMISSION 17 DATE	18 HR	19 TYPE	20 SRC	21 D HR	22 STAT	23 MEDICAL RECORD NO	CONDITION CODES 24	25	26	27	28	29	30	31
[redacted]		S	020905	13		1	23	01	6375174								

	32 CODE	32 OCCURRENCE DATE	32 CODE	32 OCCURRENCE DATE	34 CODE	34 OCCURRENCE DATE	35 CODE	35 OCCURRENCE DATE	36 CODE	36 OCCURRENCE SPAN FROM	THROUGH	37
a	18	040192									007043	A
b												B
												C

38 MEDICARE
127 S 500 E STE 400
SALT LAKE CITY UT 84102

	39 CODE	39 VALUE CODES AMOUNT	40 CODE	40 VALUE CODES AMOUNT	41 CODE	41 VALUE CODES AMOUNT
a						
b						
c						
d						

	42 REV CD	43 DESCRIPTION	44 HCPCS/RATES	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON COVERED CHARGES	49
1	0740	EEG	95965	020905	01	1053180		
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23	001	TOTAL CHARGES				1053180		

	50 PAYER	51 PROVIDER NO	52 REL IND	53 ASG BEN	54 PRIOR PAYMENTS	55 EST AMOUNT DUE	56
A	MEDICARE MED	460009	Y	Y	961980		
B	MEDICAID OF UT PCP	876000525088	Y	Y	91200		
C							

57 DUE FROM PATIENT --->

	58 INSURED'S NAME	59 P REL	60 CERT. SSN · HIC · ID NO.	61 GROUP NAME	62 INSURANCE GROUP NO
A	[redacted]	18	[redacted]		
B	[redacted]	18	[redacted]		
C					

	63 TREATMENT AUTHORIZATION CODES	64 ESC	65 EMPLOYER NAME	66 EMPLOYER LOCATION
A		3		
B		3		
C				

67 PRIN DIAG CD	OTHER DIAG CODES 68 CODE	69 CODE	70 CODE	71 CODE	72 CODE	73 CODE	74 CODE	75 CODE	76 ADM DIAG CD	77 E-CODE	78
34541											

79 P C	80 PRINCIPAL PROCEDURE CODE	DATE	81 OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE
9						
	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE	OTHER PROCEDURE CODE	DATE

82 ATTENDING PHYS ID 95-312149-1205
G94368 CONSTANTINO TAW

83 OTHER PHYS ID

OTHER PHYS ID

84 REMARKS

85 PROVIDER REPRESENTATIVE

86 DATE 08/16/06

UB 92 HCFA 1450

I CERTIFY THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

clarus
Ventures

52

September 25, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

I welcome the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Hospital Outpatient Prospective Payment System (HOPPS) and CY Payment Rates (published in the August 23, 2006 *Federal Register*) and would like to take this opportunity to address two areas of concern with respect to the HOPPS proposed rule; the proposed definition of a 'device of brachytherapy' and the APC assignment of CPT 77799, Unlisted procedure, clinical brachytherapy.

RECOGNITION OF THE NEW BRACHYTHERAPY SOURCES ELIGIBLE FOR SEPARATE HOPPS PAYMENT

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a *"seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."*

The evolution of technology requires the reexamination of existing assumptions, understandings, and definitions once thought to be clear. One of these assumptions is that brachytherapy sources have to be radioactive to deliver a therapeutic radiation dose. Technological advances demonstrate that non-radioactive (electronic) sources, for example, can deliver a therapeutic radiation dose similar to a radioactive source or seed. Other advances involve radioactive seed configurations different from the traditional. The legislation surrounding brachytherapy payment is not meant to be limiting, but rather inclusive of innovative devices of brachytherapy in that can provide benefit to Medicare patients in light of new technology advances.

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All new and innovative brachytherapy radiation sources which meet the criteria required by the legislation and are approved as brachytherapy sources by the FDA should thus be included in CMS' consideration of which brachytherapy devices are eligible for separate OPPS payment. By excluding new and innovative brachytherapy radiation sources from separate OPPS payment to the outpatient hospital facilities, CMS is eliminating access to FDA approved new technology for Medicare beneficiaries.

I strongly believe that CMS must consider all new technologies now FDA-cleared for brachytherapy and broaden its payment mechanism to include both innovative radioactive and non-radioactive brachytherapy sources.

