Stephen Moore, M.D.
Charles E. Allen, M.D.
Scott A. Clark, M.D.
Sheraj Jacob, M.D.
Jessica E. Collins, PA-C
Nickola F. Booker, PA-C

Gastroenterology Associates of Gainesville, P.C.

1-0
(2)

Diplomates of
American Board of
Internal Medicine and
Gastroenterology

August 9, 2006

Mark McClellan, M. D.
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

Dear Dr. McClellan:

I am a private 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 surgery centers for their services, via facility fee payments.

To be brief, if the new proposal is enacted as proposed, I plan to stop performing any endoscopic procedures on Medicare patients in our ASC. All Medicare patients would have their procedures done at the hospital at an increased cost to the patient and to Medicare. I also plan to reconsider my participation in the Medicare program. Continued cuts in reimbursement over the past few years have finally reached an intolerable level.

Respectfully yours,

Stephen Moore, M. D.

SM/jk

663 Lanier Park Drive • Gainesville, Georgia 30501-2059 • Telephone 770-536-8109 • Fax 770-536-3203

2-0
(1253)
ASC'8

GI of Norman, LLC

*Philip C. Bird, M.D. * Steve K. Arora, M.D. * Chintan A. Parikh, M.D. * Andrew W. Black, M.D.*
1125 N. Porter, Ste. 301
Norman, OK 73071
(405) 360-2777
Fax (405) 360-2780

Dana (2)
Joan
Carol
Alberta

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

Re: Medicare Program: Ambulatory Surgery 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's recent proposal to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments.

In my practice, we see a large number of Medicare patients. Treatment for a substantial percentage of these patients includes performing screening colonoscopies for those who are at average risk for colorectal cancer, as well as colonoscopies for high risk individuals and surveillance colonoscopies for those who have already been detected as having either polyps, or who have had cancerous lesions excised previously. Additionally we see a very significant number of patients with other conditions—GI bleeding, inflammatory bowel disease, gastroesophageal reflux disease (GERD), and/or Barrett's esophagus for whom ready access to an appropriate, safe, cost-efficient site for GI endoscopy is critical to either restoring them to good health, or sustaining them in good health.

Both the GAO and CMS itself have stated that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC has repeatedly endorsed the concept that medical procedures and services should be site neutral. So, on its face, a proposal such as this one, which institutionalizes the concept of paying significantly more to the hospital than to the ASC, and which will likely reduce the capacity to provide GI screening colonoscopies and other GI endoscopic procedures by forcing 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, seems foolish and counterproductive.

Medicare seems to be ignoring both the stated priorities of the current Administration as well as the lessons of cost management in the private sector. President Bush and his staff

are on record, on multiple occasions, stating that ASCs are a more cost-effective environment than the hospital to receive key medical services. When private sector insurers have sought to reduce total health care costs, they have actively sought to encourage patients to receive their services in the ambulatory surgery center, instead of in the hospital outpatient department. In a recent example, Blue Cross of California has announced that it will pay a 5% premium to physicians for every GI endoscopy that is performed in the ASC, rather than in the HOPD. This CMS proposal, which would always pay more to HOPDs and always pay less to ASCs, is directly antithetical to the direction adopted by the private sector insurers.

The agency's concept of budget neutrality in this proposal is incorrect, unfair and shortsighted, for multiple reasons. First and foremost, the agency proposes to increase markedly the number of procedures, from a variety of different specialties, that are performed in the ambulatory surgery center. By raising, markedly, the reimbursement for vascular, orthopedic and urologic services, much larger numbers of these services will be performed in ASCs. But in computing budget neutrality, CMS appears to believe that exactly the same pool of dollars should cover in full the payment, even if, because of expansion of the ASC approved list, millions of procedures that once were performed in the HOPD are now reimbursed under the ASC payment policy. Congress could never have intended that CMS would secure twice as many services for the same number of dollars. Every new service that is added to the ASC list, under this interpretation, forces the facility fee payment for a GI endoscopy performed in an ASC that much lower. This approach is unfair, nonsensical and bad health policy.

