30
OPPS

NT Data
Drugs APC

September 25, 2006

Marjorie (2) Joan
Rebecca (2) Carol
Anita (2) Alberta
Dana (2)

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Attn: CMS 1506-P: CMS proposed Rule on Hospital Outpatient Prospective Payment System and CY2007 Payment Rates

Dear Dr. McClellan:

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

Cytogen Corporation is dedicated to improving the lives of patients with cancer by developing innovative products that target cancer progression. Cytogen provides a diagnostic radiopharmaceutical, ProstaScint® (capromab pendetide), that is the first and only FDA approved product targeting prostate-specific membrane antigen (PSMA), a unique marker that is abundantly expressed on prostate cancer cells at all stages of disease. Prior to ProstaScint, there were no reliable, noninvasive tests to identify metastatic disease in newly diagnosed and recurrent prostate cancer patients.

ProstaScint is a FDA approved kit for the preparation of Indium In111 Capromab Pendetide, a diagnostic imaging agent used by intravenous injection. The use of ProstaScint for early detection of lymph node involvement has potentially significant impact on the management of medical treatment of cancer patients and on the decrease of cost of care. ProstaScint is reported by hospitals using HCPCS A9507 and is been paid separately under the APC system.

CMS proposes to set fixed payment for all radiopharmaceuticals in 2007 after only one year of transition to the charge reduced to cost (CCR) methodology. There is support from a number of sources for CMS to continue CCR including the APC Advisory Panel on August 24, 2006.

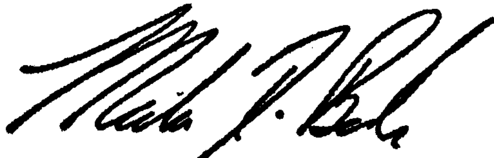
We understand that the APC initiative is to assure that hospitals are appropriately paid for products and services provided to patients. However, when a high cost product such as ProstaScint is utilized by the hospital, an appropriate payment methodology must be established to ensure payment is based upon the cost to prevent severe payment reductions that undermine the hospitals ability to provide these products to patients.

Cytogen supported the 2006 payment methodology change for radiopharmaceuticals to charges reduced to cost because this offered a reliable methodology for providing appropriate payments to hospitals, and permitted CMS to collect more accurate claims data. However, this payment methodology was implemented in 2006 and the claims data utilized for the 2007 proposed payment system is the 2005 claims data. Use of the median payment rate proposed for 2007 fails to reflect the average acquisition cost for ProstaScint and will impose a radical reduction in the payment level, thus limiting patient access to this important diagnostic cancer study. Under the APC payment system, CMS has continued to show concern when radical payment reductions are proposed and has continued to make adjustments to protect hospitals and patients.

Cytogen respectfully recommends that CMS continue the current CCR payment system for ProstaScint in 2007 to ensure that hospitals make this important diagnostic radiopharmaceutical available to patients. CMS should be aware that if the proposed payment rate for 2007 is implemented, hospitals will not be able to make this diagnostic cancer product available to Medicare beneficiaries.

Thank you again for the opportunity and reconsideration of the proposed changes in payment methodology under the 2007 hospital outpatient prospective payment system.

Sincerely,



Michael Becker
President and CEO
Cytogen Corporation
650 College Road East Suite 3100
Princeton, NJ 08540

cc: Carol Bazell, M.D.

Radiation Oncology
Mississippi, P.A.

31
OPPS

NT
Brachy

Gregg A. Dickerson, M.D.
Richard B. Friedman, M.D.
S. Albert Johnson, Jr., M.D.
David A. Wahl, M.D.
Steven E. Zachow, M.D.

September 22, 2006

Marjorie (2)
Barry (2)
Joan
Carol
Alberta

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 am the President of the Mississippi Radiological Society, a Fellow of the American College of Radiology, and a Diplomate of the American Board of Radiology. I practice at St. Dominics / Jackson Memorial Hospital in Jackson, MS.

I appreciate the opportunity to provide comments on the CMS HOPPS proposed rule # CMS-1506-P. I am extremely 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 and the proposed new payment methodology for brachytherapy sources in 2007.

I highly recommend CMS 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	30	$2,508.17	($741.83)	-22.8%
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	-37.0%

Should CMS finalize the proposed APC assignments, 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.

P.O. Box 4997 / Jackson, Mississippi 39296-4997

Treatment Facilities

Central Mississippi Medical Center
Jackson, Mississippi
601-376-2074

Mississippi Baptist Medical Center
Jackson, Mississippi
601-968-1416

St. Dominic Cancer Center
Jackson, Mississippi
601-200-3070

Additionally, our hospital purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with the cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospitals 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.

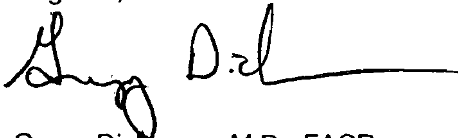
In closing, and as the President of the Mississippi Radiological Society, I recommend:

1. 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.

