The Charlotte Hungerford Hospital
Comments on proposed changes to the " Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates" published on August 23, 2006 At 71 *Fed Reg* 49506 *et seq.* CHH is a 109 bed hospital located in Torrington, Connecticut, serving the population of the Northwest corner of Connecticut.

In October 1996 Winsted Hospital, a full service hospital closed due to bankruptcy. CHH worked with the community to reopen medical care services at the site of the old hospital. The provision of less than 24 hour Emergency Department services was approved on July 15, 1997 (Docket # 97-513) by the State of Connecticut's Office of Health Care Access through a Certificate of Need process. These Emergency Department services were clearly defined as a satellite of CHH's 24 hour on-site Emergency Department. The appropriate resources including staffing, equipment, and physician credentialing were delineated out to provide for Emergency Department level of care; as stated in the final decision " the Emergency Department at the Winsted Health Center would be staffed and equipped to provide stabilization of life-threatening emergencies." On April 13, 1998 the services were licensed by the Department of Public Health as a satellite of CHH. Both facilities operate under the CHH Emergency Department Policies and Procedures. Our facility accepts ambulances from all area towns, and is equipped with a heliopad allowing transfer of patients directly to tertiary care/trauma hospitals. Local EMS services are supported through our facility as the paramedic intercept program is housed on-site at our facility providing area towns with service and case review is done monthly with local EMS staff. The Emergency Department of Hungerford Emergency and Medical Care at the Winsted Health Center meets all the provider-based requirements under 42 CFR 413.65, our emergency department services are an integrated part of CHH's 24 hour Emergency Department.

CHH also owns and operates the NW CT Medical Walk In; an urgent care facility. That facility operates without appointments, and is held out to the public as a facility that handles urgent, non-life threatening injuries and illnesses. This facility is clearly what CMS is defining as a clinic operation. It does not have a code cart or other required equipment to deal with life-threatening emergencies, does not accept ambulances, or have transfer by helicopter capabilities. Staffing at that facility is predominantly by radiology technicians trained in medical assisting, not registered nurses. The physicians are Board Certified in Internal, Family Practice, or Emergency Medicine; and are credentialed within the Ambulatory Services department of the Medical Staff.

We reiterate the arguments YNHH has submitted, they clearly articulate the issues needing to be addressed in developing the OPPS final rule for 2007.

The CPT coding and reimbursement of office visits was built to reflect the costs of the services of physician offices and clinics as the NW CT Medical Walk In. To propose that these clinic rates should sustain operation of emergency level services until CY 2009, is unrealistic. As stated by Yale, Hungerford Emergency and Medical care Emergency Department salary and non-salary costs (excluding physician salaries) are at least 425% higher than the national median cost of clinics and of our NW CT Medical Walk In.

Especially if other payors are affected, the financial burden to CHH to retain this level of service until Type B rates are developed would be very detrimental.

The state of Connecticut is undergoing special hearings on the overcrowding of Emergency Departments. I can not believe it is your intent to put an increased financial burden on hospitals trying to meet the needs of their populations or consider not providing these services in an already congested environment. The Hartford Courant published in the beginning of July the increased visits sustained in the State's hospital emergency departments; CHH was at the top of the list with a 36% increase in visits in the last 2 years. In this time of homeland security issues, pandemic, etc fears it seems unlikely that CMS intent was to decrease the access to Emergency Department services. And although these scenarios may seem unlikely in the sleepy Northwest corner of Connecticut, we are within two hours of both New York City and Boston.

Please reconsider your proposed ruling on mapping the Type B rates to the clinic reimbursement.

Charlotte Hungerford Hospital also fully endorsed the comments submitted by Gregg Grinspan, MD.

Sincerely,

Dawn Connelly

Dawn Connelly
Director
Charlotte Hungerford Hospital
540 Litchfield St
Torrington, CT 06790

:nts Languish In Overloaded Emergency Rooms, A Connecticut Task Force Begins The Hunt For A Cure

Attention

ergency room visits in the state from 2001 to 2004.

	% Change '01-'04	HOSPITAL	LOCATION	% Change '01-'04
l	+36	Middlesex Memorial	Middletown	+7
	+21	New Milford Hospital	New Milford	+7
	+21	Milford Hospital	Milford	+5
n	+19	Day Kimball Hospital	Putnam	+3
	+17	St. Mary's	Waterbury	+3
er	+17	Bradley Memorial	Southington	+2
	+15	Lawrence & Memorial	New London	+2
	+12	St. Raphael	New Haven	+2
	+11	MidState Medical	Meriden	+1
n	+11	Bristol Hospital	Bristol	Unchanged
n	+11	Griffin Hospital	Derby	Unchanged
	+10	Essent-Sharon	Sharon	-2
	+9	St. Francis	Hartford	-5
	+9	Windham Hospital	Windham	-5
	+8	Stamford Hospital	Stamford	-7

Care Access

THE HARTFORD COURANT

TRAUMA IN THE ER

BY HILARY WALDMAN ■ COURANT STAFF WRITER

The death of a woman from a heart attack after two hours waiting to be seen in an Illinois emergency room last week didn't surprise emergency physicians in Connecticut.

Similar scenarios are common across the state — and only luck has prevented a tragedy here so far, they said.

"That is what we are experiencing every day," said Michael Carius, chairman of the department of emergency medicine at Norwalk Hospital.

While Carius said he did not know of any deaths directly related to long emergency room waits, he said he has witnessed too many close calls.

Gridlock has made long waits in emergency rooms common. Doctors blame a confluence of factors, from jammed hospital inpatient units to nurse and doctor shortages to a population that is living longer but requires more medical attention.

Tuesday, Carius joined a group of physicians, nurses, hospital administrators and state officials in Hartford for the first meeting of a task force seeking solutions.

Nationally, emergency room visits increased by 26 percent between 1993 and 2003, according to a June report by the National Institute of Medicine. In Connecticut, many hospitals experienced double-digit percentage increases in ER visits — up to 36 percent — between 2001 and 2004.

"There is a crisis that has been here so long that we don't

PLEASE SEE **HOSPITAL**, PAGE A10

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RELIGIOUS LEADERS REJECT 'OUTRAGEOUS PROPOSAL' ON INTERROGATIONS

FROM PAG

Hospital Waits Getting Longer

CONTINUED FROM PAGE A1

even recognize it as a crisis anymore," said Dr. Phil Brewer, an emergency physician who is also a candidate for the state's 103rd House District. Brewer cited an Australian study suggesting that emergency room patients in overcrowded hospitals are at greater risk of dying than those in less crowded settings.

Emergency room doctors say there are a few simple ways to break the logjam, at least temporarily, including moving patients who need to be admitted into the hallways of medical units while they wait for beds there.

But hospital administrators say emergency room crowding is just a symptom of a far more complex crisis in the nation's health care and social service systems. Kevin Kinsella, vice president of Hartford Hospital, said some of the biggest contributors to the emergency room overload include:

■ Decisions by younger, middle-class people to forgo health insurance, making the emergency room a provider of last resort if they get sick.

■ The unwillingness of many private physicians to accept Medicaid, leaving emergency rooms as a primary care provider for the state's neediest residents.

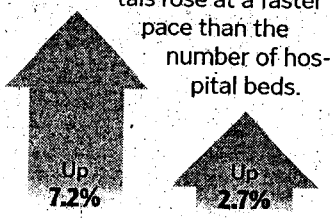
■ A shortage of treatment programs for people with psychiatric and substance abuse problems, leading to breakdowns that require emergency care.

■ Growing populations of homeless people, illegal immigrants and released inmates who cannot get care anywhere but in emergency rooms.

While these factors have in-

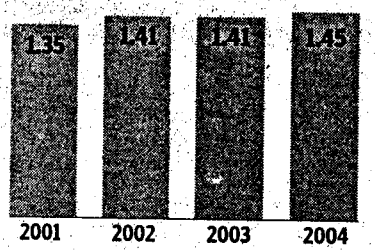
Backed Up In The ER

From 2001-2004, emergency room visits to Connecticut hospitals rose at a faster pace than the number of hospital beds.



Rising ER Visits In State

Visits to hospital emergency rooms in Connecticut in millions.



NOTE: Figures are for hospitals' fiscal years

Admissions From ERs

A growing percentage of Connecticut hospital admissions coming from emergency rooms has exacerbated ER crowding.

2001: **44%** 2004: **50%**

SOURCE: Connecticut Office Of Health Care Access

THE HARTFORD COURANT

to find a neurosurgeon," Brewer said, listing a few of the medical specialties in short supply. "While I am making phone calls looking for a specialist, it slows everything down."

Brewer and his colleagues would like to see patients who must be admitted moved to a hospital inpatient unit, even if no bed is immediately available. They contend that patients would be treated better in the hallway of an appropriate unit than if they languish in the emergency room.

But so far, federal regulators and Connecticut hospital administrators have been lukewarm about the idea.

While putting patients in hallways is not ideal, it would be an improvement over the present situation, said Dr. Gregory L. Shangold, an emergency room doctor at Windham Hospital in

Convic

CONTINUED FROM PAGE A1

fused to discuss details of the shootings, saying his devotion to Christianity forbids him from reliving and "glorifying" the events of his past.

Campbell's refusal led to a heated and often bizarre exchange with prosecutor Vicki Melchiorre, who insisted that Campbell could not truly be a changed man — or remorseful about what he did — until he owned up to the specifics of his actions that night.

Melchiorre asked Campbell if he remembered going to the home on Sargeant Street, encountering his longtime girlfriend, 20-year-old La-Taysha Logan, the mother of Campbell's son, and then, after a brief discussion, pulling out a gun and shooting Logan, who had obtained a protective order against him the day before.

"You pulled out a gun and put it to La-Taysha's head and shot her, didn't you?" Mechiorre asked.

"My past sins are forgiven, ma'am," Campbell answered.

After shooting Logan, Campbell then shot and killed her friend, 18-year-old Desiree Privette, and shot Privette's aunt, Carolyn Privette, who eventually recovered.

The two had been sitting on a stoop nearby.

for the state's neediest residents.

■ A shortage of treatment programs for people with psychiatric and substance abuse problems, leading to breakdowns that require emergency care.

■ Growing populations of homeless people, illegal immigrants and released inmates who cannot get care anywhere but in emergency rooms.

While these factors have increased the pressure on emergency rooms, hospitals also have eliminated inpatient beds, sometimes to save money and sometimes because there are not enough nurses to staff them.

So even if a patient makes it from the waiting room outside the emergency room to an examining cubicle inside, the wait may yet be far from over if he or she needs to be admitted to the hospital. Patients can tie up emergency room space for hours while doctors wait for a room upstairs. If the patient needs a specialist, the backup can get even longer.

"Try to find a hand surgeon, try to find better in the hallway of an appropriate unit than if they languish in the emergency room.

But so far, federal regulators and Connecticut hospital administrators have been lukewarm about the idea.

While putting patients in hallways is not ideal, it would be an improvement over the present situation, said Dr. Gregory L. Shangold, an emergency room doctor at Windham Hospital in Willimantic. The way things are now, he said, Connecticut emergency rooms are ill equipped to handle even small emergencies, not to mention national disasters.

"You talk about Katrina or a flu pandemic," Shangold said. "What about a bus crash down the street with 10 patients? We can't even care for them."

The task force, which is scheduled to meet again in October, is hoping to make recommendations to either the General Assembly or hospital regulators.

Contact Hilary Waldman at hwaldman@courant.com

Mexican President Willing To Extradite Drug Chiefs

Associated Press

NEW YORK — President Vicente Fox said Tuesday that Mexico is willing to extradite any drug lord in its custody wanted by the United States.

Fox said Mexico has 16 "big leaders" of drug gangs in jail along with 75,000 lower level members of various cartels.

"We are fighting hard and attaining very important results," Fox said of Mexico's fight against drug dealers. He was speaking at a news conference in New York where he was attending the United Nations General Assembly.

The U.S. is believed to have requested the extradition of at least three suspected drug kingpins: Benjamin Arellano Felix of the Arellano Felix smuggling syndicate; Osiel Cardenas, reputed head of the Gulf Cartel; and Hector "El Guero" Palma, a reputed leader of the Sinaloa drug cartel.

