2160-0 (10) OPPS

PROTON THERAPY CONSORTIA

Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D. Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton Radiotherapy Institute at Indiana University • University of Pennsylvania Medical Center/The Children's Hospital of Philadelphia • Arthur G. James Cancer Hospital/Ohio State University •Hampton University Proton Therapy Institute •Northern Illinois University

APC

Dana (2)
Joan
Carol
Alberta

September 26, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8011 and 8014
Baltimore, MD 21244

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which are noted below.

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy delivered in the Hospital Outpatient Hospital Department (HOPD) setting are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States.

Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

Freestanding Proton Therapy Centers

The Proton Therapy Consortia (Consortia) is concerned with the proposed treatment of the Freestanding Proton Therapy Centers by the Centers for Medicare and Medicaid Services (CMS) contracted Carriers in the State of Texas, Florida and Indiana. Contracted Carriers deviate significantly from the CMS National policy concerning proton beam therapy used to establish the existing payment rates as noted above for CY'06 and CY'07.

For Freestanding Proton Therapy Centers, CMS has given its contracted Carriers significant latitude with limited guidance from which to determine payment rates for proton therapy. As each State has its own Carrier, significant variations in payment rate determinations are occurring by State, as noted below.

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	-	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

Source: Indiana data provided by MPRI, as of September 29, 2006
University of Florida Health Sciences Center, as of September 11, 2006
TrailBlazer Health Enterprises, LLC provided to The University of Texas M.D. Anderson Cancer Center on September 1, 2006

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

Rationale for HOPD and Freestanding Payment Consistency: Capital Resources and Operating Costs

A typical proton beam therapy center will consist of 2-6 treatment rooms of which most include rotating gantry structures. Each gantry weighs in excess of 100 tons and is capable of rotating 360 degrees around the patient so as to deliver the proton beam therapy with sub-millimeter precision. Each facility requires up to $125 million and more than three years to develop.

A proton beam therapy center can be open up to 16 hours each day and employs radiation oncologists, physicists, nurses, medical dosimetrists, therapists and technical personnel.

For comparison, a typical conventional radiation therapy center, with 1-2 treatment vaults to accommodate a linear accelerator, gamma knife or cyber knife, will take 8-12 months to construct and prepare for clinical use. Capital requirements are between $4 and $6 million. Operating ramp-up for a conventional radiation therapy facility will usually require 2-3 months, or less in some instances.

It should be noted that due to the capital cost of proton therapy, both Freestanding and HOPD centers have similar costs for patient treatments.

Practice Expense Relative Unit Value

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit (RVU) through the AMA-RUC process for proton beam therapy. Due to the limited availability of this technology in the Freestanding setting and the established coverage and payment policy established by CMS for HOPDs, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

PROTON THERAPY CONSORTIA

Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D. Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton Radiotherapy Institute at Indiana University • University of Pennsylvania Medical Center/The Children's Hospital of Philadelphia • Arthur G. James Cancer Hospital/Ohio State University •Hampton University Proton Therapy Institute •Northern Illinois University

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Proton Therapy Consortia

Proton beam therapy has been used in the clinical setting for more then 20 years, and employed in the hospital setting since 1990 to treat cancer patients (see Appendix 1 and 2). Positive clinical results from the use of proton beam therapy have stimulated worldwide interest in the clinical applications of proton beam therapy.

The Consortia consists of a group of premier cancer treatment centers in the United States that offer, or are in the process of building the capacity to offer, proton beam therapy. Members of the Consortia include nine institutions and contain both HOPDs and Freestanding centers, including:

Centers in Operations and Treating Patients:

- Loma Linda University Medical Center (October 1990): HOPD
- Massachusetts General Hospital (November 2001): HOPD
- Midwest Proton Radiotherapy Institute of Indiana University (February 2004): Freestanding
- The University of Texas M. D. Anderson Proton Therapy Center (May 2006): Freestanding
- The University of Florida Health Science Center (August 2006): Freestanding

Centers Currently Under Development:

- University of Pennsylvania Medical Center (planning stages): HOPD
- Arthur G. James Hospital / Ohio State University (planning stages): Freestanding
- Hampton University Proton Therapy Institute (planning stages): Freestanding
- Northern Illinois University (planning stages): Freestanding

Conclusion

Currently, over 40,000 patients have been treated with protons in many institutions around the world. In spite of the proven effectiveness of proton beam therapy, the development of a clinical proton beam therapy center is still challenged with the complexity, size and cost of the necessary equipment and physical facility.

Proton beam therapy is in an early stage of clinical adoption and the required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment, which is a relatively more mature technology and has a large installed base and widespread clinical acceptance.

We strongly agree with CMS's proposed CY '07 payment rule for proton beam therapy for HOPDs.

We strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates for Freestanding centers are made in a consistent manner with those currently in effect for HOPDs.

As always, please feel free to call upon us at (713) 563-2314 if you have any questions or if we can provided further data that can assist CMS's rule making.