CPT 77799 ASSIGNMENT

Ambulatory Payment Classification Groups (or APCs) are composed of groups of services that are comparable clinically and with respect to the use of resources. CMS has proposed to move CPT 77799 from APC 313 to APC 312 for CY2007. CPT 77799 is the unlisted procedure code for clinical *brachytherapy*. APC 312 (Radioelement Application) is comprised of CPT codes that are described as radiation source applications and APC 313 (Brachytherapy) includes CPT codes that are described as remote afterloading high intensity *brachytherapy*. In keeping with the intent of APC classifications to group procedures that are similar clinically and resources utilized, unlisted brachytherapy code CPT 77799 would be more appropriately included in APC 313 with other brachytherapy procedure codes.

CMS has classified CPT 77799 appropriately as a brachytherapy procedure from the inception of the APC system in 2002. Since this time CPT 77799 (clinical brachytherapy) has been placed into APC 313 with other brachytherapy procedures. In following with the APC assignment of miscellaneous procedures, the assignment to the lowest paying brachytherapy APC is the most appropriate for 77799. The only brachytherapy APC that is appropriate for placement of 77799 would be APC 313.

I recommend that the unlisted brachytherapy CPT 77799 remain in the appropriate brachytherapy APC 313 for CY2007.

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Once again, I would like to thank you for the opportunity to comment on this year's proposed rule. Should you have any questions please do not hesitate to email me at kwheeler@clarusventures.com

Respectfully,

Kurt C. Wheeler
Managing Director
Clarus Ventures

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Sicel Technologies, Inc.

3800 Gateway Centre Boulevard • Suite 308 • Morrisville, NC 27560 • (919) 465-2236 • FAX (919) 465-0153

53

BY FEDERAL EXPRESS

October 3, 2006

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

RE: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

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

Our comments relate to a letter of denial recently received for a New Technology APC code for the **Implantation of the DVS® Dosimeter**. As the Hospital Outpatient Prospective Payment System comment period for calendar year 2007 is currently in the proposed comment period, we would like to take this opportunity to submit the following remarks.

Sicel Technologies was founded in 1999 to develop a miniaturized, implantable device utilizing multiple sensors in a closed loop telemetry system. The Company's efforts have been focused in the oncology market segment to develop products that can continuously monitor the changes within tumors of patients undergoing radiation and chemo-therapy. The ability to know what is happening at the tumor level during a course of treatment allows therapy to be optimized.

The DVS is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient. The system is specifically indicated for breast and prostate cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the in vivo radiation dose received at the tumor periphery, tumor bed, and and/or surrounding normal tissues for validation of the prescribed dose.

CMS stated that the reason stated for denial of the New Technology APC code was that *"the service is described by existing HCPCS codes or combination of HCPCS codes".*

It was also communicated to us that a review of the product labeling found that the DVS System is to be "used for dose verification and not for adjustment of dose during treatment." This information lead CMS to conclude that, in the context of radiation treatment procedures, Implantation of the DVS Dosimeter is a part of quality assurance that is integrated into radiation oncology services provided to patients, and thus described by existing HCPCS code.

It is our strong opinion that CMS has taken this particular section of the labeling out of context which has lead to a misunderstanding of the technology and the application. We would also like to emphasize that our request for a New Technology APC code was for the ***Implantation of DVS Dosimeter*** and not the actual measurement of the radiation dose delivered to the targeted site and its subsequent interpretation..

Before discussing the DVS technology in the context of its role in treatment planning and dosimetry, as opposed to quality assurance, it is important to review how and why this technology is different from existing dosimetry technologies and therefore meets the criteria of a **new technology**. The DVS Dosimeter is the ***first and only implantable dosimeter*** of its kind making the dosimeter and its associated use, different and unique from existing technologies and procedures. The DVS, unlike any currently existing technology, provides critical information to providers that up to now, has been unavailable. Providers may have had the capability to verify dosage **settings** of treatment delivery devices compared to the prescribed dose, but they have never had the capability to measure the **actual radiation dose delivered *in vivo*** to the targeted site and compare the dose delivered to the prescribed dose. The DVS now makes this possible by placing the dosimeters at the targeted site of the radiation dose, as opposed to the skin surface, to insure the delivery of the prescribed tumoricidal dose of radiation. Because the DVS implantable dosimeter(s) is the first of its kind and provide information unavailable with previously existing technologies, the implantation of dosimeter(s) is ***not*** described by existing codes, making the Implantation of the DVS Dosimeter eligible for a New Technology APC assignment.

