West Glen GI Consultants 7230 Renner Road Shawnee, KS 66221 October 8,2006

Mark McClellan MD Centers for Medicare and Medicaid Services Department of Health & Human Services Attention: CMS-1506-P PO Box 8014 Baltimore, MD 21244

Dear Mark:

With the changes in health care and monetary constraints that face our country, I don't envy the dilemmas and challenges of your job. As is the case with most problems, the solution often times lies within the problem itself. I believe that healthcare although unique as human life is priceless can be approached in this manner with both political and economic solutions that are fair and socially acceptable.

The vast majority of physicians welcome accountability and more efficient utilization of limited resources in the care of its citizens. However at times it seems that reimbursement decisions are made without long term vision. The universal coverage of colorectal screening has made a huge impact in the lives of those with cancers detected at an earlier stage with improved survival rates and less costly treatment. Unfortunately, recent decisions have been published indicating that two-tier reimbursements will be implemented with inefficient systems being rewarded and more efficient systems being punished with the pay differential of HOPD rates versus ASC rates.

Within health care itself, the disparity of physician service reimbursement is appalling. In particular lab and x-ray services have been paid a premium to the physicians involved compared to the clinicians who have borne the brunt of the "sweat equity" in terms of labor as well as dealing with the families on a daily basis. Yet the pathology and radiology fields are more lucrative than ever as the majority of their work is now performed after hours and weekends by off site technicians and physicians in other countries while the American physicians still bill Medicare full rates and pay their contract labor a fraction of the total charges while pocketing the remainder themselves. Furthermore, the above mentioned fields don't have office staff on their overhead nor do they have offices that they would otherwise have to pay fair market value for like the clinicians do because the hospitals provide this as part of their monopolistic contracts. In effect, the continued maintenance of HOPD reimbursements for procedures helps maintain this discrimination against clinicians and at the same time reduces their pay to maintain the inefficient status quo. Perhaps Medicare would be better served by immediately reviewing lab

GASTROINTESTINAL ASSOCIATES, P.A.

BARBARA J. MACCOLLUM, M.D.
PAUL J. BERGGREEN, M.D.
BRENDA DENNERT, M.D.
JOSEPH DAVID, M.D.

September 20, 2006

Marc McClellan, M.D. Centers for Medicare and Medicade Services Department of Health and Human Services Attention CMS-1506-P P.O. Box 8014 Baltimore, MD 21244-8014

RE: MEDICARE PROGRAM AMBULATORY SURGICAL CENTER PPS PROPOSED RULE

Dear Dr. McClellan:

I am a private practice gastroenterologist in Phoenix. I am writing to express my concerns with the CMS proposal to change the way your agency pays ambulatory surgical centers regarding their facility fee payments.

The proposed rule change as I see it will be of significant detriment to Medicare patients by institutionalizing a higher payment for hospital outpatient departments for the same procedure that we perform more efficiently and at lower cost in an outpatient endoscopy center. This will only serve to lower access to Medicare beneficiaries for colorectal cancer screening.

Additionally, by penalizing ambulatory surgical centers for providing access to Medicare beneficiaries for a screening colonoscopy, you are actually initiating a system which will cost more money for Medicare in the long run, and at the same time, decrease access to screening colonoscopy for Medicare beneficiaries. This is obviously bad for the budget as well as bad for screening colonoscopy, a concept which has been proven to dramatically decrease rates of colon cancer.

Therefore, I am respectfully requesting that this issue be reviewed and modified to be less punitive towards ambulatory surgical centers. This will avoid the closure of gastroenterology ASCs and

BOARD CERTIFIED IN INTERNAL MEDICINE AND GASTROENTEROLOGY

1300 NORTH 12TH STREET • SUITE 608 PHOENIX, ARIZONA 85006 • 602/254-5321 RE: MEDICARE PROGRAM AMBULATORY SURGICAL CENTER PPS PROPOSED RULE SEPTEMBER 20, 2006
PAGE TWO

a reduction in access in colorectal cancer screening rates and ultimately prevent an increase in the number of GI procedures performed in a more costly hospital outpatient department setting.

Your attention to this matter is appreciated.

Respectfully,

Barbara J. MacCollum, M.D.

