The Urological Center, P.A.

70-0
(5)

Adult &
Pediatric
Urology

Diplomates,
American Board
of Urology

H.J. Talton, M.D., F.A.C.S.
\. McWilliams, M.D., F.A.C.S.
P.J. Dennis, M.D., F.A.C.S.
K.C. Hackett, M.D., F.A.C.S.
I.R. Chaudhry, M.D., F.A.C.S.

D.J. Lamont, PA-C, C.U.P.A

October 27, 2006

ASC8

Dana (2)
Joan
Carol
Alberta

Centers for Medicare/Medicaid Services
Department of Health and Human Services
Attention: Colin CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-8013

Dear Sirs and Madams,

After review of the information that I received regarding proposed changes in Ambulatory Surgery Center reimbursement rates for 2008 and 2009, I am shocked and dismayed at the drastic reductions proposed. Specifically I am greatly concerned about the ASC payment rate for cystoscopy (52000), prostate biopsy (55700), CMG (51726), UPT (51771), EMG (51785), and ESWL (50590). In our urology practice of five busy urologists, we have a state of art Ambulatory Surgery Center providing excellent urologic services to Medicare and Medicaid beneficiaries. We provide these services to these beneficiaries under the highest quality standards. We are much more efficient in our surgery center than could possibly ever be achieved in a hospital setting. We have already made great attempts to streamline our efficiency both in scheduling and treating patients and find that the "bottom line" for these procedures keeps shrinking. It is quite difficult to maintain the current quality care that we provide our patients with shrinking reimbursement rates. With the proposed changes, providing this care may be impossible. Stating that many of these procedures should be "office procedures" and therefore reimbursed at a lower rate is a generalization which does not reflect the case mix which we handle in our surgery center. Often we will treat patients with significant health care issues which would not be managed well in an office atmosphere. It is likely that many of these cases would be returned to the hospital setting at a more expensive cost of government reimbursement programs. If these payment caps are applied to all procedures that need be "office based" criteria, it would be devastating for urologic ambulatory surgery centers. Payment rates for a cystoscopy, prostate biopsy, urodynamics and other urologic procedures would be slashed by over 90%. CMS has recognized this fact and that the proposal exempts all procedures that are presently on the ASC list from application of the office-based classification. It is critical that this exemption be part of the final rule. Therefore I would strongly urge you to exempt the procedures that are on the 2007 ASC list from the office-based classification.

With regard to the 62% conversion factor where CMS is proposing to set ASC reimbursement levels at 62% of the hospital outpatient reimbursement level, this would make it financially impossible for ambulatory surgery centers to provide services where high cost prosthetics and implantable devices contribute to most of the cost of the procedure expense. For these procedures the cost of the implant usually dictates the cost of the procedure and therefore the

11110 Medical Campus Rd.
Suite 228
Hagerstown, MD 21742
301-733-0022
1-888-326-0022
301-733-3461 (Fax)

continued page 2

Centers for Medicare/Medicaid Services
Department of Health and Human Services
Attention: Colin CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-8013

ASC and the hospital outpatient department should be reimbursed at the same level. This is also true in procedures where expensive technology must be leased through the ambulatory surgery center to provide state of the art treatment to our patients. This includes lithotripsy (50590), laser treatment of the prostate (52647, 52648).

Hopefully you will reconsider the proposed changes which if implemented would be financially crippling if not fatal to most outpatient urologic ambulatory surgery centers. As the number of patients requiring urologic services will increase in the coming years, and with the growing trend for treating in an outpatient setting, it does not make sense for these ambulatory centers to be penalized financially for providing efficient cost-effective care toour Medicare and Medicaid beneficiaries. I thank you for your consideration regarding these important issues.

Sincerely,

Hugh J. Talton, M.D.
The Urological Center, P.A.
Antietam UroSurgical Center, L.L.C., ASC

HJT:ldw

North Atlanta Endoscopy Center
AN AFFILIATE OF HEALTHSOUTH

October 27, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Resources
Attention: CMS-4125-P
P. O. Box 8011
Baltimore, Maryland 21244-8150

Dear Mr. Norwalk:

This letter is in response to the proposed Medicare Ambulatory Surgical Center (ASC) payment system and ASC list reform. My position as Administrator is for an ASC that provides the single specialty of GI. When a Medicare beneficiary chooses an ASC to have their procedure performed, they and Medicare save money. The proposal presents a few concerns for ASC's that are a single specialty GI center.

ASC's have always provided patients with an alternative setting to have procedures performed while providing high quality care at a less expensive rate. Outpatient ASC's also allow for reasonable scheduling of patients for procedures. With the proposed ruling it would generate a migration of healthy patients back into a hospital setting which would result in a higher expense for CMS and a delay in receipt of healthcare for patients. While it is understandable all agencies are cutting cost – the proposed ruling would actually cost CMS more money. The single specialties (GI and eye centers) would feel more of an impact due to rates not covering cost of procedures.

Both HOPD and ASC's face the same challenges with keeping our cost down. Inflation with staffing cost is the same whether you are an ASC or HOPD; as well as medical supplies, liability, etc... It would only seem reasonable that the pricing updates with CMS would reflect these processes accurately.

I would hope that your department would consider the above concerns when making a final proposal for the new ASC payment system. Otherwise, many procedures that could be safely performed in an ASC setting will not be available because payments will remain below cost.

Respectively,
T L Butterworth
Terri L. Butterworth
Administrator

5555 Peachtree Dunwoody Road, Suite G-70 • Atlanta, GA 30342 • 404 843-0500 • Fax 404 843-0675

atlantic urological associates
a professional service corporation

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Reply to: Daytona

October 19, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-8013

Dear Sirs:

This is my comment to object to the ASC payment plan which is presently being highlighted in the Regulation known as CMS-1506-P. At this present time, if these caps are applied to all procedures that meet the office based criteria this would be devastating for urological ASC's. Payment rates for cystoscopy, prostate biopsies, urodynamic studies and other high volume procedures would be slashed by 90%. The 62% conversion factor results in ASC's unable to higher a nurse for 62% of what the hospital would pay. This also would drastically reduce the quality of care that one would receive in a surgical center.

At this time, surgical centers have extremely high satisfaction rates with most of the satisfaction rates being close to 98-99%. Also the high cost of lease technology that are being performed in surgical centers again shows that surgical centers are able to do procedures that require same day surgeries and that these cost cuts would drastically reduce the reimbursements making the high fixed cost of elite technology impossible.

Please reconsider physician comments as cutting these costs, will basically reduce the ability to perform these high tech procedures.

Sincerely,

Anthony L. Cantwell, MD, FACS

ALC/sfm

MANGAT MEDICAL, LLC

133 Barnwood Drive, Edgewood, KY 41017
(859) 426-1616 t / (859) 578-3321 f
surgerycenter@fuse.net

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October 26, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medical & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Norwalk:

I write today to provide my view regarding the ongoing analysis by CMS and the reimbursement plan being considered for ambulatory surgery centers. I am an administrator of an ambulatory surgery center in Northern Kentucky and I encourage you to consider the economic impact on small businesses engaged in providing very safe, cost effective surgical services to highly satisfied clients in ambulatory surgery centers across our nation. Your consideration of the effect of the current realignment of surgery center reimbursement must include the following information:

1. To assure Medicare beneficiaries' access to ASC's, CMS should broadly interpret the budget neutrality provision enacted by Congress. A 62% relationship to HOPD rates is simply not adequate or acceptable.

2. The limitations proposed in this draft proposal on the ASC list is too limited. CMS should expand the list of procedures to include any and all procedures that can be safely performed in a hospital OPD. If a patient can be safely discharged to home from a hospital OPD, it is irrefutable that the quality and safe treatment in ASC's can provide the patient the same opportunity to be discharged to home and at a substantially lower cost. CMS should exclude only those procedures that are on the in-patient list.

3. ASC's should be updated based upon the hospital market basket because this more appropriately reflects inflation in providing surgical services than does the consumer price index. Also, the same relative weights should be used in ASC's and hospital outpatient departments. The provision of high quality service in ASC's reacts to the same market forces as any other small business. Cost pressures and inflation figures are a fact of life. Penalizing ASC's by increasing reimbursement levels for hospitals and forcing ASC's to absorb inflationary costs is both unequal treatment of a small business and unfair to a segment of small business owners.

4. Aligning the payment systems for ASC's and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that the benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law.

Since I am sure you will receive similar letters from other ASC owners and administrators across the nation, I will add my views to those of the industry to which I belong. I have been a healthcare provider all my professional life and I am committed (as are my colleagues) to providing safe and effective surgical services to our patients. Your revision of the payment rates in the reimbursement system affecting both our Center and our patients must include an equitable and fair system providing an acceptable level of payment for the services we provide to your beneficiaries across this nation.

Thank you for your consideration.

Sincerely,

Nelson B. Rue, III, RN, MBA, CHE
Executive Director, COO
Mangat Medical, LLC
Edgewood, KY

CC: Lisa Spoden, PhD
Robert C. Williams

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7777 Southwest Freeway #708
Houston, TX 77074
October 28, 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 Center PPS Proposed Rule

Dear Dr. McClellan:

I am a gastroenterologist in private practice who treats a large number of Medicare beneficiaries in my practice. I am writing to you to express my concern about the recent proposal by CMS to change the way that the agency pays ambulatory surgery centers for their services, via facility fees.

A substantial portion of the Medicare beneficiaries that I see require colonoscopy, either as screening for patients at average or above-average risk for colorectal cancer, or as a diagnostic study for evaluation of gastrointestinal symptoms. In addition, I see a large number of patients with other conditions for which endoscopic evaluation is necessary for a complete evaluation. For these patients, having access to a safe, cost-efficient center for their endoscopic procedure allows them to be restored to good health (or maintained in good health) in a timely fashion.

The current CMS proposal will pay substantially more to the hospital than the ASC for performing the same procedure. Under this proposal, the Medicare payment to our ASC for endoscopic procedures will barely cover our costs of the procedure (and will exceed them in some cases where a large amount of disposable equipment will be required). This will force us to deny access to our ASC to Medicare beneficiaries, thereby shifting them to the hospital outpatient department for their procedures, and increasing costs to the Medicare program, as well as inconveniencing our patients. I fear that this will have the effect of reducing the number of Medicare beneficiaries that undergo colorectal cancer screening, a benefit that is already being underutilized, according to both GAO and CMS.