Sincerely,

M. Mitchell Latinkic
Division Administrator
Division of Radiation Oncology
The University of Texas
M. D. Anderson Cancer Center

Allan Thornton, M.D.
Medical Director
Midwest Proton Radiotherapy Institute
at Indiana University

Appendix 1

UNDERSTANDING PROTON BEAM THERAPY

Principles of Radiation Oncology

The beneficial aspects of all forms of radiation oncology result from ionization. Because of ionization, radiation damages DNA within the cells. Damaging the DNA destroys specific cell functions. While both normal and cancerous cells go through a repair process, the ability of cancer cells to repair after injury is frequently inferior. As a result, higher levels of ionization in cancer cells will ensure that they sustain more permanent damage and subsequent cell death, minimizing ionization to normal cells will allow them to repair and survive. This selective cell destruction is the objective of all sound cancer therapies.

Increased Effectiveness and Utilization

Physicians have looked for ways to use radiation to treat cancer since the discovery of x-rays by Wilhelm Roentgen and radioactivity by Marie and Pierre Curie 100 years ago. Advances in technology and a better understanding of its effects on the body have made radiation therapy an important part of cancer treatment.
The first proposal for the medical use of protons was made in 1946 in a paper by physicist, Robert Wilson, Ph.D. By 1954, proton beams from a high-energy physics research accelerator were first used to treat humans.

Over the last decade, radiation therapy has grown in its utilization as a result of early detection and cancer awareness programs. With greater emphasis placed on organ preservation, quality of life and productivity, the role of radiation oncology is expected to increase.

In fact, according to the American Cancer Society, about half of all people with cancer will receive radiation during their cancer treatment.

Objectives of Radiation Therapy

The classic intent of radiation oncology is to deliver ionizing radiation only to diseased tissue. In practice, this ideal is compromised; normal tissue is always included in the radiation fields. The tolerance of the normal tissue in those fields often determines the dose the radiation oncologist can deliver; the resulting dose is frequently insufficient to control the cancer.

Radiation oncologists seek the lowest rate of side effects and complications as possible, consistent with the attempt to achieve the best possible local and local/regional cancer control. Complications include disability, disfigurement, dysfunction, and even death.

Conventional Radiation Therapy Constraints

Radiation therapy requires delivery of photons and electrons into the body in total doses sufficient to ensure that enough ionization events occur to damage all of the cancer cells.

Unlike protons, photons lack charge and mass, thus most of their energy is deposited in normal tissue near the body's surface, as they travel through tissue, and beyond the targeted cancer. This undesirable pattern of energy placement results in unnecessary damage to healthy tissues.

Attempting to overcome the inherent characteristics of photons and electrons, radiation oncologists employ multi-field treatment delivery arrangements to build up the tumor dose and spare as much of the normal tissue as possible by restricting the dose in those tissues to a tolerable level.

Rationale for Proton Beam Therapy

Protons, unlike photons or electrons, are energized to specific velocities. These energies determine how deeply in the body protons will deposit their maximum energy. The precise stopping point of protons in the body is where the highest radiation dose is released; this is called the Bragg Peak. Protons' favorable absorption characteristics result from their charge and heavy mass, which is 1,835 times that of an electron. These factors allow the physician to predict and control their depth of travel within the patient. The heavy mass of protons results in minimal travel deviation, which reduces unwanted side effects and improves treatment benefit.

Appendix 2

MAJOR COMPONENTS OF A PROTON BEAM THERAPY SYSTEM

A proton beam therapy treatment center consists of a number of distinct technical components. All of the components are based on an established accelerator, medical physics, control systems and software technologies. The proton beam treatment center typically consists of a separate building or designated space to house all of the proton beam therapy equipment coupled with up to four distinct patient treatment rooms.

Accelerator: High energy proton beams are generated by a synchrotron or cyclotron accelerator, a compact particle accelerator that accelerates protons that can be reduced to variable energies in the range from 70 to 250 MeV. The accelerator consists of a ring of magnet(s) having a circumference length of approximately 23 meters that constrains the protons to travel in a circumscribed path inside a high vacuum chamber. Accelerated protons are extracted into the beam transport line, which directs the proton beam to the patient treatment room.

Beam transport line: The proton beam travels through the beam transport system inside a vacuum tube. The beam transport line consists of a series of bending and focusing magnets, which control the beam's focus and position as it travels to the patient treatment rooms.

Rotating gantry treatment rooms: Gantries are massive rotating steel structures that support the bending and focusing magnets, vacuum system, nozzle, and all equipment necessary for controlling and monitoring patient treatment. This complex structure, three floors in height, weigh in excess of 100 tons and rotate 360 degrees around the patient with sub-millimeter precision. The gantry is rotated to prescribe angles around the patient, thus directing the proton beam toward the tumor from different directions. In this manner, multiple portals (or beam entry points) can be used during a treatment session while keeping the patient in a fixed position.

Horizontal, fixed-beam treatment room(s): A fixed, horizontal, non-moveable beam transport and delivery system and an adjustable patient treatment couch or chair are used for large-field treatments, including treatments of prostate, and head and neck cancers. A small-field treatment system is specially designed to treat tumors of the eye.

Treatment delivery nozzle: In each of the patient treatment rooms, a nozzle is located at the terminus of each beam line. The nozzle contains devices that shape, focus and direct the proton beam to the precise configuration of the involved area specified by each patient's treatment plan, thereby allowing three-dimensional conformal treatment to the exact tumor volume. Advanced nozzle designs include magnets that sweep a pencil-beam of protons through the tumor volume, while varying the intensity of the beam or the speed of the sweeping pattern. This advanced form of treatment, called intensity modulation, will offer the optimum radiation treatment for cancer.

