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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:

The Pinnacle Health Group is pleased to provide these comments regarding the hospital outpatient prospective payment system and calendar year 2007 payment rates. Our comments are based upon a decision by CMS that does not permit appropriate payment for a new technology that is used to treat malignant breast tumors: the VISICA™ Treatment System.

In the United States, it is estimated that between 390,000 and 650,000 patients per year are diagnosed with a breast fibroadenoma, which is the most common benign finding on breast biopsies. Approximately 30% - 50% of patients seek treatment. This new technology is designed to provide a definitive minimally invasive treatment for these patients.

In addition, breast cancer is the most common non-skin cancer and the second leading cause of cancer related deaths in women in the United States. One in eight women will be diagnosed with breast cancer. Breast Conservation Surgery (BCS) for early stages of this disease has been demonstrated in multiple trials to provide equal survival rates compared with mastectomy. Cryo-Localization of breast lesions provides a key advance in the ability of surgeons to remove malignant tumors with adequate margins.

The VISICA technology utilizes a cryoprobe and the application of freezing temperatures followed by a thawing period, commonly referred to as a freeze-thaw cycle. The first freeze-thaw cycle achieves tumor localization, while the second freeze-thaw cycle results in tumor ablation.

This new technology allows for the localization of both benign and malignant tumors of the breast followed by tumor freezing. In the case of malignant tumors, after localization the physician surgically excises the frozen breast lesion. For benign fibroadenomas, a second freeze cycle is applied, which subsequently kills the tumor and allows for re-absorption in the body. Cryo-Localization is performed by a radiologist or surgeon with the assistance of a nurse and/or ultrasound technician. The procedure may take place in an operating room and requires the VISICA Treatment System, a single-use cryoprobe, and ultrasound equipment for image guidance. Cryo-Localization allows the

physician to isolate and prepare a tumor for excision or ablation by creating a firm, palpable ice ball with clearly defined and controlled margins.

CMS has denied a request for a New Technology APC on the premise that the service is described by existing HCPCS codes or combination of HCPCS codes. CMS has also recommended that hospitals report the appropriate device HCPCS C-code for the cryoprobe utilized in providing the services. HCPCS code C2618 *Probe, cryoablation* is the most appropriate HCPCS code available to describe the cryoprobe used with the VISICA Treatment System. At the time this code first assigned, the cryoprobe technology was used for **prostate** applications only. Use of the cryoprobe technology for breast tumor localization was not approved at this time.

As a result, the cost associated with C2618 was mapped to APC 0674 Prostate Cryoablation when it was not longer paid separately as a pass-through device. Since the cryoprobe for breast localization has been introduced, the status of the C2618 was non-payable, as a result of the cost of the device packaged with the prostate cryosurgery APC.

CMS' recommendation to use existing CPT codes to report tumor localization (76942 Ultrasonic guidance for needle placement and 76986 Ultrasonic guidance, intraoperative) would not appropriately describe the procedure or support the cost of the cryoprobe.

Based upon this information, we request that CMS assign a New Technology APC code for Cryoprobe placement breast, tumor location which would appropriately map to Level XXIII, APC 1523 with a payment rate of $2,750, as requested in the original New Technology Application that was denied by CMS.

Cryo-Localization represents an exciting new technology to help treat women with malignant or benign breast tumors. It presents the opportunity to shift the paradigm for treating early stage malignant breast tumors and benign fibroadenomas from aggressive surgical resection to more conservative surgical and non-surgical procedures. This in turn will improve the quality of life for women affected by breast lesions while lowering the cost of care.

We would like to thank you for taking the time to review our comments. Should you have any questions please do not hesitate to contact us.

Respectfully,
THE PINNACLE HEALTH GROUP, INC.

Kathy A. Francisco
Principal
kfrancisco@thepinnaclehealthgroup.com

CC: Carol Bazell, MD, Acting Director, Division of Outpatient Care (email)

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October 5, 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
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

The Pinnacle Health Group is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

This comment letter specifically addresses the proposed payment for breast brachytherapy including the high dose rate brachytherapy source required to perform breast brachytherapy.

Breast conservation therapy is a treatment alternative for breast cancer patients that allows patients the option to treat breast cancer while preserving the breast. Breast brachytherapy allows patients better access to treatment by reducing treatment time from six weeks to five days. This treatment cannot be performed without the use of high dose rate brachytherapy.

According to the National Institute of Health consensus statement regarding treatment of early-stage breast cancer "Breast Conservation surgery plus radiotherapy is preferable to total mastectomy because it provides survival equivalence while preserving the breast".

The proposed changes in the CMS hospital outpatient payment system will limit patient access to breast conservation therapy and may cause more patients to opt for more costly alternatives such as Mastectomy. The impact of these changes will weigh significantly on hospitals ability to offer breast conservation therapy to Medicare beneficiaries.

BREAST BRACHYTHERAPY (CPT 19296 and 19297)

Breast brachytherapy codes (CPT 19296, 19297 & 19298) were implemented January 1, 2005 and have been assigned to appropriate New Technology APCs. CMS proposes to

reassign two of the three codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment would result in significant decreases in 2007 payment, (see table below) which range from -22% to -37% and -$741 to -1017.31.

HCPCS	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percentage Change 2006-2007
19296	1524	$3,250.00	30	$2,508.17	($741.83)	-22.8%
19297	1523	$2,750.00	29	$1,732.69	($1,017.31)	-37.0%

Another significant issue of concern is the change in status indicator if the proposed change is made effective. Breast brachytherapy CPT codes 19296, 19297 and 19298 require the use of a high cost device that is bundled into the procedure payment thus classifying these procedures as device-dependent. 19297 is ALWAYS performed at the time of lumpectomy. Lumpectomy procedures map to a clinical APC that also has a T status indicator. This procedure would be reduced by 50% each time the procedure is performed as the code descriptor indicates "concurrent with partial mastectomy (list separately in addition to code for primary procedure". The table below outlines the proposed change in status indicators for CPT 19296 and 19297.

HCPCS	2006 APC	2006 Status Indicator	2007 Proposed APC	2007 Proposed Status Indicator
19296	1524	S	30	T
19297	1523	S	29	T

During the review of CMS claims data, it was noted that the reporting of the required catheter code (C1728) was non-existent on a majority of the claims used to calculate the median costs for these procedures. More accurate median costs are reported when using single claims that include the cost of the catheter.

HCPCS	Single Frequency	Median Cost
19296	491	$2,879
19296 + C1728	32	$3,508
19297	36	$1,631
19297 + C1728	1	$3,371

CMS has proposed to map 19296 and 19297 to clinical APCs in which the current procedures are not similar clinically or in resource utilization. These procedures do not utilize a high cost device, and the median cost of the procedures within these APCs violate the two times rule when the device dependent median cost is utilized (19296 and 19297 + C1728).

APC 30		
CPT	Median Cost	Median Cost 19296+C1728
19240	2,479.58	$3,508
19340	1,974.69	
19380	2,002.58	

APC 29		
CPT	Median	Median 19297 +C1728
19180	1,942.76	$3,371
19182	1,390.91	
19316	2,116.31	
19328	1,397.57	
19330	1,356.21	
19355	1,169.32	
19366	1,890.47	
19370	1,875.37	
19371	1,837.35	
19396	38.48	

CPT 19296 and 19297 were new codes in 2005 so no claims were available for 2006. The number of hospital outpatient claims for 2005 is low and inadequate for CMS to make assumptions regarding which clinical APC to assign these codes. The proposed clinical APC assignment is based upon only one year of CMS claims data. Further, the volume of procedures in 2005 for CPT codes 19296 and 19297 were low in comparison to other device-dependent procedures

CPT	2004 Claims - 2006 Payment (number of single frequency claims)	2005 Claims – Proposed 2007 Payment (number of single frequency claims)
19296	n/a	491
19297	n/a	36
19298	n/a	49

If CMS finalizes the proposed clinical APC assignment, this will limit the hospitals ability to offer breast brachytherapy as a cancer treatment option to Medicare beneficiaries. The cost of the device itself exceeds the proposed APC assignments for 2007. Hospitals will not be able to purchase the high cost device required to implant into the breast to perform breast conservation therapy. Therefore, the CMS proposed APC assignment will limit patient access to this less invasive breast cancer treatment.