2. that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

I respectfully request that CMS heed my recommendations. I would like to continue providing this important service to your Medicare beneficiaries.

Regards,



Gregg Dickerson, M.D., FACR

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee
Senator Dianne Feinstein, Ço-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, MPH, Director, Division Outpatient Services
Carolyn Mullen, Deputy Director, Division of Practitioner Services
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation Oncology
W. Robert Lee, MD, President, American Brachytherapy Society

14922 Valley View Drive
Mount Vernon WA 98273

32 OPPS

NT

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

Sept. 10, 2006

Marjorie (2)
Joan
Carol
Alberta

Dear Dr. McClellan,

I understand the CMS is soliciting comments for procedure codes for a new type of surgery- MRgFUS, which uses ultrasound and an MRI to give women an alternative to hysterectomy due to uterine fibroid tumors, the most common cause of hysterectomy (CMS-1506-P).

I had this surgery May 18, 2006 and would like to offer you a patient's perspective. This highly technical procedure required a sophisticated MRI suite so it wasn't cheap but the risk of complications was minimal and I was back to work the day following surgery. There is no incision with MRgFUS and you'd be shocked at the change it made in my health immediately.

Friends who had the alternative procedure, hysterectomy, had far higher initial surgical costs and they missed an average of six weeks work. Complications like infection, blood loss and so on are common. I had surgery on Thursday, and on Saturday morning I opened the largest trade show of my career.

This surgery had two CPT codes created in 2004- 0071T and 0072T, which was a problem because they were part of APCs 195 and 202, for Female Reproductive Procedures which take place in an operating room. In reality, MRgFUS is not a treatment for a reproductive issue but for tumors, which are treated in a very sophisticated MR imaging suite with procedures that are far more complex.

I'm asking that you re-examine the coding and ask the committee to assign codes 0071T and 0072T to APC 127 Stereotactic Radiosurgery on an interim basis or reassign another similar code with a similar payment schedule.

The reality of the situation for women like me is this:

We are forced to choose between a hysterectomy, a radical procedure that costs much more and brings more trauma to body and psyche, and forces 6 weeks off work, or MRgFUS, which is a far gentler high tech solution that takes only a day or two of recovery. Hysterectomy is covered fully by insurance. MRgFUS, because it's new technology, is not yet covered and the level of HOPPS coverage is still uncertain.

MRgFUS costs a hospital about $7500 to $9400. If it doesn't get a code that makes this new technology economically viable, women like me will be forced into a far more extreme solution for their problem.

In my case, I was bleeding to death because of uterine fibroid tumors and could no longer ignore it. I faced a complete hysterectomy which would have meant disaster for the business I own. I was blessed to get treatment as part of an FDA study this May and am now completely healthy again. If you have any questions or would like to talk with someone who has actually had the new surgery, I would love to hear from you.

I appreciate your time, Dr. McClellan.

Thank you,

Sharyn Sowell

14922 Valley View Drive
Mount Vernon WA 98273

Tel. 360-424-5846
Email: sowell@fidalgo.net

Gastrointestinal Associates, P.A.

Diplomats of the American Board of Internal Medicine and Gastroenterology

33

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• FAX (913) 492-2432

KC-GI.COM

October 2, 2006

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

Re: Medicare program: Ambulatory surgical centers PPS proposed rule

Dear Dr. McClellan:

I am a private practice physician who presently treats Medicare beneficiaries in my practice. I am writing to express my grave concern with CMS' recent proposal to change the way the agency pays ambulatory surgical centers for their services, via facility fee payments. This proposal will pay significantly more to a hospital then to an ASC for the same procedure. This would force a significant number of ASCs to close their doors to Medicare beneficiaries, if not to all patients, because Medicare's payment level will drop so precipitously that these ASCs can no longer meet their expenses and render a reasonable return on investment.

With fewer ASCs, a larger proportion of all GI procedures will need to be performed in the hospital, where the facility fees CMS pays will be higher. So, the inevitable result of this proposed CMS action will be: (a) total Medicare costs for GI facility fees will rise, (b) available access by Medicare beneficiaries for GI colonoscopies and other endoscopic procedures will decline, (c) more Medicare beneficiaries will die unnecessarily from colorectal cancer as screening rates decline.

It is hard to believe that these are the results the CMS is seeking, but the only way to avoid this outcome is to modify this proposal so as to increase, not decrease, the facility fees to GI ASCs. This will avoid the closure of GI ASCs, and thus avoid a reduction in access and colorectal cancer screening rates. It will also prevent an increase in the number of GI procedures performed in the more costly hospital setting.

Sincerely,

Jeff L. Young M.D.

Pulse/gm

34

GASTROINTESTINAL SPECIALISTS, P.C.