"We will extradite all of those who have pending matters with U.S. justice," Fox said.

It was the first time Mexico's president had made such a commitment to send wanted drug lords to face charges in the U.S.

MGI PHARMA

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October 9, 2006

Terence Green
Vice President, Assistant General Counsel
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Via Overnight Mail

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P): Payments for Drugs

Dear Dr. McClellan:

MGI PHARMA appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year (CY) 2007 Payment Rates (the "Proposed Rule"), 71 Fed. Reg. 49,506 (August 23, 2006). MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi® (palonosetron hydrochloride) injection is one of MGI's products that is made available in the hospital outpatient setting.

MGI PHARMA seeks to ensure that Medicare reimbursement for oncology drugs and other innovative pharmaceutical products is adequate to support Medicare beneficiary access to these therapies in the hospital outpatient setting. Our comments therefore focus on the Proposed Rule's provisions addressing reimbursement for drugs and biologicals.

OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

CMS is proposing to reduce Medicare payments for nonpass-through drugs in the hospital setting to average sales price ("ASP") plus five percent. We are concerned that this proposed reduction in reimbursement will not adequately compensate hospitals for their drug acquisition and pharmacy handling costs, and could threaten patient access to needed drugs. Moreover, we believe it is inappropriate to reimburse hospitals at a lower rate than physicians' offices for the same drug products, particularly since CMS has expressed concerns in the past regarding site-of-service payment differentials. We therefore urge CMS to reimburse nonpass-through drugs at least at ASP plus six percent.

Pass-Through Drugs

With regard to pass-through drugs, Congress instituted pass-through pricing to appropriately recognize and cover the "additional costs of innovative medical devices, drugs, and biologicals." See Section 1833(t)(6)(D)(i) of the Social Security Act. We commend CMS for recognizing under the Proposed Rule that drugs that meet the criteria for HOPPS pass-through status warrant a distinct reimbursement policy that compensates hospitals for the higher costs associated with pass-through drugs compared to non-pass-through products. In the final rule, we urge CMS to ensure that its reimbursement policy achieves the intent of pass-through status. CMS therefore should recognizes the unique costs for pass-through drugs by adopting a reimbursement level for pass-through drugs that is higher than a reimbursement level of ASP plus six percent for non-pass-through drugs.

Packaging Threshold

In the Proposed Rule, CMS proposes to increase the current $50 threshold required for separate payment of outpatient drugs, biologicals, and radiopharmaceuticals under the HOPPS. Specifically, beginning with CY 2007, CMS would adjust the packaging threshold by the Producer Price Index ("PPI") for prescription drugs, rounded to the nearest $5 increment. CMS estimates that using this methodology, the threshold for 2007 would be $55.

We agree with the APC Panel that the threshold should be maintained at $50 to preserve separate payment for relatively-expensive drugs and biologicals. Continuing the $50 threshold would help ensure adequate compensation for hospitals furnishing drugs and biologicals, preserve stability in payment policy, and safeguard Medicare beneficiary access to medically-necessary drugs and biologicals. CMS itself observes in the Proposed Rule preamble that maintaining the $50 threshold is "a reasonable policy option that would provide stability to the payment system." MGI PHARMA therefore urges CMS to maintain the $50 packaging threshold for CY 2007 and not adopt the proposal to increase the threshold.

* * * * *

MGI appreciates this opportunity to present these comments to CMS. Please do not hesitate to contact us if you have any questions.

Sincerely,

Terence Green

Vice President, Assistant General Counsel

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Ohio Ambulatory Behavioral Healthcare Association
C/0 Cincinnati V.A. Medical Center, ML.116A6
3200 Vine Street
Cincinnati, Ohio 45220

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

The Ohio Ambulatory Behavioral Healthcare Association represents Partial Hospitalization Programs and Outpatient Services that are both Hospital and Community based throughout Ohio.

We are a long-standing supporter of Partial Hospitalization services (since 1985). 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 membership has to absorb this extreme revenue reduction again. It is very difficult to convince provides 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.

OABHA considers itself the state partner of the Association of Ambulatory Behavioral Healthcare, (AABH). Our organization and it membership 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% copay 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 -

8. 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, The Ohio Ambulatory Behavioral Healthcare Association 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,

Ric McAllister, ACSW
Vice President and Chair, Public Policy Committee

Riverain MEDICAL

Early. Detection. Now.

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October 9, 2006

Mark McClellan, MD, PhD
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: File Code CMS-1506-P; Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates - Proposed Rule

Dear Administrator McClellan:

Riverain Medical appreciates the opportunity to submit these comments regarding the Outpatient Prospective Payment System (OPPS) Proposed Rule for Calendar Year (CY) 2007. Riverain Medical is a healthcare company that offers the only chest radiography (CXR) computer-aided detection (CAD) software for early lung cancer detection approved by the Food and Drug Administration (FDA). Riverain Medical is committed to being a leader and innovator in CAD and diagnostic technologies that significantly aid medical practitioners in the early-stage detection of diseases.

Riverain Medical wishes to comment on the payment of CXR CAD under the proposed OPPS Rule for CY 2007. Under the proposed rule CXR CAD, described by Category III Current Procedural Terminology (CPT) code 0152T, Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; chest radiograph(s), will not receive a separate APC payment in proposed rule for CY 2007 because of CMS' decision to assign it a status indicator of "N." CMS also decided to bundle payment for CXR CAD into payment for APC 0260, Level I Plain Film Except Teeth.

We wish to point out that 0152T will be deleted as of January 1, 2007 and replaced by CPT Codes 0174T and 0175T. These comments apply to Codes 0174 and 0175T. For your convenience, the codes are likely to be:

> +0174T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation, and
> 0175T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation

Riverain Medical disagrees with CMS' decision to assign our technology a status indicator of "N" and bundle it into payment for APC 0260 for CY 2006.

While we understand that the Advisory Panel on Ambulatory Payment Classification Groups recommended that CMS assign status indicators of "N" to 0174T and 0175T for CY 2007, we respectfully disagree with their recommendation and ask that CMS assign status indicators of "S" and place them in New Technology APC 1492 with a payment rate of $15, for the following reasons:

1. CXR CAD is a diagnostic tool, not a screening test.

There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.[1] Patients who have smaller primary lung tumors at diagnosis have better clinical outcomes than patients with large tumors at diagnosis. CXR is currently the most frequently used test to detect lung lesions that are suspicious for lung cancer. Unfortunately, CXR is a poor test for detecting cancers that are less than 14 mm in size. For example, one study found that radiologists missed 71%, 28%, and 12% of lesions $\leq$ 10 mm, 10-30 mm, and 30-40 mm, respectively. The authors estimate a 23% drop in five-year survival for those patients whose lung cancers were missed.[2] Another study indicated that survival is correlated with pathological stage (pStage) of detection where pStages IA, IB, IIA, IIB, and IIIA were associated with 67%, 57%, 55%, 39%, and 23% respectively[3]. Therefore, a diagnostic tool that can detect lung lesions when they are small in diameter and in an early pathological stage should result in earlier detection and treatment of lung cancer. Riverain's technology for CXR CAD is the only PMA approved diagnostic tool available for this purpose. Moreover, recent evidence has shown that early detection and treatment of lung cancer with chemotherapy is correlated with prolonged five-year survival rates.[4] Therefore, CXR CAD should improve clinical outcomes for these patients.

CXR CAD identifies regions of interest on CXRs that are suspicious and may represent nodules, which could represent early-stage lung cancer. It employs a multi-step image enhancement and analysis processing system that consists of a series of algorithms and classification technologies to identify regions that may contain indications of cancer and isolating them from the normal structure of the heart, blood vessels, ribs and other structures of the chest. The system includes digital image processing for noise reduction, image enhancement, anatomy segmentation, feature extraction, pattern recognition, neural network computing, and fuzzy logic.

A recent study conducted at the University of Chicago indicated that 37% of missed lung cancers could have been detected earlier if CXR CAD was used. Similarly, a recent study at the University of Maryland demonstrated that 38% of the patients with missed lung cancer could have been detected earlier if the x-rays were interpreted with CXR CAD.

One study showed that approximately 2/3 patients with early stage lung cancer present with pulmonary symptoms[5]. The authors concluded that, "...a delay of even 3-4 months might be

[1] Mery, C.M., Pappas, A.N., Burt, B.M., et al. Diameter of non-small cell lung cancer correlates with long-term survival implications for T stage. *Chest, 2005*(128), 3255-3260.
[2] Quekel L, Kessels A, Goei R, et al. Miss rate of lung cancer on the chest radiograph in clinical practice. *Chest*, 1999(115), 720-724.
[3] Mountain, C.E., Revisions in the international system for staging lung cancer. *Chest*, 1997(111), 1710-1717.
[4] Winton, T., Livingston, R., Johnson, D., et al. Vinorelbine plus cisplatin vs. observation in resected non-small-cell lung cancer. *N Engl J Med, 2005*(352), 2589-2597.
[5] Christensen ED, Harvald T, Jendresen M, et al. :The impact of delayed diagnosis of lung cancer on the stage at the time of operation *European Journal of Cardio-thoracic Surgery* 12 (1997), 880-884.

[illegible] Cincinnati, OH 45342 • Phone [illegible]

fatal and send the patient into a stage with a poor prognosis." The American College of Chest Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer[6]. Such patients with suspicious chest x-rays could benefit from CXR CAD.

CXR CAD is not a chest x-ray and is not a screening test. CXR CAD is not a screening test; it is a diagnostic tool that identifies patients who are most likely to benefit from a Computed Tomography (CT) scan of the chest. This is important because the first step in the diagnostic work-up for patients with clinical and CXR findings suspicious for lung cancer is a CT Scan of the chest.

CXR CAD is performed separately from, and after, a CXR when there is a finding from the patient's history and physical (e.g., a smoker with bloody sputum) that indicates a high risk of lung cancer and/or the radiologist continues to be suspicious of lung cancer after interpreting the CXR. CXR CAD results in the production of new images which must be read by a radiologist in addition to the initial CXR images. Typically, the radiologist will review the CXR CAD images side-by-side with the CXR images in order to determine whether a lesion requires a chest CT scan. CXR CAD independently identifies suspicious and/or subtle nodules the radiologist may have not seen on the CXR.

Data submitted by Riverain Medical to the FDA[7] in order to obtain premarket approval shows that use of CXR CAD for select patients results in a significantly higher sensitivity for lung cancer detection. Ultimately, because CXR CAD is able to identify patients who may benefit most from chest CT, its use may result in an increase in true positives found on chest CT scans and a significant reduction in total chest CT scans performed to follow up on suspicious CXR findings.

There is no basis for believing that CAD will increase the number of CXRs performed in the outpatient or office setting because CXR CAD is not a screening tool and is not applied "automatically" to screening CXRs. It should be applied only to CXRs suspicious for lung cancer on the basis of a high prior probability of lung cancer based on a patient's history or physical examination. In other words, using CXR CAD for screening is not its proper use.

Riverain Medical understands that Medicare does not pay for screening.

2. CXR CAD should not be bundled into the APC Payment for CXR.

It is inappropriate to bundle payment for CXR CAD into the payment for CXR, APC 0260. CMS policy is to bundle the costs of two procedures when the resources used to provide those procedures cannot be distinguished. For example, the vast majority of radiology related procedures with status indicator "N" are "injection" procedures (e.g., injection of contrast into a blood vessel) where the hospital also bills for the actual x-ray as well. It is extremely difficult, if not impossible, for the hospital or CMS to distinguish between the cost of the "injection" and the cost of the x-ray itself.

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[6] Kvale, P.A. Chronic cough due to lung tumors: ACCP evidence-based clinical practice guidelines. *Chest, 129*(1), 147S-153S, January 2006 Supplement.