The reality is that for every single case that moves from the HOPD to the ASC under this expansion of the ASC approved list, the Medicare program will save money. This is so because at the current rates, ASC payments are always lower than, or at least never greater than the facility fee that CMS pays to HOPDs. Again, if the pool of dollars for ASC payments were fixed despite a large increase in the number of cases done in the ASC (because of expansions to the ASC list), then the pool of dollars paid out to HOPDs will decline, because fewer cases are likely to be done there. So, the only accurate approach to budget neutrality is to consider the impact on the total pool of BOTH ASC facility fee payments and HOPD facility fee payments. In summary, the agency currently has budget neutrality completely wrong—(1) you cannot expect the same pool of funds to cover all costs when the expansion of the ASC approved list will likely result in millions of additional cases moving to the ASC; and (2) CMS must take into account, and not ignore, the savings that are generated in HOPD payments because many cases will likely move from HOPD to the ASC setting.

In the gastroenterology area, CMS's proposed policy virtually assures results inimical to the public health. Today, when a GI procedure, such as a screening colonoscopy is performed in an ASC, that ASC receives a facility fee which on the average amounts to 89% of the facility fee CMS pays to the HOPD if that same procedure is performed there. We need to provide a bit of background relating to the effectiveness of the Medicare colorectal cancer screening benefit. Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the

average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has done everything possible to emasculate the effectiveness and utilization of that benefit. Since 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction would almost certainly be in excess of 50%). According to information from the American College of Gastroenterology, no other Medicare service has been cut this much. Now, CMS issues a new proposal which would further undercut and devastate the prospects for Medicare beneficiaries to receive a colorectal cancer screening colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS foolishly has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs, as by far the biggest potential loser, with the prospect of cuts from 89% of the HOPD payment to 62%.

If CMS is bound to peg ASC payments at a percentage of HOPD, it must adopt a bi-level approach, with ASCs in groups like GI and pain management at a higher tier of payment that is at or higher than the current 89% we now receive, and then a second, lower tier as the facility fee percentage for ASCs in other specialties, which are not involved in life-saving preventive services like colorectal cancer screening tests.

It is clear what will happen if this CMS proposal is adopted in anything close to its current form:

For Patients:

Utilization of the Medicare colorectal cancer screening benefit, already anemic, will be further devastated—the collision of false payment "savings" vs. sound preventive public health policy will be dramatic. Utilization of CRC screening will decline still further, cancers will go undetected, and in life and death terms, many Medicare beneficiaries will die unnecessarily because the access to sites where colonoscopies can be performed will be reduced as GI ASCs close, waiting times for screening will increase, and the overall rate of CRC screening will plummet farther.

For the Medicare System:

Medicare facility fee payments for GI services will increase, rather than decrease. Having dealt a death-blow to many GI ASCs by draconian reductions in payment, the access of Medicare beneficiaries to GI ASCs will be markedly reduced. CRC screening colonoscopies will be reduced, but the volume of diagnostic colonoscopies and endoscopies will not decline.

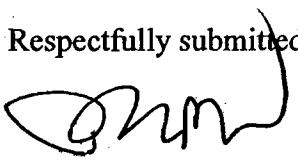
With fewer ASCs, a larger proportion of all GI procedures will need to be performed in the HOPD, where the facility fees CMS pays will be higher.

So, the inevitable result of this proposed CMS action, if implemented will be: (a) total Medicare costs for GI facility fees will rise (although the per unit facility fee for

decreased number of these performed in the ASC may well decline); (b) available access by Medicare beneficiaries for GI colonoscopies and other endoscopic procedures will decline; and (c) more Medicare beneficiaries will die unnecessarily from colorectal cancer will increase 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 CRC screening rates. It will also prevent an increase in the number of GI procedures performed in the more costly HOPD setting.

Respectfully submitted,



Philip C. Bird, M.D.