HIGH DOSE RATE BRACHYTHERAPY (HDR)

Breast brachytherapy requires the use of a High Dose Rate brachytherapy source. The HDR source is a unique brachytherapy source that requires allocation of the quarterly source cost by each hospital. The actual cost of the source is based upon the number of treatments or fractions that are administered to patients over the life of the source.

CMS claims data shows a huge variation in cost per unit reported on claims data across hospitals for the source:

APC	Number of Hospitals	Number of Claims	Variation of Cost per Unit
1717	283	4740	$0-4,746

In addition to the large variation of cost per unit across the hospitals and claims in the CMS data, the highest utilization hospital should have the lowest cost for the HDR

source and hospital cost from there should increase in numeric succession. The analysis of the top five volume hospitals, per CMS claims data, indicates significant anomalies in the data. Clearly this information should cause CMS to question the accuracy of the data when considering payment based upon the claims data.

HCPCS	Hospitals	Median	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5
C1717	283	$135	$3	$9	$479	$118	$95

To further validate the variation in cost per unit, a survey of eighty hospitals was conducted by The Pinnacle Health Group to determine the actual cost of the HDR source to the hospital. This survey was originally conducted using 2002 hospital data and was updated using 2005 hospital specific costs and actual source runs. The findings indicated that the variation in cost per unit among these 80 hospitals range from $4-5,775. These findings validate the CMS claims data that indicate variation in cost per unit of ($0-4,746).

Number of Hospitals	Total ACUTAL Source Runs	Average Quarterly Unit Cost	Average Quarterly Source Service Cost	Average Quarterly Source Cost	Variation of Cost per Unit
80	47,050	$17,500	$7,150	$10,000	$4-5,775

In addition to the variation in HDR source cost in the CMS claims data and the actual hospital survey, the GAO had an opportunity to review the HDR source cost as part of the report published by the agency this year. The GAO stated "data from 8 hospitals was determined to be usable to evaluate Ir-192 causing the GAO to recognize there was too much variability in Ir-192 source cost and therefore no recommendations could be made."

The cost of the HDR source is a fixed cost. Hospitals must purchase the source and have it available to treat cancer patients at any time. HDR cost varies from other diagnostic imaging technologies that may also have associated fixed costs. The HDR source must be on hand at all times so the hospital incurs the cost on a daily basis. For imaging services, the cost of the imaging agent is only incurred by the hospital if a study is performed or ordered by the physician. The cost of the source is incurred by the hospital even if patients are not treated.

RECOMMENDATIONS

Due to the low volume of procedures in the CMS claims database, CMS should maintain 19296 and 19297 in New Technology APCs 1524 and 1523 respectively, so that additional claims data may be collected through calendar year 2006. At this time the claims data should be reevaluated for possible reassignment to a more appropriate clinical APC in 2008.

As an alternative, CPT 19296 and 19297 are similar both clinically and with respect to resource costs to procedures included in APC 648 Breast Reconstruction with Prosthesis. The identical medical device is required for both breast brachytherapy procedures (CPT 19296 and 19297) and the cost of the catheter is exactly the same. All of the current procedures in APC 648 involve the placement of an expensive device, as do breast brachytherapy codes 19296 and 19297.

PROPOSED APC 648 – Breast Reconstruction				
HCPCS	Description	APC Value	Single Frequency	Median Cost
19357	Breast reconstruction	$3,002	200	$3,016
19296	Post-op implant of breast cath	$3,002	491	$2,879
19342	Delayed breast prosthesis	$3,002	65	$2,775
19325	Enlarge breast with implant	$3,002	6	$2,414
19297	Implant of breast cath for rad	$3,002	36	$1,631

The Pinnacle Health Group recommends that CMS maintain breast brachytherapy codes 19296 and 19297 in their current New Technology APCs (1524 and 1523 respectively) for 2007. Alternatively, CMS could assign CPT codes 19296 and 19297 to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the APC group title from "Breast Reconstruction with Prosthesis" to "Level IV Breast Surgery."

The required brachytherapy that follows the implant of the catheter to perform breast conservation therapy requires the use of the HDR brachytherapy source (C1717). In addition, we agree with the recommendations by the APC panel and PPAC that CMS should continue to reimburse hospitals for the HDR brachytherapy source based upon charges reduced to cost.

We appreciate the opportunity to provide comments during this proposed rule period and thank CMS for the opportunity to meet and discuss these important issues in person.

Sincerely,
THE PINNACLE HEALTH GROUP, INC.

Kathy A. Francisco
Principal
kfrancisco@thepinnaclehealthgroup.com

cc: Carol Bazell, MD, Acting Director, Division of Outpatient Care (via email)

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October 3, 2006

BY FIRST CLASS MAIL

Centers for Medicaid and Medicare Services
Department of Health and Human Services
Attention: CMS-1506-P, or CMS-4125-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Medicare Administrator Contractor Candidates for Jurisdiction 4

Dear Madam or Sir:

This letter is written in anticipation of the upcoming issuance of CMS' Request for Proposal for interested potential Jurisdiction 4 Medicare Administrator Contractors ("MACs"). A Medicare-participating supplier and firm client has requested that we forward its concerns about a potential contractor, TrailBlazer Health Enterprises ("TrailBlazer"). The supplier is located in a region for which TrailBlazer is the Medicare carrier. The supplier has found TrailBlazer's guidance to be ambiguous and contradictory on many occasions. When the supplier has requested written clarification from TrailBlazer regarding compliance with certain Medicare requirements, the carrier oftentimes has failed to respond. Further, when the supplier has contacted TrailBlazer staff for oral guidance, it often has received inconsistent explanations or answers. In addition, the supplier believes that TrailBlazer's local coverage policies are often inconsistent with the local coverage policies of other Medicare carriers (for example, LCD L-95B).

Given the degree of difficulty this supplier has experienced in dealing with TrailBlazer over the years, it felt compelled to communicate confidentially its concerns about this carrier as the possible Jurisdiction 4 MAC Contractor. The supplier hopes that you will consider its concerns in your decision-making regarding the Jurisdiction 4 MAC contract award.

Thank you for your consideration of this matter.

Very truly yours,

Thomas E. Dowdell

TED/ask

Society for Thermal Medicine

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October 5, 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**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

The Society for Thermal Medicine is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

The Mission of the Society for Thermal Medicine (STM) is to facilitate interaction and communication between clinicians and medical sciences that contribute to the understanding and use of hyperthermia; to promote original research in hyperthermia and to promote diffusion of knowledge of hyperthermia to persons in the diverse disciplines.

The Society for Thermal Medicine (formerly known as the North American Hyperthermia Society) was founded in 1981 by those who shared the opinion that hyperthermia continues to show promise as a therapeutic modality, and that the growing number of investigators and amount of data produced required a separate forum for discussion of results and planning of future research and application.

STM is pleased to provide comments regarding the payment for hyperthermia procedures (CPT 77600-77620) in the proposed hospital outpatient rule for calendar year 2007.

HYPERTHERMIA

When cells are heated beyond their normal temperature they can become sensitized to therapeutic agents such as Radiation and Chemotherapy. If they are heated higher still the heat will irreparably damage them. The application of heat in a therapeutic setting is called Hyperthermia. Tumor cells have been shown to be more sensitive to some levels of hyperthermia than normal tissue cells.

Biological studies have shown that there is a time and temperature relationship for the effectiveness of heat; two different temperatures may cause the same biological effect if the

time is adjusted to account for the difference in temperatures. This phenomenon is known as thermal dose and has led to different applications of Hyperthermia: using moderate temperatures as therapeutic sensitizers, or using higher temperatures as a method of ablating tissue minimally invasively or noninvasively.