[7] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

[illegible] • Westerville, OH 43082 • Phone: 866.[illegible]

Bundling APC 0260 does not and is not likely to ever cover costs of CXR CAD. For those who use CXR CAD, cost is never recovered because it applies to only one procedure in the APC (CXR) and to a vast minority of those procedures. Costs will always be incompletely reflected in APC payment. A user of CXR CAD always ends up with incomplete reimbursement for expense of providing CXR CAD. In effect, those hospitals that do *not* use CXR CAD are rewarded while those that use CXR CAD are penalized. An analysis of the utilization data that CMS provided with the proposed rule indicates that the median is not likely to be impacted unless CXR CAD is used in a very high percentage of chest x-rays. For example, with a 50% utilization the median is only impacted by $2.00; $1.00 for the CXR CAD and $1.00 for utilization of the other items in APC 0260. At 75% and 95% utilization a hospital can expect to receive a total of $9 and $14, respectively. Riverain Medical does not expect that utilization of CXR CAD, if it is assigned a status indicator of "N," will ever be high enough to appropriately and adequately change the median cost of procedures in APC 0260.

Please note that $15.00, the requested payment amount, is 33.5% of $44.78, the proposed payment for APC 0260. 33.5% is a very high percentage of total payment. It is much higher than is typically associated with bundled procedures. In fact, CMS recognizes that low-cost new technologies should be paid separately because it established new technology APC's for that very purpose.

Separate resources are necessary for CXR CAD. The resources, including the staff and equipment needed to deliver CXR CAD, are completely different, and distinguishable from, those required to perform a CXR. Specifically, CXR CAD requires special software, hardware, information systems, and information technology staff whereas taking a CXR requires an x-ray machine, a radiology technician, and film (or, in the case of digital CXR, software that is entirely different from CXR CAD software).

Furthermore, CXR CAD is not only performed separately from a CXR, but is performed, not infrequently, at a different time and/or location and/or by a different radiologist from the CXR. Typically this happens when a CXR is obtained in the emergency department or a clinic on one day with the interpretation performed (by a radiologist) on another day. The interpretation would include a recommendation that CAD be applied to the images. Subsequently, after discussion with the treating physician, CAD is ordered and applied to the original CXR images on a different day. In this situation it is appropriate for the hospital to bill separately for CAD because it is an entirely different procedure performed on an entirely different day from the CXR. This example illustrates that the resources required for CXR CAD are entirely different from the resources required for CXR and thus it is inappropriate to bundle payment for CXR CAD into payment for CXR.

FDA recognized that CAD would be performed after reading the chest x-ray. The labeling for the device states, "The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph."

The American Medical Association (AMA) recognizes that CXR can be read remote from the chest x-ray.

Below are several examples of radiologic procedures that are similar to CAD yet paid separately:

- **Three-dimensional post-image processing** - CMS, in the OPPS final rule for CY 2006, announced it would make separate payment for CPT codes 76376 and 76377, "3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image post-processing on an independent workstation" (76376), and "requiring image post-processing on an independent workstation" (76377). These codes are used to report the use of image post-processing technologies similar to CXR CAD and, just like CXR CAD, the resources (e.g., the software, hardware, and staff time needed to apply computer algorithms to radiologic images) used to generate these new images are entirely different, and distinguishable from, the resources used to generate the original images (e.g., the CT scan). These technologies, like CXR CAD, generate new images that must be interpreted in addition to (i.e., side-by-side with) the original radiologic (or MRI) images.

- **Mammography CAD** - Mammography CAD, CPT code 76082, Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography, is paid separately under OPPS. Because separate payment, at the same rate as under the Medicare Physician Fee Schedule (MPFS), is required by statute, the same policy should be applied to CXR CAD as it is virtually the same technology with virtually the same clinical benefits.

- **Radiology "guidance" procedures** - CMS makes separate payment for radiology "guidance" procedures. These are procedures where radiology equipment such as a CT scanner is used at the time of a surgical procedure to help "guide" the surgeon to improve the outcome or reduce the risk of a procedure such as a tumor removal or biopsy. This policy exists because CMS recognizes that the resources used to provide "guidance" are different and distinguishable from the resources used to perform the surgical procedure.

By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries. CXR CAD represents an additional and non-reimbursable cost to the hospital above and beyond the cost of a CXR. If hospitals, especially rural and smaller community hospitals, are not paid separately for CXR CAD, they may be less likely to invest in this technology, thereby denying beneficiary access to CXR CAD. In addition, mammography CAD and three dimensional post-processing imaging are paid separately, creating an incentive for hospitals to provide those technologies but not CXR CAD. This is unfair and does not permit the marketplace to assess the true value of CXR CAD as it does for the other comparable technologies. Bundling creates an unfair playing field and does not allow the marketplace and the medical community to determine the value of CAD and make a judgment as to its relative costs and benefits. CMS should not substitute its own value judgment for that of the marketplace. More importantly, however, not having CXR CAD available may limit the quality of care afforded to patients who may have lung cancer. Please note that 2/3 of lung cancer diagnoses are 65 years old or older. Denying beneficiary access to CXR CAD is effectively delaying their chance of early detection and treatment (i.e., reducing their chance of surviving lung cancer).

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CXR CAD should be paid separately under OPPS both as a matter of policy consistency and as a matter of fairness. Separate payment for post-processing technologies is consistent with current CMS policy and bundling is a deviation from that policy. CXR CAD is a new technology with its own Category III CPT code and OPPS policy is to assign a payment amount to Category III CPT codes irrespective of their costs or clinical benefits.

3. APC Assignment for CXR CAD

A Payment of $15 should be made for CXR CAD. This technology represents a significant additional cost to the hospital above and beyond the cost of other radiology supplies and equipment. We propose that CXR CAD be placed in APC 1492, which has a payment rate of $15. A payment rate of $15 will enable hospitals to be reimbursed for the cost or purchasing and using CXR CAD. Alternatively, we propose assigning a status indicator of "Q" to 0152T (0174T and 0175T in CY 2007) with a separate payment of $15. We would like to point out that in August 2006 the Advisory Panel on Ambulatory Payment Classification Groups initially voted to recommend a "Q" status for CXR CAD.

Conclusion

CXR CAD identifies regions of interest on CXRs that are suspected nodule sites, an important indicator of early lung cancer. For CY 2006, CMS gave CXR CAD a status indicator of "N" and bundled it into payment for APC 0260. Resources used to deliver CXR CAD are completely different from those required to perform a CXR. Riverain Medical disagrees with the Advisory Panel on Ambulatory Payment Classification Groups' recommendation to again assign its technology a status indicator of "N" and bundle it into payment for APC 0260. We request, as a matter or policy, consistency, fairness, and Medicare beneficiary access, that CMS make a separate payment for CXR CAD and change the status indicator of CPT code 0152T (and 0174T and 0175T in CY 2007) to "S" and assign it to APC 1492 with a payment rate of $15.

We appreciate the opportunity to submit these comments on the Proposed Rule CMS-1506-P and would be happy to answer any questions you may have. I may be contacted at 800.990.3387 or my mobile phone at 330.284.3264.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

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October 9, 2006

VIA OVERNIGHT MAIL

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P): APC Relative Weights for Pathology Services

Dear Dr. McClellan:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year (CY) 2007 Payment Rates (the "Proposed Rule").

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries.

Our comments focus on proposed Medicare outpatient hospital payments for Ambulatory Payment Classification ("APC") 344, Level IV Pathology services. Level IV Pathology tests represent complex, resource-intensive laboratory tests. In fact, the tests within this APC generally are considered to be High Complexity tests under the Clinical Laboratory Improvement Amendments, involving specialized scientific and technical knowledge and training, special handling requirements, and independent physician interpretation. These tests are used to enable physicians to detect diseases earlier and more accurately, select the appropriate therapies, and improve the monitoring of diseases ranging from cancer to infectious diseases to genetic disorders.

CMS is proposing a 2007 HOPPS reimbursement level for APC 344 of $49. We are concerned that this reimbursement amount is far below the level of reimbursement necessary to compensate hospitals for the substantial resources associated with performing these tests. Moreover, this proposed payment level would be substantially lower than Medicare Part B payments for the same tests under the Medicare Physician Fee Schedule ("MPFS"), which would result in a significant and unwarranted site-of-service differential. For instance, the following chart compares the proposed 2007 payment level under the HOPPS rule with the 2006 payment level for the same tests under the Medicare physician fee schedule:

CPT CODE	Description	APC	Proposed 2007 Relative Weight	Proposed 2007 APC Payment Rate	2006 MPFS Rate- Facility *	2006 MPFS Rate- Non-Facility*
88307	Tissue exam by pathologist	0344	0.8107	$49.90	$205.10	$205.10
88309	Tissue exam by pathologist	0344	0.8107	$49.90	$286.23	$286.23
88325	Comprehensive review of data	0344	0.8107	$49.90	$131.73	$216.64
88356	Analysis, nerve	0344	0.8107	$49.90	$309.55	$309.55
88358	Analysis, tumor	0344	0.8107	$49.90	$84.78	$84.78
88361	Tumor, immunohistochem/comput	0344	0.8107	$49.90	$187.16	$187.16
88362	Nerve teasing preparations	0344	0.8107	$49.90	$295.47	$295.47
88365	Insitu hybridization (fish)	0344	0.8107	$49.90	$141.04	$141.04
88367	Insitu hybridization, auto	0344	0.8107	$49.90	$231.39	$231.39
88368	Insitu hybridization, manual	0344	0.8107	$49.90	$165.29	$165.29
88385	Eval molecul probes, 51-250	0344	0.8107	$49.90	$369.73	$369.73
88386	Eval molecul probes, 251-500	0344	0.8107	$49.90	$385.19	$385.19

* Calculated for Chicago region.

In order to ensure beneficiary access to these important pathology tests, we urge CMS reexamine its pricing for APC 344. We recommend that the payment for APC 344 in the final rule reflects the complexity and resource-intensive nature of the pathology texts within this category. This reimbursement level should more closely approximate payment for these services under the Medicare physician fee schedule.

* * * * *

We appreciate your consideration of our comments. Please feel free to contact me if you have any questions or if you need additional information.

Sincerely,

Virginia Tobiason

Virginia Tobiason
Senior Director,
Corporate Reimbursement

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ASTRO
American Society for Therapeutic Radiology and Oncology

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October 9, 2006

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

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

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide comments on the Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates announced in the Federal Register on August 23, 2006. Our comments focus on: (1) stereotactic radiosurgery (SRS) treatment delivery; (2) prostate brachytherapy; (3) proposed reassignment of stereoscopic x-ray guidance (CPT® code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy*) from a New Technology APC to a clinical APC; (4) proposed APC reassignment of breast brachytherapy catheter placements from New Technology APCs to clinical APCs; (5) brachytherapy sources; (6) hyperthermia therapies; (7) proposed use of single and multiple procedure claims; (8) radioimmunotherapy; (9) proton beam therapy; and (10) a proposed APC assignment for a new CPT code for placement of a device for radiation therapy guidance.

I. New Technology APCs [71 Fed. Reg. 49551]

Stereotactic Radiosurgery (SRS) Treatment Delivery Services

For CY 2007, CMS proposes to create several new SRS clinical APCs of different levels to assign the HCPCS codes describing linear accelerator-based SRS treatment (HCPCS codes G0173, G0251, G0339 and G0340) based on their clinical and hospital resource similarities and differences.

[1] *ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.*

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CMS proposes to assign HCPCS codes G0339 and G0173 to the same Level III SRS APC. The codes describing subsequent fractions of image-guided, robotic (G0340) and non-image guided, nonrobotic SRS treatments (G0251) will each be assigned to their own clinical APCs. Finally, CMS proposes to continue the assignment of HCPCS code G0243 for multi-source photon (Cobalt 60-based) SRS treatment delivery to clinical APC 0127, renamed Level IV Stereotactic Radiosurgery. A table listing the code descriptions and payments is provided below.

HCPCS Code	Short descriptor	CY 2006 APC	CY 2006 Payment Rate	Proposed CY 2007 APC	Proposed 2007 APC Median Cost
G0173	Complete course of non-image guided, non-robotic linear accelerator-based SRS treatment	1528	$5,250	67	$4,059.61
G0251	Fractionated non-image guided, non-robotic linear accelerator-based SRS treatment	1513	$1,150	65	$1,386.20
G0339	Complete course of therapy in one session or first fraction of image-guided, robotic linear accelerator-based SRS	1528	$5,250	67	$4,059.61
G0340	Second through fifth sessions of image-guided, robotic linear accelerator-based SRS treatment	1525	$3,750	66	$2,916.68
G0243	Complete course of multi-source photon SRS	0127	$7,305	0127	$7,808.00

Recommendation #1: ASTRO does not oppose these proposed APC assignments; although we are concerned by the extent of the payment reductions for some of the services. For example, CMS proposes to decrease the payment for G0173 and G0339 by 23 percent. We request that CMS re-check the cost calculations for all SRS services using the most current claims data available at the time the payment rates for the final rule are determined.