Gastroenterology
CONSULTANTS, P.A.

N.S. Bala, M.D., F.A.C.P., F.A.C.G., A.G.A.F. • S.K. Raj, M.D., F.A.C.P., A.G.A.F., F.A.C.G.
H.S. Ojeas, M.D. • F.E. Schneider, M.D. • D.H. Darmadi, M.D. • J. Rao, M.D.
Diplomates, American Board of Internal Medicine & Gastroenterology

75-0
(3)

October 19, 2006

Mark McClelland, M.D.
Center for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1506-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

RE: Medicare Program; Ambulatory Surgery Centers
PPS Propostural

Dear Dr. McClelland,

I am a Board Certified gastroenterologist who has been practicing in Houston for the last 14 years and has been treating a large number of Medicare beneficiaries. I am writing to express my serious concern with the proposed change in the way CMS pays Ambulatory Surgery Centers for their services, in the form of facility surgical fee payments.

Over the last 14 years, I have been part of a single specialty gastroenterology group consisting of eight highly qualified gastroenterologists. We see a large number of Medicare patients and provide services including screening colonoscopies for these patients in a very efficient, cost-effective manner.

We also see these Medicare beneficiaries for various other reasons including anemia, weight loss, gastroesophageal reflux disease, peptic ulcer disease, malabsorption, chronic diarrhea, etc. In order to provide time-efficient, quality services, we have developed our own Ambulatory Surgery Center (Bay Area Endoscopy Center). This entity has been accredited by Joint Commission (JACHO) with commendation. Without any exaggeration, I am proud to say that this Endoscopy Center clearly is the best Endoscopy Center in the Southeast part of Houston, even compared to all the four acute care hospitals endoscopy centers. We have the state-of-the-art endoscopy equipment and very well trained, friendly, professional nursing staff assisting your Medicare beneficiaries. Because of this, we have an excellent name in the community and the Medicare beneficiaries who use our facility are extremely pleased.

They are so pleased with the services that we provide, they are very unhappy if they are asked to use the hospital endoscopy facilities.

(Continued)

As you know, both the GAO and CMS have stated that Medicare colorectal cancer screening benefit is under utilized. MEDPAC has repeatedly endorsed the concept that medical procedures and services should be site-neutral.

A proposal such as this one, which proposes paying significantly more to the hospital than to the ASC, will be extremely unfair and will make providing these services to Medicare beneficiaries economically impossible and some of the ASCs may have to stop accepting them.

Even today, ASCs receive significantly lower payment for a screening colonoscopy compared to the hospital because they receive only 89% of the facility fee paid by CMS to HOPD. Our ASC has invested a large amount of money compared to the hospitals in keeping newer, latest model endoscopy equipment. CMS has cut the physician fee payment for screening diagnostic colonoscopies by almost 40% since 1997 – from a little over $300 to the current level of just around $200.

According to information provided by the American College of Gastroenterology, no other Medicare service has been cut this much. The current proposal drastically cuts the payment from 89% of the HOPD to 62% of the HOPD.

As this proposed payment is not economically feasible for ASCs to continue to perform the services for Medicare beneficiaries, they will divert these procedures to HOPDs and Medicare total payment for endoscopy facility fees will increase dramatically.

I strongly feel that if the proposed changes are implemented, this will result in:

1. Total Medicare cost for GI facility fees will raise (as more and more of the procedures will be done at HOPD and not at the ASCs.
2. Available access by Medicare beneficiaries for GI colonoscopies and life-saving screening colonoscopies will decline, even from the current anemic level.
3. More Medicare beneficiaries will die unnecessarily from the delayed diagnosis of colon cancer.

I strongly urge you to review this matter carefully and withdraw the proposed reduction in facility payment to the ASCs for GI endoscopies.

Thank you very much.

Suresh K. Raj, M.D., FACG, FACP, AGAF
SKR:nbh

University of Maryland Medical Center

THE MARYLAND
PROSTATE CENTER

Michael J. Naslund, M.D.
410 328-0800 FAX: 410 328-2048
Richard B. Alexander, M.D.
410 328-5109 FAX: 410 328-7813

University of Maryland Professional Building
419 West Redwood Street, Suite 320
Baltimore, Maryland 21201-1734

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October 18, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4125-P
PO Box 8011
Baltimore, MD 21244-8013

To Whom It May Concern:

I'd like to comment on your proposed changes to the payment mechanism for ambulatory surgical centers. This proposal is going to make it financially impossible to offer many urologic procedures in an ambulatory surgical center because of the significant decrease in reimbursement which is proposed. This will impact Medicare patients in a negative way, preventing them from having access to the advantages of procedures performed in an ambulatory setting.

The proposal to move many office based procedures into a status where they can, in appropriate circumstances, be performed in an ambulatory surgical center is laudable and actually long overdue. However, the plan to reimburse ASC procedures at the office based level when they are being done in the more complex and expensive ambulatory surgical setting will effectively prevent patients from the opportunity to get procedures in the ASC environment. CMS should recognize the additional costs involved in providing care in the ASC setting and reimburse for procedures at an appropriate level.

For procedures where prosthetics or other high cost components are used, CMS proposes to reimburse an ASC at 62% of the hospital outpatient reimbursement. This is not well thought out when one considers that the large part of expenses for these procedures are the implants or technologies themselves. An ASC is not able to obtain these products at a lower cost than a hospital so reimbursement for these types of procedures should be the same in both the ASC and the hospital outpatient setting. The same argument applies to procedures where expensive equipment is leased or rented. The price of these leases for an ASC is basically identical to that for a hospital and thus these procedures should be reimbursed at the same level in the ASC as they are in the hospital outpatient department.

My final concern is the proposal by CMS to exclude some procedures on the ASC list because of historical data indicating that most of the time they are done in a hospital setting. These procedures include fluoroscopy of renal calculus, renal cyst unroofing and laparoscopic urethral suspensions and urethral lysis. It is correct that historically these types of procedures have been hospital based. However because of improvements in laparoscopic technology, these procedures can now be done consistently on an outpatient basis in selected patients. I believe these procedures should be left on the ASC list with the recognition that urologists would exercise appropriate judgment in which patients should have these procedures done in the ambulatory surgical setting versus the hospital setting.

Overall I agree with CMS that the ASC rules need to be revised. My overriding concern is that CMS' plan to decrease ASC reimbursement will make it financially impossible to provide these services to patients and will thus undermine patient access to care. If there are any further questions please contact me at 410-328-0800.

Sincerely,

Michael J. Naslund, M.D.
Professor of Surgery (Urology)
Chief, Division of Urology
University of Maryland School of Medicine

MJN:blg

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1412 DeFoors Dr., NW
Atlanta, GA 30318-2971
06 Oct 26

Dr. Mark McClellan
Centers for Medicare/Medicaid Services
DHHS
Attn: CMS-1506-P & CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

SUBJECT: Opposition to CMS Proposal

Dear Dr. McClellan:

When I recently had a procedure at the DeKalb Gastroenterology Assoc., LLC, I was made aware of the pending proposal that would reduce insurance reimbursement for tests, such as I underwent, at freestanding centers. I am indicting my opposition to this proposal because this and similar proposals are being made for reasons other than concern for the PATIENT!

Additionally, I'm disturbed that under this proposal the reimbursement to freestanding centers will be reduced by 35%; whereas, the reimbursements to hospital-based centers would become 60% higher than that to such freestanding centers, which I understand will be raised this makes NO SENSE!

If there are concerns about the care and/or cleanliness of free standing centers, I submit that hospitals are similarly deficient. This requires specific review of a center, freestanding or hospital-based, to determine if it meets the requirements for care and/or cleanliness; not "bending" to hospital lobbyists.

Sincerely,

George B. Pilkington, II

cc: DGA
Rep. John Lewis
Sen. Saxby Chambliss
Sen. Johnny Isakson

78

BILLINGS GASTROINTESTINAL ASSOCIATES

THOMAS W. KORB, M.D.
NINA TOMASZEWSKI, M.D.
STEPHEN E. BAUM, M.D.

October 24, 2006

Mark McClellan, M.D.
ATTN: CMS-1506-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

Our specialty society, the American College of Gastroenterology, recently pointed out that it is Medicare's intention to make a drastic reduction in payment for surgery center administered colonoscopies and other endoscopic procedures. The cut apparently is from 89% of average hospital down to 62%, which probably would make the difference between profit and loss for the surgery centers. We do not have a surgery center in my practice, nor is one available to use, but there are a number of people who do who have invested time and effort into a surgery center in order to provide care on a convenient, expeditious, and reasonably economic way to their Medicare and other patients. The attempt to salvage Medicare's budget on the back of the physicians and the institutions has probably gone about as far as it can go. We physicians in private practice find ourselves supporting an ill-conceived program which was not at all favored by the American Medical Association, partly because it felt that the government didn't know what it was getting into. This Medicare has been in place all of my 35 years of practice, so I know what it got into, and it got into a whole lot more than it thought it should. I think rather than attempting to ride this dying horse on the back of the physicians, honesty and forthrightness should prevail, and Congress has to deal with the problem that they created.

I would encourage you and those whom you contact to attempt to put off any significant payment changes which would make colonoscopy the most hacked-upon procedure in Medicare. This is a rather strange way to treat a procedure that has been encouraged upon both the doctors and the patients for screening purposes. Perhaps if you served any purpose at all, you could appear before the great but apparently useless U.S. Congress and tell them to shape up and solve the problem. This having to deal with threatened cuts of 5 to 6% in our reimbursements plus a big one like this is getting old, and sooner or later I think that the situation will become untenable. Physicians will not be able to take on any more burdens and Medicare will suffer, as will the care of those

YELLOWSTONE MEDICAL CENTER • 2900 12TH AVENUE NORTH • SUITE 500E • BILLINGS, MT 59101-7506
406-238-6380 • 800-648-6274

who have become dependent on it, which at this point includes me. I would like to see my care not threatened, and I would also like to see my physicians adequately compensated. I hope this information is helpful to you in your decision making.