Gastroenterology, Hepatology and Therapeutic Endoscopy

THOMAS J. ALEXANDER, M.D., F.A.C.P., F.A.C.G.
MICHAEL C. DUFFY, M.D., F.A.C.P., F.A.C.G.
ATULKUMAR S. PATEL, M.D., F.A.C.P., F.A.C.G.
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Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
PO Box 8014

RE: Proposed Rule – Ambulatory Surgery Centers PPS

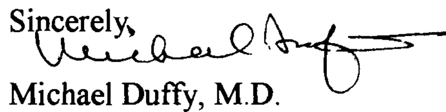
Dear Dr. McClellan:

I am a gastroenterologist who treats Medicare beneficiaries in our private practice and in our ambulatory surgical center. I am writing to vigorously protest the proposed rule change for draconian cuts in ambulatory surgical center payments. Our ASC operates in a cost-efficient manner at a substantial cost savings compared to the same procedures performed in a hospital endoscopy center.

The unintended consequence of this proposal, if implemented, will be to move Medicare patients back to the hospital as we will not be able to offer these same services at a drastically reduced rate in our ASC. This in turn will actually increase the cost to CMS for these procedures.

I would request that this proposed rule be scrapped and a more equitable financial solution found that does not unfairly punish patients and gastroenterologists attempting to provide endoscopic services for them.

Sincerely,



Michael Duffy, M.D.

Naperville Gastroenterology

Stephen Holland, MD, FACP
1828 Bay Scott Circle - Suite 112
Naperville, IL 60540

Tel: 630-357-4463
Fax: 630-357-8325
sholland@napervillegi.com

Mark McClellan, MD
Centers for Medicare and Medicaid Services
HHS
Attention CMS-1500-P
PO Box 8014
Baltimore, MD 21244-8014

5 October 2006

Dear Dr. McClellan:

I am bringing to your attention an error in the calculation of budget neutrality regarding ASC budget portion of the Medicare budget.

Medicare is proposing shifting procedures from hospital settings to ASC settings. Since there will be more procedures done in the ASC setting under this proposal the reimbursement for procedures will be decreased to keep the ASC budget unchanged.

That is an error. The budget that needs to be kept neutral is the combined budget of the hospital and ASC portion.

If the rule were being carried out correctly the hospital reimbursements would need to be increased to stay budget neutral. Thus, if Medicare is going to be budget neutral either the two budgets need to be considered together or Medicare needs to increase reimbursement for hospital services.

Sincerely,

Stephen Holland, M.D.

36

1 October 2006

To: Mark McClellan, MD
Department of Health and Human Resources

From: Robert T. Barbour

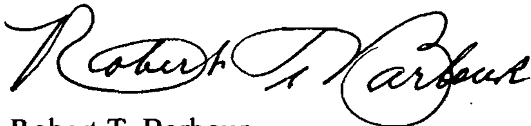
Re: CMS-1506-P and CMS-1512_PN

Recently I have been reading about the proposed changes that your department is considering for the reimbursements to Ambulatory Surgery Centers. If the proposed changes are executed, there is a perception that many of these centers will not be able to maintain an adequate level of profitability.

As a senior citizen, I have no financial or personal interest in any of these Centers but I do worry that if many of these centers disappear, we (senior citizens) will be compelled to go to a hospital for these procedures that are presently performed at these Centers. As we all know, the incidence of risk of contracting a serious and sometimes fatal infection rises almost exponentially when one goes to a hospital for a procedure.

Ignoring the pain and suffering of the patient, the increased cost to Medicare/Medicaid for the additional care required to cure this contracted disease would seem to offset any proposed initial savings.

I do hope that there will be sufficient due diligence given to this matter before a final decision is made that might reduce the availability of these relatively *'risk free'* facilities.



Robert T. Barbour
PO Box 306
Sewickley, Pa. 15143

37

September 29, 2006

Mark McClellan, M.D.
CMS – Dept HHS
Attn: CMS-1506-P and CMS-1512-PN
P.O. Box 8014
Baltimore, Maryland 21244

Dear Dr. McClellan,

I am at a loss to understand why CMS is proposing to change the payment plan for ambulatory surgery centers. By paying them less for procedures than you do the hospitals, you will surely force them out of the business and people like me will be forced to go to the hospital. Certainly you understand hospitals are usually in urban crowded areas with difficult parking and general confusion. And that doesn't even consider the germs!

If you are trying to cut costs, go for efficiency and keep the current program.

Thank you,

Carol Moritz
1815 Ardmore Blvd.
Pittsburgh, Pa 15221

38

October 3, 2006

Mark McClellan, MD
CMS – Dept HHS
Attention: CMS-1506 and CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dr. Dr. McClellan:

I have recently been made aware of the CMS proposal to reduce the Medicare fee schedule and change the payment structure for facility fees at ambulatory surgery centers. The freestanding centers are an example of what is RIGHT with the medical system and I am concerned that changing the ambulatory surgery rules will seriously jeopardize their existence.