We note that new CPT® codes for the services described by the G codes for SRS and SBRT will become effective January 1, 2007. We would like to work with CMS to ensure an appropriate transition to the new CPT codes, including the assignment of the new codes to APCs with payment rates consistent with the resource costs required to provide the service for calendar year 2007. We would like to work with CMS in drafting a billing clarification directive to ensure that providers understand the new coding schema early in 2007. In addition, we strongly urge the agency to analyze the data very carefully during the 2008 rulemaking process to ensure that claims are crosswalked appropriately and allow for the maximum number of useable claims to be included in the 2008 rate setting.

II. Complex Interstitial Radiation Source Application [71 Fed. Reg. 49563]

Prostate Brachytherapy

The proposed rule includes an extensive discussion of the coding, median cost calculations and payments for APC 0651 *Complex Interstitial Radiation Source Application.* APC 0651 includes the single CPT® code 77778; *Interstitial radiation source application; complex.* The vast majority of claims for APC 0651 are for the treatment of patients with a diagnosis of prostate cancer. The surgical component of prostate brachytherapy (placement of needles or catheters into prostate) is assigned to APC 0163 *Level IV Cystourethroscopy and other Genitourinary Procedures* and reported with CPT code 55859; *Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy.* As noted by CMS, "The coding, APC assignment, median cost, and resulting payment rate for CPT code 77778 have not been stable since the inception of the OPPS."[2] Fortunately, for CY 2007, the proposed payments for APCs 0651 and 0163 as shown in the table below more appropriately reflect the costs associated with these procedures:

APC	APC Title	2006 Pay	2007 NPRM Pay	Change in Pay	% Change in Pay
0651	Complex Interstitial Radiation Source Application	$666.21	$1,025.35	$359.14	53.9%
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	$1999.35	$2160.59	$161.24	8.1%

For the proposed rule, CMS developed a median cost for APC 0651 using 1,123 single procedure claims by applying the usual OPPS methodology. This number of "single claims" represents approximately 9 percent of all the claims for CPT code 77778 and approximately 16 percent of the appropriately coded claims where CPT codes 77778 and 55589 both appear.

Recommendation #2: ASTRO appreciates the thoroughness and care with which CMS analyzed its data and developed revised payment rates for APCs 0651 and 0163. We support the CY 2007 proposed payment rates.

However, we remain concerned that CMS continues to develop payment rates based on a small percentage of available claims. In light of the acknowledged instability in payment rates over time, we are concerned that the application of the current CMS methodology for CY 2008 (and future years) could result in reduced payments and continued instability. We continue to believe that CMS should adopt a process for using multiple procedure claims to set the median cost for APC 0651 that would sum the costs on multiple procedure claims containing CPT codes 77778 and 55859 (and no other separately payable services not on the bypass list). Then, after excluding the costs of sources, the resulting aggregate median costs on the multiple procedure claims would be split according to a pre-established attribution ratio between CPT codes 77778

[2] *Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule, 71 Federal Register 163 (23 August 2006), 49563.*

and 55859. We ask that CMS remain open to the application of this methodology in future years in the event that the median costs under the CMS methodology would result in a reduction in payment below the CY 2007 level.

III. Other New Technology Services [71 Fed. Reg. 49566]

1. Proposed APC Reassignment of Stereoscopic X-ray Guidance (CPT® code 77421) to a Clinical APC for CY 2007

On January 1, 2005, CMS created new HCPCS code C9722; *Stereoscopic kV x-ray imaging with infrared tracking for localization of target volume.* This code was assigned to APC 1502 New Technology - Level II ($50 - $100) with a payment rate of $75. HCPCS code C9722 was deleted on December 31, 2005 and replaced by new CPT® code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.* CPT code 77421 remained in APC 1502 in 2006. For CY 2007, CMS proposes to reassign CPT code 77421 to clinical APC 0257 Level I Therapeutic Radiologic Procedures with a proposed payment rate of $60.14. This proposed payment rate would represent a 20 percent reduction from the 2006 payment rate.

Recommendation #3: ASTRO recommends that CMS leave CPT code 77421 in New Technology APC 1502 for CY 2007. Although there appear to be a sufficient number of "single claims" to calculate a median cost, we believe there are appropriate reasons for not reassigning the code to a clinical APC. First, although CMS cross-walked deleted HCPCS code C9722 to CPT code 77421, the terminology of the codes is not identical and the costs associated with the codes during the two time periods might not be associated with the same services. Second, we are concerned that there has been some misunderstanding about the appropriate use of this code. Until clear instructions have been issued and appropriate coding implemented, it is premature to reassign the code to a clinical APC. ASTRO is committed to working with our members and with CMS on the development of the needed guidance.

2. Proposed APC Reassignment of Breast Brachytherapy Catheter Placements to Clinical APCs for CY 2007

According to the National Institutes of Health Consensus Statement on 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."[3] Breast brachytherapy is a component of breast conservation therapy that is an alternative to traditional external beam radiation therapy. The placement of the catheters to deliver breast brachytherapy is described by the following CPT codes:

- 19296; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy;*
- 19297; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging*

[3] *Consensus statement treatment of early-stage breast cancer. National Institutes of Health Consensus Development Panel. J Natl Cancer Inst Monogr 1992; (11): 1-5.*

guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure); and

- 19298; *Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.*

In the proposed rule, CMS proposes to reassign the CPT® codes for balloon catheter placement (19296 and 19297) from New Technology APCs to clinical APCs as shown in the table below:

CPT® Code	2006 APC	2007 NPRM APC	2006 Pay	2007 Proposed Pay	Change in Pay	% Change in Pay
19296	1524 - New Tech Level XIV	030 - Level III Breast Surgery	$3,250	$2,508	-$742	-22.8%
19297	1523 - New Tech Level XXIII	029 - Level II Breast Surgery	$2,750	$1,733	-$1,017	-37.0%
19298	1524 - New Tech Level XIV	1524 - New Technology - Level XIV	$3,250	$3,250	$0	0.0%

Recommendation #4: ASTRO is concerned that the proposed assignment of CPT code 19297 to APC 029 Level II Breast Surgery will be inadequate to cover the cost of the balloon catheter, let alone the costs of the surgical procedure itself.[4] *(We will not comment on CPT code 19296 because it is not often performed by radiation oncologists; however we are extremely concerned with that reassignment as well.)*

To avoid potential access problems for women with breast cancer, we recommend that CPT code 19297 remain in New Technology APC 1523. CMS identified 36 "single claims" in the determination of the median cost. However, we note that by definition, there can never be a true "single claim" because this procedure can only be reported in conjunction with a partial mastectomy. Thus, we view the data as unreliable and recommend that CPT code 19297 remain in a New Technology APC until such time as a valid method for determining its median costs can be established.

If CMS decides to proceed with the reassignment of this procedure to a clinical APC, then we recommend consideration of APC 0648 Breast Reconstruction with Prosthesis. This APC includes breast procedures that require the implantation of expensive devices. In fact, it has been identified as a device-dependent APC. Taking into account the cost of the balloon catheter, the resource costs associated with CPT code 19297 are comparable to the other procedures in this APC.

We examined claims data and found 9 claims for CPT code 19297 on which HCPCS code C1728 Catheter, brachytherapy seed administration also appeared. One of these claims met the criteria

[4] According to the practice expense data base maintained by CMS for use in determining practice expense relative value units under the physician fee schedule, the cost of the catheter is $2550.

for "single claims" and the cost was approximately $3400. If CMS decides to assign CPT code 19297 to APC 0648, then we also recommend that CMS establish edits comparable to those for other device-dependent APCs so that claims for CPT® code 19727 from providers that failed to include HCPCS code C1728 would be returned for appropriate coding. This would improve the accuracy of the cost data in the future and should reduce year-to-year fluctuations in payments for this important service.

V. OPPS Impact [71 Fed. Reg. 49680]

Brachytherapy Sources

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established payments for devices of brachytherapy consisting of a seed or seeds (or radioactive source) based on a hospital's charges adjusted to cost. The special rules apply to the time period January 1, 2004, through December 31, 2006. For CY 2007, CMS proposes to make a prospective payment for separately identified brachytherapy sources. Payment rates would be determined using CY 2005 claims data and the standard OPPS median cost-based methodology to set a rate for each source.

The proposed rule notes that High Dose Rate (HDR) Iridium-192 (HCPCS code C1717) is a reusable source, across treatment sessions and across patients. CMS questions whether hospitals are accurately reporting the number of units provided and invites comments on alternatives to using the median cost methodology for this source. In addition, comments are specifically sought on the basis for determining median costs per treatment day on hospital claims.

The MMA required the Government Accountability Office (GAO) to conduct a study to determine appropriate payment amounts for devices of brachytherapy and to submit a report on its study to the Congress and the Secretary, including recommendations. The GAO's final report, published at the end of July 2006, was not available in time for CMS to review and discuss it in this proposed rule.

In the report, the GAO concluded that CMS could set prospective payment rates for iodine and palladium due to the general stability in their unit cost and the availability of reasonably accurate data. However, the GAO was unable to identify a methodology CMS could use to determine future payment rates for iridium because an iridium source can be implanted in multiple patients over its 3-month life span and each patient can receive multiple treatments with the source. The GAO did not examine how payment for seven other radioactive sources used in brachytherapy (gold-198, low-dose iridium, yttrium-90, cesium-131, liquid iodine-125, ytterbium-169, and linear palladium-102) could be determined because sufficient data on those sources were not available.

Recommendation #5: ASTRO supports the concept of a prospective payment system when the payment rates can be based on data that is stable over time and reasonably accurate. We believe the GAO report is sound and we support their recommendations. Specifically, we support the proposed payment rates for the following iodine and palladium HCPCS codes:

HCPCS Code	Long descriptor	Proposed 2007 APC Pay
C1718	Brachytherapy source, Iodine 125, per source	$35.42
C1720	Brachytherapy source, Palladium 103, per source	$48.90

For other sources, ASTRO recommends that CMS continue to make payments based on a hospital's charges adjusted to cost. This is especially important for High Dose Rate Iridium 192 (HCPCS code C1717), as this source presents many additional challenges in order to gather appropriate data. For example, this source emits sufficient radiation for a minimum of three (3) months; therefore, the source must be replenished at least on a quarterly basis. In order to ensure continued access to brachytherapy, particularly low volume institutions, it is important to provide adequate reimbursement for all brachytherapy sources.

VI. ASTRO Comments on APC 0314 Hyperthermia Therapies

Hyperthermia is used as an adjunct to radiation therapy or chemotherapy. It may be induced by a variety of sources (e.g., microwave, ultrasound, low energy radio-frequency conduction, or by probes). Hyperthermia treatments as listed in *Current Procedural Terminology (CPT®) 2006 Professional Edition*[5] include external (superficial and deep), interstitial, and intracavitary. There are five (5) CPT codes for hyperthermia (77600, 77605, 77610, 77615 and 77620) and they are all assigned to APC 0314 *Hyperthermia Therapies.*

In the CY 2007 proposed rule, CMS proposes a 32 percent reduction in payment for APC 0314 to $225. As shown in the table below, payments for APC 0314 have been up and down for many years and the frequency of claims is not high.

OPPS Rule	APC Payment	% Change from Previous Year	Number of Single Claims
2002 final	$199	-32.5%	3
2003 final	218	+9.5%	448
2004 final	$251	+15.1%	351
2005 final	$243	-3.2%	548
2006 final	$332	+36.6%	408
2007 proposed	$225	-32%	192

However, there are promising new therapies under development and the frequency of claims is expected to increase in the future. Unfortunately, the volatility of the APC payment rates has hampered the growth of this treatment modality.