In clinical practice, Hyperthermia is quite effective in the treatment of cancer. Different types of thermal therapies with different goals may raise the temperature to different levels. Localized heating to temperatures in the range of 40 - 44°C have been used to sensitize cancer cells to the effects of other therapies such as Radiation therapy, Chemotherapy, and biological therapies. Although these temperatures may seem high, the heating is confined just to the area of the tumor and generally it is very well tolerated. This type of treatment can be delivered to superficial sites (such as the breast or chest wall, head and neck, etc.), to sites deep in the pelvic and abdominal region, or to the whole body. Other techniques are used to achieve much higher temperatures in order to completely ablate the tissue being treated. These techniques have been investigated in brain, liver, and prostate and require very precise placement of the energy in the tissue that needs to be ablated.

There is a range of methods used to elevate the temperature:

- Microwaves and ultrasound are the most commonly used modalities to elevate the temperature of superficial tumors. The sources can either be coupled to the heated area externally or interstitially implanted into the tissue. Typical areas of treatment are the chest wall and breast, head and neck areas, and any other sites that allow access and where the tumor is not too deep.
- Radiofrequency waves are typically used to heat deeper pelvic tumors and can be used to heat limbs as well. Typically the area to be heated is surrounded by a ring of radiating elements. The energy is directed into the tissue by including a layer of water between the radiating elements and the patient.
- High temperature thermal ablation therapies typically either implant heating sources in the area to be ablated or "focus" energy into the tissue to be heated noninvasively. This type of therapy requires image guidance in order to ensure the correct tissue is being ablated.

In all types of hyperthermia, temperature monitoring is critical. Presently this is typically done invasively by placing thin temperature probes into the tissue being heated. However, new technology now offers methods to measure temperature noninvasively using modalities such as MRI and ultrasound.

Currently, the following codes are reported by hospitals for hyperthermia treatment:

CPT	Description
77600	Hyperthermia, externally generated; superficial (ie. heating to a depth of 4cm or less)
77605	Hyperthermia, externally generated; deep (ie. heating to a depths greater than 4cm)
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
77620	Hyperthermia generated by intercavitary probe(s)

Claims Data Issues

Hyperthermia treatments (CPT 77600-77620) have been mapped to APC 314 since 2002 with a history of very unstable median cost due to low procedure volume. For example, in the table below, the median costs for 77605 increased significantly from 2003 to 2004, yet dropped each year from 2005 and 2006. In addition, CMS reports no single claims (and hence no median cost

values) for this code in 2007. As the second highest utilized code in the series, we are perplexed why no claims were reported for this period.

It has been confirmed with several hospitals (Northwestern Memorial Hospital, Duke University Hospital, Centennial Medical Center and Rush University Medical Center) that CPT 77605 was performed at their facilities during 2005, however, there is not a clear understanding as to why claims do not appear in the CMS claims data system.

Medians from Year to Year										
CPT	2003		2004		2005		2006		2007	
	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost	Single Claims	Median Cost
77600	255	$229.37	227	$190.53	395	$200.17	264	$224.34	163	$164.06
77605	175	$392.39	114	$624.09	118	$540.00	131	$460.49	NA	NA
77610	14	$186.79	5	$211.89	1	$231.07	7	$328.06	4	$308.95
77615	4	$273.81	5	$490.67	34	$233.96	5	$365.80	25	$488.55
77620	0	0	0	0	0	0	1	$137.18	0	0

The percentage change in medians from year to year is significant due to low volume and the small number of facilities reporting procedures. For example, the percent change for this set of codes over the reporting period of 2003-2007 was substantial and seemingly unrelated. 77600 showed modest increase in 2004-2006, but dropped precipitously in the proposed 2006-2007 (-27%) while the medians for 77615 decreased substantially in 2004-2005 but increased the next two years.

Percent Change in Medians				
CPT	2003-2004	2004-2005	2005-2006	2006-2007
77600	-17%	5%	12%	-27%
77605	59%	-13%	-15%	-100%
77610	13%	9%	42%	-6%
77615	79%	-52%	56%	34%
TOTAL		**-6%**	**33%**	**-32%**

The payment rates for APC 314 have increased steadily from 2003-2006 (see table below) to levels closer to the actual costs for the various hyperthermia procedures, (77600-77620). However, the proposed payment rate for 2007 is significantly lower than 2006 and is substantially lower than the median costs for this sequence of codes for hyperthermia.

APC 314 Payment Rates				
2003	2004	2005	2006	Proposed 2007
$199.54	$217.80	$251.20	$332.31	$225.17

CPT 77605 (Hyperthermia, externally generated; deep) is the second most performed hyperthermia procedure by hospitals. The CMS data indicates that **NO** procedures, single or multiple claims, were reported for CPT 77605. This raises significant questions about the accuracy of the data. The table below outlines the rank order of each CPT in APC 314. From year to year, 77600 has been reported with the largest number of procedures, followed by

77605. Clearly, the lack of any claims in 2007 raises the question of the accuracy of the claims data used to establish the median payment level for 2007.

CPT 77605 (Hyperthermia, deep) Single Claims					
CPT	**2003**	**2004**	**2005**	**2006**	**2007**
77600	255	227	395	264	163
77605	175	114	118	131	0
77610	14	5	1	7	4
77615	4	5	34	5	25

Data reported to CMS to establish the median costs for 77600-77620 originate from very few hospitals, most likely contributing to the unstable medians. The table below lists the number of hospitals reporting 77600-77620 for 2004 vs 2005.

Number of Hospitals Billing Hyperthermia Codes					
Year	**77600**	**77605**	**77610**	**77615**	**77620**
2004	16	8	5	5	1
2005	16	0	0	8	0

A maximum of 16 hospitals across the US reported hyperthermia codes (77600-77620) under APC 314. This is an extremely low number of institutions to provide reliable data on median costs for CPT 77600-77620.

Hospital Cost to Charge Ratio (CCR) Issues

There appear to be significant variances in the hospital cost to charge ratio (CCR) within the hospitals reporting costs for Hyperthermia. The Hospital CCRs for hospitals reporting Hyperthermia procedures range from 14% to 50%. The top five hospitals reporting Hyperthermia procedures in the CMS database have very different CCRs as indicated below.

2005 Imputed Hospital CCR			
Hospital	**Charge per line**	**Cost per line**	**Imputed CCR**
Hospital 1	$1,005	$136	14%
Hospital 2	$1,800	$525	29%
Hospital 3	$1,337	$183	14%
Hospital 4	$3,747	$878	23%
Hospital 5	$1,588	$641	40%

In July 2006 the GAO published a report titled "*CMS's Proposed Approach to Set Hospital Inpatient Payments Appears Promising*". This report discussed the use of overall hospital CCR use on the hospital outpatient rate setting process. The GAO report stated that *"hospitals vary in how they allocate revenue center charges to cost centers on their Medicare cost reports. When estimating costs for purposes of weighting APCs, however, CMS uses its own system of mapping the hospitals' revenue center charges to cost center CCRs in order to convert the charges to an estimate of cost. This can be problematic since hospitals may allocate their revenue centers to cost centers in a different manner from CMS."*

The GAO sited that "some hospitals allocate charges from the same revenue center to separate cost centers; others allocate charges from several revenue centers to a single cost center.

CMS's use of a single method in mapping charges to costs and then applying that methodology across all hospitals for purposes of cost estimation does not recognize the differences in hospital allocation decisions when estimating costs. As a result, some service costs are "*systematically overestimated and some are underestimated.*" Further, the report states that *"The differences between aggregate estimates using the OPPS method and hospitals reported costs indicate that a single approach to mapping cost center CCRs to revenue center charges is problematic because CCRs are applied to certain charges that do not capture the cost-to-charge relationship for those charges."*

We believe that in the situation of hyperthermia codes (77600-77620), the combination of low utilization among few institutions, hospitals cost allocation methodology and CMS's application of hospital specific CCRs leads to the fluctuations in median costs of APC over the past five years and has resulted in a payment structure which does not support the use of the technology to help cancer patients who need this therapy.