I strongly encourage you to reject the CMS proposed changes to the ambulatory surgery rules in support of the freestanding centers. As a patient, I feel much more relaxed and "safe" in that environment. As a taxpayer, I would like to see support for a system that is successfully working – the freestanding centers.

Thank you for your time and attention to this matter.

Sincerely,

Mary Christiana
3338 S. Parkside Dr.
New Castle, Pa. 16105

marychris2@verizon.net

39

asrt
American Society of
Radiologic Technologists

October 2, 2006

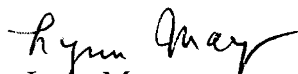
Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore MD 21244-8018

Dear Dr. McClellan:

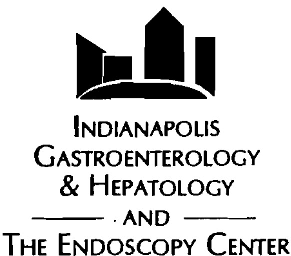
The American Society of Radiologic Technologists supports the proposed calendar year (CY'07) Hospital Outpatient Prospective Payment System (OPPS) payment rates for proton beam therapy proposed by the Centers for Medicare and Medicaid Services (CMS).

We are concerned, however, the way that contracted carriers have addressed reimbursement for free-standing proton therapy centers and urge CMS to work with its carriers to ensure that these rates are in keeping with the rates paid to hospital outpatient departments.

Sincerely,



Lynn May
Chief Executive Officer
American Society of Radiologic Technologists
15000 Central Avenue, SE
Albuquerque, Nm 87123



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E. David Brown, M.D.
Frank P. Troiano, M.D.
David C. Pound, M.D.
James A. Jacob, M.D.
J. Scott Buckley, M.D.
G. Todd Lemmel, M.D.
A. Thompson Colley, M.D.
Brian G. Sperl, M.D.
Michael S. Morelli, M.D.
Ruth L.M. Mokeba, M.D.
Paul K. Haynes, M.D.
Ernest J. Orinion M.D.
Linda Ritchison, MSN, RN/C
Martin Bielawski, RN, CS, ANP

PRACITICE SITES

Community Hospital South
Johnson Memorial Hospital
Major Hospital
Saint Francis Beech Grove
Saint Francis Indianapolis Campus
Saint Francis Mooresville

September 25, 2006

ASC8

40-0

ASC8

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

Dana (2)
Joan
Carol
Alberta

Dear Dr. McClellan:

I am writing this letter regarding the proposed cuts to physicians and Ambulatory Surgery Centers (ASC) by CMS.

- Docket Nos. CMS-1506-P (Ambulatory Surgery Center Rules)
- Docket Nos. CMS-1512-PN (Physician Fee Rules)

I know you are tired of hearing about this but someone needs to stand up and fight for the physicians of this country. The insurance companies are destroying health care and our hands are tied. It is sad when medicine is more highly regulated than gaming in this country. We have no way to fight the constant cuts in our fees against big monopolies like Anthem/Wellpoint, Aetna, United, and CMS.

Nothing costs less today than it did ten years ago, yet we are paid less. Just like everyone else in this great country the cost of food, electricity, and transportation have all risen and so have our costs such as rent, staff salaries and equipment costs. Add to this the additional personnel necessary to deal with the constant hassles of the commercial carriers which further increase the cost to physician practices.

We keep thinking it can't get any worse and then CMS proposes a 5.1% decrease in fees for 2007 for physicians and anywhere from a 15% to 35% cut in facility fees for Ambulatory Surgery Centers in 2008. And it doesn't stop there, because commercial insurance carriers follow suit using Medicare methodology and cut their fees also. It is a vicious cycle. We built our Endoscopy Center 11 years ago because of the bureaucracy of the hospital systems and the inefficiencies we and our patients deal with on a daily basis, yet the hospitals charge at least twice what we do and are reimbursed at a <u>much</u> higher rate. Commercial carriers are starting to realize this inequity and are encouraging their members to use ASC's. We are already paid at a much lower rate than hospitals for an outpatient procedure by commercial carriers. Why are you looking at penalizing us more?

What the federal government pays for services and procedures provided by gastroenterologists has progressively gone down—Medicare payments for many services have already dropped 50% or more. How much longer can we continue to participate in the Medicare program?

I am concerned about where health care is going in this country. It is not the physician who dictates medical care, but the insurance carrier.

If cuts continue, ASC's will have to close, throwing life saving GI procedures to be performed in the HOPD, <u>where the facility fees CMS pays will be higher</u>. Along with this, physicians will opt out of Medicare or close their doors leaving the growing Medicare population without medical providers.

Sincerely,

G. Todd Lemmel, MD

Visit our website at

www.indygastro.com

Accredited by
Accreditation Association for Ambulatory Health Care, Inc.