Tarbay mer Collin ma

BJM/CMT/jeb

Dictated But Not Read



Georgetown University Hospital

Division of Nuclear Medicine

September 12, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective

Payment System and Calendar Year 2007 Payment Rates: Payment

for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Georgetown University Hospital, Division of Nuclear Medicine to address an issue of great importance to Medicare beneficiaries with cancer. Georgetown operates an independent diagnostic testing facility (IDTF), which provides PET/CT imaging services. We serve approximately 1,500 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay IDTFs, and could compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by free standing facilities traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS has proposed to reduce the hospital outpatient rate for PET/CT to \$865—the same rate proposed for conventional PET—from its current rate of \$1,250. For IDTFs that represents a cut up to 60% to 70% in one year from current carrier based prices.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

The proposed payment rate reduction for PET/CT would seriously underpay IDTFs, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of \$1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

With best regards,

Devid A. Earl-Graef, MD Director, Nuclear Medicine

Assistant Professor of Radiology

Office: 202-444-3360

dea4@gunet.georgetown.edu





Department of Radiation Oncology

Sinai Hospital of Baltimore Mt. Pleasant Building 2401 West Belvedere Avenue Baltimore, MD 21215

October 4, 2006

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

Re: New Technology APC's – Section c. Pages 49553 and 49554

To whom it may concern:

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

New Technology APC's

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APC's) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of (\$1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of (\$833.32). These proposed revisions would result in a reduction in payment averaging (\$2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. I have serious concerns about this review, and it is my hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007.

Let me acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and to maintain a process that allows for tracking of new technology claims. In the hope that I can assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery, let me first give a brief historical overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session...".1 Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite - predominantly an outpatient staged treatment. CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."2 Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum.3 While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this

² Federal Register, November 30, 2001, page 59866.

³ CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002, Stanford University Hospital submitted its cost data in January 2003, and the University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of \$1,125, which did not reflect the consistent use and cost of resources for each treatment.4 As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APC's applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS

⁴ Federal Register November 30, 2001, page 59868

G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. I believe that the decisions that were made were—and are still today—correct.

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that "any SRS code changes would be premature without cost data to support a code restructuring". (CMS-1506-P, page 156).

CY 2006

At the August 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel 's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173, G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.

It is my understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the

Coalition, I also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. Specifically, I support the CyberKnife Coalition's assertions that:

The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife[®] (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

By the end of CY 2005, there were thirty-five (35) centers operating:, of which fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year. Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

Furthermore, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported. The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at \$6,203.27 per unit. For non-CyberKnife centers, the average cost is \$3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services. Additionally, the 2004 Identifiable Data Set Hospital OPPS file does not include numbers from several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown (which had the 2nd highest procedure volume in the U.S.), my institution, Sinai Hospital of Baltimore, (the 6th highest), and Miami CyberKnife Center (the 7th highest). Other smaller, less urban centers are also not included.

The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown (not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

I have noted that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that it is a "mature technology [with] stable median costs" (CMS-1506-P, p 157). This is, to be sure, an accurate reflection of the well-established nature of the Gamma Knife, technology that has been in existence for over 30 years and with significant and mature data with which to establish an appropriate median cost. But since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extra-cranial image-guided robotic stereotactic radiosurgery with the CyberKnife are at least as great as, if not greater than those in the use of the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers that had no established costs on which to set charges.

	# centers operating Jan 1 st	New centers treating during year	% of centers in first year
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively. Furthermore, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from \$3,479.65 (non-robotic SRS centers) to \$6,203.27 (for image-guided r-SRS centers).

I believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery d o not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340. It was my hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September, but it was recalled by CMS. I regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As I have indicated, however, I would expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file, and I would respectfully urge CMS to review the 2005 data with these comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. I understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient, due both to the large number of new centers submitting less than a full year of data for 2004 and 2005, and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years—the Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge. We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition

undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

In closing, I would respectfully offer the following two recommendations:

- 1. That no changes should be made in the APC's or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007, and
- 2. That CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Respectfully yours,

Mark J. Brenner, M.D., FACR

Chairman, Department of Radiation Oncology

Sinai Hospital of Baltimore

Tel. 410-601-5689; Fax 410-601-6307

Email: mbrenner@lifebridgehealth.org

MJB/jmb

October 4, 2006

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

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

Dear Dr. McClellan:

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

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

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

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

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

Catherine/M. Griffin 1017 Ripple Ridge Road

Darien, IL 60561

espectful



MOREHOUSE SCHOOL OF MEDICINE

195

Department of Obstetrics and Gynecology

Roland Matthews, MD Chairman

October 6, 2006

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

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

Dear Dr. McClellan:

As a Chairman of the Department of Obstetrics and Gynecology at the Morehouse School of Medicine with privileges at Grady Memorial, Emory Crawford Long and South Fulton Medical Center Hospitals, I am pleased to have the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007. This rule will have a direct effect on the medical care delivered to a significant number of my patients.

Uterine fibroids are a very prevalent disease among women of childbearing age in the United States and they are three to five times more prevalent among women of color. The fibroids present earlier and African American women tend to have more fibroids than other populations. As a result a much greater percentage of these women undergo hysterectomy for this condition. This often leads to significant time away from their normal activities compared to a less invasive procedure. As you know a high percentage of these women are Medicare or Medicaid recipients.