Sincerely,

Tom Korb MD

THOMAS W. KORB, M.D.

TK/td

Cc: The Honorable Conrad Burns
United States Senate
187 Dirksen Senate Office Building
Washington, DC 20510-2603

The Honorable Max Baucus
United States Senate
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Dennis Rehberg
United States House of Representatives
516 Cannon House Office Building
Washington, DC 20515-2601

Loyola Ambulatory Surgery
Center at Oakbrook

79

LOYOLA
UNIVERSITY
HEALTH SYSTEM

Loyola University Chicago

1 S. 224 Summit Avenue, Suite 201
Oakbrook Terrace, IL 60181
Telephone: (630) 916-7088
Fax: (630) 916-6665

October 24, 2006

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

Re: CMS proposed rule on new ASC payment system

Dear Sir/Madam:

I am writing in regards to the CMS proposed rule on a new ambulatory surgery center payment system. I have been in health care for 24 years and have found it to be a very rewarding field. For the first 12 years I was in hospital finance and administration with several hospitals and the last 12 years I have been in ambulatory surgery center administration. As a result I have had the opportunity to compare the important roles that both types of institutions have in our health care system. While surgery centers obviously cannot replace hospitals in many health care areas I have found that the rapid growth of surgery centers has come about because they provide important services in a more comfortable environment and at a reduced cost.

However to be able to offer outpatient services at the highest level of care, surgery centers must be reimbursed at an appropriate level. From my experience over the last 24 years and what I have learned from it is that the proposal that ASC's be paid only 62% of HOPD for providing identical outpatient surgical services falls considerably short of the level required to equitably reimburse ASC's. I've heard 75% proposed as a far more equitable level and I admit that I cannot throw a bunch of figures at you to "prove" that the 75% level is the "correct" level. However, my health care experience with both hospitals and surgery centers in the administrative as well as financial areas tells me that 75% is a level that surgery centers can live with regardless of which and to what extent are the specialties they offer. It is my firm belief that such would not be the case at a level which is much below 75%.

Thank you for your efforts in arriving at an ASC payment system which is fair to all parties involved including the ambulatory surgery center industry.

Sincerely,

Geoffrey J. Abbott
Administrator

Presidio Surgery Center

A California Pacific Medical Center Affiliate

80-O
(34)
ASC 8

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

October 23, 2006

Dana (2)
Joan
Carol
Alberta

To Whom it May Concern;

I am writing to give my thoughts on the CMS proposed rule for the new ambulatory surgery center payment system.

Ambulatory surgical centers (ASCs) provide patients with a high-quality, convenient and less expensive option for their outpatient surgery. When Medicare beneficiaries choose ASCs for their outpatient surgery, they and Medicare saves money.

The Medicare Modernization Act requires that the ASCs be transitioned from their current Medicare payment system to a new payment system by 2008. This provides an opportunity to provide more transparency across sites of service and permit ASCs to be a vital and viable competitive alternative to more expensive outpatient hospital departments.

CMS rule misses opportunity

MedPAC and the ASC community support moving to the hospital outpatient prospective payment system (HOPPS). The proposed rule would tie ASCs payments to the HOPPS in some but not all respects.

The six year payment freeze to ASCs and the cuts in the Deficit Reduction Act have resulted in a much lower payments to ASCs relative to payments made when services are provided in the HOPD. During this time, HOPD has received significant payment updates. In the proposed rule, CMS estimates that ASCs should be paid only 62% of HOPD for providing the identical outpatient surgical services. That low payment rate will result in significant cuts to a number of important, commonly performed services in ASCs including GI and ophthalmology. At the same time, payments for other specialties such as orthopedics will rise but it is not clear whether they will increase enough to become viable and be provided ubiquitously at ASCs.

1635 Divisadero Street, Suite 200
San Francisco, CA 94115
415.346.1218
Fax 415.346.2930

CMS can help Medicare and beneficiaries save money by making ASCs a viable, competitive alternative to outpatient hospitals by fixing the following problems in the proposed rule.

1. **Adopt an expansive, realistic interpretation of budget neutrality that examines total Medicare spending on outpatient surgery.** It is clear that the new payment system and the expansion of the ASC list will result in migration of services from one site of service setting to another. CMS has the legal authority and the fiduciary responsibility to examine the consequences of the new ASC payment system on all sites of care – the physician office, ASCs, and HOPD. The ASC industry is working with respected actuarial and Medicare payment experts to present quantitative analysis on the ASC percentage of HOPD that should be provided if CMS adopts a realistic interpretation of budget neutrality that examines the impact of the new ASC payment system on all Medicare spending on outpatient surgery. We expect that number to be substantially higher than the 62% CMS announced in its "alternative methodology."

2. **Create a truly exclusionary list for ASC services, as suggested by MedPAC and Secretary Leavitt.** Of the many payment systems administered through CMS, only the ASCs are bound to a list of permitted procedures determined by CMS. In December 2005, Secretary Leavitt wrote a letter to Senator Crapo that HHS intends to "maximize choices" for beneficiaries by significantly expanding the list of procedures that could be performed in an ASC. While the proposed rule would add 750 procedures to the ASC list, most are low complexity procedures and are capped at the physician fee schedule rate, not paid using a percentage of HOPD rates. CMS failed to include on the list many higher complexity services that have for years been safely and effectively performed in ASCs through the country. By not creating a truly exclusionary list, CMS is losing an opportunity to increase patient choice and rely on the clinical judgment of the surgeon.

3. **Do not widen the gap between HOPD and ASC payments over time.** ASCs confront the identical inflationary pressures as hospitals – hiring and retaining qualified OR nurses, purchasing medical supplies and the like. Yet CMS has proposed updating ASC payments by the consumer price index, a general measure of inflation of the economy rather than the hospital market basket update. This will result in a full percentage differential each year. Over time, the disparity in payments will create deeper divisions between prices paid in the HOPD and the ASC without any evidence that different payment rates are warranted.

4. **Create a truly parallel system to HOPD in all aspects.** The CMS proposed rule continues to treat HOPD and ASCs differently in certain key respects. These differences should be eliminated and ASCs and HOPD payments made on the same basis. For example, prosthetic devices and implantable DME are bundled in HOPD payments at rates that allow a full pass though of the DME costs. Payment levels for ASCs should be set at similar levels to allow full reimbursement for DME costs (*i.e.*, whatever discount factor is used to determine ASC payments relative to HOPD should not apply to the portion of the payment related to DME cost). Otherwise, many procedures that could be safely performed in an ASC more conveniently for patients and at less cost to the Medicare program will not be available because payments will remain below cost.

Sincerely,

Jessie Scott

Jessie Scott
Administrator
Presidio Surgery Center

DIGESTIVE DISEASE MEDICAL CONSULTANTS, P.C.

DIPLOMATES AMERICAN
BOARD OF INTERNAL MEDICINE
WITH SUBSPECIALTY IN
GASTROENTEROLOGY
PRACTICE LIMITED TO GASTROENTEROLOGY

DAVID H. CORT, M.D.
JAMES H. PETERSEN, M.D.
PAUL E. BUSE, M.D.
BRUCE H. WITTE, M.D.
DAVID T. WALDEN, M.D.
MARC J. BERNSTEIN, M.D.
DAVID S. LOTSOFF, M.D.
MICHAEL J. CLEARY, M.D.
JOHN J. KELLY, M.D.
MICHELE C. WOODLEY, M.D.
MICHAEL J. ZEREGA, M.D.
RACHEL PRANGER, PA-C
KAREN H. PLATT, PA-C

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October 10, 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 Surgery Centers - PPS Proposed Rule

Dear Dr. McClellan:

I am a practicing gastroenterologist in St. Louis, Missouri. We treat a large number of Medicare beneficiaries. I am communicating to you to emphasize my grave concern regarding CMS's recent proposal to change reimbursement to ambulatory surgery centers.

In our practice we try to provide high-quality, cost-effective medicine. For this reason, we perform endoscopies in our ambulatory surgery center. As you are aware, we are currently reimbursed at 89 percent of what hospital outpatient departments are paid. Our patients not only receive high-quality and cost-effective care, but they do so in an environment that is very conducive to deliver these services in an efficient and unintimidating fashion.

Our endoscopy center has actually improved patient acceptance of colorectal cancer screening recommendations. This has proven invaluable in detecting and preventing colon cancer. We also treat patients with a variety of other gastrointestinal disorders in an environment that allows for easy and efficient access to appropriate diagnostic and therapeutic endoscopic studies.

By further reducing our reimbursement to the proposed 62 percent of hospital outpatient reimbursements, this will result in an additional 30 percent cut in our payments. This level of reimbursement would certainly result in bankruptcy and closure of many ambulatory endoscopy centers. This would have a significant negative effect on both the quality of healthcare delivery in the United States as well as on the economics of how these services are delivered. If we close our endoscopy center, we will then need to perform these procedures at the hospital which will result in a significant increase in cost to the Medicare system. This would certainly be a tragedy both to our patients as well as to the healthcare budget and the economy of the United States. If

226 South Woods Mill Road
Suite 52 West
Chesterfield, MO 63017
314-434-2399
FAX 314-434-5653

3023 North Ballas Road
Suite 520-D
St. Louis, MO 63131
314-569-2620
FAX 314-996-6902

200 Brevco Plaza
Suite 208
Lake St. Louis, MO 63367
636-561-9020
FAX 636-561-6208

anything, I would expect the CMS to encourage a higher rate of utilization to these outpatient facilities to help provide easier access to screening, diagnostic and therapeutic endoscopic services as well as to control our healthcare costs.

It is hard to believe that this is the intention of the CMS. If we continue with the proposed recommendations, then this will lead to limited access, increased costs and decreased quality of care.

Please help us prevent a possible disaster in the delivery of gastroenterology services in the United States.

Sincerely,

Paul E. Buse, M.D.

PEB/dmh t:10/11/06 SL:pw

cc: Allan P. Weston, M.D.