41

Suite 210, Urology
- Jack H. Philbrick Jr., M.D.
- John C. Russell, M.D.
- Lester P. Wong, M.D.

Suite 230, General Surgery
Surgery - Oncology
- Douglas R. King, M.D., FACS
- Robert E. Marsh, M.D.
- Kenneth A. Feucht, M.D., FACS

Urology
- Ivan R. Zbaraschuk, M.D.
2709 East Main, Puyallup, WA 98371

October 03, 2006

Centers for Medicare and Medicaid Services
Department of Health & Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

Attention CMS-4125-P

To Whom It May Concern:

I am writing to comment on the proposed revised ambulatory surgery payment system apparently under consideration by CMS. It is my understanding that the revised payment system would reimburse ambulatory surgery centers at 62% of the hospital outpatient department rate. I also understand that ambulatory surgery centers would not receive the annual payment rate updates that hospitals are to receive. My partners and I currently own and operate an ambulatory surgery center as part of our office practice. We are able to deliver high quality, efficient surgical care to our patients. If our reimbursement is decreased as proposed, it may be difficult for us to remain in business. We are doing over 100 anesthesia cases a month in our surgery center. Operating room time at our hospital is already difficult to schedule. If our 100 cases per month return to the hospital, our surgery schedule would be significantly disrupted. The inconvenience to the patients and the physicians would be immense.

In the current healthcare environment, it seems to me to be foolish to threaten the existence of highly efficient and cost-effective entities such as freestanding surgery centers. The return of our outpatient surgery center's cases to the hospital would undoubtedly result in more expensive medical care. On top of this, physicians have suffered substantial decreases in reimbursement in the last 15 years. Our ability to generate income from business ventures such as surgery centers has allowed us to keep our practices open and to continue to accept Medicare patients. A business model involving increasing expenses and decreasing reimbursement is simply nonviable. I would like to ask that you reconsider the current proposed rules concerning ambulatory surgery center reimbursement.

1519 THIRD STREET SE, SUITE 210 ■ PUYALLUP, WA 98372 ■ 253.840.4994
A DIVISION OF
UROLOGIC CONSULTANTS, PLLC

I would ask instead that we be reimbursed on an equitable basis with hospitals and subjected to the same rules concerning payment adjustments, wage index adjustments, and add-on expenses such as medical devices and implants. I would be happy to speak to you in person concerning these issues.

Please feel free to call me.

Sincerely,

John Russell, M.D.

MEDICAL DIAGNOSTIC ASSOCIATES, P.A.
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October 2, 2006

Mark Barr McClellan, M.D.
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS - 1506 - T
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

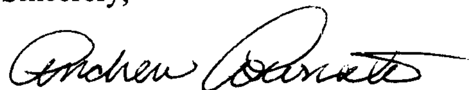
I am board-certified gastroenterologist in the private practice of medicine in Westfield, New Jersey. I am a participating Medicare provider and I am part owner in a single specialty gastroenterology ambulatory surgery center in Mountainside, New Jersey. This ambulatory surgery center also participates with Medicare. Last year, we preformed approximately 2400 endoscopic procedures on Medicare recipients. This is a high profile,extremely desirable facility for patients to have access to gastrointestinal endoscopy. It is often the requested location by Medicare patients who are scheduled to have gastrointestinal endoscopy.

At the current rate of reimbursement, which is 89% of what is paid to hospital outpatient departments, we realize a profit of approximately $50 per procedure. My understanding is that this current reimbursement will be cut from 89% to 62% of what is currently paid to hospital outpatient departments. That means that we will be reimbursed an amount, which is less than our current cost of performing a procedure. As such, we will be forced to close our center to all Medicare recipients. These patients will all then be done at our neighboring hospital at an increased cost to Medicare. In addition, patients have come to appreciate the advantages of having these procedures done in an out of hospital setting. Moving all of these patients out of the ambulatory surgery center and into the hospital will adversely affect patient compliance for screening colonoscopy. All of these factors will ultimately increase the cost to Medicare.

GASTROENTEROLOGY
ANDREW CORONATO, M.D., F.A.C.P., F.A.C.G.
PAUL K. LERER, M.D.

When Medicare decided to decrease the reimbursement to ambulatory surgery centers, a study should have been done to determine what the actual cost of performing this procedure is in an ambulatory surgery center. Had this been done, you would have realized the unreasonableness of decreasing reimbursement from 89% to 62% of what is paid in hospitals. Medicare is currently realizing significant savings, which will be lost when all these patients are shifted back to the hospital setting. I ask you to reconsider this drastic reduction.