PCB/cmj

3

GASTROENTEROLOGY INTERNAL MEDICINE

KENNETH T. ROOST, M.D., INC.
1828 EL CAMINO REAL #604
BURLINGAME, CALIF. 94010
(650) 697 - 9146; Fax (650) 697 - 5514

August 24, 2006

Mark McClellan, M.D.
Center for Medicare and Medicaid services
Department of Health and Human Services
attention: CMSs -- 1506 -- P
P.O. Box 8014
Baltimore, Maryland 21244 – 8014

Dear McClellan,

I'm a gastroenterologist in private practice in the treatment of Medicare patient. I am very concerned with CMS recent proposed changes in payment for ambulatory surgical centers.

My patients and I find ambulatory surgical care centers provide better care for outpatient colonoscopy. I am worried that reduced payments will make reduced availability and thus hurt the health of a community.

I understand that private insurance companies are making deliberate efforts to encourage the use of ambulatory surgical centers. Further, I believe that reimbursement rates for Medicare are already unfavorable.

Please reconsider any policy changes that may adversely affect my patients' access to ACS(ambulatory surgical centers).

Sincerely Yours,

Kenneth T. Roost, M.D.

2222 53rd Avenue
Bettendorf, Iowa 52722

Gastroenterology
Associates P.C.
at
Center for Digestive Health

(563) 383-2686
FAX: (563) 383-2572

4-0
C.I.O.D
ASCs 08

Dana (2)
Joan
Carol
Alberta

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1512-PN & CMS-1321-PN
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Medicare Program: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

To Whom It May Concern:

I have reviewed CMS' proposed rule relating to the five-year review of work relative value units, as published in the Federal Register dated June 29, 2006. I wish to take the opportunity to provide my comments to the agency on this proposal.

I am practicing gastrointestinal specialist, involved in the treatment of patients, including performing colonoscopies for colorectal cancer screening, as well as treatment of patients with indications for any of a myriad of different GI disorders.

1. Action Relating to Recommendation of the RUC Relating to Gastrointestinal Services Reviewed

In general, we applaud the agency for adopting the recommendations of the RUC with respect to retaining the identical work RVUs for the major GI codes. This has not always been the case, and we have objected in prior years when the agency decided not to follow the RUC recommendations.

That having been said, it is nonetheless clear that the RVUs assigned to GI colonoscopies and other procedures are not nearly high enough. Since the Medicare colorectal cancer screening benefit was enacted in 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction would almost certainly be in excess of 50%). No other Medicare service has been cut this much since Congress decided to make the eradication of colorectal cancer a national priority by encouraging every Medicare beneficiary over the age of 50 to receive screening.

Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has consistently emasculated the effectiveness and utilization of that benefit, by relentless and devastating cuts. When one looks at the bottom line on this proposal, it is clear that this disastrous trend would continue with major new cuts. We will address later the agency's proposal for a 10% across-the-board cut in work RVUs in the name of budget neutrality. At this point, we must simply say that—to the extent that increases in RVUs for cognitive and other services necessitate a decrease in the GI work RVUs, and therefore discount the RVUs which the RUC said should remain unchanged, we oppose those increases. And to the extent that CMS's concept of budget neutrality demands a 10% across-the-board cut in the payment for services, we believe the interpretation of budget neutrality adopted by the agency is incorrect and the result patently unfair.

Budget Neutrality

CMS argues in this proposal and elsewhere that: (1) the SGR will automatically cut the reimbursement for all Medicare services by somewhere around 5% next year; (2) the budget neutrality under the 5-year review necessitates an additional 10% across-the-board cut in the work RVUs for all Medicare services, including life-saving colorectal cancer screening colonoscopies; and (3) proposes to cut precipitously the facilty fees paid for cases performed in ambulatory surgery centers. This cumulatively would result in cuts of at least