Magnetic Resonance Imaging Guided Focused ultrasound (MRgFUS) (CPT codes 0071T and 0072T) offers women the opportunity to undergo an outpatient, non-invasive procedure to eliminate symptoms and also enables them to get back to normal life and work almost immediately. However, these codes are currently assigned to APCs 195 and 202 with national unadjusted payment rates of \$1,595 and \$2,454, respectively. At these rates, which are significantly lower than hospitals costs to perform the procedure, hospitals and outpatient clinics will be disinclined to offer this service, preventing access to the technology for a large percentage of the population.

The procedures in the current APC assignments are less resource intensive procedures for the hospital to offer making the APC assignments for CPT 0071T and 0072T inappropriate. The time and resources associated with MR guided Focused Ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources assignment. We would ask that CMS consider assignment to APC 127, which has a more appropriate clinical and resource cost assignment.

I thank you for your consideration to reassign CPT codes 0071T and 0072T Magnetic Resonance Imaging Guided Focused ultrasound ablation of fibroids (leiomyomata) to an APC with a more clinical and resource cost that is appropriate. The reassignment will allow the hospital outpatient departments and women to have access to this important and long awaited treatment option.

Our hospitals and patients appreciate CMS's consideration of this important issue.

Sincerely,

Roland Matthews, MD

Gordon G. Koltis, M.D., FACRO Board Certified Radiation Oncologist

Andrej V. Hnatov, M.D. Board Certified Radiation Oncologist

199

Alex V. Hnatov, M.D. Radiation Oncologist

Cancer Treatment Center 801 W.H. Smith Blvd. Greenville, NC 27834

Phone: (252) 329-0025 Fax: (252) 329-0325 www.CarolinaRadiation.com



LMH Cancer Center 703 Doctors Drive Kinston, NC 28501

Phone: (252) 522-7600 1-800-Hope4Me (467-3463) Fax: (252) 527-2476

October 4, 2006

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

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System

and CY 2007 Payment Rates;

Dear CMS Administrator:

I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am very concerned about the impact these new rates will have on breast conservation therapy in relation to the proposed assignment of 19296 and 19297 to new APCs.

CMS should continue with CPT codes 19296 and 19297 being assigned to New Technology APCs 1524 and 1523 respectively. The CMS proposed reassignment of these codes from New Technology APCs to clinical APCs in 2007 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006- 2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	\$3,250	0030	\$2,508.17	(\$741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	\$2,750	0029	\$1,732.69	(\$1,017.3 1)	-37.0%

Should CMS finalize the proposed APC assignments, the cost of the device will surpass the proposed payment rate. This will severely limit our ability to offer this breast cancer treatment option to Medicare eligible women.

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

Additionally, our facility purchases the radiation source to be used in breast conservation treatment. Our facility must be able to cover the costs of the radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In closing, I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. I respectfully request that CMS heed my recommendations. I would like to continue servicing your Medicare beneficiaries.

Regards,

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee

Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee

Senator Sam Brownback, Co-Chair, Senate Cancer Committee

Senator Thad Cochran, Chairman, Senate Appropriations Committee

Representative Michael Bilirakis, Energy and Commerce Health Subcommittee

Representative Ginny Brown-Waite, Co-Chair, Congressional Caucus for Women's Issues

Representative Katherine Harris, Member House Cancer Caucus

Representative Ileana Ros-Lehtinen, Vice Chair, Congressional Caucus for Women's Issues

Carol Bazell, MD, Director, Division of Outpatient Care

James Rubenstein, MD, Chairman, American College of Radiation Oncology

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

W. Robert Lee, MD, President, American Brachytherapy Society

Jaeneta acionan of and of the Center for Medicare and Medicaid Services: Lan a patient receiving Services at a partial II hospital program. The services I receive are important to Desple like me, and I would like to stop the proposed 15% reduction Sincerely

Jackit Warren

Lam Philip Lonia, a therapist at Ms Warren's Program, and assisted her in writing this letter.

Center, for Medical and Medical Services The 15% medicand medicaid services is too much of a cut please stop, the cut dags a patient at PAPA services are very important to me! I would like continue for me and others who tean benefit from these service Suganne M. Montes

Date, 3006

Center for Meticare and Medicail, Services

Desire Mutin, who is, a Seria, Like a many mue. Would appoite Veryit it possal, Leane the Center as it is.

and do not appoint of 15%.

Nictors Mulin

The Service here are Very at and it is a ling help to us Semines

Center for Medicare and Medicial service I am as Patinon at program I object to the 15% cut back, the services received here are important to me:

Dorothy Zajac

204 10/6/06 Contenfor medicaid & mediase Parn curreilly a patient of receiving Dervices. Dabject to the 150% reduction of the coroso

Fril cx6, 2006 and Medical Services, Janua featient and of Object to the 15 per cent saise cut Staide P. It askington Center for Medicare and Medicaid Services. I am a partient at a partial hospital program and the services provided to people like we are important. I would like t

important. I would like to stop the proposed 15% cut in services.