Sincerely,



A. Coronato, M.D., F.A.C.P., F.A.C.G.

AC/bba

cc: Congressman Michael Ferguson

43

Jimmy J. Morrison, MD, FACP
Arkansas Gastorenterology Consultants
813 Linwood Drive
Paragould, AR 72450

October 3, 2006

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

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan,

I am a practicing gastroenterologist. I treat Medicare beneficiaries in my practice. In fact, a majority of our current patients are Medicare patients. I am writing you to express my grave concern over the impact the above referenced proposed rule will have on the services available to Medicare patients. In particular, the proposal to reduce the fees paid to ambulatory surgery centers for provision of services, especially colonoscopy, appears likely to reduce the availability of needed medical services to Medicare recipients, while simultaneously increasing the per-endoscopy cost to Medicare. Surely this cannot be your intent.

Let me say at the outset that I do not own any interest in any ASC.

Treatment for a substantial portion of our patients includes colonoscopy. This diagnostic and therapeutic procedure reduces morbidity and mortality from colorectal cancer in average and high-risk individuals. In 1997 and again in 2000 measures congress passed to make these procedures more widely available to Medicare patients. The reductions proposed in this rule will have the effect of reversing the availability of services that congress intended when it passed the aforementioned measures.

Other endoscopic modalities are also known to be cost effective and life saving, such as surveillance for Barrett's esophagus and intervention in gastrointestinal hemorrhage. The list is extensive, and I am sure you are familiar with the health benefits of endoscopy when performed by an appropriately trained gastroenterologist.

The health of these patients depends upon access to these endoscopic services. Both the GAO and CMS have stated that colon cancer screening is underutilized. This rule will do nothing to remedy this problem, and will likely worsen this it.

It is clear from the medical literature that in excess of 90% of colorectal cancer can be prevented, and at a cost that is a fraction of the cost of treating colorectal cancers when they are not prevented. That cost savings does not account for the many shattered lives that colon cancers leave in their wake in the US each year. This proposed rule would potentially exacerbate this problem.

MEDPAC has repeatedly endorsed the concept ***that medical procedures and services should be site neutral – this is apparent at the most basic level of common sense.*** This proposal, which institutionalizes higher payment for hospitals as opposed to ambulatory surgical facilities and office based-procedures, will increase the cost per procedure by shunting endoscopies to hospital labs when ambulatory centers are forced to limit access to Medicare patients. ***But beyond that, it is patently unfair and un-American to pay an office or ASC less for the SAME SERVICE.*** Ultimately, the overall capacity to provide life saving and cost saving services to Medicare patients will be further diminished. Cost per procedure will increase. Lives will be cut short unnecessarily. The only obvious reason for making this sort of change unilaterally to ASC's and not including hospitals is that you are being influenced politically.

In my own practice, we have been forced to limit new Medicare patients entering our practice, largely due to the continued stream of fee reductions to endoscopy, particularly colonoscopy. We no longer offer office endoscopy for Medicare patients. Only those with private insurance are reimbursed in a way that allows us to provide these services in our office. Further cuts in reimbursement will have unfortunate consequences for Medicare patients.

This measure will have a grave effect on the way Medicare patients are treated.

These are substantial fee reductions, and may well lead to closure of ambulatory facilities, further limiting access for patients, and shunting patients to more expensive hospital facilities. This seems imprudent on your part.

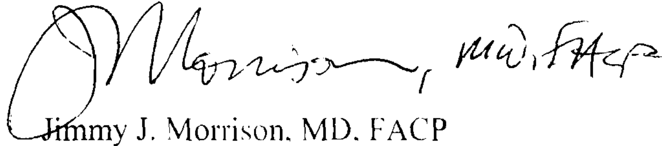
ASC's and office endoscopy are more cost effective than hospital-based endoscopy labs. Ultimately, this proposed rule will increase the average cost of endoscopic procedures provided for Medicare recipients by forcing labs to turn away Medicare patients, and perhaps by forcing closure of ASC's who cannot operate at such a narrow margin. Private insurers in some areas are actually giving financial incentives to physicians to use ASC's, noting the remarkable savings compared to hospital-based labs. You would do well to take advantage of their insight.

If numerous other procedures are to be covered in the ASC setting, as I understand to be the case, "budget neutrality" must take this into account by adding funds to cover these procedures, rather than by removing funding for other essential services, such as colonoscopy.

The end result of implementing the proposed rule will be increased morbidity and mortality from colorectal cancer and other gastrointestinal diseases, and an increase in the

cost per case for gastrointestinal endoscopy. This action will essentially negate the progress gained in patient care by the Medicare colorectal cancer screening benefits passed in 1997 and 2000. Gastroenterologists' reimbursement for colonoscopy has already been effectively cut 40-50% over the past few years. Please do not institute this foolhardy measure, which will ultimately hurt our patients.

Thank you for your consideration,



Jimmy J. Morrison, MD, FACP

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Pasadena Endoscopy Center
55 W Valley Street
Pasadena CA 91105
626 793-9900

October 2 2006

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

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule (CMS 1506-P)

RE: CMS proposed rule to change Ambulatory Surgery Center (ASC) payments
October 1 2006

We are a group of 10 full-time practicing gastroenterologists in Pasadena, and we are writing to express deep concern over Medicare's proposed rule to change the payment system for ambulatory surgery centers (ASC) (CMS 1506-P).