82

GREGORY H. JOHNSON, M.D.
227 W. JANSS ROAD, SUITE 215
THOUSAND OAKS, CALIFORNIA 91360
TELEPHONE (805) 497-9597

DIPLOMATE AMERICAN BOARDS OF
INTERNAL MEDICINE & GASTROENTEROLOGY

October 13, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: 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 physician engaged in the private practice of gastroenterology and belatedly becoming involved in the development of an ambulatory surgical center which will have two dedicated gastrointestinal endoscopy suites.

I have just become aware of the proposed reduction in reimbursements for the ASC facilities and wish to express what I think is lack of wisdom in this probably shortsighted effort to reduce expenses.

If fees are reduced further, Medicare patients will probably not be welcomed into ambulatory facilities thus denying them outpatient services in a pleasant, professional, and courteous setting. The only alternative would be hospital-based facilities which are, and will continue to be, substantially more expensive and difficult for the Medicare population.

I would urge you to reconsider the proposal to decrease the reimbursement to the ambulatory surgical facilities and actually consider increasing the reimbursement. If not, the law of unintended consequences will almost certainly apply and anticipated savings will never materialize.

Sincerely,

Gregory H. Johnson, M.D.

GHJ:plp
cc: American College of Gastroenterology

CHARLOTTE GASTROENTEROLOGY & HEPATOLOGY, P.L.L.C.

83

Thomas A. Roberts, Jr., M.D.
John H. Moore, III, M.D.
Thomas J. Gavigan, M.D.
John S. Hanson, M.D.
Thomas A. Carr, M.D.
James L. Toussaint, M.D.
David G. Scholz, M.D.
Sam R. Fulp, M.D.
Dennis D. Kokenes, M.D.
Thomas E. Werth, M.D.
Gardiner Roddey, M.D.
Steven A. Josephson, M.D.
Lauren I. Browne, M.D.
Robert J. Schmitz, M.D.
Scott A. Brotze, M.D.
Simon Prendiville, M.D.
Sanjib P. Mohanty, M.D.
Linda Nutt, PA-C
Kristy Putts, PA-C
Ruth Perry, FNP-C

Kathy J. Sammis
Administrator

Appointment Line All Offices
(704) 377-0246

Charlotte Office
2015 Randolph Road
Suite 208
Charlotte, NC 28207-1200
(704) 377-4009
(704) 375-6970 Fax

Matthews
Matthews Medical Office Building
1450 Matthews Township Pkwy.
Suite 400
Matthews, NC 28105
(704) 849-8939
(704) 844-2679 Fax

Ballantyne
Ballantyne Medical Two Building
15830 John J. Delaney Drive
Suite 175
Charlotte, NC 28277
(704) 543-1220
(704) 543-3198 Fax

Huntersville
North Point Medical Mall
16525 Holly Crest Lane
Suite 120
Huntersville, NC 28078
(704) 892-8301
(704) 892-6638 Fax

Mooresville
Fairview Center
150 Fairview Road
Suite 120
Mooresville, NC 28117
(704) 235-2880
(704) 235-2899 Fax

October 9, 2006

Mark McClelland, M. D.
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-1506-P
P. O. Box 8014
Baltimore, Maryland 21244-8014

RE: **MEDICARE PROGRAM: Ambulatory Surgery Centers PPS proposed rule**

Dear Dr. McClelland:

I am writing to express my opposition to the recent proposal by CMS to change the way Ambulatory Surgery Centers are paid for their services. The proposed changes will cut payments to Ambulatory Centers by approximately 30%. These payments will apply to Medicare beneficiaries. It is obvious that CMS is trying to save money.

Unfortunately this will cost CMS more money. Medicare patients will be shifted to hospitals and CMS will wind up paying the higher facility fees to hospitals in order to get those patients their colonoscopies.

This proposed rule actually serves as a disincentive to perform endoscopy on Medicare beneficiaries in ambulatory settings. It provides an incentive to shift those patients to hospital facilities. The result will be that CMS, and hence the taxpayer, will be paying more for colonoscopies than they should.

I trust you will do everything in your power to prevent the adoption of this shortsighted rule change.

Sincerely,

Gardiner Roddey

Gardiner Roddey, M. D.

GR/jdp
Cc: The Honorable Elizabeth Dole, The United States Senate
The Honorable Sue Myrick, The United States House of Representatives
The Honorable Richard Burr, The United States Senate

Central Jersey Gastroenterology, PC

84

Brian Katz, M.D.

505 Raritan Avenue
Highland Park, NJ 08904

190 Prospect Plains Rd
Monroe Twnshp, NJ 08831

App't: 732-690-4219
Fax: 732-393-0575

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Dep't of Health & Human Services
Att'n: CMS-1056-P
POB 8014
Baltimore, Maryland 1244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

October 21 2006

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. **I DO NOT HAVE ANY FINANCIAL STAKE IN ANY AMBULATOY SURGICAL CENTER.**

I see a large number of Medicare patients. It is obviously clear to any practicing gastroenterologist that endoscopic and colonoscopic procedures are notoriously inefficient in the hospital setting. On numerous occasions, the emergent cases themselves can barely be accomplished within reasonable time. The proposed fee cut to ambulatory surgical centers will cause many of them to close and push my patients back to an already inefficient hospital setting. This will decrease access by my patients to their deserved procedures.

It is my sincere hope that CMS will not pursue and finalize this proposed fee cut.

Sincerely,

Brian Katz, M.D.

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(82)
ASC8

October 25, 2006

Dana (2)
Joan
Carol
Alberta

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P2
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

Please consider the following comments for CMS 1506-P2; The Hospital Outpatient Prospective Payment Systems and CY 2007 payment Rates; FY 2008 ASC Payment.

General Comments

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures **would** provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

ASC Payable Procedures (Exclusion Criteria)

We support CMS' practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

Thank you.

Sincerely,

Mary Cecelia Johnson

Mary Cecelia Johnson RN, BSN, CNN

333 Cassell Drive Suite 2300

Baltimore, Maryland 21224

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Oct 21, 2006

Mark McCellan M.D

I am writing to you to ask you to please not cut any Medicare benefits. We are seniors who have worked all our lives and paid our taxes and debt to society. We should be entitled to what we get from the government. It should not be taken away. Most of us live on a fixed income and will not have the cash to go to the Dr. or for test and our health is at risk. Please, Please re think this and leave Medicare where it is. I hope you re-consider and make the right decision. God Bless You!

Sincerely
Mary A. Volden
280 N. Main St 4A
Liberty, NY. 12754

Digestive Healthcare Consultants
3439 Granite Circle
Toledo, OH 43617
Phone : (419) 843-7996
Fax : (419) 841-7725

10/04/2006

The Honorable George Voinovich
United States Senate
140 Russell Senate Building
Washington, D.C. 20510

Dear Senator Voinovich,

I am writing to strongly oppose legislation aimed at decreasing pay to ambulatory surgical centers (ASC) to 62% of hospital outpatient departments (HOPD) beginning in January of 2008.

Congress was correct in 1997 when it enacted the Medicare colorectal cancer screening benefit and again in 2000 when it added average risk colonoscopy benefit. Unfortunately, the current plan to decrease reimbursement rates to ASCs is likely to result in further underutilization of screening colonoscopy at a time when current data suggests that it is already underutilized. Sadly, this will cause an increase in anticipated colorectal cancer and the added cost that it will bring.

Additionally, by reimbursing ASCs at a lower rate, it is likely to drive care to HOPDs where reimbursement rates are significantly greater, thereby increasing Medicare expenditures.

It is clear that if the Center for Medicare and Medicaid Services' (CMS) proposal is adopted that utilization of Medicare colorectal cancer screening is likely to further decline and that overall healthcare costs will increase as procedures are done in hospital outpatient departments with their higher fees. This will result in more undetected cancers with resultant short life spans and increased cost for management of this problem.

It is hard to believe that these are the results that the Center for Medicare and Medicaid Services is seeking. Unfortunately, the current proposals to decrease ASC reimbursement rates to 65% of hospital outpatient departments only guarantees that there will be decreased colorectal cancer screening and an increase in overall healthcare costs.

Again, I would strongly oppose any legislation which adopts these changes.

Respectfully,

Kevin K. Koffel, M.D.

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

Patient:
DOB: 12/30/1899
Date: 10/19/2006 8:33:59 PM

88

October 24, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P2
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

Please consider the following comments for CMS 1506-P2; The Hospital Outpatient Prospective Payment Systems and CY 2007 payment Rates; FY 2008 ASC Payment.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

I am a patient on dialysis for one year and has had a clotted fistula cleared in an ambulatory surgical center by Dr. William Julien, Vascular Surgeon (954) 975-6161. They just gave me a local to numb the area and I didn't feel a thing the whole procedure took about 1 ½ hours. I also, had maintenance done three months after to clear the fistula again and the next visit is in three months and he will put a stent in the area that keeps narrowing and causing me problems. He is the best, it is so non-invasive and painless and you are able to return to work the same day. He is a pioneer in this field!

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

Thank you.

Sincerely,

Victoria Baierlein

Victoria Baierlein
7630 Westwood Drive #321
Tamarac, FL 33321

VALLEY
OUTPATIENT
SURGERY
CENTER

N. 1414 Houk Rd.
Suite 204
Spokane, WA 99216
509-922-0362

89

October 26, 2006

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

I am writing to address the CMS proposed rule on the new ASC Payment system hoping that my voice from our own ASC will impact a difference. Our Ambulatory Surgery Center has established itself as a community leader in the ASC industry since 1989. We are highly respected for our expertise and skill in all aspects of our same day surgery procedures including fast track anesthesia, expedient turn around time between cases, our low infection rate and paramount to all our record of safety. Our facility is one of the most highly regulated surgery centers in Eastern Washington. We are accredited by the national Joint Commission of Accreditation Hospital Organization and standing members of both the Washington State Freestanding ASC Association and the national Federated Ambulatory Surgical Association.

We are a multi-specialty surgery center and perform surgery in the specialty areas of ENT, Ophthalmology, OB-GYN, Orthopedics and General Surgery. Our patient satisfaction surveys are remarkably and consistently high and the surgeons who utilize our services do so because we are able to help them with their own time management due to our quick turn around time between cases and they are confident in our safe, efficient environment.

Please consider a criteria that focuses patients who meet hospitalization criteria to have their surgeries conducted in the hospital setting and those who meet outpatient criteria to have their surgeries performed in ASC settings. Many patients are having surgeries performed in hospitals at a **significantly** higher cost to both Medicare and insurance companies daily and routinely.