Procedure Cost

An analysis of hospital costs required to perform Hyperthermia reveals that the actual cost to perform the procedure significantly exceeds the APC value proposed by CMS. Members of the Society of Thermal Medicine (STM) were surveyed for three levels of hyperthermia treatment. The average costs for the facilities responding to the survey, regarding time and cost were as indicated on the table below.

CPT	Description	Estimated Hospital Cost
77600	Hyperthermia, externally generated; superficial (ie. heating to a depth of 4cm or less)	$885.00
77605	Hyperthermia, externally generated; deep (ie. heating to a depths greater than 4cm)	$1,205.00
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators	$1,005.00
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators	$1,005.00
77620	Hyperthermia generated by intercavitary probe(s)	$1,005.00

The detail for each of the hyperthermia treatment types are outlined in the following tables.

Hyperthermia Treatment Delivery, Superficial	
Procedure	**Average Cost**
Treatment suite, 2-4 hours	$180
Required treatment hardware and software/per treatment	$60
Engineer/Physicist (2 hours)	$130
Technician (2 hours)	$80
Nursing Staff (3 hours) patient preparation and monitoring	$135
Medical Supplies/Disposables	$280
Administrative Staff/Secretary (0.5 hour)	$20
TOTAL COST	**$885**

Hyperthermia Treatment Delivery, Interstitial/Intracavitary

Procedure	Average Cost
Treatment suite, 3-5 hours	$240
Required treatment hardware and software/per treatment	$120
Engineer/Physicist (2 hours)	$130
Technician (2 hours)	$80
Nursing Staff (3 hours) patient preparation and monitoring	$135
Medical Supplies/Disposables	$280
Administrative Staff/Secretary (0.5 hour)	$20
TOTAL COST	**$1005**

Hyperthermia Treatment Delivery, Deep	
Procedure	**Average Cost**
Treatment suite, 4-6 hours	$300
Required treatment hardware and software/per treatment	$260
Engineer/Physicist (2 hours)	$130
Technician (2 hours)	$80
Nursing Staff (3 hours) patient preparation and monitoring	$135
Medical Supplies/Disposables	$280
Administrative Staff/Secretary (0.5 hour)	$20
TOTAL COST	**$1,205**

Recommendations

Based upon the unstable medians, low utilization, seemingly lack of claims data for 77605, application of overall hospital CCR and actual hospital cost survey results, we believe that it is necessary to establish an exception to the median claims application for APC 314.

We recommend that CMS consider the one of the following options as an alternative to the proposed payment for APC 314.

OPTION 1

CMS use external hospital survey data provided above to establish a more appropriate median payment rate of $1,005 for APC 314.

OPTION 2

CMS consider applying an average cost for 77605 from 2004-2006 to the 2007 medians for other procedures in APC 314 to establish a more appropriate payment rate for 2007 of $398.75. The average cost for 77605 for 2007 is the average of the median cost from 2004-2006.

HCPCS	Description	Median Cost			
		2004	2005	2006	Proposed 2007
77600	Hyperthermia	190.53	200.17	224.34	164.06
77605	Hyperthermia	624.09	540.00	460.49	**541.53**
77610	Hyperthermia	211.89	231.07	328.06	308.95
77615	Hyperthermia	490.67	233.96	365.80	488.55
				Computed Median	**$398.75**

OPTION 3

Hold the payment rate for APC 314 at the current 2006 payment of $332.31 while more accurate claims data can be evaluated for 2008.

Hyperthermia offers a treatment option to patients with advanced or recurrent cancer when there is often no other viable option for treatment. The Society for Thermal Medicine is concerned that if an appropriate payment for hyperthermia treatment (APC 314) is not established by CMS for the hospital outpatient payment system in 2007 that the availability of hyperthermia for patients in need, already limited in part due to reimbursement concerns, may be further jeopardized.

A more appropriate option, such as the options outlined above, for hyperthermia is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of these important issues.

Sincerely,
THE SOCIETY FOR THERMAL MEDICINE

Mark Hurwitz, M.D.
Vice-President Elect, Society For Thermal Medicine
Director, Regional Program Development
Department of Radiation Oncology
Dana-Farber/Brigham and Women's Cancer Center
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Memorial
HEALTH
University Medical Center

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October 4, 2006

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

Re: CMS-1506-P – Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule (71 *Federal Register* 49506).

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning the Hospital Outpatient Prospective Payment System. Memorial Health University Medical Center (MHUMC) is a 530 bed teaching hospital with Level I Trauma Center status located in Savannah, Georgia.

This letter will focus on the proposed changes to Hospital Outpatient Outlier Payments (pages 49546-547).

I. Changes to OPPS Outlier Policies (pages 42701-702)

"Changes to OPPS Outlier Policies"

Outlier payments are an important component of the OPPS because they provide some financial cushion when hospitals treat high cost cases. For CY 2007, CMS proposes to continue its policy of setting aside 1.0% of aggregate total payments under the OPPS for outlier payments. In order to achieve this stability, CMS would increase the fixed dollar threshold from $1,250 to $1,825 while keeping the multiplier threshold at its current level of 1.75. The payment percentage would remain the same: 50% of the difference between the cost of furnishing the service and 1.75 times the APC payment rate.

"Outlier Payments" Comment

According to CMS, the change in the outlier threshold will keep constant the percentage of OPPS payments that are attributable to outliers. This would support the thought that outlier payments to individual hospitals as a dollar amount, as opposed to a percentage of total OPPS payments, would remain relatively consistent. However, the proposed rule contains no analysis to support that this would be the reality of adopting the proposal. Furthermore, it is unclear whether the outlier pool has been overspent or underspent. We urge CMS to review data from CY 2005 claims before making changes to

the outlier payment. We feel that the proposed increase to the fixed-dollar threshold from $1,250 to $1,825 is too drastic and will have a negative impact on most, if not all, hospitals.

Thank you for considering our remarks on the proposed rule. If you have any questions about our comments, please feel free to contact me.

Sincerely,

Darcy Davis

Darcy Davis

Vice President of Finance, MHUMC

80

Texas Association of Ambulatory Behavioral Healthcare
9007 Cliffwood Drive
Houston, Texas 77096

October 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

To Whom It May Concern:

Re: PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient Psychiatric Services

The Texas Association of Behavioral Healthcare (TABH) represents providers of Outpatient Behavioral Health Services in the sate of Texas, including Hospital Outpatient Departments, Community Mental Health Centers, Psychiatrists, Advanced Practice Nurses, and Psychiatric Practitioners.

Providers of Outpatient Services in Texas are concerned, as for the second consecutive year, **APC Code 0033** is being significantly reduced.

Table A below outlines the PHP per diem National Rate for each of the last 5 years.
Actual/Proposed Medicare Per-Diem National Rates
Table A

APC	2003	2004	2005	2006	2007
0033 Partial Hospitalization	$240.03	$286.82	$281.33	$245.91	$208.27

There is no doubt that the implementation of the proposed reduced rate will have a ruinous effect on the providers of psychiatric programs and services, thereby reducing the access to the services by the mentally ill and the elderly.

The proposed 2007 rate will result in 26% cut in last two years, but the providers of psychiatric services are zealous about fighting for, and preserving the right of the beneficiaries to choose this outpatient level of psychiatric care. **It seems unwise for CMS to entertain the idea of rate cuts to outpatient services, as the alternative services fall into the hands of inpatient hospitals and emergency departments, both of which are more costly to provide and less appropriate methods of treatment.**

It is our feeling that when calculating the figures for APC Code 0033, CMS did not take into consideration the fact that an entire level of psychiatric services was in jeopardy. We believe that CMS did not intend to establish rates so low that services could not be provided, therefore programs would be closed and patients

would not be served. We believe that CMS appreciates the importance of APC Code 0033, and understands the need for these programs and services.

In addition, CMS proposes to cut the rates for the most often used APC codes for outpatient psychiatric services. What that means to the provider of the psychiatric services is if they continue to provide the services, they will do so at a cost that is more than the reimbursement they receive for the services.