We represent two independent groups of practicing physicians, who joined together as one entity to develop and now run the Pasadena Endoscopy Center, a single-specialty facility, opened in 2002, which now provides over 8, 000 endoscopy procedures yearly to regional citizens; about 75% of these are screening related to colon cancer. As awareness of colorectal cancer screening grew, the demand for these services outstripped the ability of our regional medical center, Huntington Hospital, to provide us time and facilities to efficiently care for our patients. The Pasadena Endoscopy Center offers a very cost-efficient, patient-friendly high quality facility (certified by a national credentialing agency with the highest rating available--AAAHC). Approximately 2/3 of our patients are Medicare patients, whether FFS or through managed care programs. We developed and continue to run the center at a significant economic risk to ourselves, and only through a substantial amount of physician time and work by our associates. We are proud of what we have accomplished, but greatly fear the impact of the CMS proposal.

The CMS proposal will clearly affect our entire business. Consider that most private and managed care contracts are negotiated on a basis of "percent of medicare" fee schedule; consider that we cannot run a center efficiently with a group of highly skilled specialty trained RNs and technical staff if we can only run a half-time operation. Thus if we cannot provide services to Medicare, we NO DOUBT will have to close our center.

If the proposal by CMS goes through as published, we will be forced to either shut down altogether in 2008, or at least send 1/3 of our patients back to the over-stretched outpatient facilities at Huntington Hospital. Instead of paying our center about 85% of what medicare now pays for hospital outpatient services, Medicare will then pay 15%

MORE than it pays now, IF we can manage to get the time and procedure facility to provide the service. For example, our center is 30% more efficient in procedures per day than the hospital department can be. We cannot schedule procedures in as efficient a manner at the hospital as in our center, and the result will be great delays for our patients in obtaining their services. Another 1/3 of our patients will likewise be required to have procedures (not just colon cancer screening) at the hospital outpatient facility if we cannot renegotiate contracts with managed care plans to dis-connect our fees from the revised ASC payment scheme.

Medicare is proposing to reduce its ASC payment for endoscopy more than 25% by 2008 (from approximately 85% of the Hospital Outpatient rate to 62%; and the proposal by no means assures any appropriate inflation adjustments). The rates Medicare is suggesting are below our costs (we've reviewed the actual financial figures in details!) of performing these endoscopic procedures, including screening for cancer. Our center will lose money on every Medicare patient that comes to our ASC. By instead forcing our patients to have their procedures at the hospital, it will also cost our patients more in out of pocket expenses. For example, we see bills from the hospital of $3000 for colonoscopy services, and copayments may amount to 1/3 of this amount, compared to approximately $120 if they come to our center for the same procedure

This is unfair to our patients and a needless expense for Medicare. Medicare says that it has to set rates this low because Congress requires that the new payment system be budget neutral and many new procedures are going to be added to the ASC list of covered services in 2008. In order to pay for these new services, reimbursement for endoscopy and many other surgical procedures will have to be cut.

The ASC is a safe, economic site for these services and is very popular with our elderly patients because of its convenience. It would be a disservice to these beneficiaries to adopt Medicare's proposal.

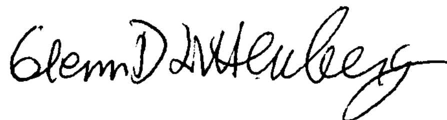
Either CMS or Congress needs to change its instructions on budget neutrality to avoid this result. We know we can continue to provide services to Medicare patients in the ASC and save Medicare money if the reimbursement rules make sense. This proposal, however, does not pass that test. Furthermore, we have no reason to believe our situation in Pasadena is unique. We have spoken with our counterparts in all geographic regions in the country, those in multi-specialty ASCs, those who perform office based endoscopy, and those who primarily utilize HOPDs; all are alarmed by the impact of the CMS proposal.

Several changes in the proposal would go a long way to remedy the problem:

--make the budget neutrality adjustment applicable across ALL ambulatory surgery procedures, not just within the group of ASC-based procedures. This may well take legislative action and may not be within ability of CMS to change itself
--Allow an expanded group of procedures to be performed at ASCs which are now required to be performed in hospital outpatient facilities, but do NOT allow what are currently office-based procedures to shift to ASCs. The latter will markedly distort the incentives to keep procedures where they are most cost efficient, and the impact of this shift would be extremely hard to calculate, thus result in inevitable inappropriate excessive cuts in ASC payments
--There must be a bi-level or multi-level of payments, if payment is to be based on a percentage of HOPD (hospital outpatient department). Specialties like GI and pain medicine would be affected as noted above; other specialties like orthopedics and urology now receive a much lower percent of HOPD for ASC services, and will have either positive or minimally negative impact of the proposed change. One size does NOT fit all!
--Transition any change over 4 years, not 2 years, which is consistent with how CMS has implemented any major fee schedule changes for hospitals, physicians and other providers.