James Mc Christian

Tam Philip Lamia, a therapist I assisted Ms McChristian inwriting this lefter.

207

Center for Melicine and Melicine Service would not Cut the problem I am a patent wearing service & a yatunt in a property poblim Service and do not want service to plop 152 ent he potago please Lua Do atseus Centers for Medicare and Medicaid Soppices:

I am a patient receiving services at a partial hospital program. These Services one important to people like me rand I would like to stop the 1570 reimbursement out.

Barbara Ann Harleman

Jam Philip Lavia potherapist of Ms Hardeman's program, and assisted her inwriting this letter. S(NVICES

TRAY BENBY 17AS BEEN SERVICE

BY THIS ONE MIZATALL, PARD THINK THEY

HAVE DONE D NONDLATUL TO B OF HELA
ILLE THOSE IN MECH, IT WOULD BE SHOWE
FUL FUR YOU TO EUT BACK THE SERVICE

US THIS GROUP, PAIN DT ATMS WHEN.

SERVICES LIKE THE V.A. HAS BEEN CUT

ENOCH GIVING THE PRECIL + CORP TAX

LUT'S.

Dan O G.

OFFICE BY THE PEOPLE OF THIS

CREAT MATION

CEWTER FOR MEDICARE
AND MEDICAID SERVICES

2502 HOPE WELL LN

HOUSTON TX

DCTOBER, 6, 2006

Dear Sir,

PATIAL HOSPITALIZATION RESPONCE ON PROPOSED CHANGES

TO THE HOSPITAL OUTPATIEN (PPS-CMS-506-P)

) am a Dapa Getriatric patient

I am a recovery cocaine addict and Schizophrenic.

I appose the 15% reinbursment cut because the

Services I recieve are beneficial to my growth

and recovery.

Willian curtis Barrett

I am Laura Powell CMA
EmployEE OF Mr. Bacretts
program and assisted
him in his letter.

To: Center For Medican and Medical Servicer

From: William Chamber 5620& North Fray. Howton, TX 77076

I am a patient of Dapa PHP and the services that I am receiving is beneficial to my recovery. I would like the 1570 reinburrement reinstated. Os a potrent who has been diagnosed as parawid schizophrenic, manic depressive, and a recovering one are essential to my recovery: recovery.

Dapa provider group, individual and family therapy which allows me to with the took needed to lead a productual life. Without there services, my growth will be stiffed. So with this in mind, please don't discontinue there services which have proven to be exertial to me and others.

Iam Carmen Carter, Theropis Chambers OF William Barrett, I assisted Yourstruly,

Mr. William Chambers him in his letter. Centu for Medicare and Medicade Service.

My nam is Berutta Suckett,

I am a patent at Dapa PHP.

The treatment that a receive

is very important to my

reconsor and mestal stability.

I am asking you to take my

Situation into Consideration

and stop the 15% reinbursment

Cut.

Bernstle Suckett 10-6-06

I am laura POWELL C.M.A

I am on Employer OF

Bernatte luckett

ME Barrett place OF Service

and I assisted him in

his letter.

Order for Medicare and Medicade Services

My name is Mary McElroy.

I am presently recuring Services

from Dapa PH. I Strengly

appose the 15% reinbursment

Cut. The Services o recurrence

are beneficial to my recovery.

Hosing these Services would

be a great loss to me and

hundrens of other people who

despiratly need these Services.

Mory McElroy 10-6.05

Tam Lanca POWEII CMA
EmployEE OF mary MC. E1134
program and I assisted
him in his letter.

To: Center for Medicare and Medicaid Services

From: Charles Butord
14151 Fleetwell Ave.
Howston, TX

Lam apatient of Dapa PHP and the service that I receive are beneficial to my recovery.

I would like the 1590 reinbursement reinstated.

As apatient who has been diagnored with depression and anxiety, all of the service provided to me are exceptial to my growth?

recovery:

Dapa provide group in durch and finity

therapy which equips me to the touts

needed to lead a productive life. Without

there services my growth will be stilled.

So with this is mind, please don't distantinive

there services which have proven to be essential

to me and attens.

Sincerely, Sincerely, Literaprol of Charle Byon 9 assisted him in his Mr. Charles Burard letter

D. tober 6, 2006

Centers for Modicare and Medicaid Services Pept of Health and Human Sorvices

Re: PPS-CMS-1506 P

Lam a therapist at a partial hospital program. The services

provided to our potients is

vital to the potients recovery,

and to the community as a

cost saving measure over other

forms of treatment. Please stop

the proposed 15% rate reduction

for these services so that

we can continue high quality

care for those in need thank

you for your consideration.

Sincerely, Dilip Alamia, LMSW. Program therapist and Team Leader DAPA-Houston, TX