Actual/Proposed Rates For Individual Treatment Modalities

Table B

APC	2003	2004	2005	2006	2007
0322 Brief Individual Therapy	$69.23	$69.35	$73.60	$73.22	$72.32
0323 Extended Ind. Therapy	$96.01	$101.97	$100.23	$97.59	$105.68
0324 Family Therapy	$128.35	$133.53	$161.59	$137.58	$135.95
0325 Group Therapy	$74.28	$81.10	$83.62	$79.95	$66.40

Again, we believe that if CMS takes a closer look at what the implementation of these APC Codes would do to patient access of psychiatric care, different decisions will be made.

1. **Methodology of calculation.**

CMS-1506-P (on pages 99-105) describes the CMS methodology of rate calculations for PHP each year since 2000. A close review indicates that CMS arbitrarily applies its own bias assumptions and methodology on a different basis every year from 2003 through 2006. Only the rates for 2006 and 2007 were computed the same way. That way was illogical – a simple 15% reduction each year from the previous year's per-diem rate.

Here are the year-to-year quotes of the CMS methodology to calculate the Partial Hospitalization per diem from CMS-1506-P:

- **2003 – p 101** CMS said "the median cost for each APC was scaled relative to the cost of a mid-level office visit and the conversion factor was applied. The resulting per diem rate for PHP for CY 2003 was $240.03."

- **2004 – p 101** CMS said "Therefore, in calculating the PHP median per diem cost for CY 2004, we did not apply the .583 adjustment factor to CMHC costs to compute the PHP APC. After scaling, we established the CY 2004 PHP APC of $286.82.

- **2005 – p 102** CMS said "We used data from all hospital bills reporting condition code 41 and all bills from CMHCs. We used CCRs from the most recently available hospital and CMHC cost reports to convert each provider's line-item charges, to **estimate** the provider's cost for a day of PHP services. Per diem costs were then computed by summing the line-item costs on each bill and dividing by the number of days on the bills."

- **2006 – p 103 CMS** said "Therefore we considered the following three alternatives to our update methodology for the PHP APC for CY 2006 to mitigate this drastic reduction in payment for PHP services … (3) apply a 15 percent reduction to the combined hospital-

based and CMHC median per diem cost that was used to establish the CY 2005 PHP APC."

2. **CMS does not support a PHP per diem rate of $208.27.**

   - During the identification of the proposed rate in CMS-1506-P, CMS referenced the CY 2005 combined hospital-based and CMHC median per diem costs of $289.00. As providers in the medical industry, we are well aware that the industry inflation rate is approximately 3.5% which creates an approximate cost of $299.12 per day for the coming year. As providers, we are very conscious that salaries, benefits, insurance, supplies, utilities, etc. have not gone down. These figures strongly conflict with a per diem rate of $208.27.

   - In addition, CMS has identified the true Median Cost of APC 325 for group therapy at $66.40. With a minimum of 4 services per day (many programs offer more), CMS would recognize the minimum cost at $265.60 per day. These data are inconsistent with a rate of $208.27 and indicate that a higher payment rate is necessary to prevent PHP from running substantial deficits that will risk financial viability.

3. **Medicaid cuts substantially impact copays.**

   - At the proposed CMS rate of $208.27, the Medicare payment is actually 80% or $166.62 with the copay of $41.65. Not all, but most Medicare recipients eligible for this benefit are also Medicaid recipients for their copay.

   - Many states (example-West Virginia) have recognized partial services as a Medicaid benefit. Unfortunately, their reimbursement rates are generally one-third to one-half of the Medicare rate at best. These states have declared that when crossover claims are submitted for the copay, that if the provider has already received payment above the state rate, then they do not pay any of the copay. This in essence creates a per diem rate of $166.62 for CY 2007, further below the unacceptable rate of $208.27.

4. **CMS's calculations for the CY 2007 PHP per diem payment is diluted**

   - 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 can severely dilute the rate and penalize providers. All programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 services. Programs must report these days to be able to meet the 57% attendance threshold and avoid potential delays in the claim payment. Yet, programs are only paid their per diem when 3 or more qualified services are presented for a day of service. If only 1 or 2 services are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. Even days that are paid but only have 3 services dilute the cost factors on the calculations. With difficult challenges of treating the severe and persistently mentally ill adults, these circumstances occur frequently.

5. **The proposed PHP per diem rate also compromises Hospital Outpatient Services.**

   - CMS pays hospital facilities for Outpatient Services on a per unit basis **up to** the per diem PHP payment. As previously shown, CMS has identified Group Therapy APC 0325 with a true Median Cost of $66.40. Most patients involved in the Outpatient Services are participating 1-3 days and generally receive 4 or more services on those days. While programs provide 4 services the per diem limit will only allow them to be "paid their cost" for 3 services (3 x $66.40= $199.20). The fourth service again is "on the house" and is paid at only $9.07.

6. **Cost Report Data frequently does not reflect Bad Debt expense for the entire year.**

   - As the cost report data is proposed surrounding Bad Debt, many "recent" bad debt copays of the last 4-5 months of the fiscal year have not completed the facility's full collection efforts and therefore are not eligible for consideration of bad debt on the cost report. Those that are, can only be recovered up to 55%. These costs are not being considered in the CMS data and severely short change the rate calculations.

7. **Data for settled Cost Reports fail to include costs reversed on appeal.**

   - CMS historically has reduced certain providers' cost for purposes of deriving the APC rate based on its observation that "costs for settled cost reports were considerably lower than costs from 'as submitted' cost reports." (68 Federal Register 48012) While CMS's observation is true, it fails to include in the provider's costs, those costs denied/removed from "as submitted" cost reports, and subsequently reversed on appeal to the Provider Reimbursement Review Board ("PRRB"), subsequently settled pursuant to the PRRB's mediation program, or otherwise settled among the provider and intermediary. During the relevant years at issue, providers of PHP incurred particularly significant cost report denials, but also experienced favorable outcomes on appeal. Because the CMS analysis did not take into consideration what were ultimately the allowable costs, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs subsequently allowed.

Recommendations

Based on the above information, TABH would recommend that CMS take the following course of action:

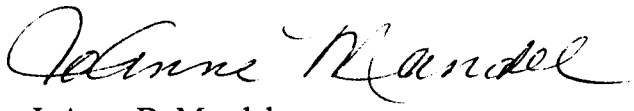
1. **Not implement** the PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient psychiatric services, until CMS examines the data and researches the numerous problems identified.

1. **Consider a consistent methodology** that can stabilize the PHP per diem rate and avoid the drastic year-to-year fluctuations that threaten the very existence of the program services for this targeted, severely mentally ill population.

2. **Allow time and resources** to develop a reasonable payment methodology by working with provider and community organizations who would welcome the opportunity to work with CMS to develop a payment rate that is fair, consistent and predictable.

Thank you, for the opportunity to respond to this critical issue.

Respectfully,



JoAnne D. Mandel
President – Board of Directors
Texas Association for Ambulatory Behavioral Healthcare

InnerWisdom, Inc.
1325 La Concha Lane
Houston, Texas 77054

October 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

To Whom It May Concern:

Re: PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient Psychiatric Services

Understanding that CMS has to follow a budget for all Medicare services, that the nations' Medicare beneficiaries are increasing, and that CMS needs to stretch Medicare dollars to meet all the beneficiaries' needs, it still does not make sense why CMS would so brutally slash the daily rate for CY 2007 for the most economically provided psychiatric services.

Mentally ill and elderly patients will need more psychiatric services in 2007 as they needed in 2006, as there are more patients with more acute problems than there were in 2006. In most cases, they will look to receive assistance, as they have in the past, from outpatient psychiatric programs and services. Where will they find them? The patients won't go away, but if the CY 2007 proposed rate cuts are allowed to go forward, the programs that serve them will go away.

The patients will need the treatment whether outpatient programs survive or not. The services that will be available will be found in inpatient hospitals and emergency departments and clinics. These two remaining options are at capacity now. In Houston, patients already must wait days for an impatient psychiatric bed. Emergency psychiatric cases already clog the emergency departments of both private and county hospitals, waiting sometimes up to 24 hours before they are seen and treated.