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15%, and when the new ASC payment reform policy is factored in, one-year cuts could be 30% or more. Basic economics demonstrates that no business/sector in the economy can endure the type of budget neutrality driven proposal being pursued by CMS, to cut all work RVUs by an additional 10% and still continue to function anywhere close to normally. The cumulative effect of these three CMS proposals, and specifically the 10% budget neutrality adjustment is to force physicians to limit access to Medicare beneficiaries or force them out of business altogether. This 10% across-the-board cut is wrong, and cannot stand. The alternative suggested by CMS of a roughly 5% cut to the conversion factor is equally unacceptable. At this point, CMS and the government have simply extracted too much money out of the system already; further cuts of the magnitude suggested will cause the system to collapse. My practice cannot continue to screen Medicare beneficiaries for colorectal cancer screening on the same basis and timetable as private pay patients if we are looking at cumulative cuts in excess of 50% since the colorectal cancer screening benefit was enacted in 1997. As we noted above, to the extent that CMS's concept of budget neutrality demands a 10% across-the-board cut in the payment for services, we must oppose all increases for cognitive services and other Medicare services for which increases would drive such precipitous cuts elsewhere in the system.

Changes to Practice Expense Methodology

We support in principle the proposal insofar as it relates to changes in the resource-based practice expense methodology. One of the few positive features of this rulemaking is the possibility that CMS will finally adopt the refinements to GI practice expense RVUs which were proposed, but then withdrawn by the agency last year. A single bright spot is the possibility that supplemental practice expense data may be accepted this year, which could moderate the net Medicare fee reduction for some GI services—unfortunately that modest moderation in the decline is not enough.

Conclusion

As we have noted above, despite our concurrence in retaining the work RVUs for the key GI services at their current level, as recommended by RUC and CMS, we are deeply concerned that the cumulative cuts from this rule, the SGR and the pending reform to the ambulatory surgery payment system will drive many practices (and ASCs) out of the Medicare system of out of business. These proposals may be the final straw in terms of breaking the American health care system, which has been the victim of a vicious and unprecedented cost-cutting siege, largely at the hands of the federal government, CMS, and the Medicare program over the past dozen years. This downward spiral must stop.

We appreciate the opportunity to submit our comments of this proposal, and we would be pleased to answer questions or otherwise engage in dialogue with the agency about how to improve/remedy the deficiencies in the current proposal.

Very truly yours,

Anjana Kumar, M.D. 8/21/06

Ernest F. Ribera, M.D.
GASTROENTEROLOGY

Tel: (650) 342-6506
50 South San Mateo Drive, Suite 330
San Mateo, CA 94401
Fax: (650) 340-9032

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August 22, 2006

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

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:

I am a private practice physician who currently treats Medicare beneficiaries in my practice. I am writing to voice my concern relative to CMS's recent proposal to change the way ambulatory surgery centers are paid for their services, via facility fee payments.

As a practicing gastroenterologist, we have seen fees slashed over the past 20 years that I have been in practice. Establishing an endoscopy center has allowed us to become much more efficient in delivering needed procedures, such as screening colonoscopies. It would certainly be more cost efficient, from a business standpoint, to simply walk away from Medicare patients. However, I, along with my colleagues, wish to continue to participate in the care of our senior citizens. Because endoscopy centers have allowed greater access to all our patients at a cost savings to payors, I would thus ask you to please modify the current proposal so as to increase, not decrease, facility fees to GI ASCs. If the proposal goes forward as is, more and more procedures will be done back at the hospital in a less efficient and more costly manner. Ultimately, participation in the Medicare program by my colleagues may erode.

Thank you very much for your time and attention to my comments.

Sincerely,

Ernest F. Ribera, M. D.

EFR:db
cc: American College of Gastroenterology

6

~~CMS-1506-P-1~~

Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates

Submitter :

Date & Time: **08/10/2006**

Organization :

Category : **Physician**

Issue Areas/Comments
Medicare Contracting Reform Impact

Medicare Contracting Reform Impact

The proposed changes to the ASC payment system will certainly put a lot of gastroenterologists out of business.

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P and CMS-1512-PN
P.O. Box 8014
Baltimore, Maryland 21244-8014

ASC8

T-0 (658)

As a patient, I am writing to express my concern and opposition to CMS' proposal to reduce markedly the Medicare fee schedule by virtue of the SGR, the budget neutrality aspect of Medicare fees and to the proposed change the payment structure for separate facility fees at ambulatory surgery centers (ASCs).