Recommendation #6: ASTRO recommends that CMS take steps to prevent a 32 percent reduction in payment for hyperthermia treatments in 2007. We recognize that some APC cost variation from year to year is to be expected - whether increasing or decreasing. However, significant

[5] *Current Procedural Terminology (CPT®) 2006. Professional Edition. Copyright 1995-2005. American Medical Association. All Rights Reserved. 310.*

variation from year to year is inconsistent with the principles of a prospective payment system. One option for mitigating the proposed reduction of 32 percent for 2007 would be to limit the reduction in the median costs of APC 0314 to no more than 10 percent. Another option would be to calculate a median rate for the 2007 final rule based on the costs of all "single claim" hyperthermia services provided in the most recent 4-year period for which data is available, i.e., 2002-2005. We estimate this approach would result in a median cost for APC 0314 of approximately $289. While this payment rate would represent a 13 percent reduction from the 2006 payment rate, it is much less likely to limit access or discourage the development of new programs than the proposed 32 percent reduction.

VI. APC Relative Weights [71 Fed. Reg. 49514]

Proposed Use of Single and Multiple Procedure Claims

As we have commented to CMS in the past, we are in support of methodological changes to increase the number of single bills which could be used to calculate the relative weights. These changes include refinement of the policy for determining which HCPCS codes could be bypassed for purposes of creating single bills from multiple bills. In the proposed rule, CMS requests comments on the list of codes that the agency is proposing to add to the existing bypass list for creation of "pseudo" singles for CY 2007.

The current bypass list includes CPT® code 76950; *Ultrasonic guidance for placement of radiation therapy fields.* CMS proposes to add the following radiation oncology guidance CPT codes to the list for CY 2007:

- 76370; *Computed tomography guidance for placement of radiation therapy fields; and*
- 76965; *Ultrasonic guidance for interstitial radioelement application.*

Recommendation #7: ASTRO supports the proposed inclusion of CPT codes 76370 and 76965 on the bypass list. In addition, we recommend the addition of CPT code 77421; Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy. This addition will make the bypass list inclusive of all the guidance codes used in radiation oncology and will increase the number of "single claims" eligible for use in OPPS rate-setting.

VII. ASTRO Comments on Radioimmunotherapy: Zevalin and Bexxar

Radioimmunotherapy uses an antibody labeled with a radionuclide to deliver radiation to a target cell. An antibody with specificity for a tumor-associated antigen is used to deliver a lethal dose of radiation to the tumor cells. The ability of the antibody to specifically bind to a tumor-associated antigen increases the dose delivered to the tumor cells while decreasing the dose to normal tissues.

There currently are two FDA-approved radioimmunotherapies for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma, including patients with Rituximab refractory follicular non-Hodgkin's lymphoma. The brand names of these products are Zevalin and Bexxar.

For CY 2006, CMS adopted a temporary one-year policy to pay for separately payable radiopharmaceuticals (including radioimmunotherapy) at charges reduced to cost, where payment is determined using each hospital's overall cost-to-charge ratio. Hospitals were instructed to set charges for radiopharmaceuticals based on all costs associated with the acquisition, preparation, and handling in order for payments to accurately reflect all actual costs associated with making these products available to patients. CMS indicated that it anticipated different purchasing, preparation and handling practices to be reflected in charges. In this year's proposed rule, CMS considered a continuation of the 2006 policy of basing payment on billed charges reduced to costs. CMS did not propose this option, however, and instead proposes to set rates based on the median costs of the products, consistent with the determination of payment rates for other services under the current OPPS system.

The result is a significant reduction in payment for radioimmunotherapies as shown in the following table which lists the payments for Zevalin and Bexxar over the past three years. The coding for these products has changed over time. To simplify the table, only the current codes are listed. Note that for both Zevalin and Bexxar there are two codes; one for the initial diagnostic dose and one for the subsequent therapeutic dose. No payments are listed for 2006 because during this year payments can vary based on each hospital's charges and its cost-to-charge ratio.

HCPCS Code	Description	Brand Name	2004 Pay	2005 Pay[1]	2006 Pay[1]	2007 NPRM Pay	% Change 2005-2007
A9542	In111 ibritumomab, dx	Zevalin	$2,260	$2,420	Cost	$1,344	-44.4%
A9543	Y90 ibritumomab, rx	Zevalin	$19,565	$20,948	Cost	$12,130	-42.1%
A9544	I131 tositumomab, dx	Bexxar	$2,260	$2,241	Cost	$1,368	-38.9%
A9545	I131 tositumomab, rx	Bexxar	$19,565	$19,422	Cost	$11,869	-38.9%

[1] *charge reduced to cost by hospital's cost-to-charge ratio*

<u>Recommendation #8:</u> *ASTRO is concerned that the proposed payment rates will cover only about 60 percent of the cost of acquiring these products. This will create a significant barrier to beneficiary access to radioimmunotherapy, a potentially life-saving treatment for non-Hodgkin's lymphoma.*

Based on our experience, the current policy is fair because it allows hospitals to cover their costs without any financial incentives or disincentives to use the products. Therefore, ASTRO recommends that CMS extend the current CY 2006 cost-based policy for radioimmunotherapy products for one additional year. During this time, we recommend that CMS explore with the manufacturers the possibility of basing future payment rates on average sales price (ASP) data. We believe the use of ASP data has the greatest potential for establishing adequate, fair and stable payments in future years.

IX. OPPS: 2 Times Rule [71 Fed. Reg. 49549]

Exception to the 2 Times Rule - Proton Beam Therapy

Proton treatment is a precise form of radiation treatment available for certain cancers and other diseases. The precision of the treatment is beneficial to the patient because it minimizes the harm to surrounding healthy tissues and allows the patient to resume normal activities with few to no side effects. There are only a few facilities providing proton therapy at this time. In the proposed rule, CMS includes APC 0664 *Level I Proton Beam Radiation Therapy* in its list of proposed exceptions to the 2 times rule for CY 2007. Under the 2 times rule, CMS may make exceptions to the statutory 2 times limit on the variation of costs within each APC group in unusual cases such as low volume items and services.

Recommendation #9: ASTRO supports the proposed exception to the 2 times rule for APC 0664. We also support the proposed payment rates of $1,136.83 for APC 0664 Level I Proton Beam Radiation Therapy and $1,360.10 for APC 0667 Level II Proton Beam Radiation Therapy. These proposed payment rates are more reflective of the significant capital demands associated with developing and the high costs of operating a proton therapy center. ASTRO recommends that CMS make the proposed payments final for CY 2007.

X. ASTRO Comments on New CPT Code for Placement of Device for Radiation Therapy Guidance

We would like to bring to the attention of CMS a new CPT® code related to prostate radiation therapy that will be utilized by hospitals upon its effective date of January 1, 2007. The CPT code is:

> 55876; *Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial marker, dosimeter), prostate (via needle, any approach), single or multiple.*

Recommendation #10: ASTRO would like to recommend assignment of new CPT code 55786 to a New Technology APC. We reviewed the direct costs associated with this procedure, and based on those costs and comparison to other equivalent services paid under the OPPS, we recommend assignment of this new code to APC 1511: Level XI or APC 1512: Level XII.

Conclusion

ASTRO applauds the CMS staff for their continued efforts to improve the OPPS. The following is a brief summary of our comments and recommendations:

- ASTRO does not oppose the proposed APC assignments for stereotactic radiosurgery. However, we request a re-analysis of current claims data in light of the proposed payment reductions.
- ASTRO supports the CY 2007 proposed payment rates for prostate brachytherapy APCs 0651 and 0163, but we request reconsideration of ASTRO's proposed methodology for increasing the number of claims used to determine the median costs.
- ASTRO recommends that CMS leave CPT code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy,* in New Technology APC 1502 for CY 2007.

- ASTRO recommends that the placement of a catheter for breast brachytherapy (CPT code 19297; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)*) remain in New Technology APC 1523. Alternatively, we recommend reassignment of the code to APC 0648 Breast Reconstruction with Prosthesis.
- ASTRO supports establishing payment rates for iodine and palladium brachytherapy sources. For other sources, especially HDR iridium, we recommend continuation of the 2006 payment methodology with payments based on a hospital's charges adjusted to cost.
- ASTRO recommends an alternative methodology for calculating the payment rate for hyperthermia therapies (APC 0314) to prevent the proposed payment reduction of 32 percent in CY 2007.
- ASTRO supports the proposed inclusion of CPT® codes 76370; *Computed tomography guidance for placement of radiation therapy fields*, and 76965; *Ultrasonic guidance for interstitial radioelement application*, on the bypass list to increase the number of claims used in rate-setting. In addition, we recommend the addition of CPT code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy,* to the bypass list.
- ASTRO recommends that CMS extend the current CY 2006 cost-based policy for the radioimmunotherapy products Zevalin and Bexxar and that the agency explore the possibility of basing future payment rates on average sales price (ASP) data.
- ASTRO supports the proposed payment rates for APC 0664 Level I Proton Beam Radiation Therapy and APC 0667 Level II Proton Beam Radiation Therapy.
- ASTRO recommends assignment of new CPT code 55786; *Placement of interstitial device(s) for radiation therapy guidance,* to a new technology APC.

The American Society for Therapeutic Radiology and Oncology appreciates the opportunity to offer these comments and looks forward to working with CMS to address these important issues. If you require further information, please contact Trisha Crishock, MSW, Director, Health Policy Department at (703) 502-1550.

Respectfully,

Laura Thevenot

Laura Thevenot
ASTRO, Chief Executive Officer

Cc: Herb Kuhn
Ken Simon, MD
Edith Hambrick, MD
Dana Burley
Alberta Dwivedi
Trisha Crishock, MSW

St. Luke's Behavioral Health Center

Outpatient Services
1800 East Van Buren
Phoenix, Arizona 85006
Tel 602.251.8535

103

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

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

Our hospital, St. Luke's Behavioral Health Center, is an acute care Hospital facility in Phoenix, AZ. We provide intensive psychiatric programs, including partial hospitalization services that are greatly needed by the severe and persistently mentally ill in our community. We serve over 250 patients on an annual basis in this program.

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,

Gregory L. Jahn R.N.
Administrator, CNO
St. Luke's Behavioral Health Center

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*SABS

SOUTHWEST AMBULATORY BEHAVIORAL SERVICES, INC.

P. O. BOX 370
CROWLEY, LA 70527-0370

TELEPHONE: (337) 788-3600
FAX: (337) 785-1188
E-mail: sabs@sabsusa.com

September 29, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-p, or CMS-4125-P
P. O. Box 8011
Baltimore, MD 21244-1850

RE: Comments to CMS-1506-P PARTIAL HOSPITALIZATION PROGRAM (PHP)

Southwest Ambulatory Behavioral Services, Inc. (SABS) was certified by Medicare on January 23, 1997 as a Community Mental Health Center and has continued to provide all core services incumbent upon us, including PHP since that time in Crowley, LA. We have gone through medical review, cost report audits and have maintained our certification through all. When OPPS was implemented and we went from a cost based program to fee for service, we asked CMS to utilize the mandated cost reports that we are required to file on an annual basis and give PHP a fair daily rate that would allow us to continue providing quality service to the mentally ill population we were serving. CMHCs do not have the luxury that a hospital based program has in being able to allocate costs for the time employees are in the outpatient department along with other variable costs directly related to the PHP while in operation. CMHC employees, rents, benefits, insurances, etc are borne by the facility regardless of what time the PHP is operable. We have four core services to provide, not just PHP. Our staff is hired for 8 hours a day and not just for the time the PHP is operating; thus we believe any reductions to the current daily rate for PHP is totally unwarranted. We have adjusted our operations and programs to match the daily rate of PHP to a point that any further cuts will jeopardize the quality of service. We have not received any transitional outlier payments for the past three years, operating only on the daily rate. The professional staff we employ and clients we serve attest to the need for PHP (see attached Petitions).