Physicians will implant the DVS Dosimeter at the *start of therapy*, before the delivery of any radiation treatments. For this reason, *Implantation of the DVS Dosimeter* is an integral part of accurate treatment planning and dosimetry. Furthermore, the package labeling for the DVS states that "*DVS is specifically indicated...as an* adjunct to treatment planning..." This labeling clearly states that use of the DVS, and hence its *implantation*, is **part of the treatment planning process**, and not part of quality assurance/treatment management.

Furthermore, because this measurement is made from an *in vivo* source and in real time, it allows for absolute dosimetry, as opposed to a one time or periodic quality assurance check at the skin surface. Current dosimetry technology only permits dosimetry calculations from the skin surface. *In vivo*, absolute dosimetry, as determined by the DVS, provides the ability to identify dose errors not previously identified by quality assurance dosimetry such as inhomogeneity correction, tumor/organ shifting, tumor shrinkage and dose planning. DVS is also able to identify more common dose discrepancies related to patient setup and patient positioning. This is different from dosimetry for quality assurance. Dosimetry for quality assurance is most commonly used to identify initial set up errors at the surface only.

We would also like to take this opportunity to address the following package labeling:

"The DVS system is not intended to specify adjustments to dose. Dose measurement data obtained using the DVS System should be used in conjunction with existing planning and delivery tools to verify delivered dose rather than as a stand alone tool for determining dose adjustments".

The first sentence of this statement was recommended specifically to discourage physicians from "chasing" or altering the measured dose variance from day to day. The FDA and Sicel Technologies agreed to make this wording more apparent by outlining it in a black box because both were concerned that physicians might use the daily difference between observed and expected dose, to raise or lower the subsequent day's dose. The concern was that using the information in this manner does not take into consideration the typical dose variation observed, and the fact that most cancer patients receive 25-30 radiation treatments, each with some variation in dose. The second portion of the statement clearly positions use of the DVS in conjunction with treatment planning and delivery. Furthermore, specific guidelines following this statement, which were also approved by the FDA, include the following recommendations:

- Systematic dose deviations of ≥5-7% over a number of fractions should result in a re-evaluation of the treatment plan, patient setup, and equipment function to determine the reason for the variation. A change or correction to the plan should be considered after careful evaluation of the above mentioned parameters.
- Random variations of ≥5-7% observed in each of five or more consecutive measurements should result in an evaluation of positioning consistency or patient or organ movement during treatment.
- A single reading of 10% or greater should be immediately reported to the radiation oncologist and a review of the patient set up, treatment plan, and portal images should be undertaken.

Thus, although daily dose changes are to be avoided, ***changes to the treatment plan and dose adjustments or corrections are recommended***. The dosimeter's implantation before the start a radiation therapy, combined with aforementioned guidelines for use, clearly position the DVS as an adjunct to treatment planning and dosimetry.

We would like to thank you again for the opportunity to submit these comments. Should you have any additional questions, please do no hesitate to contact us.

Sincerely,
Sicel Technologies

Michael D. Riddle
President & CEO

CC: Carol Bazell, MD, Acting Director, Division of Outpatient Care
Charles W. Scarantino, MD, PhD, Sicel Technologies, Inc.

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SightLINE

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BY FEDERAL EXPRESS

October 3, 2006

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

RE: CMS-1506-P; Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

We would like to thank CMS for taking the time to participate in our conference call August 29, 2006 to discuss the APC reassignment of the Magnetic Resonance Guided Focused Ultrasound (MRgFUS) procedure reported by providers using HCPCS codes 0071T and 0072T.

As a follow-up to the conference call, we respectfully submit these comments regarding appropriate APC assignment for the MRgFUS technology under the Hospital Outpatient Prospective Payment System comment period for calendar year 2007 payment rates.

As discussed during our call, the technology simultaneously combines continuous Magnetic Resonance imaging (MRI) and Focused Ultrasound (US) to non-invasively ablate uterine fibroids. The ultrasound waves are directed from a transducer into a small focal volume. During treatment, the beam of focused ultrasound energy penetrates through soft tissue to ablate the targeted tissue. Multiple focused ultrasound beams referred to as "sonications" are required to ablate the targeted tissue. As the treatment is performed, the MR thermal mapping system continuously measures temperature changes inside the body in real time during treatment. Based on these observed temperature changes, the physician can adjust treatment parameters accordingly to ensure safe and effective thermal ablation. Following the treatment, anatomical MRI contrast enhanced images are used to evaluate treatment outcome.