I am concerned that CMS' proposal would unfairly and arbitrarily shift fees with minimal objective data, and could significantly compromise the quality of care I receive. These dramatic cuts likely will result in some physicians significantly reducing (or even eliminating) Medicare patients from their practice, and reduced access for Medicare patients at ambulatory surgery centers. Some physicians may not be able to afford to spend as much time with their Medicare patients. I am especially concerned about CMS' attempts to create incentives to steer patients toward specific settings for economic reasons rather than maintaining site neutrality.

Citizens who are growing older deserve better! CMS should suspend its plans to implement the proposed changes to the five-year review budget neutrality adjustment to the Medicare fee schedule, should defer indefinitely the ambulatory surgery rules, and should revise the unfair SGR.

Very truly yours,

(Name) JODY BERNSTEIN

(Address) 318 DELAPLANE AVE

(City/State/Zip) NEWARK, DE 19711

Dana (2)
Joan
Carol
Alberta

8-0
ASC8 (1910)

Dana(2)
Joan
Carol
Alberta

Mark McClellan, MD
CMS - DEPT HHS
Attn: CMS-1506-P and CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan,

As a U.S. citizen and taxpayer, *I wish to voice my concern and opposition to the CMS proposal to reduce markedly the Medicare fee schedule and to change the payment structure for facility fees at ambulatory surgery centers (ASCs).* I am especially concerned about CMS attempts to create incentives to steer patients from freestanding centers back into the less cost-efficient and less patient-friendly hospital environment. CMS should suspend its plans to implement the proposed changes and defer indefinitely the proposed new ambulatory surgery rules.

Sincerely,

(Name) Evelyn Hufnagel

(Address) 300 Palomino Drive

(City/State/Zip) Oakdale, Pa 15071

Srinivas S.Vasireddi,M.D.,FACP
Diplomate American Board of Gastroenterology

To

Mark McClellan,M.D
Center for Medicare and Medicaid Services
Copy to Senate/Congress

RE: CMS-1506-P/CMS-1512-PN

Sir,

I would like to congratulate your office and the federal government on finally having the guts and conscience to do the right thing and plug the CMS "site fees" 1991 loophole in the law , which has fortunately enriched scores of my physician colleagues and driven the cost of endoscopic procedures through the roof. Many non-profit hospitals are nearing the verge of bankruptcy due to skimming of these paying cases by the ASC's to pocket the site fees.

I have always been a strong advocate for income parity between all physicians, and I feel we have a strong ethical and moral obligation to keep the heath care costs down, through cost-effective and safe delivery. Your bold and righteous move will appropriately move ASA class 1(>98%) endoscopic procedures into the office setting with the higher risk ones(class 2 and higher) appropriately being done in the out-patient hospital settings, like in the rest of the world.. The savings will be over a billion dollars to medicare and will eliminate unnecessary procedures and income disparities between physicians and will bring the costs down, and believe me, we gastroenterologists will still make a decent income in the office setting, unlike scores of my colleagues in other non-procedural cognitive medical fields. There is a lot of lard in the system which has to be trimmed and this is a bold and appropriate move, and my sincere congratulations again to the CMS, the President, Senate and the Congress.

Sincerely

PS: enclosed please find excerpts from a previous talk advocating office based endoscopy like in the rest of the world.

205 Bridge Street, Metuchen, NJ 08840 • Telephone: (732)205-9886 • Email: vasiboy@verizon.net

Office Endoscopy:
A Physician's Perspective

Srinivas Vasireddi, M.D., FACP
May 25, 2005

WHEN our GI colleagues SAY:

"It's Not About the Money...

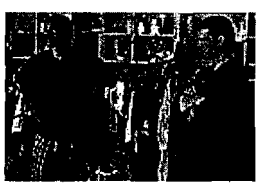
..... IT'S ALWAYS ABOUT THE MONEY!!!!

GI Dollar Pyramid Exists

- Hospitalist GI's: $$
- Office based GI's: $$$$
- ASC GI's: $$$$$$

- Income disparity exists because of 1991 CMS 'loophole' Clubbing endo procedures with surgeries enabling OR/facility fees to be paid
- $1 Billion paid annually to all ASC's since 1991 (facility/tray fee)

"SHOW ME THE MONEY JERRY, SHOW ME THE MONEY!"