Please reconsider the proposed ASC payment system. While we are able to provide ASC services at much less cost we still need to pay for supplies, staffing and overhead. Please reconsider the expansion of the CPT codes approved for the ASC's. There are so many that can safely be done in ASC at a profound savings to the government. Thank you for your consideration.

Respectfully,

Lyndee R. Czech, Administrator
Valley Outpatient Surgery Center
1414 N. Houk Rd, Suite 204
Spokane, WA. 99216

90

TRI·CITY REGIONAL
SURGERY CENTER

1096 Goethals Drive
Richland WA 99352
Phone 509 943 9700

October 27, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1506-P
Room 445-G
Hubert H. Humphrey Bldg.
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Norwalk:

As the Executive Director of the Tri-City Regional Surgery Center in Richland, Washington, I'm submitting comments on the CMS proposed rules which will change the way Ambulatory Surgery Centers (ASCs) are paid starting in 2008.

First, I want to commend CMS for proposing the significant expansion of the number of procedures that will be permitted to be done in ASCs for Medicare beneficiaries. This will give Medicare beneficiaries more choice as to where they have their surgeries performed. That said, I believe that CMS did not go far enough in this proposal. I believe that an ASC should be able to do ANY AND ALL procedures that can be performed in a Hospital Outpatient Department (HOPD). In other words, CMS should exclude only those procedures that are on the INPATIENT ONLY list.

Second, I would encourage CMS to broadly interpret the budget neutrality provision enacted by Congress. Please permit me to explain what I mean. The current proposal for CMS to pay ASCs approximately 62% of what it pays to HOPDs is simply not adequate. I believe that this low reimbursement rate will put many ASCs out of business, particularly if private insurers (which often follow Medicare's lead) do the same. To more readily illustrate why 62% of the HOPD rate is not adequate, I would point out that ASCs cannot purchase medical implants, medical supplies, and medical equipment for 38% less than a hospital can. We cannot hire operating room nurses and scrub techs for 38% less than a hospital can. We cannot pay 38% less than a hospital can for health insurance, for computers, or for virtually anything else. How can we compete, let alone stay in business, if we are paid 38% less than an HOPD? If a significant number of ASCs are put out of business by low reimbursement rates, the net effect will be that the Medicare beneficiaries who would have been served by the ASCs that have gone out of business will then have their surgeries performed in the HOPD (which will receive 38% more reimbursement than the defunct ASCs would have received), and that will SIGNIFICANTLY INCREASE Medicare's expenses!

Broadly interpreting the budget neutrality provision would therefore entail paying ASCs more so we can be more effective competitors to the HOPDs. As more surgeries are shifted from the HOPD to ASCs, Medicare will save significant dollars because of the lower ASC reimbursement rate. We feel we should be paid at very least 75% of what the HOPDs receive, if not more.

So, by narrowly interpreting the budget neutrality provision, you will actually raise Medicare's costs. By broadly interpreting the budget neutrality provision and paying ASCs a more competitive reimbursement rate, Medicare's costs will actually be reduced.

Third, I would encourage CMS to align the payment systems for ASCs and HOPDs to the maximum extent permitted by law. This will allow consumers to compare services and prices in an "apples to apples" manner. In other words, it will increase the transparency of cost and quality data so that Medicare beneficiaries can more readily effectively evaluate their choices as consumers of medical services. This also provides as level a playing field as possible so ASCs can be effective competitors to HOPDs.

Fourth, given the point I made above about aligning the payment systems for ASCs and HOPDs, I express grave concern about the CMS proposal to base the ASC yearly inflation update on the consumer price index while basing the HOPD yearly update on the hospital market basket. It is conceivable that over five to ten years, ASCs could be reimbursed at 45% to 50% of the HODP rates rather than the currently proposed 62%, because of the difference in the yearly update. That is ludicrious!!! ASCs need to have the same hospital market basket update as HOPDs in order to maintain at least a semblance of a level playing field and in order to continue providing Medicare beneficiaries with a choice of providers of surgical services. Further, the same relative weights should be used in ASCs as in HOPDs.

I appreciate the opportunity to provide comments on the proposed 2008 ASC payment system reform. I feel that the ASC industry is providing high quality and cost-effective service to our patients. A recent Federated Ambulatory Surgery Association (FASA) study showed that surgical cases performed in ASCs saved Medicare an average of $320 per case vs. the same cases performed in an HOPD. Multiplied by the millions of cases ASCs perform every year, and we're talking BIG DOLLAR savings for Medicare. We are positioned to continue saving Medicare BIG DOLLARS, but only if we're paid at rates that allow us to survive and even thrive. Please don't allow the ASC industry to be harmed by short-sighted policies and rules that will backfire on CMS.

Sincerely,

Francis Langston

Francis Langston
Executive Director
Tri-City Regional Surgery Center

DaVita.

DaVita Inc.
601 Hawaii St.
El Segundo, CA 90245
Tel: 310-536-2400 Fax: 310-536-2675

October 25, 2006

Department of Health and Human Services
Attention: CMS-1506
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

I support CMS' practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, **a less expensive and more accessible option than the current prevalent hospital setting.**

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to **reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.**

Sincerely,

Peter C. Donald
Vice President

SURGICAL
LICENSED WARD

q2

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms Norwalk:

I am writing to you concerning the Notice of Proposed Rulemaking published on June 12, 2006, regarding updates to rate-setting methodology, payment rates, payment policies, and the list of covered surgical procedures for ambulatory surgical centers. I am the facility Administrator at the Surgical Licensed Ward Ambulatory Surgical Center, an Endoscopy/Colon/Rectal facility located in Orlando, Florida.

The goal for all of us--providers, physicians, and payors--is to create a health care system that delivers excellent clinical outcomes in a cost efficient environment. It is with this goal that I submit the following comments.

The broad statutory authority granted to the Secretary to design a new ASC payment system in the Medicare Modernization Act of 2003 presents the Medicare program with a unique opportunity to better align payments to providers of outpatient surgical services. Given the antiquated cost data and crude payment categories underlying the current ASC system, we welcome the opportunity to link the ASC and hospital outpatient department (HOPD) payment systems. Although the HOPD payment system is imperfect, we believe it represents the best proxy for the relative cost of procedures performed in the ASC. In the comments to follow, we focus on three basic principles:

- Maximizing **alignment of the ASC and HOPD payment** systems to prevent the introduction of new disparities between the payment systems that could drive site of service selection,

- Ensuring **beneficiary access** to a robust range of surgical procedures that can be safely and efficiently performed in the ASC, and

- Establishing **fair and reasonable payment rates** to allow beneficiaries and the Medicare program to save money on procedures that can be safely performed at a lower cost in the ASC than the HOPD.

Phone: (407) 648-9151 FAX (407) 426-7017 110 W. Underwood St., Suite B, Orlando, Florida 32806

SURGICAL
LICENSED WARD

I. Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that the benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law.

While we appreciate the many ways in which the agency proposes to align the payment system, we are concerned that the linkage is incomplete and may lead to further distortions between the payment systems. Many policies applied to payments for hospital outpatient services were not extended to the ASC setting, and these inconsistencies undermine the appropriateness of the APC relative weights, create volatility in the relationship between the ASC and HOPD payment rates, and embed in the new payment system site of service incentives that will cost the taxpayer and the beneficiary more than necessary.

There are many components of the regulation where we believe a more complete alignment of the ASC and HOPD payment systems is appropriate. The major areas where we see a need for further refinement are:

A. **Procedure list:** HOPDs are eligible for payment for any service not included on the so-called inpatient only list. The CMS proposal to limit physician's ability to determine appropriate site of service for a procedure excludes many surgical procedures appropriate for the ASC setting.

B. **Treatment of unlisted codes:** When HOPDs perform services or procedures for which the CPT book does not provide specific codes, they use an unlisted procedure code, identify the service and receive payment for which we believe ASCs should also be eligible.

C. **Cap on office-based payments:** CMS proposes to cap payment for certain ASC procedures commonly performed in the office at the physician practice expense payment rate. No such limitation is applied to payments under the OPPS, presumably because the agency recognizes the cost of a procedure varies depending on the characteristics of the beneficiary and the resources available at the site of service. We likewise believe this cap is inappropriate for the ASC and should be omitted from the final regulation.

Phone: (407) 648-9151 FAX (407) 426-7017 110 W. Underwood St., Suite B, Orlando, Florida 32806

1. **Use of different billing systems:** The HOPD and ASC use the UB-92 and CMS-1500, respectively, to submit claims to the government for services. Use of different forms prevents ASCs from documenting all the services provided to a Medicare beneficiary, therefore undermining the documentation of case mix differences between sites of service. Most commercial payors require us to submit claims using the UB-92, and we suggest that the Medicare program should likewise align the payment system at the claim level.

II. Ensuring Beneficiaries' Access to Services through Fair And Reasonable Payments

Ambulatory surgery centers are an important component of beneficiaries' access to surgical services. As innovations in science and technology have progressed, ASCs have demonstrated tremendous capacity to meet the growing need for outpatient surgical services. In some areas and specialties, ASCs are performing more than 50% of the volume for certain procedures. Sudden changes in payments for services can have a significant effect on Medicare beneficiaries' access to services predominantly performed in ASCs.

If the facility fee is insufficient to cover the cost of performing the procedure in an ASC, responding to the change may mean that we are forced to relocate surgeries to the HOPD. Such a decision would increase expenditures for the government and the beneficiary.

Examples of procedures that we perform in our ASC that will have more than a 10% decline in reimbursement under the proposed regulations are:

CPT Code	Description	Volume in your Facility	Proposed Payment Rate	Change in Revenues
45378	*Colonoscopy*	*2,200*	*$ 397.91*	*($31,739.40)*
43239	*Upper GI*	*785*	*$387.84*	*($13,696.68)*
51785	*EMG*	*120*	*$54.89*	*($10,011.96)*

To remedy this situation and offset future financial losses we strongly recommend that CMS create a final rule that does not make drastic rate cuts and that makes the computation of rates and rate changes the same for both the HOPD and the ASC reimbursement.