I feel I must ask what measures CMS has taken to help communities deal with this most certain crisis if providers and physicians refuse to treat Medicare patients because the cost of treating them is more than the compensation.

I am looking to CMS to help me understand the basis for the sizeable rate cut. In August, 2006, CMS published the "Proposed Changes to the Hospital Outpatient PPS and CY 2007 Payment Rates". This proposed rule would reduce Medicare payments for outpatient mental health services provided by all psychiatric provider types.

From 2004 to 2006, CMS reduced the per diem rates for PHP services from **$286.82** to **$245.65,** a reduction of **14.4** percent. For CY 2007, CMS is proposing to cut the per diem rate by an additional **15** percent to **$208.80**.

Table 1
Partial Hospitalization Program (APC 033)
Per Diem Rates

Calendar Year	National Rate	Actual Change	Percent Change
2003	240.03		
2004	286.82	46.79	.195
2005	281.33	-5.49	-.019
2006	245.65	-35.68	-.127
Proposed 2007	208.80	-36.85	-.150

CMS has developed the above rates based on its estimates of provider costs for a day of PHP services (CMS-1506-P pages 101,102,103, and 105). CMS derives its estimates of costs by applying Cost-to-Charge Ratios (CCRs) to the median per diem charges for CMHCs and blending the resulting "cost" with the cost of hospital-based PHP services obtained from the hospital cost reports.

I question the accuracy and necessity of using this methodology for three reasons.

- First, cost report data is available for every CMHC that bills the Medicare program. Actual cost report data will yield actual operating cost data that could be used to calculate the true cost of providing these services as opposed to an estimate of the costs.

- Second, CMHCs generate a significantly larger number of claims than do hospital-based PHPs. In its document, "Medicare 2007 OPPS NPRM Claims Accounting," CMS reports that it used 146,060 CHMC claims and 35,186 hospital-based PHP claims to develop the 2007 proposed rate. Blending the estimated costs from CMHCs with the actual cost of a much smaller sample size could dilute the estimated cost of providing these services

- Third, in the proposed rule, CMS established APC rates for individual units of psychotherapy provided in a hospital outpatient department. According to CMS, these rates are based on the actual costs of providing these services.

Table 2
Hospital Outpatient Department – Mental Health Services
Proposed APC Rates

APC	Description	2007 Proposed Rate
322	Brief Individual Therapy	$72.32
323	Extend Individual Therapy	$105.68
324	Family Therapy	$135.90
325	Group Therapy	$66.40

CMS reports that, "the median per diem cost for hospital-based PHPs has remained relatively constant **($200-$225)**, (CMS-1506-P, page 100). Partial Hospital Programs, whether CMHC-based

or hospital-based, provide each of the services listed in Table 2. CMS recognizes that a PHP is, "a program that often spans 5-6 hours a day", (CMS-1506-P, page 104).

The most common therapy provided is Group Therapy. Multiplying the Group Therapy **($66.40)** rate by the four (4) units typically provided in PHP yields a per diem rate of **$265.60** and yet CMS is proposing a per diem of only **$208.80** for partial hospitalization.

This rate is particularly egregious when you consider that PHPs are required to have a greater staff compliment and treat patients who are much more acutely ill than hospital psychiatric outpatient departments. It is obvious that CMS' own analysis argues for a rate increase for Partial Hospital Programs instead of a cut.

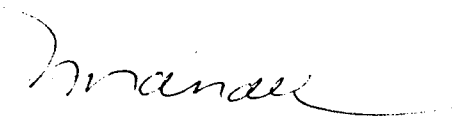
The severity of these cuts will **reduce, or completely destroy** the availability and accessibility to these lower costs, more appropriate psychiatric services during a time when the need for these services is rapidly growing.

CMS should delay implementation of any further cuts to psychiatric outpatient program until:

- it has undertaken a thorough study of the actual costs of providing these services;
- it has determined the impact the rate cut will have on the accessibility and quality of outpatient mental health services; and
- It has determined what action communities will take if outpatient services are no loner available to Medicare beneficiaries.

Thank you, for the opportunity to respond to this critical issue.

Respectfully,



JoAnne D. Mandel, LMSW, RN, CNS

CEO – InnerWisdom, Inc.

Association for Ambulatory Behavioral Healthcare

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October 7, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Sirs:

Re: Response to Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P Partial Hospitalization (APC 0033)

On behalf of the Association of Ambulatory Behavioral Healthcare (AABH), we appreciate the opportunity to submit comments regarding CMS's proposed OPPS rates concerning APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient Psychiatric Services

AABH represents over 270 providers of partial hospitalization and other ambulatory behavioral health services across the country. Our members consist of hospitals, community mental health centers (CMHCs), physicians, psychiatric nurses, advanced practice nurses, individual providers, and volunteers dedicated to cost effective patient treatment within the ambulatory continuum.

Since 1975, AABH has worked cooperatively with state and federal agencies, professional groups, payers and others to provide research and training, and to better define and support the understanding of ambulatory approaches to behavioral healthcare.

Our members subscribe to a code of ethics requiring the highest standards for professional and programmatic conduct, and share a common belief that individuals with acute mental illness have a better chance of recovery and healthy functioning if treated in the same communities where they work, attend school, and maintain family relationships. Based on our long-standing work in this area, we wish to work in partnership with CMS to ensure preservation and proper recognition of Medicare's partial hospitalization benefit.

AABH is deeply concerned about the grave impact a second rate reduction of 15% in two years could have on partial hospitalization and hospital outpatient services. We believe this type of cut will severely jeopardize the very existence of the partial hospitalization benefit itself, similar to the impact the cuts for CY2006 have had. Our Association membership of 350 providers in 2005 has dwindled 23% to 270 participants, as of August 2006 due strictly to the cuts of last year.

The Association of Ambulatory Behavioral Healthcare respectfully comments as follows:

1. **CMS data does not support a PHP per diem rate of $208.27 by its' own methodology of calculation.**

CMS-1506-P on pages 99-105 describes the CMS methodology of rate calculations for PHP each year since 2000. A close review indicates that CMS applies its own assumptions and methodology on

a different basis every year from 2003 through 2006. Only the rates for 2006 and 2007 were computed the same way – a simple 15% reduction each year from the previous year's per diem rate.

Here are the year-to-year quotes of the CMS methodology to calculate the Partial Hospitalization per diem from CMS-1506-P:

- 2003 – p 101 CMS said "the median cost for each APC was scaled relative to the cost of a mid-level office visit and the conversion factor was applied. The resulting per diem rate for PHP for CY 2003 was $240.03."

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2. CMS does not support a PHP per diem rate of $208.27.

During the identification of the proposed rate in CMS-1506-P, CMS referenced the CY 2005 combined hospital-based and CMHC median per diem costs of $289.00. As providers in the medical industry, we are well aware that the industry inflation rate is approximately 3.5% which creates an approximate cost of $299.12 per day for the coming year. As providers, we are very conscious that salaries, benefits, insurance, supplies, utilities, etc. have not gone down. These figures strongly conflict with a per diem rate of $208.27.

In addition, CMS has identified the true Median Cost of APC 325 for group therapy at $66.40. With a minimum of 4 services per day (many programs offer more), CMS would recognize the minimum cost at $265.60 per day. These data are inconsistent with a rate of $208.27 and indicate that a higher payment rate is necessary to prevent PHP from running substantial deficits that will risk financial viability.

3. Medicaid cuts substantially impact copays.

At the proposed CMS rate of $208.27, the Medicare payment is actually 80% or $166.62 with the copay of $41.65. Not all, but most Medicare recipients eligible for this benefit are also Medicaid recipients for their copay.

Many states (example-West Virginia) have recognized partial services as a Medicaid benefit. Unfortunately, their reimbursement rates are generally one-third to one-half of the Medicare rate at best. These states have declared that when crossover claims are submitted for the copay, that if the provider has already received payment above the state rate, then they do not pay any of the copay.