Patient positioning system: The patient positioning system includes digitally controlled platforms that hold the patient in a secure treatment position and moves the patient to the exact position required for treatment. Advanced imaging systems provide necessary data for movement corrections that position patient's cancer in the treatment beam to within sub-millimeter accuracy.

Treatment control and safety systems: The treatment control system is a fully integrated hardware and software system that monitors and controls all aspects of beam production, transport and delivery. The control system includes monitoring devices and diagnostics software that provide rapid problem identification and error reporting. Additional software displays the patient's treatment field, setup information, patient-specific treatment device information, and real time monitoring and reporting of the delivered dose. The safety system operates independently of the control system. It has both software and hardware systems that monitor all of the critical elements of beam delivery.

Treatment planning, record-and-verify, and interface software: In addition to the foregoing, treatment planning, information and image management software systems and workstations are needed to integrate with the facility control system.

Development Period: The full proton beam therapy treatment system requires an extensive period of time to install, test and commission prior to first patient treatment. The building, up to approximately 85,000 square feet in size, needed to house the proton beam therapy hardware and software takes approximately 12 months to complete before equipment can be installed. Approximately 24 months, if not more, are required to install and commission the proton accelerator, beam transport lines and gantries, to install and integrate the software systems, and to finish, test and commission the resulting integrated system to clinical specifications.

217-0
(49)

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

Re: Partial Hospitalization Response on Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P.

Our agency, DAPA Family Recovery Programs is a freestanding Community Mental Health Center near the Medical Center of Houston, Texas. We serve approximately 944 general adults and 194 geriatric patients on an annual basis. We provide intensive psychiatric programs, including partial hospitalization services that are greatly needed by the severe and persistently mentally ill in our community.

We are requesting the proposed 15% cut for Partial Hospitalization Services be stopped. Coupled with last year's 12.5% reduction, the proposed rate will make it impossible to cover the costs needed to provide our intensive programs. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Please consider not cutting the Partial Hospitalization Program rate so drastically when most medical costs are actually increasing by 4-6% annually. These programs need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing services to such a needy population.

Thank you for your consideration.

Sincerely,

Don M. Seeley

October 5, 2006

218-O
(33)

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

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P

DAPA Family Recovery Center is a freestanding Community Mental Health Center near the Medical Center of Houston, Texas. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1506-P and another 15% rate reduction for CY2007 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction again. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $37.64/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1506-P pp. 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 CY2003 through CY2006. Only the methodology from CY2006 and CY2007 are the same and there is no calculation of a methodology. It is nothing more than an arbitrary decision by CMS. We quote CMS on p. 105 to say "To calculate the CY2007 APC PHP per diem **cost,** we reduced $245.65 (the CY2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 15 percent, which resulted in a combined median per diem cost of $208.80."

2. CMS-1506-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00 in the last paragraph of p. 105. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas over the past two years. A daily per diem of $208.27 cannot be justified with these expenses.

3. CMS identified the Median cost of group therapy at $66.40. Our program offers 4 group services per day at a minimum. This summarizes to a median cost of $265.60. A per diem of $208.27 cannot be justified with these expenses.

4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

5. Based on the above issues, DAPA Family Recovery Center asks that CMS leave the per diem unchanged from the CY 2006 rate of $245.91. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 944 general adult admissions and 194 geriatric admissions so far in CY 2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Dan M. Seeley

219-0
(70)

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

Re: Partial Hospitalization Response on Proposed Changes to the Hospital Outpatient PPS-CMS-1506-P.

I am a client at DAPA Family Recovery Programs, which is a freestanding Community Mental Health Center near the Medical Center of Houston, Texas. DAPA serves approximately 944 general adults and 194 geriatric patients on an annual basis. They provide intensive psychiatric programs, including partial hospitalization services that are greatly needed to cope with my severe and persistently mental illness. I am in great need of these resources to keep me from needing hospital emergency rooms and/or prison facilities.

I am requesting the proposed 15% cut for Partial Hospitalization Services be stopped. Coupled with last year's 12.5% reduction, the proposed rate will make it impossible for DAPA to cover the costs needed to provide the intensive programs I need to resume a normal life and contribute in a positive manner to our society. I strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Please consider not cutting the Partial Hospitalization Program rate so drastically when most medical costs are actually increasing by 4-6% annually. These programs need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing services to such a needy population. I and many other like me desperately need programs like this in order to live a better life, contribute to society in a positive manner, and keep from becoming disenfranchised.

Thank you for your consideration.

Sincerely,

Jo Ann Williams

220

Georgetown
University
Hospital
Lombardi Cancer Center

Department of Radiation Medicine

October 4, 2006

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

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

Meticulous arguments have been presented by others about the reimbursement reductions proposed to CyberKnife radiosurgery. Let me just add a note from someone who works with the technology, sees its unique capabilities and sees the therapeutic results in treated patients.