In addition, CMS should expand the list of approved procedures to include any and all procedures that can be performed in an HOPD. CMS failed to include on the procedure list many higher complexity services that have for years been safely and effectively performed in ASCs throughout the country. CMS is losing an opportunity to increase patient choice and rely on the clinical judgment of the surgeon.

In summary, while there are elements of the proposed rule I support, my overreaching concern is that the proposed major overhaul of ASC payment policies contains serious flaws that must be addressed in order to keep the program viable for ambulatory surgery centers. I urge the Agency to give serious attention to the items discussed above. Please contact me to discuss this further:

Thank you for your time and attention in reviewing this correspondence.

Sincerely,
Walt T. H

William Hughes, Administrator
110 W. Underwood St., Suite B, Orlando, FL. 32806
(407) 648-9151 Email: slw@crcorlando.com

Enclosure 2 copies

Oct 27, 2006
93

Dear Doctor McClellan

I am opposed to the proposed rule change to drastically reduce insurance reimbursement for tests performed in a free standing ambulatory surgery center. It makes absolutely no sense to increase fees paid to inefficient hospital-based centers. I much prefer, as many of my friends and family do also, the efficient, safe, private and profession expertise service I receive at free standing centers. Please reconsider the proposed rule change.

Yours truly,
Michael Coppola
Michael Coppola

"Open our eyes to behold your gracious hand in all your works; that rejoicing in your whole creation we may learn to serve you with gladness . . ."

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Coalition For The Advancement Of Brachytherapy

660 Pennsylvania Avenue, S.E.
Suite 201
Washington, D.C. 20003
(202) 548-2307
Fax: (202) 547-4658

November 3, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Ms. Norwalk:

The Coalition for the Advancement of Brachytherapy (CAB) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to your August 8, 2006 proposed rule regarding the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (published in the August 23, 2006 *Federal Register*).

CAB was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies (see attachment 1). CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer.

CAB commends CMS on its efforts to develop a new ambulatory surgical center (ASC) payment system for implementation in 2008 as mandated by the Medicare Modernization Act of 2003 (MMA). In general, the Coalition supports the CMS proposal to align the new ASC payment system with the hospital outpatient prospective payment system (HOPPS). Although we understand the need to create a payment system that is budget neutral, the differential between the HOPPS rates and the proposed ASC rates exceed what CAB believes to be reasonable. Further, CAB remains concerned about the hospital claims data used to determine current HOPPS payment rates and the basis for ASC payment rates beginning in 2008. We are concerned that fluctuations in APC payment rates, including unstable rates for brachytherapy procedures, which result from use of inaccurate data could lead to limited patient access to these innovative cancer treatments and medical devices in both the hospital outpatient and ASC settings.

Additionally, there are a number of high volume procedures that CMS proposes to pay in the ASC setting in 2008 that are safely performed in a physician's office (i.e. office-based procedures). We believe that the affect of adding these office-based procedures to the ASC would result in a lower than reasonable payment rate for all procedures performed in an ASC. Therefore, we strongly encourage CMS to re-evaluate its criteria for procedures paid in an ASC and also ensure that an adequate number of <u>accurate</u> hospital claims are utilized to set appropriate ASC payment rates.

The CAB recommendations are discussed in detail in subsequent sections of this letter and include:

- CMS should maintain the "S" status indicator for all breast brachytherapy codes (CPT 19296, 19297 and 19298) thereby exempting them from the multiple procedure discount. In addition, CPT 19296 and 19297 should be added to Table 46 that lists procedures exempted from the multiple procedure discount.
- CMS should continue the current ASC policy of separate payment for items and services paid under the Medicare Part B Physician Fee Schedule, including brachytherapy sources and diagnostic and therapeutic imaging not directly related to performance of the surgical procedure. Similar to the HOPPS APC payments, these medical devices and services would <u>not</u> be packaged in the ASC facility fee.
- CMS should establish a fair and reasonable ASC conversion factor.
- CMS should use the hospital market basket to update the ASC conversion factor for inflation on an annual basis.
- CMS should ensure Medicare beneficiary access to new technologies by extending the use of New Technology APCs and Pass-Through Payments for medical devices in the ASC setting.

I. ASC Ratesetting: Payment Policy for Multiple Procedure Discounting

CMS proposes to mirror the HOPPS policy for discounting when a beneficiary has more than one surgical procedure performed on the same day at an ASC. The most costly procedure is paid the full amount and all other procedures are discounted by half. Procedures that require implantation of costly devices would be exempt from the multiple procedure discounting.

The current HOPPS status indicator for breast brachytherapy codes CPT 19296, 19297 and 19298 is "S" designating these as significant procedures that are not discounted when multiple surgical procedures are performed.

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

- 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy

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

All breast brachytherapy codes (CPT 19296, 19297 and 19298) require the use of high-cost medical device(s) that are bundled into the procedure payment, thus categorizing these procedures as device-dependent. For breast brachytherapy codes 19296 and 19297, the required medical device (a soft balloon catheter) is attached to a breast brachytherapy catheter that is inserted inside a lumpectomy cavity. For breast brachytherapy code 19298 multiple double lumen catheters (15-35 catheters) are implanted into the breast. These breast catheters (balloon and multiple double lumen) are connected to a high dose rate brachytherapy afterloader that provides high dose rate brachytherapy treatment.

In the 2008 ASC proposed rule, CMS includes breast brachytherapy code 19298 on the list of procedures proposed for exemption from the multiple procedure discount but does not include CPT 19296 and 19297. (See Table 46, pages 49652-49654, August 23, 2006 *Federal Register.*)

The 2007 HOPPS proposed rule maintains a status indicator of "S" for CPT 19298 that is consistent with the code being placed on the 2008 ASC multiple procedure discount exemption list. CMS proposes a change, however, in the status indicator for CPT codes 19296 and 19297 effective January 1, 2007. Comments were submitted by individual CAB member companies requesting that the status indicator for all three (3) breast brachytherapy codes be maintained and assigned status indicator "S," which correctly describes these as significant procedures.

CAB requests that CMS consider coherence and consistency to the clinical characteristics, resource use and code descriptions relevant to breast brachytherapy codes 19296, 19297 and 19298 and maintain their current status indicator of "S" thereby exempting them from the multiple procedure discount. Further, CMS should add CPT 19296 and 19297 to Table 46 that lists procedures exempted from the multiple procedure discount.

Breast conservation therapy (BCT) is now widely accepted as a treatment option for most women with Stage I and II invasive breast cancer and most patients with ductal carcinoma in situ. Partial breast irradiation with HDR brachytherapy lends itself to much shorter treatment times (one week) and the toxicities to adjacent normal structures (i.e., heart, lung, chest wall, skin, and contralateral breast) should be considerably reduced with this approach. This significantly shortened treatment time could potentially reduce health care costs, improve the quality of life of many patients undergoing BCT, and just as importantly, extend the conservation option to more women by reducing the inconvenience of external beam radiation therapy. We commend CMS on providing breast brachytherapy in the ASC setting but the proposed multiple procedure reduction policy may deter access to this important cancer treatment. We do not believe it is CMS' intent to decrease or limit Medicare eligible women access and choice to various surgical sites-of-service when she is faced with a diagnosis of breast cancer.

II. ASC Packaging

CMS proposes changes to some of the packaging rules under the new ASC payment system effective January 1, 2008. CAB supports applying the current HOPPS packaging rules to the new ASC system. Comparable packaging rules advance the CMS goal of parallel payment systems.

Under HOPPS, diagnostic and therapeutic imaging services are paid separately and in addition to the surgical procedure. The CMS proposal to package the costs of these otherwise separately payable items into the ASC facility fee would lead to significantly reduced payment for these procedures when performed in the ASC and reduce the ability to provide these procedures in that setting. We support the HOPPS policy and recommend that it be applied to the ASC system.

Further, brachytherapy sources are paid separately and in addition to the brachytherapy procedures in both hospital outpatient departments and ASCs. Under the new ASC payment system, we support continued separate payment for brachytherapy sources payable under the Medicare Part B Physician Fee Schedule.

CAB supports continuation of the current ASC policy of separate payment for items and services paid under the Medicare Part B Physician Fee Schedule, including brachytherapy sources and diagnostic and therapeutic imaging not directly related to performance of the surgical procedure. These medical devices and services would not be packaged in the ASC facility fee.

Further CAB supports applying the current HOPPS packaging rules to the new ASC system as it relates to items and services directly related to performing the surgical procedure.

III. ASC Conversion Factor

For 2008, CMS estimates a budget neutral ASC conversion factor of $39.688. CMS currently estimates that the revised ASC rates would be 62 percent of the corresponding HOPPS payment rates effective January 1, 2008.

CAB is greatly concerned that the proposed conversion factor will result in insufficient payment to ASCs for their services across the board. Paying for procedures performed in the ASC setting at 62 percent of the hospital outpatient payment rate may be too low to ensure Medicare beneficiary access to surgical services in the ASC setting.

For example, many procedures provided in the ASC setting involve the use of expensive medical devices (i.e. single patient use breast and rectal brachytherapy catheters). When the cost of the device exceeds the proposed CMS payment rate for the surgery, ASCs have a strong financial disincentive to perform the procedure and typically will not offer it. The 2008 conversion factor as proposed will result in decreased Medicare beneficiary access to breast and rectal brachytherapy in the ASC setting.

Surgical procedures performed in the ASC are efficient and cost-effective. CMS should examine the consequences of the new ASC payment system on all sites of care and adopt alternative methodologies to determine the conversion factor.

In order to ensure Medicare beneficiary access and availability of surgical procedures in the ASC setting, we urge CMS to adopt a fair and reasonable conversion factor to adequately reimburse ASCs for their services.

IV. ASC Inflation

Effective January 1, 2008, CMS proposes to apply a Consumer Price Index for all urban consumers (CPI-U) adjustment to update the ASC conversion factor for inflation on an annual basis. CMS states in the proposed rule that they are "not compelled to do so by the statute." (See page 49655, August 23, 2006 *Federal Register.*)

Currently, CMS updates the HOPPS conversion factor for inflationary changes by using the hospital inpatient market basket. CAB supports the CMS proposal to align the new payment system for ASC procedures with HOPPS and believes that the agency should mirror the HOPPS policy by adopting the hospital market basket as the preferred methodology to update the ASC conversion factor for inflation.