Compared to surgery (hysterectomy), which is the primary treatment option for uterine fibroids, MRgFUS offers both clinical and economic advantages. Because it is a non-invasive procedure, patients avoid the risks associated with surgery, require only limited conscious sedation, and can return to normal activities the next day. From an economic perspective, patients who undergo the MRgFUS procedure have fewer disability days (decreased days of missed work or days in bed) and lower use of medical resources: 83% fewer physician visits, 66% fewer additional diagnostic tests, and 66% fewer additional procedures.

MRgFUS APC History
In January of 2005, the MRgFUS procedure was assigned to CPT codes 0071T and 0072T.

0071T Focused ultrasound ablation of uterine leiomymata, including MR guidance; total leiomyomata volume less than 200cc of tissue
0072T Focused ultrasound ablation of uterine leiomymata, including MR guidance; total leiomyomata volume greater or equal to 200cc of tissue

Both of these codes were mapped to APC 193 with a payment rate of $758.17. In August of 2005, after reviewing the costs associated with the procedure, the APC Panel recommended to CMS that 0071T and 0072T be assigned to appropriate New Technology APC's. CMS determined that the procedure should be classified into an appropriate clinical APC and assigned 0071T and 0072T to APC 195 and APC 202 respectively beginning January 2006.

The APC classifications are intended to appropriately group services that are similar both clinically and in terms of the resources they require. The payment rate established for each APC is based upon claims data submitted by hospitals and is designed to cover hospitals' operating and capital costs.

The current APC assignments for MRgFUS, APC 195 and 202, consist primarily of surgical excision/repair procedures of female reproductive organs/areas such as the following:

- 57230-57260 (Repair (surgical) of urethral lesion, bladder, vagina, rectum)
- 58920-59100 (Repair (surgical) of ovary, cysts, uterus lesion)
- 57220-57556 (Repair, removal, (surgical) bladder, urethrovaginal lesion, cervix, bowel, etc.)

While MRgFUS is treating the same anatomical site, the clinical similarity and resources utilized differ dramatically. The surgical procedures reported by the CPT codes within APC 195 and 202 do not utilize imaging technology, do not require continuous monitoring and require only approximately 30 minutes from start to finish. These procedures are not similar clinically or compared to the resources that are required to perform the MRgFUS procedure.

As a hospital outpatient facility with physicians that offer several of the procedures found in APC 195 and 202, I can assure CMS that the resources required for each of the APC categories are dramatically different than MRgFUS. The costs for performing MRgFUS are several times greater than the cost to perform procedures in APC 195 and 202.

We urge CMS to strongly review our following request for reclassification, or we will be forced to significantly limit or eliminate our MRgFUS program and therefore will be denying a procedure to many women who could benefit from it greatly.

Request to Reclassify MRgFUS to Appropriate APC

A review of existing APC classifications revealed that APC 0127 (Stereotactic radiosurgery) more accurately reflects the MRgFUS procedure from both a clinical and resource utilization perspective. Stereotactic radiosurgery (SRS) is a highly precise form of radiation therapy used to treat tumors. Treatment planning is required using three-dimensional computer-aided planning software. SRS utilizes ionized radiation transmitted from many directions that intersect at the target. The dose delivered is determined during a treatment planning phase and is intended to destroy the tissue. The treatment requires immobilization using a helmet-like device that keeps the head completely still during treatment. SRS minimizes the amount of radiation to healthy brain tissue.

As demonstrated in the table below, MRgFUS and SRS share several clinical as well as resource utilization characteristics. Both technologies are used to non-invasively treat tumors by using highly focused sources of energy and require extensive treatment planning with customized software and precise alignment of source to the target. Treatment is similar in that SRS uses ionized radiation transmitted from many directions which is targeted to a focal point with a radiation dose high enough to destroy the targeted tissue. MRgFUS transmits acoustic waves from many directions that intersect at a focal point generating a thermal dose that will destroy the targeted tissue.

As such, these two procedures fulfill the basic tenet of APC system: *Services in each APC are similar clinically and in terms of the resources they require.* Based upon this principle, we request that code 0071T and 0072T be appropriately reassigned to APC 127. It should be emphasized

that patients' only other option is often invasive surgery, which is accompanied by greater clinical risks as well as costs that exceed $9,000.