Rod Tidwell (Cuba Gooding Jr.) to his agent Jerry Maguire (Tom Cruise) in the move Jerry Maguire.

- "We have an obligation to society to hold down procedural costs, do the right thing for patients, and still have an acceptable level of income."

- Dr. Vasireddi on Office Endoscopy

South Denver
Gastroenterology, P.C.

10

Specializing in Digestive Diseases, Liver Diseases and Nutrition

Board Certified Gastroenterologists

Pete H. Baker, M.D., FACP
Philip D. Hanna, M.D.
Dan S. Hruza, M.D.
Lawrence S. Kim, M.D., FACG
Marcelo Kugelmas, M.D.
Frederick W. Lewis, M.D., FACP, FACG
Luette S. Morton, M.D.
Cary Patt, M.D.
Erik J. Pieramici, M.D.
Bernard J. Powers, M.D.
Richard M. Roman, M.D.
John S. Sabel, M.D., FACP, FACG
David M. Scheider, M.D.
Paula Armstrong, NP

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Lone Tree Colorado 80124
TEL 303-790-7334
FAX 303-790-2567

September 12, 2006

Centers for Medicare and Medicaid Services
Department of Health Human Services
Att.: CMS-1506-P
Mail Stop C4-26-05
7300 Security Blvd.
Baltimore, MD 21244-1850

RE: ASE Rules

To Whom It May Concern:

I am distressed over the recent recommendations for the reimbursement for procedures performed at an amateur surgery center. If these radical decrease in reimbursement for the ASE takes effect in 2008 it will lead to significant problems for the Medicare patients as this reimbursement level will not allow these patients to be done in amateur surgery centers and will force them in a hospital which will result in higher fees and much more inconvenience to the patient. At the present reimubursement level expenses barely meet the fees that reimburse at the present time. At the same time that the CMS has encouraged colon cancer screening in the elderly patients you are now proposing to decrease the reimbursement to such a level that it will be impossible for gastroenterologists to provide this service.

Therefore utilization of colon cancer screening will decline further, cancer will go undetected and actually patients will die unnecessarily and there will be increased costs because of surgery regarding the colon cancer. I would hope that this would be reconsidered and more rational treatment of the ASE reimbursement would be suggested.

Sincerely,

John Sabel, MD, FACP, FACG

American Association of Oral
and Maxillofacial Surgeons

9700 West Bryn Mawr Avenue • Rosemont, Illinois 60018-5701 • 847.678.6200 • 800.822.6637 • FAX 847.678.6286 • 847.678.6279

Daniel J. Daley, Jr., DDS, MS
President
Robert C. Rinaldi, PhD, CAE
Executive Director

September 22, 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: August 23, 2006 Proposed Rule: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Sir/Madam:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) appreciates the opportunity to comment on the August 23, 2006 Proposed Rule for the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates. The AAOMS is specifically interested in commenting on the CPT surgical procedures proposed to be excluded from payment of an ASC facility fee.

The AAOMS represents approximately 8,000 U.S. oral and maxillofacial surgeons. The mission of the Association is to provide a means of self-governance relating to professional standards, ethical behavior and responsibilities of its fellows and members; to contribute to the public welfare; to advance the specialty; and to support its fellows and members through education, research and advocacy.

The AAOMS Committee on Healthcare and Advocacy convened a special meeting to discuss this proposed rule and reviewed each code independently to assess the merits of deleting specific codes. However, we cannot support the entire proposed rule, and we strongly urge that certain procedures be retained on the coverage list.

The Association ***does not support*** the deletion of the following codes and we hope to be able to work with CMS in reconsidering maintaining ASC coverage for:

21049 Excision of benign tumor or cyst of maxilla; requiring intra-oral osteotomy

program. We also believe that removing these codes actually could increase costs by shifting those services which could be safely performed in the ASC to the more costly hospital setting.