CyberKnife technology is totally unique in the realm of radiation therapy and radiosurgery. The accuracy to which a treatment can be delivered is truly equal to the accuracy obtainable in the treatment planning. The ability to track the patient's anatomy or implanted fiducials in real-time **during** the treatment, and for the robot mounted linear accelerator to make real-time pointing corrections based on that tracking **during** treatment is unsurpassable. This has solved the major problem that has plagued radiation delivery for decades. Although other technologies use the term Image-Guided Radiation Therapy *(IGRT), it is a misnomer.* It only means image matching at the time of set-up and takes no account of any motion-related inaccuracies during treatment.

The additional ability of CyberKnife to track tumors moving rapidly during respiration revolutionizes the ability to treat lung cancers. The ability to track the prostate during its continuous movements related to bowel changes makes it possible for the first time to deliver very high, curable

Georgetown
University
Hospital
Lombardi Cancer Center

Department of Radiation Medicine

doses to many patients who would otherwise fail treatment. There are many other aspects of CyberKnife's capability that are just coming to maturity as patient follow-up reaches appropriate durations and numbers to provide convincing clinical data.

To apply this technology is labor intensive from the physicist's, physician's and therapist's perspective. The technology is expensive to obtain and operate. But, the quality of patient treatments is commensurate with this. If it were me on the table, I'd want it because I know how good it is.

Sincerely,

Donald A. McRae, Ph.D.
Chief of Physics
Department of Radiation Oncology
Georgetown University Hospital
3800 Reservoir Rd. N.W.
Washington, DC, 20007

SIEMENS

221 Rec'd 10/11/06

October 10, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S. W.
Washington, D.C. 20201

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

Dear Dr. McClellan:

Siemens Medical Solutions USA, Inc. welcomes the opportunity to provide comments on the proposed rule Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.

Siemens Medical Solutions, headquartered in Malvern, Pennsylvania and Erlangen, Germany, is one of the largest suppliers to the healthcare industry in the world. The company is known for bringing together innovative medical technologies, healthcare information systems, management consulting, and support services, to help customers achieve tangible, sustainable, clinical and financial outcomes. Siemens Medical employs approximately 31,000 people worldwide and operates in more than 120 countries.

Proposed Movement of Procedures From New Technology APCs to Clinical APCs:

PET/CT Scans

Siemens is concerned with CMS's decision to move PET/CT scans from new technology APC 1514 to new APC 0308. The proposed change does not distinguish between this technology and PET scans. PET/CT scans have emerged as one of the most important technologies used to manage cancer patients. Patients benefit from PET/CT scans through earlier diagnosis, more accurate staging, precise treatment planning, and improved monitoring of therapy. The enhanced images generated by these scans allow physicians to pinpoint tumor position and detect cancer cells often well before they are readily visible.

In 2004, PET/CT was a new technology with no established codes. This technology was granted three separate CPT codes by the American Medical Association (AMA) and in March 2005, CMS assigned these codes to New Technology APC 1514. In the 2007 proposed rule, CMS states there is adequate claims data for CPT codes 78814, 78815,

Siemens Medical Solutions USA, Inc.

Sales and Service
51 Valley Stream Parkway
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and 78816 to move from the New Technology APC 1514 (New Technology- Level XIV, $1,200-$1,300) to a "clinically appropriate" APC (proposed APC 0308, $865.30). This represents a 30 percent decrease in payment, far below the costs of providing this service.

PET/CT is an enhanced technology that is not comparable to PET or CT scans alone. CMS is required to place CPT codes in APCs that are similar clinically, as well as on the basis of average resource use. CMS currently does not have sufficient, accurate, claims data to justify movement of these new technologies into an existing clinical APC. Maintaining the PET/CT codes in their existing New Technology category will ensure that they are appropriately reimbursed. The Advisory Panel on Ambulatory Payment Classification recently recommended that CMS maintain CPT codes 78814, 78815 and 78816 in New Technology APC 1514 for CY 2007. Siemens agrees with the APC Panel recommendation and recommends that CMS adopt this is the final rule.

Proposed Payment Rates for CT and CTA

CT Angiography (CT) displays the vasculature in a three-dimensional format enabling a wide variety of clinical uses and benefits. The procedure itself consists of a conventional CT scan, combined with sophisticated three-dimensional post processing to render images of arterial and venous vasculature. Siemens is concerned regarding the proposed payment levels for CTA procedures (APC 662, $302.85). CTA procedures continue to be reimbursed at a lower rate than conventional CT procedures, although the resource costs of CTA consistently exceed conventional CT.

Inaccurate CTA claims data coupled with CMS methodological issues involving application of cost-to-charge ratios for procedures introduced after 2001, have resulted in an APC payment rate for CTA procedures that is significantly below that for CT procedures alone. We urge CMS to set reimbursement for CTA procedures at a level at least on parity with the sum of that of the CT APC payment, plus the post processing APC payment. This may be accomplished by adjusting upward the payment rate for APC 662, or alternatively assigning CTA procedures to an existing APC that more closely reflects the resource costs of performing this service.

Myocardial PET Scans

Siemens believes that CMS's proposal to assign multiple myocardial PET scans to the same APC as single myocardial PET scans will significantly underpay providers for multiple scanning procedures. Multiple scans require greater hospital resources, as well as scan times, than single scans. CMS currently divides these PET scans (single and multiple) into two separate APCs paid at $800.55 and $2,484.88, respectively. The placement of both PET scans into one APC (APC 0307, $721.26) will cause an onset of dramatic declines in payment for these facilities.