This in essence creates a per diem rate of $166.62 for CY 2007, further below the unacceptable rate of $208.27.

4. CMS's calculations for the CY 2007 PHP per diem payment are diluted.

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 can severely dilute the rate and penalize providers. All programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 services. Programs must report these days to be able to meet the 57% attendance threshold and avoid potential delays in the claim payment. Yet, programs are only paid their per diem when 3 or more qualified services are presented for a day of service. If only 1 or 2 services are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. Even days that are paid but only have 3 services dilute the cost factors on the calculations. With difficult challenges of treating the severe and persistently mentally ill adults, these circumstances occur frequently.

5. The proposed PHP per diem rate also compromises Hospital Outpatient Services.

CMS pays hospital facilities for Outpatient Services on a per unit basis up to the per diem PHP payment. As previously shown, CMS has identified Group Therapy APC 0325 with a true Median Cost of $66.40. Most patients involved in the Outpatient Services are participating 1-3 days and generally receive 4 or more services on those days. While programs provide 4 services the per diem limit will only allow them to be "paid their cost" for 3 services (3 x $66.40= $199.20). The fourth service again is "on the house" and is paid at only $9.07.

6. Cost Report Data frequently does not reflect Bad Debt expense for the entire year.

As the cost report data is proposed surrounding Bad Debt, many "recent" bad debt copays of the last 4-5 months of the fiscal year have not completed the facility's full collection efforts and therefore are not eligible for consideration of bad debt on the cost report. Those that are, can only be recovered up to 55%. These costs are not being considered in the CMS data and severely short change the rate calculations.

7. Data for settled Cost Reports fail to include costs reversed on appeal.

CMS historically has reduced certain providers' cost for purposes of deriving the APC rate based on its observation that "costs for settled cost reports were considerably lower than costs from "as submitted cost reports." (68 Federal Register 48012) While CMS's observation is true, it fails to include in the provider's costs, those costs denied/removed from "as submitted" cost reports, and subsequently reversed on appeal to the Provider Reimbursement Review Board ("PRRB"), subsequently settled pursuant to the PRRB's mediation program, or otherwise settled among the provider and intermediary. During the relevant years at issue, providers of PHP incurred particularly significant cost report denials, but also experienced favorable outcomes on appeal. Because the CMS analysis did not take into consideration what were ultimately the allowable costs, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs subsequently allowed.

Based on the above issues, AABH would recommend that CMS take the following course of action:

1. Allow the PHP per diem to remain the same as the 2006 per diem rate of $245.91 while CMS examines the data and researches the numerous problems identified, before a mental health crisis ensues.

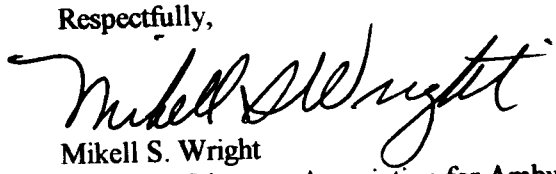
2. Consider a consistent methodology that can stabilize the PHP per diem rate and avoid the drastic year-to-year fluctuations that threaten the very existence of the program services for this targeted, severely mentally ill and elderly population.

3. Allow energy, time and resources to develop a reasonable payment methodology by working with national behavioral healthcare organizations such as AABH. We would welcome the opportunity to study and research data with CMS to develop a payment rate that is fair, consistent and predictable.

4. Consider that APC Code 0033 represents an entire level of outpatient psychiatric care. Reducing the daily rate to a level that would prompt programs to close, or to cease from admitting Medicare patients would devastate communities, as no other options for the care of the mentally ill and elderly are in place.

Thank you for the opportunity to respond to this critical issue.

Respectfully,



Mikell S. Wright
Executive Director, Association for Ambulatory Behavioral Healthcare

Intermountain
Eye Centers
Physicians, Surgeons and
Eye Care Consultants.
1-800-888-8393

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Katherine A. Lee, M.D., PhD
Molly J. Mannschreck, M.D.
Adam C. Reynolds, M.D.
James R. Swartley, M.D.
James P. Tweeten, M.D.
Paul D. Whitesides, O.D.
Mark D. Mifflin, M.D.

October 4, 2006

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Sir or Madam:

I am a fellowship trained glaucoma subspecialist currently practicing in Boise, Idaho, providing a significant portion of glaucoma surgical intervention for patients in southern Idaho, eastern Oregon and western Montana. I have been very active in the development of safer, more effective and more predictable surgical interventions for glaucoma at the national and international level. Every expert in this field, and I humbly include myself as one, would agree that this is a desperately needed area of innovation in surgical ophthalmology.

I am respectfully requesting that CMS add the CPT codes 0176T (Transluminal dilation of aqueous outflow canal; without retention of device or stent), and 0177T (Transluminal dilation of aqueous outflow canal; with retention of device or stent) to the list of procedures provided in the ASC setting. Transluminal dilation of the aqueous outflow canal is also known as canaloplasty, and it is an outpatient ophthalmic procedure for the treatment of glaucoma with the potential to give safer as well as more reliable intraocular pressure lowering in patients going blind from this disease who need surgical intervention.

This procedure is similar to most other ophthalmic surgical procedures, the majority of which are done in an Ambulatory Surgery Center (ASC). These procedures are almost never done in a hospital setting or an office setting. Surgeons in the ASC setting performed most of the clinical investigation for the canaloplasty procedure. In order for these surgeons and myself to provide canaloplasty in ASCs, CPT codes 0176T and 0177T will need to be on the ASC list for 2007.

In addition to implementing this recommendation, I would request that CMS add the canaloplasty to payment group 9. I-Science Interventional has applied for a New Tech APC for reimbursement within the hospital outpatient department. Cost information is detailed within their application.

As a glaucoma surgeon very interested in providing safer and more cost effective surgical care for my glaucoma patients who are Medicare beneficiaries and need surgical intervention, I need access to the best therapeutic technologies in the most appropriate and cost effective site of service. I appreciate the work entailed in developing the new surgical codes, and I appreciate the members of the CMS and their efforts involved in developing the new ASC payment system for 2008. I have actually volunteered through Dr. Greg Skuta and Dr. Bill Rich to serve in any way I can to help with this and related issues. If I can be of service in any way, feel free to contact me.

Sincerely,

Adam C. Reynolds, MD
Intermountain Eye Centers

ACR / yg

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S4

September 24, 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
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

North American Scientific is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

This comment letter specifically addresses the proposed payment methodology for brachytherapy sources in 2007 and the rationale for recommending the current payment methodology of hospital charges reduced to costs be continued.

Since 1997 our company has manufactured iodine and palladium brachytherapy sources used for the treatment of cancer. North American Scientific is one of the few companies that manufacture and supply high activity iodine sources supplied to hospitals across the country.

HOPPS Proposed Payment Methodology for Brachytherapy Sources

Currently, there are twelve very different brachytherapy sources recognized by CMS and used to treat a number of different cancers. The current configurations of the brachytherapy sources and the wide range in radioactive intensities offer physicians an appropriate array of treatment approaches to ensure the therapy effectively treats the size, location and histology of the tumor.

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We believe that it would be inappropriate to implement a new payment system for 2007 that would establish payment rates for each of these brachytherapy sources. The variations in cost of each source requires a unique payment methodology for radioactive sources. High activity sources supplied to hospitals across the country have a cost variation of over 10 times based upon the intensity of the source.

The CMS claims data shows large variations in per unit cost reported on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007. Further, the median cost for high activity sources proposed in the rule does not accurately reflect the true cost of the source to hospitals.

The data used by CMS to establish proposed payment rates for 2007 (see table below) shows a huge variation in per unit cost reported on claims by hospitals across the county. This variation validates our concern regarding the data that CMS is using to establish payment rates for fiscal year 2007.