The AAOMS appreciates your consideration of our comments. Should you have any questions, please contact Karin Wittich, Associate Executive Director, Practice Management and Governmental Affairs, at (847) 233-4334 or via e-mail at karinw@aaoms.org.

Sincerely,

President

cc: Committee on Healthcare and Advocacy
Committee on Governmental Affairs
Robert C. Rinaldi, Ph.D., CAE, executive director
Karin K. Wittich, Associate Executive Director,
Practice Management and Government affairs
Patricia Serpico, Manager, Practice Management

12

Grutzmacher Lewis
A Medical Corporation
Surgical Eye Specialists

Richard D. Grutzmacher, M.D.
Cornea, Cataract and Laser Vision Correction
Richard A. Lewis, M.D.
Glaucoma and Cataract
Monica C. Robinson, O.D.
Optometry
Kristie L. Teets, O.D.
Optometry

Richard A. Lewis, MD
Grutzmacher & Lewis
1515 River Park Dr., Suite 100
Sacramento, CA 95815

September 24, 2006

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

RE: Ambulatory Surgical Center Payment System and CY 2008 Payment Rates [CMS-1506-P]

Dear Sir or Madam:

My name is Richard A. Lewis, MD and I am an ophthalmologist practicing in Sacramento, California. The purpose of this letter is to provide a response to recent CMS guidance documents re: ASC reimbursement for CAT III CPT codes. I appreciate this opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) on August 23, 2006, which proposes, among other things, updates to the ASC list effective for services furnished on or after January 1, 2008.[1]

As an owner of an ASC and an ophthalmologist with a broad-based surgical practice, I support CMS's proposed definition of the term "Surgical Procedure."[2] In particular, I am encouraged by CMS's proposal "to include within the scope of surgical procedures payable in an ASC certain services that are described by HCPCS alphanumeric codes (Level II HCPCS codes) or by CPT Category III codes which directly crosswalk to or are clinically similar to procedures in the CPT surgical range."[3]

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[1] See Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program -- HCAHPS® Survey, SCIP, and Mortality, 71 Fed. Reg. 49,506, 49,636, August 23, 2006).

[2] Id. at 49636.

[3] Id.

	(eg, locally aggressive or destructive lesion (s))
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints
31040	Pterygomaxillary fossa surgery, any approach
42225	Palatoplasty for cleft palate; attachment pharyngeal flap

The Association understands and appreciates the statutory requirement that mandates review and updating of the ASC list. **Our concern with deleting the above services from the coverage list is that it will create patient hardships and impede access to care, as well as increased program expenses.** Oral and maxillofacial surgeons are the primary surgical providers of patient services associated with this subgroup of codes. As such, we know that reliance on a methodology of using solely Medicare claims data on site of service to define where a procedure is commonly performed is flawed in instances where the vast majority of these services are provided for patients who are not part of the Medicare data base. The flaw in this methodology is clearly supported by the extremely low frequency of many of these procedures in the Medicare population: The 8,000 fellows and members of the AAOMS primarily perform these procedures in younger, non-disabled patients.

In addition, failure to take into account the clinical population of patients who undergo these services, the data wholly fails to incorporate or even consider the *type of anesthesia* associated with these care scenarios. For instance, CMS is proposing the exclusion of CPT code 21195 which was performed only five times in 2004 for Medicare covered patients, according to published CMS data. Although we agree that this service may be performed in an inpatient setting, there are numerous instances when this procedure, can be performed in an ASC where it can be accomplished under conscious sedation/general anesthesia.

As a specialty society, we recognize that the CMS classification of ASC procedures dictates the pattern of coverage in the ASC industry, both for federally funded programs and the commercial carriers. The effect of arbitrarily deleting codes that require general anesthesia in a non-Medicare population has the potential of leading to industry chaos and seriously undermines standardization and quality of care. We encourage CMS to take a leadership position on this issue by recognizing the special needs of the pediatric population and the historical fact that ASCs have proven to be very cost effective in the pediatric surgery arena.