CMS indicates that the 2005 claims data show a reduction in costs for multiple PET scans. However, over the past several years, reimbursement for myocardial PET scans has wavered. As such, Siemens recommends that the current APC assignments for single

and multiple studies be maintained in 2007, allowing for additional, accurate claims data to be captured for these procedures in order to establish more appropriate APC assignment in 2008.

Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA):
Siemens commends CMS for its proposals offering appropriate and reasonable coverage and payment for this preventive service utilized to detect life-threatening aneurysms.

Payment for Multiple Imaging Procedures in 2007:
Siemens agrees with CMS' proposal to postpone implementation of the multiple imaging payment reduction for imaging services. We encourage CMS to continue obtaining and evaluating data on the efficiencies related to multiple imaging procedures which may already be reflected in the HOPPS payment rates for imaging services.

*****

Thank you for your consideration of our request. Please contact me directly if you would like additional information with respect to our above comments.

Sincerely,

Diane M. Wurzburger
Director, Health Policy and Reimbursement
Siemens Medical Solutions USA, Inc.

222

octapharma

For the safe and optimal use of plasma

October 10, 2006

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

Re: CMS-1506-P; CMS-4125-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates)

Dear Administrator McClellan,

Octapharma USA is pleased to respond to the proposed rule concerning the 2007 hospital outpatient prospective payment system ("OPPS") rates that was published in the Federal Register on August 23, 2006 (Proposed Rule, 71 FR 49506). Octapharma USA is a subsidiary of Octapharma AG, a manufacturer of human immune globulin, intravenous (IVIG). Our organization is deeply committed to advancing the safe and optimal use of plasma with the goal of providing the best possible plasma-based human therapies to patients worldwide.

Octapharma USA is concerned that the proposed CMS reimbursement rates for IVIG furnished in hospital outpatient departments, has been reduced to ASP plus 5 % even in light of evidence that suggests that an increasing number of hospital outpatient departments are having difficult furnishing IVIG even at the current 2006 payment rate. Further, if CMS were to discontinue the reimbursement payment for preadministration-related services for IVIG, then hospital outpatient departments would be even more pressured to recover acquisition and overhead costs. In sum, we believe that the proposed OPPS rate and elimination of preadministration payment will exacerbate the reimbursement problems currently faced by hospital outpatient department resulting in further patient dislocations and access problems.

In addressing the issues related to reimbursement for hospital outpatient administered IVIG products, Octapharma USA restates and endorses the reimbursement recommendations outlined in the response to 71 FR 49506 submitted by the industry trade association - the Plasma Protein Therapeutics Association (PPTA)[1]. These recommendations include:

[1] For a more detailed examination of each of the recommended reimbursement steps for IVIG administered in hospital outpatient departments, please refer to the comments submitted by the Plasma Protein Therapeutics Association.

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ENSURING ADEQUATE PAYMENT RATES FOR PLASMA THERAPIES ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

The basis for CMS' proposal to pay for IVIG at ASP plus 5%, rather than the current ASP plus 6% is an evaluation of the mean costs of drugs using hospital claims data compared to the ASP data CMS receives on a quarterly basis. Octapharma USA believes that reliance on hospital claims data is flawed because:

- Poor data quality due to the inability to properly code for drugs and units,
- Hospital IVIG claims data are subject to charge compression – a phenomenon in which hospitals tend to mark-up high cost items to a lesser extent than mark-ups of lower cost items,
- Inclusion of 340B prices not available to most outpatient departments in claims data artificially lowers actual acquisition costs,
- Differentials in payment rates for IVIG depending on site of service would be detrimental to beneficiary access to product and is troubling from a policy perspective,
- Creation of different payment methodologies within OPPS (*i.e.*, pass-through *vs.* nonpass-through *vs.* competitive acquisition program drugs and biologicals) works against CMS' stated goal of streamlined payment mechanisms.

CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES ["OPPS Drug Administration"]

This payment reimburses hospital outpatient departments for the additional resources that are associated with locating and acquiring adequate IVIG products and preparing for an infusion of IVIG, monitoring and managing inventory, and rescheduling infusions due to product availability and patient needs and physician determinations on product selection. This preadministration payment is still relevant as hospital outpatient departments will continue to incur the same costs in 2007 that they are incurring in 2006 to ensure that they can provide the proper IVIG product to Medicare beneficiaries.

SEPARATE HCPCS CODES FOR IVIG PRODUCTS ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

IVIG is somewhat uniquely situated in that it is one of the few products for which there are multiple brand name products, but no generic products, with its HCPCS codes. In this fairly unique circumstance the ASP methodology does not generate representative payment rates for each of the different IVIG products within each HCPCS code. Therefore, CMS should establish unique HCPCS codes for each brand name product so that the ASP rate for each product is based on its own ASP information, as is the case for other biologicals.