The CPI-U is a general measure of inflation of the economy and not representative of inflationary changes in health care. The CMS proposal to use CPI-U is unreasonable and illogical and creates disparity between payments to hospital outpatient departments and ASCs. The MMA provides discretion in creating the ASC payment system and the methodology used to determine the annual ASC conversion factor for inflationary changes. **Therefore, CAB recommends that CMS adopt the same method for updating the ASC conversion factor for inflation as it has for the HOPPS conversion factor—the hospital market basket.**

V. ASC Rate-Setting: Payment for New Technology

In the 2008 ASC proposed rule, CMS does not provide discussion or a methodology for providing payment for new technology in the ASC setting. We urge CMS to extend the use of New Technology APCs and Device Pass-Through Payments from the HOPPS to the ASC setting whenever appropriate for patient care. This will further CMS' goal of having the new ASC payment system parallel the HOPPS when possible and will ensure Medicare beneficiary access to new technologies in the ASC setting.

Specifically, CMS should permit payment to ASCs for new technologies using the same methodology and application process as for the HOPPS. In fact, for ease and simplicity, we recommend that CMS allow applicants for New Technology APCs and Pass-Through Payments the option to request payment in both the hospital outpatient and ambulatory surgical center when they submit their application. The application would need to be modified to provide for additional information to demonstrate that the new technology satisfies ASC facility fee criteria and requirements. We believe that extending the current HOPPS new technology policy to ASCs is the best way to ensure Medicare beneficiaries have access to new technologies and innovative procedures in the most appropriate, efficient, and cost-effective clinical setting.

CAB recommends that CMS ensure Medicare beneficiary access to new technologies by extending the use of New Technology APCs and Pass-Through Payments for medical devices in the ASC setting. We request that CMS implement this policy in the ASC final rule.

Conclusion

Brachytherapy offers important cancer therapies to Medicare patients. Appropriate payment for brachytherapy-related surgical procedures and sources will ensure that Medicare beneficiaries have full access to high quality cancer treatment in an ambulatory surgical center.

We hope that CMS will take these issues under consideration during the development of the 2008 Ambulatory Surgical Center Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (703) 534-7979.

Thank you for your consideration.

Sincerely,

Lisa Hayden

Lisa Hayden
Chair

Janet Zeman
Vice-Chair

Attachment 1

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

Member Companies

BrachySciences
C.R. Bard, Inc.
Cytyc Corporation
IsoRay
MDS Nordion
Mentor Corporation
Nucletron Corporation
Oncura
SIRTeX Medical, Inc.
Theragenics Corporation
Varian Medical Systems
Xoft, Inc.

CAB Advisory Board

American Brachytherapy Society
American College of Radiation Oncology
Association for Freestanding Radiation Oncology Centers
Society for Radiation Oncology Administrators

APMA
American Podiatric Medical Association

95

9312 Old Georgetown Road
Bethesda, Maryland 20814-1621
Tel: 301.581.9200
Fax: 301.530.2752
www.apma.org

November 6, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Ms. Norwalk:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's foot and ankle physicians and surgeons, is pleased to provide comments on the proposed rule that would revise the Ambulatory Surgical Center (ASC) facility payment system and update the ASC payment rates. The APMA offers the following comments:

ASC Payable Procedures (p. 49636)

We support the proposal to allow payment to an ASC facility for any surgical procedure except those that CMS explicitly excludes from payment. Additionally, we agree that beneficiary safety and the need for an overnight stay are reasonable factors to be used in determining whether payment of an ASC facility fee would be allowed for a particular surgical procedure.

Definition of Surgical Procedure (p. 49636)

Currently CMS defines a surgical procedure as any procedure described within the range of CPT Category I codes 10000-69999. CMS questions whether procedures that are primarily office-based or procedures that require relatively inexpensive resources to perform should be excluded from the list of approved procedures. CMS also questions whether a dollar threshold should be established for excluding procedures from the list. We do not believe that any procedure that falls within the CPT range identified should be excluded from the list. Additionally, to select a payment threshold that would be used in excluding procedures from the list requires the arbitrary assignment of a dollar amount, which we do not support. Instead, we believe that all surgical procedures, with the exception of those excluded for safety reasons or the need for an overnight stay, should be included on the list.

Significant Safety Risk (p. 49637)

CMS proposes to exclude from payment of an ASC facility fee procedures that the CY 2005 Part B Extract Summary System (BESS) data indicate are performed 80 percent or more of the time in the hospital inpatient setting, even if those procedures are not included on the OPPS "inpatient only" list. In reviewing Table 44 *(CPT Surgical Procedures Proposed for Exclusion from Payment of an ASC Facility Fee Because at Least 80 Percent of Medicare Cases are Performed* *on an Inpatient Basis)*, we did not identify any procedures included on the list that are typically performed by podiatric foot and ankle surgeons. Still, we remain concerned with the assignment of 80 percent for determining whether a procedure may safely be performed in the ASC setting. We believe there are procedures that, despite being typically performed in the inpatient setting, may safely be performed in the ASC. Further, we note that adoption of this additional criterion will create a discrepancy between the procedures that may be performed in an ASC and the procedures that may be performed in a hospital outpatient department (OPD). Specifically, there would be more exclusions from the list of eligible ASCs procedures because the only procedures excluded in OPDs are those on the "inpatient only" list. We believe the policy regarding exclusions should be consistent across settings and recommend application of the "inpatient only" list to both ASCs and OPDs. Rather than assign the 80 percent threshold, CMS should rely on input from the specialties performing the procedures in the development of the "inpatient only" list. If a specialty recommends that for safety reasons, a procedure should only be performed on an inpatient basis, CMS should include it on the "inpatient only" list it. If, however, a specialty believes a procedure can safely be performed on an outpatient basis (ASCs and OPDs), CMS should reconsider its decision to categorize it as "inpatient only."

ASC Unlisted Procedures (p. 49638)

We are concerned with CMS's decision to continue to exclude the unlisted surgical codes from payment of an ASC facility fee under the revised payment system. We understand that unlisted codes present unique challenges and that there is a potential for safety risks with some of the procedures. We believe, however, that there are procedures reported with the unlisted codes that can safely and reasonably be performed in the ASC setting. Certainly, many of the procedures performed by podiatric physicians and surgeons can safely be performed in the ASC setting and, ideally, each of these procedures would have their own code yet that is not always the case. We would prefer a system that reviews the unlisted codes on a case-by-case basis and allows for individual determinations of payment. We realize that implementing that type of system is resource-intensive, yet believe it could yield cost savings overall because if a procedure will not be recognized for payment in the ASC setting, it will need to be performed in a different setting with potentially higher costs associated with it.

ASC Office-Based Procedures (p. 49639)

The APMA supports the proposal to allow payment of an ASC facility fee for surgical procedures that are commonly and safely performed in the office setting. For a variety of reasons, the physician may determine that it is in the patient's best interest to have a particular procedure performed in the ASC setting and this policy would allow that to occur. We think this change is appropriate and necessary and will allow physicians to utilize their best medical judgment in determining the site for surgery. Additionally, we support the decision to limit the payment for these procedures so as not to encourage the migration of these procedures from the office setting to the ASC. The selection of a surgical setting should be dependent on the patient's needs and eliminating any financial incentives regarding office-based procedures is reasonable.

Procedures Not Proposed for Addition to the ASC List

We have several identified procedures that are performed by podiatrists that are not proposed for addition to the ASC list in CY 2008. These procedures do not appear, however, to have been specifically excluded from the list by CMS as they are not included in Table 44 *(CPT Surgical Procedures Proposed for Exclusion from Payment of an ASC Facility Fee Because at Least 80 Percent of Medicare Cases are Performed on an Inpatient Basis)*, Table 45 *(CPT Surgical Procedures Codes Proposed for Exclusion from ASC Facility Fee Payment Because They Require an Overnight Stay)* or Addendum E *(CPT Codes That Are Paid Only as Inpatient Procedures).*

We believe that there are procedures that should be added to the list since they can safely and reasonably be performed in the ASC setting. We recognize that they fall outside of the CPT range of surgical procedures yet recommend adding the following CPT codes as additions to the ASC list in 2008: 97605 *(Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters)*; 99183 *(Physician attendance and supervision of hyperbaric oxygen therapy, per session)*; G0247 *(Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include if present, at least the following. 1. local care of superficial wounds, 2. debridement of corns and calluses, and 3. trimming and debridement of nails)*; G0281 *(Electrical stimulation (unattended), to one or more areas, for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care)*; and G0283 *(Electrical stimulation (unattended), to one or more areas, for indication(s) other than wound care, as part of a therapy plan of care).*

In particular, we believe that the addition of code G0247 would be consistent with CMS's decision to add CPT codes 11055-11057, which describe the paring or cutting of lesions, and 11719-11721, which describe the trimming or debridement of nails, to the list. We believe that by adding code G0247, which includes the services reported with the CPT codes identified, CMS will achieve greater consistency with its list for 2008.

We believe there may be an error in Addendum BB that impacts codes of interest to us. There are some codes which are listed as eligible in some files yet are not included in Addendum BB. Specifically, codes 20974 *(Electrical stimulation to aid bone healing; noninvasive (nonoperative))*; 20979 *(Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative))*; and 64550 *(Application of surface (transcutaneous) neurostimulator)* are missing from Addendum BB. We believe these codes should be added to the ASC list and request that CMS revise Addendum BB to include them. Further, we believe that their addition lends support for including codes G0281 and G0283 on the list as well.

ASC Packaging (p. 49647)

The APMA is concerned with the proposal to package into the facility fee all direct and indirect costs incurred by the facility to perform a surgical procedure, including all biologicals. We assume that this policy would impact all skin substitutes and grafts. In reviewing the proposed 2008 ASC payments, we question whether they are sufficient to cover the costs of the products associated with each of the skin substitutes and grafts.