SIMILARITIES OF MRgFUS AND SRS PROCEDURES		
	MRgFUS	**SRS**
Clinical Characteristics		
Treatment goal is ablation of tumor	✓	✓
Customized focus of treatment source	Ultrasound waves	Radiation beams
Requires patient immobilization and localization	✓	✓
Multiple treatment applications in succession to achieve ablation	✓	✓
Precise alignment of source to target	✓	✓
Resource Utilization		
Extensive treatment planning with customized software	✓	✓
Requires specialized equipment housed in treatment rooms	✓	✓
Continuous monitoring during treatment	✓	✓
Total procedure time form 120-300 minutes	✓	✓

We would like to thank you for taking the time to speak with us and for your consideration of this APC reassignment. Should you have any questions please do not hesitate to contact me.

Respectfully,
SightLine of Houston, LLP

TJ Farnsworth
President and CEO
tfarnsworth@sightlinehealth.com
713-795-5010

55 Rec'd 10/3/06

ALLIANCEIMAGING

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www.allianceimaging.com

October 2, 2006

The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: FILE CODE CMS-1506-P

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates/New Technology APCs: Nonmyocardial Positron Emission Tomography (PET) Scans and PET/Computed Tomography (PET/CT) Scans

Dear Dr. McClellan:

Alliance Imaging ("Alliance") is pleased to have this opportunity to comment upon the Centers for Medicare and Medicaid Services' ("CMS's") recently proposed rule, CMS-1506-P (the "Proposed Rule"), which includes the collective reassignment of PET and PET/CT (CPT codes 78814, 78815 and 78816) scans from their current new technology APCs to clinical APC 0308. For the reasons set forth below, and consistent with the August 2006 recommendations of the Advisory Panel on APC Groups, Alliance urges CMS to retain the current new technology APC for PET/CT scans.

Alliance is the largest national provider of diagnostic imaging services in the United States and provides in the aggregate approximately 1 million diagnostic imaging exams on an annual basis (including approximately 100,000 PET and PET/CT scans) on behalf of over 1,200 hospital and healthcare clients. Currently, Alliance operates approximately 334 MRI units and 76 PET and PET/CT scanners. Most of our diagnostic imaging services, and almost all of our PET and PET/CT services, are provided to our hospital clients on a "shared" or mobile basis where the unit is available to scan patients at a specific hospital during the day and is then moved in the evening (often several hundred miles) to another location to service a different hospital the next day.

Based on a review of IMV's Medical Information Division Benchmark Report for PET 2005/2006, we believe that substantially more than half of the roughly 1,700 current providers of PET/CT in United States utilize shared mobile services to provide this clinical service to their patients.

Over the past five years, non-myocardial positron emission tomography ("PET") has become an integral part of the diagnosis, treatment and monitoring of many cancers by allowing for the metabolic (rather than purely anatomic) imaging of diseased tissues. With the recent advent of combined PET and computed tomography ("PET/CT") scanners, physicians can simultaneously assess the aggressiveness of a tumor and its precise location more accurately than ever before. The availability of PET/CT has undoubtedly improved treatment planning, surgery staging and post-therapy monitoring of cancer patients with access to these imaging services. These technological advances in imaging have been of particular benefit to Medicare beneficiaries in light of our referral data which suggests over 40% of patients receiving PET and PET/CT scans are covered by Medicare.

We strongly believe that the proposed reduction in PET/CT's reimbursement from $1,250 to $865 per scan is unwarranted and inappropriate for the following reasons:

(i) PET/CT procedures have only been classified a New Technology APC for approximately twenty months, and insufficient PET/CT claims data supports the reimbursement reduction as set forth in the Proposed Rule;

(ii) equivalent pricing of PET and PET/CT scans ignores the significant and demonstrably higher costs of PET/CT; and

(iii) a 32% reduction in 2007 hospital outpatient reimbursement will curtail the availability of PET/CT services, particularly in rural areas, reducing beneficiary access and/or increasing patient travel times in those areas not served by a PET/CT provider.

New Technology APC Status Should Be Extended for CY 2007

As the Proposed Rule correctly states, new technology APCs are instituted to provide an appropriate period of time to collect sufficient claims data to assign new procedures to a clinically appropriate APC. Under the final rules issued in November 2001, while procedures can be reassigned from a new technology APC after two years, such a reassignment should only be considered where sufficient claims data have been gathered on the new procedure. We note that CMS obtained five years worth of hospital claims data before moving nonmyocardial PET scans from a New Technology APC to a clinical APC. Conversely, for PET/CT claims data, CMS analyzed claims submitted over the course of less than one year (CY 2005), and during a time when a significant number of providers were migrating from PET to PET/CT (as evidenced by the significant decline in PET procedures and corresponding increase in PET/CT procedures from CY 2004 to CY 2005). We believe that the data collected is not sufficient to warrant the early termination of PET/CT's new

technology APC status. In particular, we are concerned that reliance on an incomplete year's worth of data during a period of significant technology adoption is not justifiable, especially when there can be no assurance that (i) new providers of PET/CT have updated their gross charge master files to accurately reflect the costs of providing the service or (ii) the data collected reflects a sufficiently broad spectrum of providers upon which credible cost analysis can be based.