Thank you for your careful consideration of this request. I urge you to substantially rework the proposal in order to still comply with legislative requirements to overhaul the ASC payment scheme by 2008, but to do so such that Medicare beneficiaries will continue to have access to high quality, timely and cost-efficient gastroenterology services.

Sincerely,



Gastroenterology Associates
Glenn D Littenberg MD, FACP
Steven J Petit MD
Casey S Fu, MD, PhD
Waleed Shindy, MD, MPH

Alliance Gastroenterology Consultants
Sergio Stubrin MD, Medical Director, Pasadena Endoscopy Center
Kalman Edelman MD
Richard Nickowitz MD
Sassan Soltani MD
Ihab Beblawi MD
Peter Rosenberg MD

Versions also sent via email to:
http://feinstein.senate.gov/email.html

http://www.boxer.senate.gov/contact/email/policy.cfm + congressmen for all of us

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(2)

October 5, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC and CMS-1325-F
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

2006 OCT 11 PM 1:48

Re: 42 CFR Parts 410, 414, et al. Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

I am very concerned about certain provisions in the proposed Hospital Outpatient Prospective Payment System (OPPS) rule published Aug. 23, 2006. Fully 18 percent of our practice's patients are covered by Medicare. This proposed rule makes several changes to payment for procedures performed in ambulatory surgery centers (ASCs) that would harm the ability of ASCs to safely and efficiently deliver services to Medicare patients.

ASC Payable Procedures
I disagree with CMS' decision to exclude procedures from receiving an ASC facility fee if the CY 2005 Part B Extract Summary System data indicated that the procedures were performed in a hospital inpatient setting 80 percent or more of the time. This proposal includes procedures that are not listed on the OPPS inpatient list; it excludes procedures that may be performed in an outpatient setting up to 20 percent of the time. This arbitrary distinction does not adequately reflect procedures that may safely be performed in an ASC.

ASC Wage Index
I understand that CMS is proposing to apply the Inpatient Prospective Payment System (IPPS) pre-reclassification wage index values to adjust the national ASC payment rates for geographic wage differences. As CMS admits in its proposed rule, the agency is relying on 12-year-old data to determine the appropriate labor adjustment factor [71 Fed. Reg. 49,506, 49,655 (Aug. 23, 2006)]. To accurately measure ASC costs, CMS must collect new data on the costs of delivering services in an ASC. In addition, CMS has not yet published regulations to explain how this proposal will be implemented.

ASC Inflation
I am also concerned about the proposal to use the Consumer Price Index for All Urban Consumers (CPI-U) to calculate annual updates to the ASC conversion factor for inflation. As you know, the OPPS rates are measured against a "market basket" of items that hospitals use in practice. When the price of those items increases, the payment rate increases. The CPI-U does not specifically measure the cost of items used in the medical profession. Rather, the CPI-U measures the cost of consumer goods and is not tied to the highly inflationary nature of operating a health care facility.

The Medical Group Management Association (MGMA), of which I am a member, has conducted extensive surveys of ASC costs. MGMA data indicate that the cost of operating an ASC rose by an average 10 percent between 2004 and 2005. If Medicare reimbursement rates continue to fall far short of the increased cost of delivering quality services to Medicare patients, providers will face difficult decisions as they evaluate the economic feasibility of caring for Medicare beneficiaries. Medical practices' fiscal viability is further undermined by the widespread use of the Medicare reimbursement rate as a benchmark for private insurance reimbursement rates.

I strongly urge CMS to base the annual updates of the ambulatory payment classification conversion factor to the market-basket method used for hospitals. Alternatively, the agency could develop another method that would more closely approximate the rising cost of operating an ASC.

ASC Phase-In
CMS has proposed to phase in the new ASC payment system over two years. This does not give ASCs enough time to adjust to the revised payment rates. A four-year phase-in would allow a more gradual, less disruptive transition to the new system. Therefore, I strongly urge CMS to extend the phase-in period to four years.

ASC Conversion Factor
Finally, I disagree with CMS' use of a 62 percent budget-neutrality adjustment to calculate the ASC conversion factor. This calculation is based on unfounded assumptions and does not reflect the actual cost of providing services to Medicare beneficiaries in an ASC. CMS must establish ASC payment rates that more accurately reflect the cost of operating these facilities and that are not bound by Congress' recommended 62 percent adjustment.

I appreciate your consideration of these comments. It is very important that CMS understand the impact of the proposed rule on ASCs. If you have any questions or would like to discuss these matters further, please feel free to call MGMA's Amy Nordeng at 202.293.3450.

Sincerely,

Randy Huffman
Administrator