It is the firm belief of the Association that the ASC list should not restrict a practitioner from utilizing the benefits of an ASC when a patient's medical condition, age, or anesthetic requirement would best be served by performing the procedure in an ASC. Furthermore, the Association believes that, especially after reviewing the CMS frequency data for those procedures, the exclusion of these codes would not translate into significant cost savings for the

In an earlier comment letter to CMS on the 2007 update to the ASC list, I urged CMS to add the new CPT codes, 0176T (Transluminal dilation of aqueous outflow canal; without retention of device or stent), and 0177T (Transluminal dilation of aqueous outflow canal; with retention of device or stent), to the ASC list effective January 1, 2007. These codes will be implemented on January 1, 2007. Transluminal dilation of the aqueous outflow canal is also known as canaloplasty, and it is an outpatient ophthalmic procedure for the treatment of glaucoma. More details on the procedure can be found in a New Technology APC application for canaloplasty that was submitted to CMS on August 31, 2006.

For the reasons discussed in my prior comment letter, these codes should be added to the ASC list for 2007. But independent of that request, 0176T and 0177T should be on the ASC list for 2008 because these codes satisfy the definition of a surgical procedure as described in the proposed rule. CPT 0176T and 0177T describe a new treatment for glaucoma called canaloplasty, which is similar to other ophthalmic outpatient procedures described in the CPT surgical range. In particular, canaloplasty is similar in several respects to trabeculectomy (CPT 66170), another procedure for glaucoma. A table comparing the individual steps of canaloplasty to trabeculectomy was included with the New Technology APC application submitted for canaloplasty.

For additional reasons it is important that these codes are on the ASC list, because relative to most other specialties, ophthalmologists do a high percentage of their cases in ASCs. In fact, the majority of the canaloplasty procedures performed thus far have been in ASCs. Patients are accustomed to the combination of a secure operating environment and the convenience that an ASC provides for eye surgery. Therefore, CPT codes 0176T and 0177T should be on the ASC list for 2008.

In closing I appreciate the work entailed in developing the Proposed Rule, and I commend CMS on the effort involved in developing the new ASC payment system for 2008. Since I have a large glaucoma component in my surgical practice, I am eager to work with the agency to ensure that Medicare beneficiaries who have glaucoma have access to the best therapeutic technologies in the most appropriate and cost effective site of service. Thank you for your timely review and consideration of my comments on this important issue.

Sincerely,

Richard A. Lewis, MD
Sacramento, CA

NT

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Integral PET

Ronald Lissak
Chief Executive Officer
rlissak@integralpet.com

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 Integral PET Associates, LLC ("Integral") to address an issue of great importance to Medicare beneficiaries with cancer. Integral is an independent diagnostic testing facility (IDTF), which provides PET/CT services, among other imaging services. We serve approximately 13,000 cancer patients annually, many of whom lack ready access to a hospital. 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

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Submitter : Dr. Jay Malmquist **Date:** 09/26/2006

Organization : AAOMS

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Inpatient Only Procedures

Inpatient Only Procedures

See attachment

CMS-1506-P-156-Attach-1.DOC

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 to Integral 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.

Many cancer patients live far from hospitals, and rely on IDTFs for oncologic imaging. 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.

Sincerely,

Ronald J. Lissak, CEO

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OPPS

Visits

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Tamar (2)
Joan
Carol
Alberta

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

RE: Draft ER/Clinical Level Guidelines

Dear Sirs:

My comment is in regard to the Draft ER/Clinical Level Guidelines. Presently we are using the 2003 guidelines and I am lobbying to keep the 2003 Version. If conversion is made to the 2006 version we will loose our ability to charge for several items which allow us to charge for a higher leveling such as scheduling of ancillary services as a contributory factor and thrombolytic/vasopressor administration for critical care. The 2003 version allows more advantages for us for leveling which if these are taken away from us, will allow us only to do a medical screening exam on the hospital side which would not match up to physician coding. I lobby for keeping the 2003 version and not going forward with the 2006 in regards to ER and Clinical Level Guidelines.

Thank you for your attention in regards to this matter.

Sincerely,

Patricia Parvey, CCS

Patricia Parvey, CCS
HIM Manager
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