The proposed rule referenced above will place extreme hardship on providers of PHP. The rate proposed for 2007 once again falls below my actual cost of providing such services. CMS has proposed a gross APC of $208.27 for a day of services in a PHP, which results in a net payment of approximately $141.49 to my facility due to wage indexing. This is the third consecutive year of cuts for PHP, which has totaled 30% over the last 3 years (2007-15.31%, 2006-12.59%, 2005-1.91%). These severe cuts, when most outpatient services received increases over the last 3 years, indicates that there are obvious issues with the proper setting of the APC rates for a day of partial care. These rates are insufficient to cover the cost of caring for an acutely ill person with mental illness. The current standard of Practice for PHP is an average of 4-5 professional services per day. Services provided in my PHP are provided both on a group and individual basis. PHP requires extensive amounts of professional services, inclusive of nursing, social work, therapy, ancillary services and psychiatry.

CMS noted in the final rule that they would accumulate appropriate data and determine if refinements to the per diem methodology were warranted. The current proposed rule once again acknowledges that appropriate cost data from CMHC's and hospitals has not been utilized due to aberrant data. The proposed cut of approximately 15% is not reflective of the cost pattern for my freestanding CMHC. My costs have risen each year since implementation of OPPS. Over the past two years, CMS acknowledges that appropriate cost finding data was not available for PHP; therefore, recommending 15% cuts for both years. Despite not finding appropriate data for PHP, CMS did appropriately cost find and set the rate for the components of the psychiatric services that are provided in PHP, which will be discussed later in this letter.

COMMENT I - DECREASE IN PARTIAL HOSPITAL PAYMENT BY 15% WHILE LOUISIANA PARTIAL COSTS INCREASED SUBSTANTIALLY

Louisiana has seen an unprecedented increase over the past year in costs for staffing, repairs and maintenance, supplies and insurance.

In the aftermath of Hurricanes Rita and Katrina in 2005, the cost of doing business in Louisiana has risen substantially. Insurance rates across the State have risen from 50-200% (Insurance Journal 10/24/2006), Nursing Salaries have increased by 10-15% (Louisiana Nurses Association, 2005), use of high cost staffing agencies have increased by 25% and cost for labor has increased by 7.4% Statewide and 28.7% in New Orleans (US Bureau of Labor and Statistics 4th Quarter 2005). Louisiana has lost 2046 RN's by application for change of address to another State since the storms (Louisiana State Board of Nursing, 2005). This added to an already strained nursing supply and has substantially increased labor costs.

The proposed wage indexes in both Louisiana and Mississippi have been lowered post hurricane instead of adjusted upward. This results in a much lower payment rate for Louisiana and Mississippi. The wage index decrease makes the assumption that the cost of labor has actually decreased since the hurricanes. That would mean that despite the biggest shortage in staffing for hospitals in the past 20 years as well as the loss of professional and paraprofessional staff, salaries have gone down. Any employer in the Gulf Coast states can verify that this is not correct. Wages have increased substantially.

COMMENT II - PAYMENT FOR PARTIAL HOSPITALIZATION VERSUS OUTPATIENT

The Payment for Partial Hospitalization Services includes a full program, inclusive of Nursing Staff, Psychiatrists, Medical Doctors, Psychologists, Masters Prepared Therapists, Chemical Dependency Counselors, Activity Therapists, Occupational Therapists and Medical Technicians. All therapies provided are included in the one daily rate for APC 033.

In contrast, Outpatient Hospital Psychiatric Services do not require a multidisciplinary team, there are no requirements for nursing staff, and services may consist of one Psychiatrist and one Therapist. In addition, the criteria for admission for patients treated at this level are much less than for PHP, resulting in a much lower patient acuity.

We clearly believe the rates for PHP should be adequately set to reimburse providers appropriately for the setting and level of care. PHP should be reimbursed, at a minimum, the average payment rates set

for Psychiatric Outpatient Services. CMS acknowledges that they do have appropriate cost finding for these individual outpatient codes. (HCPCS 90801-90862 or APC 322-325)

CMS has clearly defined what a partial day of service must include and local medical review policy takes that a step further. Detailed below are two tables reflective of a typical day of services offered in a partial day program utilizing the outpatient psychiatric service rates proposed by CMS.

TYPICAL DAY 1

HCPCS	APC	DESCRIPTION	RATE
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 66.40
90818	323	INDIVIDUAL PSYCHOTHERAPY SESSION	$105.68
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 66.40
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 66.40
TOTAL		TOTALS FOR PARTIAL DAY SERVICES	$304.88

TYPICAL DAY 2

HCPCS	APC	DESCRIPTION	RATE
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 66.40
90818	323	INDIVIDUAL PSYCHOTHERAPY SESSION	$105.68
90853	324	FAMILY THERAPY SESSION	$135.95
TOTAL		TOTALS FOR PARTIAL DAY SERVICES	$308.03

In addition to the PHP Core Service, CMHCs must provide on call services to clients 24 hours a day 7 days per week, outpatient services, and screenings for admission to state mental facilities. We do not receive any reimbursement for any these core services, only PHP. The typical partial services day program tables above yield an average componentized rate of $306. These component costs are not reduced when given in a partial setting. If anything, they can run higher due to the inability to share costs like hospital programs can. How can CMS propose a daily rate of $208.27 for the intense services offered?

Once again, we are asking your consideration to leave the APC rate for code 033 at the 2006 rate or set it as a total of 4 of your calculated outpatient psychiatric component costs. In either case, this would not equate to a 15% cut.

Respectfully submitted,

E. Paul Broussard, CFO

Attachments

Cc: Louisiana Congressional Delegation
Ernie P. Broussard, CEO

September 1, 2006

State of: Louisiana

RE: Calendar year 2007 Partial Hospital Program (PHP) daily per diem rate and Outpatient (OP) services rate proposed by Center for Medicare and Medicaid Services (CMS)

Dear Member of Congress:

Our signatures below indicate that we are patients of psychiatric services and suffer with a chronic and persistent mental illness. Because of our illness, we are in need of reliable psychiatric care, and we will need this care all of our lives. We need medication and we need psychiatric treatment programs to keep us out of hospitals, and help us to learn to manage our illness so we can continue to live and contribute to our communities.

Even though we are incapacitated by a mental illness, we are not unaware of the way we are shunned by society. Many of us have no where to turn for assistance and have been homeless or have been in prisons because we did not have access to the medications or psychiatric care that would have allowed us to live a more normal life.

We are asking for your help in seeking a change to the proposed 2007 daily rate for Partial Hospital Programs and Outpatient services. The proposed rate reduction will put the programs that treat us in negating the ups and downs of a mental illness in great jeopardy. What will we do without these programs? There are already too few options available for us now. Some of us have been part of the growth of the homeless and prison population because of lack of appropriate treatment options. Who have you prepared to help us, and what have you planned to replace the services we are sure to loose?

We hope that you will see this petition as a cry for help from us and join us in our efforts to reverse the decision that CMS proposes to make on the PHP daily rate and Outpatient services.

Sincerely yours,

Christine Higginbotham
[illegible]
Carl Hendricks
Ricky Verdine
ANTHONY SONNIER
[illegible]
Samuel P Sonnier
[illegible] Koller
John [illegible]
Kim andrew Richard
Hazel mae [illegible]

Hilda Leger
[illegible]
Paulette M [illegible]
John R Buford
[illegible]
[illegible] Johnson
[illegible]
[illegible]
Sam Allen
[illegible] Credeur
[illegible] Monceaux
Joyce Nelson

September 1, 2006

State of: Louisiana

RE: Calendar year 2007 Partial Hospital Program (PHP) daily per diem rate and Outpatient (OP) services rate proposed by Center for Medicare and Medicaid Services (CMS)

Dear Member of Congress:

Our signatures below indicate that we are providers of psychiatric services and work with people who suffer with a chronic and persistent mental illness. Because of their illness, they are in need of reliable and appropriate levels of psychiatric care all of their lives. They need medication and treatment programs to keep them out of the hospital, a more expensive option to care, and allow them to live within and contribute to their communities.

We are asking for your help in seeking a change to the proposed 2007 daily rate for Partial Hospital Programs and reduced reimbursement for Outpatient services. The proposed rate reduction will put the programs that treat these citizens in great jeopardy. What are they to do without these programs, as there are already too few options available for the mentally ill? Over the past 5 years we have seen a growth in the homeless and prison population because of lack of appropriate treatment options. Is there a plan to provide for these patient's needs in another way?

We hope that you will see this petition as a cry for help from us and our mentally ill clients and join us in our efforts to reverse the decision that CMS proposes to make on the PHP daily rate and Outpatient services.

Sincerely,

Mandi Laper LCSW
Mary Breaux RNC
Maria Hebert, GSW
Heather Prejean, GSW
Jeni E. Dupre' MHT
April Joseph Jr

Mandi Laper, LCSW
Mary Breaux RNC
Maria Hebert, GSW
Heather Prejean GSW
Jeni E. Dupre' MHT

UPMC | University of Pittsburgh Medical Center

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October 9, 2006

200 Lothrop Street
Pittsburgh, PA 15213-2582

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

ATTENTION: CMS-1506-P

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

Dear Sir or Madam:

On behalf of the University of Pittsburgh Medical Center (UPMC) we are submitting one original and two copies of our comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule (71 FR 49505-49977, 8/23/2006) "Medicare Program; Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates."

The following is a summary of UPMC concerns and issues on the Outpatient Prospective Payment Systems (OPPS) CY 2007 proposed rules.

I. Hospital Quality Data (page 49667)

Proposed Rule: CMS is proposing to initiate a Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) under the OPPS effective January 1, 2007. CMS believes they can employ their equitable adjustment authority under section 1833(t)(2)(E) of the Act to adapt the quality improvement mechanism provided by the Inpatient Perspective Payment System (IPPS) RHQDAPU program for use in the OPPS. Initially CMS would reduce the OPPS conversion factor update in CY 2007 for those hospitals that fail to meet the inpatient quality data reporting requirements. For instance if the OPPS conversion factor update is supposed to be 3.4 percent, providers not meeting the IPPS quality data reporting requirements would lose 2.0 percent of the OPPS update and would only receiving an update of 1.4 percent. Providers fully complying with the IPPS reporting requirements would receive the full update of 3.4 percent per the above example.

Response: We do not support the application of inpatient quality measures to outpatient payment rules. We believe the application of outpatient payment penalties based on inpatient quality measures is unfair to our outpatient programs, and does not ensure improved outpatient quality. We urge CMS to withdraw this proposal and to begin working with the health care community to develop appropriate outpatient reporting measures to be applied in CY 2009, as required by the Deficit Reduction Act of 2005 (DRA) and the value-based purchasing goals.

II. **Visits** (Page 49604)

Development of National Evaluation and Management (E/M) Coding Guidelines (page 49607)

Proposed Rule: CMS is proposing for CY 2007 the establishment of new G codes to describe hospital clinic and emergency department visits and critical care services (discussed below), prior to the completion of national coding guidelines. CMS explains that the current CPT E/M codes were defined to reflect the activities of physicians and do not describe the range and mix of hospital E/M services very well. Therefore, CMS is proposing five intensity levels of clinic visit and five levels of emergency department visits. While CMS has explained that progress is being made in the development of national coding guidelines, they are not yet complete. CMS is proposing that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with their proposed five levels of clinic visits and Emergency department (ED) codes. CMS has advised that each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of the hospital resources to the five different levels of effort represented by the new G codes. New payment rates for each of the five levels have also been proposed.

Response: Due to the obvious difficulty in developing a national coding guideline acceptable to most parties from the various E/M coding models discussed, we prefer to keep our own internal guidelines for the reporting of E/M services. As such we do not support any change at this time from the current process.

Critical Care Services

Proposed Rule: CMS is proposing to replace the hospitals reporting of the CPT E/M critical care codes with two new G codes:

> #99291 Critical care, evaluation and management of the critically ill or critically injured patient; first 30 – 74 minutes
> #99292 Each additional 30 minutes
>
> Replace with:
>
> #Gccc1 Hospital critical care, 30 – 74 minutes

#Gccc2 Hospital critical care, add 30 minutes

Response: This marks a major departure from the CMS policy since the inception of the OPPS. At the outset of the OPPS (p. 18452 of the April 7, 2000 rule), CMS states: "We believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore, we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291." It was clear that CMS intended for hospitals to report critical care when the patient met the definition of being critically ill or injured, but that the time requirement threshold did not apply.