PAYMENT ADJUSTMENT FOR IVIG ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

Octapharma USA believes that reimbursement for IVIG is insufficient to ensure continued access to all IVIG products in the hospital outpatient setting. Even considering the payment for preadministration-related services, which may be discontinued in 2007, hospital outpatient departments may not be able to recoup their investments for all IVIG products. We therefore recommend that CMS include a separate payment adjustment to reimburse outpatient departments for their true acquisition costs.

PAYMENT FOR EXTENDED INFUSIONS ["OPPS Drug Administration"]

In the Proposed Rule, CMS proposed to make separate payments for each additional hour of an intravenous infusion beyond the first hour. Octapharma USA appreciates the agency's recognition of these costs and recommends that this proposal be included in the final rule.

Octapharma USA appreciates the opportunity to comment on the Proposed Rule. We urge CMS to reconsider the proposed payment rate of ASP plus 5% for IVIG since we believe that this will have a serious deleterious effect on access to appropriate therapy for patients receiving their infusions in the hospital outpatient setting. Please contact me at 703 766 4875 if you have any questions regarding our comments.

Sincerely,

Flemming Nielsen
General Manager,
Octapharma USA

COMPASS
BEHAVIORAL CENTER

1526 North Ave. I • Crowley, LA 70526 • Phone: 337-788-3380 • Fax: 337-788-3381

223-O
(2)

October 6, 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

Our hospital Crowley Psychiatric Hospital d/b/a Compass Behavioral Center of Crowley is a freestanding Psychiatric Inpatient facility in Crowley, LA. We serve approximately 960 patients on an annual basis. We provide intensive psychiatric program services that are greatly needed by the severe and persistently mentally ill and the elderly in our community.

We are requesting that CMS cease from going forward with the proposed CY 2007 15% rate cut for Partial Hospitalization (PHP) and psychiatric Outpatient Services. Coupled with last year's 12.5% reduction for PHP, the proposed rate will make it impossible to cover the costs needed to provide an intensive program.

We strongly support the position of the Association of Ambulatory Behavioral Healthcare regarding their proposed considerations, as the response from the organization goes into specific detail concerning the long reaching effects the rate cut will have on the patients who are in need of outpatient psychiatric services.

These less expensive outpatient programs need to be supported by reasonable reimbursement rates that adequately cover the costs of providing the services.

We are asking CMS to 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,

Mark J. Cullen, CEO

ST JOHN HEALTH SM

2241

28000 Dequindre
Warren MI 48092

October 6, 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

Providence Hospital and Medical Center provides psychiatric services in Southfield, Michigan.

We are a long-standing provider of Partial Hospitalization services. The initial shock of CMS-1506-P and another 15% rate reduction for CY2007 was an overwhelming blow. The very existence of this service will be threatened for the future if our facility must absorb this extreme revenue reduction again. It is very difficult to convince providers to continue programs year after year on a break-even basis at best.

A $37.64/day reduction in the daily rate will be impossible to absorb. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited in the services they can provide.

We are a member of the Association of Ambulatory Behavioral Healthcare. Our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1506-P pp. 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 CY2003 through CY2006. Only the methodology from CY2006 and CY2007 are the same and there is no

calculation of a methodology. It is nothing more than an arbitrary decision by CMS.

2. We quote CMS on p. 105 to say, "To calculate the CY2007 APC PHP per diem cost, we reduced $245.65 (the CY2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 15 percent, which resulted in a combined median per diem cost of $208.80."

3. CMS-1506-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00 in the last paragraph of p. 105. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas over the past two years. A daily per diem of $208.27 cannot be justified with these expenses.

4. CMS identified the Median cost of group therapy at $66.40. Our program offers 4 group services per day at a minimum. This summarizes to a median cost of $265.60. A per diem of $208.27 cannot be justified with these expenses.

5. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in your state. If the 20% co-pay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $166.62 ($208.27 x .80). A daily per diem of $208.27 cannot be justified with this situation.

6. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally tow years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

That being said:

7. Patients already have too few options for psychiatric care. Outpatient care is their best option. Outpatient services are a much less expensive alternative to hospital inpatient care or emergency departments. Rather than spending Medicare dollars on Outpatient services, Medicare will, most assuredly, spend more dollars on patients who use inpatient hospital units or emergency centers because patients who need psychiatric care will go where ever they have to go to get care. Why would CMS **not** support the less costly outpatient option? It is a fiscally responsible decision.

Based on the above issues, Providence Hospital and Medical Center asks that CMS:

- **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.

- **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.

- **Allow energy, 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 your consideration of our comments. We look forward to your response. We are hopeful that we will be able to continue to treat the mentally ill and elderly in the most economically responsible way and at the lowest level of care possible.

Sincerely,

Michael Breen
V.P. Behavioral Health Services
St. John Health

225-0
(2)

Hillcrest Hospital
CLEVELAND CLINIC HEALTH SYSTEM

RADIATION ONCOLOGY
6780 Mayfield Rd
Mayfield Hts, OH 44124
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FAX: 440-312-5300

October 3, 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 this opportunity to offer comment on the proposed changes to the 2007 Payment rates and to specifically comment on the impact these proposed rates will have on breast conservation therapy in patients with breast cancer.

There are two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and then the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

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

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. This is an important option for women electing breast conservation surgery followed by radiation therapy. Traditional whole breast radiation is a 5 day a week treatment, for 6-7 weeks. Breast brachytherapy offers the option of treating the lumpectomy cavity in a much shorter 5 days (twice daily) of treatment.