For this reason, we believe there is not sufficient justification for the early termination of PET/CT's new technology APC status, and instead request that new technology treatment be extended at least through CY 2007.

Equivalent Pricing of PET and PET/CT Procedures Ignores Significant Cost Differentials

As noted above, PET/CT has quickly become the standard of care in oncology related imaging. With its simultaneous fusion of metabolic and anatomical data, PET/CT is a diagnostic tool which allows for coordinated treatment, intervention and monitoring by a wide range of physician specialists. This significant technological advance in capability beyond simple PET requires the additional costs of: (i) incorporating a CT scanner onto a PET platform resulting in an average unit price today of approximately $1.85 million to $2.0 million (versus an average cost of $1.1 million to $1.2 million for a PET-only unit); (ii) maintaining and operating the PET/CT system whose average annual maintenance cost is approximately $70,000 to $80,000 more per year than an equivalent PET-only scanner (due to the added maintenance of its CT component which requires regular replacement of costly x-ray tubes) and (iii) requiring technical personnel trained and accredited in two diagnostic imaging modalities (x-ray and nuclear medicine), resulting in a wage premium over their single modality peers of approximately 20% to 30%.

The Proposed Rule's finding that median PET/CT costs are equivalent to those for PET-only procedures is inconsistent with our extensive experience in providing these services. It is unclear what may be the cause or causes of this inconsistency, but we believe using an incomplete dataset of CY 2005 claims (as compared to a PET dataset collected from CY 2002 through 2005) may be at the root of the problem. In addition to the possible over or under representation of certain classes of providers in the data set (e.g., academic versus non-academic, urban versus rural, high volume versus low volume), we believe that there was insufficient time for new hospital providers to reflect the additional costs associated with PET/CT, therefore rendering the data inaccurate and unreliable. Keeping the PET/CT procedure codes in the new technology APC for CY 2007 gives hospitals more time to update their charge masters and implement accurate coding strategies such that hospital claims going forward will adequately represent the real costs of the procedures.

Given the unexplained contradiction between (i) the demonstrable costs differences of PET and PET/CT and (ii) the Proposed Rule's finding of cost equivalence, we believe that

the Proposed Rule's reassignment of PET/CT to APC 0308 should be postponed until a more complete and reliable dataset can be collected as the basis for such reassignment.

Adverse Impact on Rural Access to PET/CT Services.

Under the Proposed Rule, the average hospital payment for outpatient PET/CT services will be reduced from $1,250 per scan to $865 per scan effective January 1, 2007. This reduction of more than 30% will have an obvious and negative impact on any hospital clients currently considering an expansion into PET/CT services as well as those that currently provide such services, particularly hospitals who contract with out-source providers like Alliance. Since many of these contracts call for fixed payments per scan in excess of the reimbursement to be imposed by the Proposed Rule, the proposed reimbursement reductions will force some providers to choose between eliminating the service altogether or providing it at a loss to Medicare beneficiaries.

We estimate that approximately 20% of Alliance's approximately 320 mobile PET and PET/CT hospital clients are located in rural areas (as defined by the Stark II regulations). In the case of such rural providers, the problems of reduced reimbursement may be further exacerbated due to lower numbers of cancer patients (and therefore lower annual PET/CT scan volumes) and higher costs of service (due to greater geographical distances which must be traveled to such facilities). For this reason, the Proposed Rules' reimbursement reductions may force rural providers to forego expanding their cancer treatment services to include PET/CT, or put more pressure on existing providers to terminate their agreements if they are already providing the service at a loss. In the event that one or two rural clients elects to terminate service based on the economic pressures of reduced reimbursement, it is possible such terminations would render their rural PET/CT route financially unsustainable, and cause all of the hospitals on such route to lose their service. If that were to occur, cancer patients in those underserved markets would be required to travel greater distances to receive appropriate medical care.