HCPCS and Descriptor	Variation of Cost per Unit (2005 Hospital Claims)
C1718 Iodine-125	$0 - $14,632
C1720 Palladium-103	$0 - $20,825
C2634 High Activity Iodine-125	$2 - $4,526
C2635 High Activity Palladium-103	$3 - $5,212

In addition to the variations in cost reported by the data, high activity source proposed payment rates have been established based upon claims data from a small number of hospitals.

HCPCS and Descriptor	Hospitals Reporting (2005 Hospital Claims)
C2635 High Activity Palladium-103	20
C2634 High Activity Iodine-125	50

CMS data outlined in the table below indicates rank order anomalies in proposed payments for high activity brachytherapy devices. High Activity Iodine-125 sources (C2634) always cost more than low activity sources (C1718). Typically, High Activity sources are 5 to 10 times more expensive than low level sources. CMS has proposed to establish payment values for high activity sources at a lower value than low activity iodine sources.

HCPCS and Descriptor	Median Cost (2005 Hospital Claims)
C1718 Iodine-125	$35.54
C2634 High Activity Iodine-125	$25.77

Based upon a review of the data, we do not believe that the recommended payment methodology will appropriately capture the variation of brachytherapy source configurations. We urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device and abandon the proposed payment methodology.

North American Scientific recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices. This recommendation also was made by the APC panel at the August 24, 2006 meeting.

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of these important issues.

Sincerely,

L. Michael Cutrer
President and CEO
North American Scientific

TEXAS HEALTH RESOURCES

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October 6, 2006

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

RE: ***Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System: the Proposed Rule for 2007***

Dear Dr. McClellan:

On behalf of Texas Health Resources (THR) and its 13 faith-based, nonprofit community hospitals throughout North Texas, including Harris Methodist Hospitals, Arlington Memorial Hospital and Presbyterian Healthcare System, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Medicare Outpatient Prospective Payment System (PPS) for calendar year 2007. The proposed rule was published in the August 23 *Federal Register* and included the following major proposals: linking a hospital's receipt of a full outpatient market basket update to the reporting of inpatient quality measures; a new coding system for hospital outpatient clinic and emergency department (ED) visits; a major revision of ambulatory surgical centers (ASCs) payment methodology for 2008; and, expanding inpatient hospital quality reporting requirements for fiscal 2008.

CMS proposes that hospitals would only receive the full outpatient market basket update if they meet the inpatient reporting requirements for a full update in fiscal 2007. Hospitals that do not meet these inpatient reporting requirements would receive an update reduced by 2.0 percentage points—which means a 1.4 percent update instead of the full 3.4 percent. THR opposes linking inpatient quality measures to the outpatient PPS update. It is not an appropriate policy. THR fully supports linking outpatient quality measures to outpatient services; consequently, any link between quality improvement and payment for outpatient services should be based on outpatient quality measures.

ED Visits, Clinic Visits and Critical Care Services

CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. To determine appropriate payment rates for the new HCPCS G codes, CMS proposes to assign the data from the 2005 CPT visit codes and the other HCPCS codes currently assigned to the clinic visit APCs to 11 new APCs, five for clinic and one for critical care services.

THR recommends that CMS reconsider implementing the proposed EM level codes for 2007. This change if finalized will be cumbersome for hospitals to implement until final CMS facility E&M guidelines are adopted. Further, THR does not support implementation of a 30-minute requirement for the critical care APC. It is possible for a hospital to consume a high level of resources and combined staff time sufficient to warrant critical care reimbursement even when the encounter is less than 30 minutes.

Infusion Therapy

THR appreciates CMS' recognition of the costs related to infusion therapy services based upon infusion types and the length of time required for the IV infusion therapy. THR supports CMS' proposal to reimburse for infusion services by assigning CPT/HCPCS to six new drug administration level APCs that compensate for infusion therapy time. Further, THR recommends that CMS permit a charge for each IV push when the same drug is pushed multiple times during the encounter.

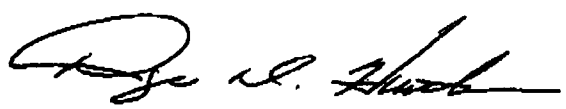
Partial Hospitalization Services

Consistent with 2006 payment policy for partial hospitalization services, CMS proposes to again reduce per-diem payment for partial hospitalization program services by another 15 percent from the 2006 per diem rate of $246.04. This results in a proposed per-diem payment rate of $208.00 for 2007.

THR does not support reduced payment for these services. Partial hospitalization is a hospital-based level of care serving as an appropriate alternative to a more costly inpatient admission. Medical justification for partial hospitalization services includes symptoms or a clinical determination that the patient is a danger to self or others; or a determination that significant deterioration or regression will require admission to an inpatient setting absent the daily structure, nursing supervision, and close medical supervision provided within a partial hospitalization program. Partial hospitalization services provide continuous professional supervision, available at least five days a week and on-site nursing services; planned, comprehensive treatment involving close psychiatric and professional multi-modal treatment. It is crucial that programs receive adequate reimbursement to care for patients who meet the criteria for partial hospitalization services. The proposed reimbursement will not sustain the staff and services required to create a safe and structured environment for these patients. Thus, it is likely that hospitals will eliminate the service creating a service shortage for the growing Medicare population.

Again, thank you for the opportunity to share our comments. We look forward to working with CMS to resolve these issues and concerns. If we can provide you or your staff with additional information, please do not hesitate to contact David Tesmer, Senior Vice President of Advocacy and Community Benefit, at 817-462-7937 or by e-mail at DavidTesmer@TexasHealth.org.

Sincerely,



Douglas D. Hawthorne, FACHE
President and CEO
Texas Health Resources

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Mark B. McClellan, MD. PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1506-P
P.O. Box 8011
7500 Security Boulevard
Baltimore, MD 21244-8014

Re: Medicare Hospital Outpatient Prospective Payment System: Proposed Rule

Dear Dr. McClellan:

We appreciate the opportunity to offer comments on the proposed hospital outpatient prospective payment rates for 2007. Our comments concern the costs of providing Magnetoencephalography (MEG) services, CPT Codes 95965, 95966 and 95967.

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

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

APC Assignments and Payment for MEG Services

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

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

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

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

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

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

We do not agree with CMS that the resources required to provide Code 95966 are at all similar to the costs of providing the EEG and sleep codes assigned to APC 0209. The costs of purchasing a MEG system are in excess of $2.5 million. In addition, the annual maintenance fee for this equipment is about $100,000 and the costs of disposable supplies are significant. We do not agree that Code 95966 should be assigned to APC 0209.

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

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

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

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

Thank you for the opportunity to offer these comments.

Sincerely,

Paul Murdoch
President & CEO
VSM MedTech Ltd.

BSD MEDICAL

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October 5, 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**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

BSD Medical Corporation (BSD Medical) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

BSD Medical develops and manufactures systems to treat cancer and benign diseases using heat therapy as provided by focused radio frequency and microwave energy. BSD Medical would like to review and make suggestions regarding the proposed CMS changes in payment for hyperthermia procedures (CPT 77600-77620) under the hospital outpatient prospective payment system for calendar year 2007.

BSD Medical works with providers across the country to provide Hyperthermia therapy. Hyperthermia therapy is a treatment used in battling cancer by heating tumors. The Heating is about as warm as a hot tub. Research has shown that heat can damage or kill cancer cells in some tumors while also making radiation therapy more effective in treating some tumors that are recurrent or progressive despite conventional therapy.

While it has been known for hundreds of years that fevers can kill cancer, only recently has technology been developed that can control and focus heat specifically on tumors. This technology is found in the BSD Hyperthermia Technology.

The BSD technology has been approved by the FDA for use alone or in conjunction with radiation therapy in the palliative management of certain solid surface and subsurface malignant tumors (i.e., melanoma, squamous- or basal-cell carcinoma, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy.

Clinical studies using BSD's hyperthermia systems in conjunction with radiation therapy have shown that 83.7% of patients had some tumor regression (reduction), 37.4% of patients had a complete tumor regression and 24.5% had a greater than 50% tumor regression.

The following codes are reported by hospitals for hyperthermia treatment:

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