If CMS intended to impose a new time-based reporting requirement for hospital critical care, it did not define the documentation requirements or the basis to count time. For example, what time counts towards the definition of critical care? Why would the physician's time be the sole criteria for the hospital to report its significant staff resources expended for critically ill or injured patients?

We currently identify and apply our critical care service based on the intervention-based guidelines developed by the American College of Emergency Physicians (ACEP) and not by time. We prefer continuing this approach since CMS is not recommending an additional critical care payment amount for the additional 30 minute increments for CY 2007.

III. Health Information Technology (HIT)

Promoting Effective Use of Health Information Technology (49670)

Proposed Rule: CMS is seeking comments on their statutory authority to encourage the adoption and use of Health Information Technology (HIT). CMS is also seeking comments on the appropriate role of HIT in any value-based purchasing program, beyond the intrinsic incentives of the IPPS, to provide efficient care, encourage the avoidance of unnecessary costs, and increase quality of care. In addition they are seeking comments on promotion of the use of effective HIT through hospital conditions of participation, perhaps by adding a requirement that hospitals use HIT that is compliant with and certified in its use of the HIT standards adopted by the Secretary.

Response: While UPMC is a leader in using health information technology (HIT), and encourages and agrees with using HIT to provide better quality service, we are concerned that the costs and staff resources needed to put this in place for rural and small community hospitals could be burdensome and as such believe this should remain voluntary. We do not believe that HIT initiatives such as electronic medical records, bar coding technology, and other HIT initiatives should be mandated as a condition of participation (COP), as it may create unintended consequences across all providers. Instead we would encourage CMS to pursue further operational studies on the potential benefits and costs, for both providers and CMS, and promote more demonstrations on this issue and the continued voluntary adoption of HIT initiatives.

IV. Outlier Payments

Proposed Outlier Payment Thresholds (49546)

Proposed Rule: CMS proposes to increase the fixed-dollar threshold by $575 (from $1,250 to $1,825), while keeping the multiplier threshold at its current level of 1.75, to meet the one percent threshold. Thus, for CY 2007, payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $1,825 fixed-dollar threshold. The payment percentage would remain the same – 50 percent.

CMS indicated that 25% of this threshold increase is due to the projected overpayment of outliers arising from the Cost-to-Charge Ratio (CCR) problem where the fiscal intermediaries were applying a different CCR computation methodology than used by CMS.

Response: The proposed CY 2007 outlier threshold is 46 percent higher than the CY 2006 level. While, CMS indicates that 25 percent of the outlier threshold increase is due to the correction of a discrepancy between its calculation of the overall cost-to-charge ratio (CCR) and the calculation used by fiscal intermediaries it contains no analyses of how it computed the remaining outlier threshold increase. We would expect that this remaining increase should not exceed the one year charge inflation factor of 1.0757. These two issues would then result in an expected outlier threshold increase of only 19.07% (46% * .25 = 11.5 + 7.57 = 19.07 %). As a result we first urge CMS to decrease its proposed outlier threshold to a level approximating $1,488. Second, we urge CMS to publish the actual total outlier payments as a percent of total expenditures so providers can see how accurately CMS predicted the outlier targets and thresholds in previous periods.

V. OPPS: Wage Indices

Occupational Mix Adjustment (page 49540)

Proposed Rule: CMS is proposing to use the revised FY 2007 inpatient PPS wage indices that will be fully adjusted for differences in occupational mix using the new survey data upon completion, in the final outpatient rule.

Response: While we realize that a court order, in the Bellevue Hosp. Ctr. V. Leavitt required CMS to apply 100 percent of the occupational mix survey data to its wage indices, we object to its anticipated adverse effect on quality/efficiency initiative requirements. The existing wage index and occupational mix process is expected to have the effect of penalizing hospitals that invest in quality/efficiency at the very time that Congress is seeking to improve quality/efficiency under the Medicare program. For example, by utilizing higher levels of Registered Nurses (RNs), hospitals are improving the quality of care provided to seniors, yet they are penalized by the CMS' refusal to

recognize these higher above-average costs under the wage index. Thus, the effect of the wage index and occupational mix on these hospitals will reduce or eliminate the annual Medicare inflation increase provided to address the increasing costs these hospitals face. This reduction is not recognized as savings under the Medicare program, but is unfairly redistributed in part to hospitals that arguably have not been as efficient, nor as focused on quality improvement. As a result, these hospitals are placed at a competitive disadvantage that adversely impacts services and limits their capacity to recruit and retain employees and to invest in new technologies.

As stated in our Inpatient Prospective Payment System responses for FY 2007, we believe that CMS should work to postpone the implementation of 100 percent of the occupational mix survey adjustment until the DRG severity refinements can be fully implemented and until the unrecognized adverse effect on quality of care outcomes can be resolved.

VI. OPPS: Non-pass-through Drugs, Biologicals and Radiopharmaceuticals

Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals (49582)

Proposed Rule: CMS indicated that the packaging threshold of $50 expires at the end of CY 2006. As a result CMS considered 4 different payment options for packaging drugs, biologicals, and radiopharmaceuticals. The four options included:

1. Pay separately for all drugs, biologicals, and radiopharmaceuticals with a HCPCs code.
2. Increase packaging threshold to a level much greater than the current $50 level
3. Maintain current packaging threshold at $50
4. Annually update current threshold level with inflation factor (Proposed $55 threshold)

CMS choose option 4 which updates the current threshold for inflation. The inflated threshold proposed is $55.

Response: We have discussed the drug threshold options with our cancer programs and they urge CMS to adopt option 1 and to pay separately for all drugs, biologicals, and radiopharmaceuticals with a HCPCs code. They have indicated that while a threshold approach may be relevant for some cancer care drugs given as single agents, many drugs are given in combination therapy and are significantly underpaid in the packaged rates. Since the vast majority of chemotherapy is administered as a combination, and not single agent therapy we urge CMS to select option 1 and to pay separately for all drugs, biologicals, and radiopharmaceuticals with a HCPCs code. We also support the elimination of drug packaging thresholds on all drugs, biologicals, and radiopharmaceuticals with HCPCs codes. We believe this will result in more accurate drug payments.

Proposed Payment for Specified Covered Outpatient Drugs (49584)

Proposed Rule: CMS indicated their proposal to pay for acquisition and overhead costs of drug and biologicals under the OPPS at ASP + 5 percent for CY 2007, while in CY 2006 CMS set payment rates at ASP + 6 percent. CMS is specifically requesting public comments on the adequacy of the payment rate to account for actual acquisition and overhead costs incurred by the hospital for these items. (Page 49585)

Response: At this time we do not support your proposal to reduce the drug and biological payment levels below the current ASP + 6 percent paid last calendar year, for several reasons. They include:

1. Current calculation problems:
   a. ASP is based on the price that manufacturers charge distributors, including any prompt pay discounts. These prices and discounts often are not passed along to providers but are included in the calculation of the ASP.
   b. ASP is based on sales to all entities, including group purchasing organizations and large hospital systems on one end of the spectrum and one-physician oncology practices on the other. It means that many hospitals, particularly the smaller ones without purchasing power, will purchase drugs above ASP.
   c. Since their appears to be a two-quarter lag in the calculation of ASP, meaning that reimbursement is based on prices that are six-months old. Since manufacturers typically raise prices two to three times per year, there is potential for hospitals to suffer losses each time they administer drugs. Even as a large volume buyer, UPMC currently pays greater than ASP for many of our most highly utilized drugs and, in some cases, pay greater than ASP + 6%.

2. Inconsistent payment rate across settings - This proposal would result in lower payment for drugs and biologicals provided in hospital outpatient departments (proposed ASP + 5 percent) than for the same drugs and biologicals furnished in a physician office setting (paid ASP + 6 percent). We do not support the proposed hospital rate reduction to a level lower than paid to physicians and urge CMS not to reduce payment below the current rate of ASP + 6 percent.

VII. OPPS: Drug Administration

Proposed Rule: CMS is proposing to assign HCPCs codes for CY 2007 to six new drug administration APCs with payment rates based on median costs for the APCs from CY 2005 claims data. These new APCs are intended to better distinguish cost related to different types of infusions and furnished over different lengths of time. In addition CMS

has proposed to make separate payment for additional hours of infusion, instead of packaging these additional services into the initial APC.

Response: We support the CMS proposal to make separate payments for additional hours of infusion.

VIII. New Technology APCs

Movement of Pet/Computed Tomography (CT) Scans (Device-Dependent APCs (page 49552)

Proposed Rule: CMS is proposing to re-assign nonmyocardial Positron Emission Tomography (PET) scans and PET/Computed Tomography (CT) scans to APC 0308 with a median cost of $865. These services were previously classified in CY 2005 under new technology APC 1513 at a rate of $1,150.

Response: While CMS generally retains a service within a New Technology APC group for at least two years, in order to collect sufficient claims data for costing / pricing purposes it appears that the PET/CT scan data was less than two full years. CMS approved PET/CT scans on January 28, 2005 and the proposed rule was published August 23, 2006. As such less than two full years of data was available for analysis and pricing. Since data received by CMS in the first year or two of adoption of new technologies may not appropriately reflect the use and cost of these services, as such we urge CMS to collect an additional year of claim data before any APC reassignment is considered. We also performed some internal costing on CY 2005 nonmyocardial PET services which revealed an average cost level of $1,259. Based on these two findings we would urge CMS to keep the PET services under the new technology APC 1513 for an additional year so more claim data can be collected, to ensure accurate pricing.

IX. Device-Dependent APCs

Proposed Payment Policy When Devices are Replaced Without Cost or Where Credit for a Replaced Device is Furnished to the Hospital (page 49574)

Proposed Rule: CMS is proposing to adjust both the APC payment to remove payment for the device furnished without cost to the hospital or beneficiary and also to decrease the beneficiary copayment in proportion to the reduced APC payment so that the beneficiary would, in many but not all cases, share in the cost savings attributable to the provision of the device without cost by the manufacturer. CMS would implement the adjustment through the use of a modifier "FB" specific to device replacement without cost or crediting of the cost of a device by the manufacturer. However two conditions would be required first, that the procedure must be assigned to one of the APCs on table 21, and second that the device must be of the type identified in table 22.

Response: CMS also discussed the inappropriate use of the "FB" modifier in cases where the replacement device is more expensive than the device being removed, but did not establish a modifier for this scenario. We would urge CMS to add a second modifier to their proposed policy to recognize situations in which the replacement device is more expensive than the device being removed, so CMS can pay the hospitals for the additional costs they are bearing for the difference between the recalled device and the upgraded device.

X. OPPS: Brachytherapy

Proposed Payment Policy for Brachytherapy Sources in CY 2007 (page 49597)

Proposed Rule: The previous provision to pay for brachytherapy sources as charges reduced to cost expires December 31, 2006. However CMS is still required to create groupings that classify brachytherapy devices separately from other services to reflect the number, isotope, and radioactive intensity of the device furnished. As such, CMS is proposing to pay for these services at aggregate hospital mean costs as determined from 2005 claims data.

Response: We are concerned that it is too soon to end the current policy of paying at hospital costs due to concerns that the claims data may be incomplete as a result of frequent code and descriptor changes for radiopharmaceuticals. Therefore, we urge CMS to continue to use the current methodology of payment at charges reduced to costs for brachytherapy sources.

XI. Partial Hospitalization

Proposed Rule: Typically CMS uses hospital-based Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) PHP data to determine PHP rates, however due to instability in CMHC PHP data these rates were based on CY 2005 combined costs of $289 with a 15% reduction in CY 2006 and another 15% reduction for CY 2007. Therefore, CMS is proposing a CY 2007 PHP per diem rate of $208.80. (CY 2005 combined cost $289 *.85% * .85% = $208.80) CMS indicated that more recent claims data and CCRs produced PHP rates of $165 for CMHCs and $209 for hospital-based PHPs. This would combine to a median rate of $172 which CMS believes is to low to cover the costs of PHPs.

Response: We do not support the proposed CY 2007 PHP per diem rate of $208.80 as we suspect that it was also based on flawed initial data. Currently our internal computations reflect partial hospitalization program per diem costs of $262.82 for our facility. As such we would urge CMS to increase the CY 2006 PHP per diem rate of $245.65 by 6.8% in order that our program break-even. We cannot sustain continued 15 percent reductions in the PHP per diem rates.