To ensure continued beneficiary access to PET/CT services, particularly in rural areas, we believe that the Proposed Rule's assignment of PET/CT services to a clinical APC should be postponed until reliable claims data can be collected and used to ensure that such procedures are assigned to a clinically appropriate APC with payment levels that will minimize any adverse impact on beneficiary access. We therefore support the August 2006 conclusions of the Advisory Panel on APC Groups, and support their recommendation that PET/CT procedure codes remain in their New Technology APC for CY 2007.

* * * * * *

We appreciate the opportunity to comment on the Proposed Rule, and thank you for your attention to this important matter. In the event that you have any questions regarding the foregoing, please feel free to contact me at (714) 688-3301 and I will be happy to assist you with your questions or concerns.

Sincerely,

Paul S. Viviano
Chairman of the Board and
Chief Executive Officer

56-OPPS (5)

Submitter : Dr. Susan Lee

Organization : New York Hospital Queens

Category : Physician

Date: 09/15/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-175-Attach-1.DOC

Attach #
175

OPPS

September 15, 2006

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

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

Dear Administrator:

Thank you for allowing our facility the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

Our facility opposes this proposal and requests CMS reconsider maintaining assignment of the New Technology APC for an additional year. The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Partial breast irradiation (PBI) allows the radiation process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, our facility may not be able to cover the cost of the procedure, which requires a device with a cost of $2750. Our procedure costs are more than the proposed Clincal APC is reimbursing.

We urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. Thank you for your careful consideration and review in this important matter.

Sincerely,

CC

REX
HEALTHCARE
Healthcare for life. Your life.

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September 26, 2006

Centers for Medicare & Medicaid Services, DHHS
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Dear Sir:

I am directing these comments to the provisions established in the August 23, 2006, Federal Register regarding the requirements for receipt of the full 2007 Medicare Annual Payment Update for outpatient services.

Rex Healthcare is a 388-bed acute care facility located in Raleigh, North Carolina and is a member of the University of North Carolina Healthcare System. We average over 90 inpatient admissions daily. We treat 150 patients each day in our emergency department. Community physicians perform over 34,000 surgeries each year at our facilities.

Rex is the proud recipient of a number of awards and accolades including being ranked by Healthgrades in the top five percent of hospitals nationally for clinical excellence in 2005 and 2006. Healthgrades considers Rex one of the best North Carolina hospitals for overall cardiac services, vascular services, gastrointestinal services and critical care services. The Rex Heart and Vascular Center-home to the Triangle's first nationally accredited Chest Pain Center-provides comprehensive invasive and non-invasive services to the community. Rex's most recent accomplishment is this year's achievement of Magnet Hospital designation by the American Nurses Credentialing Center. Only 200 hospitals in the United States and only 9 hospitals in North Carolina have earned this designation. This award is based on a grueling review of the quality care provided to our patients. All these recognitions and awards demonstrate that Rex is a hospital that seriously embraces the concept of quality care for its patients.

We constantly ensure that quality is a focal point of our mission. Rex is in the midst of implementing an electronic medical record program that will take the organization to the next level of quality care beginning later this year. At a recent board meeting, the whole day was devoted to educating the 13 board members on quality initiatives at the hospital.

Rex Blood Services
Rex Breast Care Center
Rex Cancer Center
Rex Diabetes Education Center
Rex Diagnostic Services
Rex Emergency Response Team
Rex Emergency Services
Rex Family Birth Center
Rex Healthcare Foundation
Rex Heart & Vascular Center
Rex Healthcare of Wakefield
Rex Home Services
Rex Hospital
Rex Laboratory Services
Rex Mobile Mammography
Rex Nursing Care Center of Apex
Rex Pain Management Center
Rex Pediatrics of Cary
Rex Rehab & Nursing Care Center
Rex Rehabilitation Services
Rex Senior Health Center
Rex Sleep Disorders Center
Rex Surgery Centers
Rex Urgent Care of Cary
Rex Wellness Centers

4420 Lake Boone Trail
Raleigh, NC 27607
(919) 784-3100
rexhealth.com
A member of the UNC Health Care Family

For all the focus on quality, Rex finds itself out of compliance with the 2007 Medicare APU regulations as published in the August 1, 2006, Federal Register. We believe that these proposed regulations unduly burden hospitals which like Rex have great quality track records but which failed to meet very stringent reporting requirements established by CMS.

A brief synopsis of Rex's story illustrates the issue that we and probably other facilities may face if the regulations are implemented as currently proposed.