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

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

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Henry Blair, MD
Medical Director Radiation Oncology
6780 Mayfield Road
Mayfield Heights, OH 44124
440-312-4700

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology
Harvey Neiman, MD, Chair, American College of Radiology (c/o: Mary Jane Donahue)

October 4, 2006

226-0
(5)

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:

As a patient who suffers from uterine fibroids, I am writing to you in response to what I have learned about the proposed changes for the 2007 CMS Hospital Outpatient Prospective Payment System. Uterine fibroids are a very pervasive disease with 25% of women between the ages of 25 and 50 suffer from symptomatic uterine fibroids. Symptoms include excessive and prolonged bleeding, debilitating pelvic pain, lower back and leg pain, enlarged uterus, anemia, and, often, infertility.

Statistics show that each year, between 170,000 and 300,000 hysterectomies are performed annually for the treatment of uterine fibroids. Hysterectomy is an invasive surgery and there several risks associated the procedure. Approximately 660 women die each year in the United States from complications of hysterectomy. In addition, the procedure is associated with a lengthy recovery period that can last up to six weeks resulting in lost work hours. Many women are forced to take hormone replacement therapy, resulting in an additional cost to the patient and the health care system.

As a sufferer of this disease, I have done much research on the treatment options available to me. The MRgFUS is a novel technology that provides a non-invasive treatment alternative to patients like me. The MRgFUS procedure non-invasively ablates tumors by using focused ultrasound waves to penetrate soft tissue. Because it is a non-invasive procedure, patients are able to avoid the risks associated with surgery, require only limited sedation, and can return to normal activities the next day. In addition, because the uterus is left intact, there is no need for hormone replacement therapy.

I understand that the new proposed rules for hospitals will not permit physicians and hospitals to offer this technology to patients like me. I have been informed by my physician that the cost of the procedure is much greater than what the proposed amount will allow. As a result, most hospitals and physicians are unable provide this treatment alternative to patients like myself. I am asking CMS to reconsider their proposed payment rate for MRgFUS so that it is more closely aligned with the costs associated with this procedure. This will enable all women suffering from uterine fibroids to have this treatment choice available to them.

I thank you in advance for your careful consideration of this matter.

Respectfully,

Terri Julius

226-1

October 4, 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

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I thank you in advance for your careful consideration of this matter.

Respectfully,
Susan A. Seay

1586 Thompson Rd
Cottonwood, Az 86326
(928) 634-3221

227

ISOTRON

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:

Isotron Inc. 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.

Isotron, founded in 1998, is a start-up medical technology company focused on radiation oncology.

Isotron thanks CMS for the opportunity to submit these comments related to brachytherapy sources outlined in the federal register proposed rules.

Payment Methodology for Brachytherapy Sources

We believe that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for brachytherapy sources based upon median costs. The variations in cost of each source can be huge and require a unique payment methodology for radioactive sources. One source may have a cost variation of over 10 times based upon the intensity and age of the source.

The CMS claims data shows large variations in per unit cost reported (see table below) on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007.

HCPCS and Description	Variation of Cost per Unit (2005 Hospital Claims)
C1716 Gold-198	$3 - 943
C1717 HDR Iridium-192	$0 – 4,746
C1718 Iodine-125	$0 - 14,632
C1719 Non-HDR Iridium-192	$3 – 1,761
C1720 Palladium-103	$0 - 20,825
C2616 Yttrium-90	$1,676 - 62,071
C2632 Iodine-125 solution	$0 – 7,253
C2633 Cesium-131	$28 - 15,797
C2634 High Activity Iodine-125	$2 – 4,526
C2635 High Activity Pd-103	$3 – 5,212
C2636 Linear Palladium-103	$0 -1,690

The recommended payment methodology will not appropriately capture the variation of brachytherapy source configurations and related cost. We urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device.

Isotron 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.

Payment for NEW Brachytherapy Sources

In the proposed rule, CMS solicited comments regarding establishing payment amounts for new brachytherapy sources eligible for separate payment when no hospital claims-based cost data is available. The only effective way for CMS to capture cost data regarding new brachytherapy sources is for CMS to establish payment to hospitals for new brachytherapy sources at hospital charges reduced to cost when no hospital claims-based cost data is available.

Isotron recommends that CMS implement a three year payment policy for new brachytherapy sources at hospital's charges adjusted to cost.

Summary of Recommendations

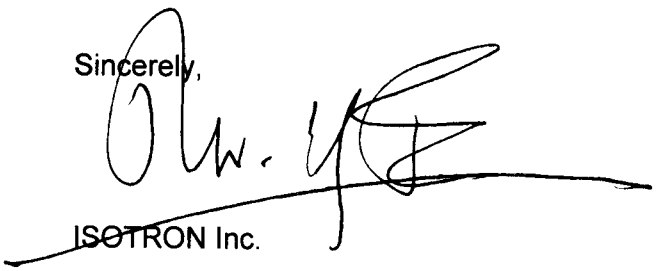
Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

In summary, Isotron recommends that CMS:

- **continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices**
- **implement a three year payment policy for NEW brachytherapy sources at hospital's charges adjusted to cost**

Thank you for your consideration of these important issues.