XII. Ambulatory Surgery Centers

APC Payment System -2007:

Proposed Rule: CMS has proposed to add 14 procedures to the current list of approved procedures when furnished in a Medicare-approved ambulatory surgical center (ASC), applicable to services furnished on or after January 1, 2007. These procedures would be assigned to one of the current nine ASC payment groups. Further, this proposed rule would revise the ASC facility payment system to implement provisions of the Deficit Reduction Act (DRA) capping ASC payments at the outpatient PPS payment rate for the same surgical procedures. It is estimated that this cap will apply to 272 ASC procedures.

Response: We are concerned that the continued shifting of surgical procedures from hospital settings to ASCs could jeopardize patient safety and quality of care since ASCs are not subject to the same facility, equipment, and staffing standards as hospitals.

APC Payment System -2008

Proposed Rule: The MMA mandated that CMS create a new ASC reimbursement system by January 1, 2008 and that the revised system be budget neutral. CMS estimates that the proposed policy changes will expand the ASC list by more than 760 procedures and exclude 270 procedures for safety concerns. CMS is proposing to use the APC groups and the relative payment weights for surgical procedures under OPPS. CMS will continue to package all direct and indirect costs into the ASC fee and stop making payments for implantable prosthetic devices. CMS has also proposed to limit ASC payment to the lesser of the ASC payment or the Medicare Physician Fee Schedule.

Response: As noted above, we are concerned that the potential weakening of the standards that determine which services may be performed in an ambulatory surgery center (ASC) could jeopardize patient safety and quality of care. This is an issue because regulations and facility standards to which ASCs are subject fall far short of the requirements that hospitals and their outpatient departments must meet in areas such as patient safety, patient rights, quality assurance, and operating (e.g., facility, equipment, staffing, etc.) standards.

We also believe there has not been adequate time for hospitals to thoroughly analyze the proposed changes and assess impacts, although large payment changes are anticipated.

Conclusion

We appreciate the opportunity to submit these comments on your proposed changes on the Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates and hope they are considered before any final rules are published.

If you have any questions regarding our comments please telephone me at (412) 623-6719.

Sincerely,

Paul Stimmel

Paul Stimmel
Sr. Special Projects Analyst

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Lewandowski, C.
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October 5, 2006

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

Re: CMS 1506P; CMS 4125-P (Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates)

Dear Acting Administrator Norwalk:

Sirtex Medical Inc. ("Sirtex") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding the Hospital Outpatient Prospective Payment System ("HOPPS") and CY 2007 payment rates. Sirtex manufactures SIR-Spheres®, which are biocompatible radioactive resin spheres that contain Yttrium-90 ("Y-90") and emit beta radiation to treat unresectable colorectal cancer metastasized to the liver. Y-90 is one of twelve radioactive brachytherapy devices paid for by Medicare. Our main points are the following:

- **CMS should base brachytherapy source payments on the mean cost per source as is proposed for radiopharmaceuticals.**
- **CMS should conduct a survey to determine an adequate payment amount for the significant costs of storing, handling and disposing of brachytherapy devices.**
- **CMS should create mandatory code edits to ensure that hospitals uniformly and consistently report charges and costs related to the procedure and source.**
- **CMS should revise the proposed definition of brachytherapy sources to include all brachytherapy sources, without limitation.**

I. Payment Methodology

The payment methodology for radioactive sources associated with brachytherapy has been altered several times since the inception of the HOPPS in 2000. This has led to some degree of instability. Beginning that year, CMS was required to make separate pass-through payments for all radioactive sources associated with brachytherapy. Most recently, as mandated by the Medicare Modernization Act of 2003 ("MMA")[1], sources and procedures have been paid for separately at rates based on individual hospital's charges adjusted to cost. Beyond 2006, the MMA required separate payment for all brachytherapy sources, but did not specify a methodology for determining the separate payment amounts. Rather, it directed the Government Accountability Office ("GAO") to conduct a study and make recommendations regarding future payment for radioactive sources.

The GAO report[2] was released in July 2006 (a year-and-a-half past the deadline set by Congress) and recommends that CMS use CY 2005 claims data to set prospective payment rates for iodine and palladium brachytherapy sources *based either on the mean—as is currently done with certain high-cost drugs—or the median.* (The GAO did not consider the seven other brachytherapy devices because there isn't sufficient data from 2003-2004.) Although CMS acknowledges that the GAO report was not available in time to "review and discuss" in the CY 2007 proposed rule[3], the agency proposes to pay separately for all brachytherapy devices on a prospective basis in CY 2007, with rates to be determined using the CY 2005 claims-based *median* cost per source for each brachytherapy device.

While Sirtex understands CMS's desire to pay for all outpatient services on a prospective basis, we feel that brachytherapy sources should be paid in the same manner in which CMS proposes to pay for radiopharmaceuticals in CY 2007 - the *mean* unit cost across hospitals. Both radiopharmaceuticals and brachytherapy devices contain radioactive material and are subject to oversight from the Nuclear Regulatory Commission. In addition, radiopharmaceuticals and brachytherapy devices have the same storage, handling and disposal requirements. The distinction is that radiopharmaceuticals are given to the patient orally, injected, or placed into the eye or the bladder and enter into the patient's bloodstream. Brachytherapy treatment involves a surgical implantation of seeds (or radioactive source) in or near a cancerous tumor. Brachytherapy is targeted at the tumor within the cancerous organ while radiopharmaceuticals operate systemically.

In developing the proposal for appropriate radiopharmaceutical payment in CY 2007, CMS compared the payment rates for drugs and biologicals using both fourth quarter CY 2005 ASP data and mean claims data. The results of the data analysis indicated that *using mean unit cost to*

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[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 621(b) (2003).
[2] U.S. Gov't Accountability Office, Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively (GAO-06-635, July 2006) [hereinafter GAO Report], available at: http://www.gao.gov/new.items/d06635.pdf.
[3] 71 Fed. Reg. 49506 (Aug. 23, 2006).

set the payment rates for drug and biologicals would be equivalent to basing their payment rates, on average, at ASP+5 percent. CMS concludes that this option provides the "most consistent, accurate, and efficient methodology for prospectively establishing payment rates for separately payable radiopharmaceuticals; in addition, (it is) consistent with how payment rates for other services are determined under the OPPS."[4] By opting to base payment for brachytherapy devices on the median unit cost, CMS effectively proposes to pay for them at a lower rate than any other drug, biological or radiopharmaceutical within the entire hospital outpatient system. We are concerned about the potential negative impact on beneficiary access to the Y-90 treatment, as it can currently only be performed in a hospital outpatient facility.

There are other situations in which CMS bases payment on the mean unit cost. As stated in the GAO report,

> "In paying separately for technologies that are not new, the Centers for Medicare & Medicaid Services (CMS) generally sets prospective rates based on the average unit cost of the technologies across hospitals. For example, CMS currently pays separate prospective rates for certain high-cost drugs *based on the mean per-unit acquisition cost*, as derived by CMS from data provided by drug manufacturers."[5]

In addition, in this proposed rule, CMS proposes to use mean costs of drugs determined using the hospital claims data in determining the packaging status of drugs and biologicals. CMS states that it limited its analysis to the mean costs, *instead of median costs*, because the Medicare statute specifies only that payment for specified covered outpatient drugs in CY 2007 be equal to the "average" acquisition cost for the drug.

Sirtex asserts that CMS has the authority and ample clinical rationale to use the same payment methodology for radiopharmaceuticals and brachytherapy devices, and urges the agency to maintain patient access to these critical treatments by reimbursing both based on the mean unit cost.

II. Storage, Handing and Disposal Costs

CMS asserts in the proposed rule that payment for storing, handling and disposing of Medicare Part B drugs, biologicals, radiopharmaceuticals and brachytherapy devices is adequately covered by the proposed prospective payment rates. Sirtex, however, is concerned that given the shift in payment methodology and the likely reduction in CY 2006 payment rates that result, hospitals will be unable to cover the source acquisition costs in addition to the storage, handling and disposal costs. The Ambulatory Payment Classification ("APC") Advisory Panel, which advises CMS on hospital outpatient coding and reimbursement issues, demonstrated its shared concern for CMS's policy of paying no additional fee to the hospital to cover these costs. At its March 2006 meeting, the Panel recommended that CMS "examine pharmacy overhead costs issues and

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[4] 71 Fed. Reg. 49587 (Aug. 23, 2006).
[5] GAO Report, p. 2.

work with appropriate associations to study how to measure pharmacy overhead costs."[6] Sirtex applauds CMS's agreement, as stated in this proposed rule, to continue to "work on" issues related to pharmacy overhead costs and when establishing a future pharmacy overhead cost methodology.

III. Claims Data Accuracy

As outlined above, there have been a significant number of changes to the payment methodology used for brachytherapy sources and procedures since the inception of the OPPS in 2000. In addition, brachytherapy is an emerging field within the oncology arena, and each year there have been several new products introduced on the market. As a result, hospitals have been faced with the significant challenge of implementing the new systems and re-training coders each year. Not surprisingly, there is a high rate of incorrectly coded claims.

Brachytherapy procedures always require the use of a brachytherapy device(s). Every hospital claim for brachytherapy treatment should therefore include at least one unit of a brachytherapy source HCPCS code ("C" code). Currently, as illustrated in table 1 below, the majority of hospitals do not include a brachytherapy source code on the procedure claims.

Table 1

Brachytherapy Procedure APC	**Percentage of 2005 Hospital Claims with a Brachytherapy Source "C" Code**
312 Radioelement Applications	29.6%
313 Brachytherapy	59.6%
651 Complex Interstitial Radiation Source Application	36.4%

Sirtex is concerned about the extent of the miscoding of brachytherapy sources and procedures and respectfully requests that CMS institute mandatory reporting of all medical device "C" codes to improve the quality of the claims data. This is especially critical given the fact that payment in CY 2007 will be based on claims data averaged across all hospitals. We also recommend that CMS consider implementing device code edits for all device-related and "device-dependent" APCs. Furthermore, we encourage CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for devices and other technologies.

At the August, 2006 APC Advisory Panel meeting[7], the American Hospital Association (AHA), the Provider Round Table group, and the APC Advisory Panel members agreed that requiring the appropriate device code on the claim prior to processing and paying the claim would be beneficial to hospitals and would aid in educating them about the appropriate device C-Codes, particularly those for more complex procedures.

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[6] Advisory Panel on Ambulatory Payment Classification (APC) Groups, Panel Recommendations (March 1-2, 2006), available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.
[7] Advisory Panel on Ambulatory Payment Classification (APC) Groups, Panel Recommendations (Aug. 23-24, 2006).

IV. Definition of Brachytherapy

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a "seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."
Section 1833(t)(2)(H) of the Social Security Act states, "The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services)." Under this section, current cancer therapy drugs and biologicals and brachytherapy are defined as follows:

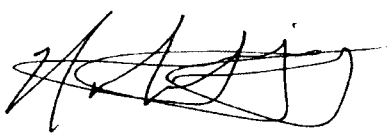
> "A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and device of brachytherapy..."

Sirtex's understanding of the MMA legislation is that it intended to provide separate payment for all brachytherapy devices, *not* to exclude certain types of brachytherapy devices. New innovative, non-radioactive brachytherapy sources meet the criteria required by the legislation and are approved as brachytherapy devices by the Food and Drug Administration (FDA). By narrowing the definition of a brachytherapy source to a radioactive source only, CMS would not only limit access to new technology but also inadvertently eliminate Medicare beneficiary access to FDA approved cancer care.

V. Conclusion

Sirtex appreciates the opportunity to comment on the issues raised in the Proposed Rule, and looks forward to working with CMS to ensure that Medicare beneficiaries continue to have access to life-saving brachytherapy treatments such as Y-90. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please do not hesitate to contact Nat Geissel, CEO, at 847-482-9023 or Desiree Gray, VP Marketing at 617-901-6808 if you have any questions regarding these comments. Thank you for the opportunity to comment on the proposed rule and your attention to this very important matter.

Sincerely,



Nat Geissel
CEO, Sirtex Medical Inc.

cc: Carol M. Bazell, M.D.