In order to receive the full APU hospitals must:

(1) register at least one person as a QNET Exchange Administrator
(2) complete a new Notice of Participation form and send to CCME by August 1, 2006
(3) continue to collect and submit all ten starter set measures to QNET Exchange
(4) sign an additional form pledging to submit 21 measures to QNET Exchange
(5) pass validation at an 80% reliability rate for the first 3 quarters of CY2005
(6) send a form to CCME attesting to the completeness of the data submitted.

Rex agrees with and supports provisions 1 through 4 and 6. However, we strongly encourage CMS to revisit the language of provision 5. Rex works with Mediqual to provide data to QIO Clinical Warehouse in accordance with the data transmission deadlines published by CMS. Our records support that we have submitted all data to that repository on a timely basis.

Once the data is received by CMS through the QIO Clinical Warehouse, CMS then requests the hospitals submit complete medical records for 5 random patients. Hospitals have 30 days to submit this data. Rex provided this data for the following quarters:

Quarter	CDAC Reliability Score
10/04-12/04	88%
01/05-03/05	93%
07/05-09/05	93%

The 5 medical records for the quarter 04/05 through 06/05 were copied by the Medical Records department in December 2005, delivered to the Shipping and Receiving Department the week of Christmas 2005 and

misplaced. It was not until mid January that the package was discovered in the Shipping area. The package was immediately sent to CDAC via overnight carrier, but the 30-day deadline had passed and CDAC could not process the data.

Looking at Rex's trend in reliability scores and our review of the 5 cases, we conclude that CMS's processing of those 5 medical records would have resulted in reliability scores similar to the other three quarters. Now Rex finds itself in a situation where it does not meet one of the provisions in the proposed regulations for receipt of the full APU amount. This 2% penalty equates to almost $2 million in lower reimbursement to Rex for a clerical mistake. This represents over 16% of Rex's operating income. A penalty of this magnitude will significantly impact the services Rex provides to the community. We do not believe CMS intended for this rule to negatively impact hospitals' ability to render services to both Medicare and other patients.

Rex believes this penalty is unduly burdensome in light of the circumstances. We clearly have focused on quality for the last several years. The data supplied to CMS confirms Rex's accomplishments and yet we find ourselves penalized by a proposed rule that is so tightly written there is room for no errors in manual processes.

Hospitals need to be held to high quality standards, and Rex is a proponent of this. However, CMS needs to provide some latitude in the process to ensure that quality hospitals are not inappropriately punished.

We ask that CMS reconsider attaching the quality criteria to the OP PPS program. We are already being penalized in the IP PPS payments. An additional penalty for OP PPS seems draconian for our specific issues.

Sincerely,

Bernadette M. Spong

Bernadette Spong
CFO

BMS:sec

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Advanced Surgery Center, Inc.
STONCREST CENTER
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September 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATT: CMS – 1506 – P
PO Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

As an experienced professional involved in both the direct care of patients as well as the over-all responsibility for delivery of clinical services in the facility, I have multiple concerns regarding the CMS proposal for (ASC) payment system changes.

This proposal would have a direct impact, and not a positive one, on many levels of ASC healthcare. Decreased and inequitable reimbursements would, without a doubt, adversely affect our ability to ensure crucial components of patient quality-of-care:

- Securing and retaining qualified professional staff
- Securing and maintaining appropriate and adequate equipment directly related to the safe, efficient performance of procedures,
- Upgrading equipment when necessary
- Securing reliable, trustworthy suppliers, vendors, and systems maintenance services

The ultimate impact, of course, will be that patients will have fewer choices as to where they obtain care, and more importantly, that access to a streamlined, convenient, credentialed facility will be seriously compromised.

Nothing costs less than it did five years or ten years ago – how can medical care? Utilities, food, transportation, salaries, rents, taxes, equipment, have all risen. It is extremely tough now to stay budget-balanced for patient care costs for the facility; reduced reimbursements and/or added low-level procedures at a capped rate would make it virtually impossible.

CMS advocates that optimal use of healthcare resources requires a high quality level of patient services in an efficient, cost-effective setting. Because of its inequities, and the subsequent inability of ASC's to survive, the net effect of this payment system would be to force patients eventually, and unnecessarily, back into the hospital setting to obtain services at a much higher cost than are currently readily and safely provided in the ASC setting. President Bush is on record stating that ASC's are more cost-effective.

Thank you for your attention. I am also writing to my legislative representatives to share these important issues for the future of healthcare services in this nation.

Sincerely,

Sherri L. Reynolds, RN, BSN, CNOR

Sherri L. Reynolds, RN, BSN, CNOR
Director of Nursing