Sincerely,



ISOTRON Inc.

Robert W. Ebling, III
President & CEO
ISOTRON INC.
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Boston, MA 02108

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Email: rebling@vermontel.net

FLORIDA HOSPITAL ASSOCIATION

An Association of Hospitals & Health Systems

228

October 3, 2006

Leslie Norwalk, Interim Administrator
Centers for Medicare & Medicaid 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 CY2007 Payment Rates (71 *Federal Register* 49505), August 23, 2006

Dear Ms. Norwalk:

The Florida Hospital Association, on behalf of its member hospitals and health systems, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed Medicare outpatient prospective payment system (OPPS) rule for calendar year 2007, as published in the *Federal Register* dated August 23, 2006. Since its implementation, the outpatient prospective payment system has presented significant implementation challenges to hospitals, to CMS, and to the intermediaries. We have been faced with repeated clarification and revision of policy, a trend that would continue under the proposed rule for 2007.

In addition to the lack of a payment system that is consistent from year to year and devoid of significant changes, there are several areas of concern with the provisions included in the proposed rule for calendar year 2007. These concerns and comments are detailed below –

Proposed OPPS Payment Changes for Devices

Device Dependent APCs

In the proposed rule, CMS includes a reduction in the Ambulatory Payment Classification (APC) payment and beneficiary copayment for selected APCs in which an implanted device is replaced "without cost" to the hospital or with "full credit" for the removed device. While the FHA supports this position, we do not believe that the response should be to adjust the APC payment rate by the entire cost of the replaced device. Such an action does not take into consideration the administrative handling costs associated with a replacement device – or the fact that these costs will increase as we will now be required to use specific modifiers to designate these items, increasing costs related to coding and claims submission. We urge CMS to reevaluate the proposed percentage offsets related to these devices to allow for administrative resources and associated handling costs required in the provision of these replacement devices.

Proposed Hospital Coding and Payment for Visits

Hospital Coding for Evaluation and Management Services

The FHA encourages CMS to move ahead in issuing a proposed national, uniform evaluation and management (E&M) coding system for hospitals. It will take providers a minimum of 6 months after release of a final rule on E&M facility coding to train their staff and modify internal systems before we could move to a standard.

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With this said, however, we do not support the move to the proposed G-codes for hospital E&M services at this time. We are still required to bill the CPT codes to other payers and this would just add to the administrative burden on hospitals. CMS should work with the AHA/AHIMA Expert Panel to develop clear and concise definitions for the various levels for both hospital emergency department services and clinics and then work with the American Medical Association's CPT Editorial Panel on the development of hospital-specific CPT codes with standard definitions – applicable for all hospitals and all payers.

CMS has proposed separate E&M codes for Type A and Type B emergency departments. The FHA believes that the codes should be assigned on the basis of the services provided to the patient, not on the license of the facility. If there is a need to distinguish between these facilities, it should be done through the provider profile. We do not support a separate payment level for EDs that are not open 24/7 –these departments are placed to better serve the community and are acting as departments of already overcrowded facilities. From a cost report perspective, the costs associated with these offsite EDs are included with other ED costs and are not separately identified. To stratify payment levels merely because a facility is not open 24/7 does not address the costs associated with the patients actually treated in the department.

In addition, the FHA opposes the proposed restructuring of critical care coding on the basis of time. Time is not a relevant factor in determining *facility* resource use and is an element that could easily be subject to gaming for increased reimbursement.

Reporting Quality Data for Improved Quality and Costs under the OPPS

Hospital Quality Data

CMS has proposed linking failure to report and validate the inpatient quality measures to the outpatient payment update. We do not support this linkage under the concept of "equitable payment authority." We support the adoption of outpatient quality measures and their linkage to the outpatient update, but do not believe that the proposed linkage is appropriate. Before linking any set of measures to the payment for outpatient care, however, there needs to be clear evidence that the measures used have an impact on the quality and outcomes of patients treated in hospital outpatient settings. Until such indicators are developed, CMS should eliminate any link between reporting inpatient quality measures and outpatient hospital payment rates.

Proposed Updates Affecting OPPS Payments for CY2007

Payment for Outliers

The proposed rule would increase the dollar threshold for receiving outlier payments to $1,875 - $625 more than the current threshold. We are concerned that the proposed threshold is too high and urge CMS to report, on an ongoing basis, outlier payments as a percent of total expenditures.

Proposed OPPS Payment Status and Comment Indicators

Proposed Changes to Packaged Services

While CMS has addressed some packaged services and identified instances in which they will be eligible for separate payment, we would urge inclusion of 36500, Insertion of catheter, vein, in the list of codes that, although usually packaged, would be separately payable when there are no other separately payable services on the claim. It is our understanding that many times this is the

only procedure that the patient is having. We are pleased to see that CMS has proposed to include 75893, Venous sampling through catheter, as a "special" packaged CPT code.

Again, the Florida Hospital Association appreciates the opportunity to provide these comments on the proposed rule for outpatient prospective payments for calendar year 2007. If there are any questions on these comments, please do not hesitate to contact me at (407) 841-6230.

Sincerely,

Kathy Reep

Kathy Reep
Vice President/Financial Services