Clearly, there are real costs associated with the procedures performed to apply each of these products. Some codes, including 15340 *(Tissue cultured allogeneic skin substitute; first 25 sq cm or less)*, 15341 *(Tissue cultured allogeneic skin substitute; each additional 25 sq cm)*, 15430 *(Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children)* and 15431 *(Acellular xenograft implant; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof)* also include the wound preparation and debridement procedures that must be performed prior to the application of the product. Without question, the cost of the products themselves cannot be overlooked or undervalued. We urge CMS to ensure that ASC payments fairly and sufficiently capture all costs associated with the delivery of these services.

Similarly, we are concerned with the proposal to cease making separate payment for implantable prosthetic devices and implantable durable medical equipment (DME) inserted surgically at an ASC. If CMS finalizes this proposal, it must ensure that the payment for the device or implantable DME is fairly reflected in the ASC payment. In evaluating proposed payments for the series of codes 28290-28299, which are used to report the correction of hallux valgus, we appreciate that payments will increase between $199 and $335 for the codes in question. We question, though, why the increase in payment for CPT code 28293 *(Correction, hallux valgus (bunion), with or without sesamoidectomy; resection of joint with implant)*, which includes an implant whose cost, according to the CMS proposal, would now be captured in the ASC payment, will actually be less than or equal to that of most of the other codes in the same series that do not include a joint implant. Costs for implants are not insubstantial yet the 2008 payment for code 28293 does not appear to capture the actual cost of the implant.

In order to address the potential payment inequities that could occur in these situations, we believe that CMS could consider a couple of potential options. Either CMS could pay the proposed ASC amount and also continue to pay for the individual product as a separately identified item on the Durable Medical Equipment (DME) fee schedule. Or, alternatively, CMS could take the 2007 proposed OPPS payment amount, deduct the full product cost and reduce the remaining amount by the 62 percent adjustor. CMS could then add the full product cost to the adjusted amount and use that figure as the ASC payment.

To illustrate what we are suggesting, consider a procedure that involves a product or item that has an OPPS payment rate of $1729.40. If the product or item costs $1,000, CMS would start by removing the full product cost from its calculations. The remaining amount, $729.40, would then be adjusted by 62 percent and the resulting amount, $452.23, would then be added to the full product cost to arrive at the final ASC payment. In this example, the final proposed ASC payment would be $1452.23.

In general, we support the concept of creating a single ASC payment but believe the payments must fairly and appropriately capture the costs of the procedure performed. We urge CMS to review the proposed payments for procedure codes involving products or items. If the proposed payments are not increased to cover the costs of the products or items in their entirety, those products or items should continue to be allowed to be billed separately.

Multiple Procedure Discounting (p. 49651)

We support the proposal to adopt the Hospital Outpatient Prospective Payment System (OPPS) discounting policy that is applied to surgical procedures so that the costs of performing multiple procedures that require implantation of costly devices are taken into account. We agree that the cast and strapping procedures listed in Table 46 *(Procedures Proposed for Exemption from Multiple Procedure Discounting)* are appropriate but question whether the codes used to report the application of skin substitutes and grafts should also be included on the list. As discussed previously, if those codes include payment for the actual products, the product costs are real and should be fairly reimbursed. Subjecting the codes to the multiple procedure discount could result in
payments that do not even capture the cost of the product, much less the direct and indirect costs associated with the application of the product.

ASC Conversion Factor (p. 49656)

In detailing the proposed calculation of the ASC payment rates for CY 2008, CMS states in Step 4, "To determine the CY 2008 ASC conversion factor, we multiplied the estimated CY 2008 OPPS CF by the results in Step 3. Our current estimate of the CY 2008 OPPS CF is $64.013. Multiplying the estimated CY 2008 OPPS conversion factor by the 0.62 budget neutrality adjustment yields our current estimate of the CY 2008 ASC conversion factor: $39.688."

We realize that Congress required implementation of a new payment system that is budget neutral, but we disagree that costs incurred in the ASC setting are 38 percent less than those incurred in the OPPS setting. We believe that overall, CMS's calculations could result in underpayments to ASCs. Some of our members own and operate ASCs, either independently or in cooperation with other physicians and will be directly impacted by CMS's proposals. While we recognize that CMS will need to rely on input from those in the ASC industry in determining whether the proposed payment system will provide fair reimbursement for the procedures performed, we are concerned that a system that underpays ASCs could adversely impact all of our members who perform procedures in that setting. If payments are insufficient to cover costs, some ASCs may decide that certain procedures may not be performed in that setting. If that occurs, another setting, such as the outpatient hospital or inpatient hospital will need to be used, which will increase costs to the Medicare program.

In terms of future updates to the ASC payment rates, it appears that CMS is suggesting use of the Consumer Price Index for all urban consumers (CPI-U).

There is nothing in section 1833(i)(2)(D) -- which requires establishment of the new ASC payment system – that explicitly addresses the "updating" requirements for the new system. The statutory language of section 1833(i)(2)(D)(ii) requires budget neutrality in the initial start-up year for the new system but does not address what happens in subsequent years. The issue of annual updates under the new system is addressed only indirectly in section 1833(i)(2)(C) (the CPI-U default) where it says "if the Secretary has not updated "amounts established under such subparagraphs [ed: (2)(A) and (2)(B)] ***or under subparagraph (D)*** ... such amounts shall be increased by the percentage increase in the Consumer Price Index..." The highlighted phrase assumes that updating will occur under the new payment system, while the statutory provisions for such system do not address the update issue. This leaves open the question whether "updating" means the same thing under the new system as under the old – since the statute for the new system makes no reference to rates approximating costs – except in the initial start-up year.

We believe the statutory language provides sufficient flexibility to permit the use of the hospital market basket to update ASC payments and that the CPI-U is simply a default. Therefore, we recommend the use of the hospital market basket update for ASCs to provide consistent updates for both ASCs and hospital OPDs and to better align the two payment systems.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

David M. Schofield, DPM
President

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November 6, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS – 1506 – P; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Norwalk:

The American College of Osteopathic Surgeons (ACOS) and the American Osteopathic Academy of Orthopedics (AOAO) appreciate the opportunity to comment on the Proposed Rule published in the August 23, 2006 *Federal Register* with respect to proposed revisions to the Ambulatory Surgical Center (ASC) payment system for services furnished on or after January 1, 2008.

Proposed ASC Ratesetting

The current ASC payment methodology of nine standard categories ranging in payments from $333 to $1,339 does not adequately reflect the costs incurred by the ASC and has effectively prevented the ASC from being a viable setting to treat Medicare beneficiaries for a number of procedures. This result is clearly not what CMS or the Bush Administration intended, nor is it conducive to optimal patient care. Therefore, it is imperative that the payment methodology be changed in a manner that would allow the ASC to be a viable option for all procedures that can safely and effectively be performed there.

Further, once a new payment methodology is in place, there must be an effective manner to increase these payments to keep pace with inflation. The overhead amounts for the ACS payment groupings are based on a 1986 survey of ASC costs.

Since 1990, Congress has frozen or reduced updates to ASC rates for varying periods of time. Currently the ASC payment rates are frozen at their FY 2003 level. Such failures to keep pace with inflation cannot continue under the new payment methodology without even more impact on access to care for Medicare beneficiaries.

We support the proposal by CMS to base the new ASC rates on the APC groupings and weights used in the hospital outpatient setting. We understand that these weights would be multiplied by an ASC conversion factor. We do, however, see a continuation of the current problem of underpayment for a variety of ASC services because CMS is bound by statutory language in the Medicare Modernization Act (MMA) to ensure that the aggregate payments under the new ASC payment methodology are no greater than what they would be under the current methodology. Given that significant and unreasonable constraint, we do not comprehend how a new methodology could achieve the goal of encouraging procedures to be provided in an ASC, which might very well be the most cost-effective setting if reimbursed fairly and therefore physicians used it to provide services.

If the Medicare payment rates for procedures performed in an ASC setting continue even under the new methodology to be reimbursed at such low amounts that an ASCs costs are not even captured, then physicians will continue to choose the hospital outpatient department as the preferred setting.

We understand that this budget neutrality requirement is being imposed on CMS by Congress. Nevertheless, we wanted to voice our extreme concern over this provision in these comments.

Proposed Packaging Policy

Currently, CMS packages drugs, biologicals, and diagnostic services into the ASC grouping rate. Under the hospital outpatient prospective payment system, Medicare pays separately for many of these same items in addition to the Ambulatory Patient Classifications (APCs) payment for the underlying procedure. Meanwhile ASCs currently receive separate payments for prosthetic implants and implantable durable medical equipment (DME), while under the hospital outpatient prospective payment system reimbursement for these items is bundled into the APC payments.

CMS is proposing to continue bundling all drugs, biologicals, contrast agents, anesthesia materials, and imaging services into the new ASC rates, and is also proposing to end separate payment for implantable prosthetic devices and implantable DME. The only separate payments under the new ASC payment methodology would be for physician services, laboratory services, x-rays or other diagnostic procedures that are not directly related to performing the surgical procedure, nonimplantable prosthetic devices, ambulance services, leg, arm, back and neck braces, artificial limbs, and DME for use in the patient's home.

The appropriateness of any packaging proposal is directly related to the appropriateness of the payment for the underlying procedure. Since it appears that the payment for the underlying procedure will continue to be inadequately reimbursed under the new system, we would support separate payment for all items and services. Either the new system must appropriately reimburse for all the costs of performing a surgical procedure, including any implantable DME or drug that is necessary, or there must be another mechanism available to pay for these items. Without appropriate payment, access to care will again suffer for Medicare beneficiaries.

Proposed Payment for Office-Based Procedures

CMS is proposing to even allow procedures that are performed over 50% of the time in a physician's office to be paid for in an ASC, because there are some situations where, in the physician's judgment, due to the patient's condition, an ASC is a more appropriate venue. We agree that the physician should have the discretion to determine that a particular procedure should be performed in an ASC setting as opposed to an office setting.

However, CMS points out that if a high volume of services move from the less expensive office setting to the more costly ASC setting, then CMS will have to reduce the ASC conversion factor even more to maintain the statutorily mandated budget neutrality. Therefore, CMS is requesting comment on whether physicians really do want this option of performing these office-based procedures in an ASC setting.

We do not believe that physicians will unnecessarily perform procedures in an ASC setting if these procedures could safely be performed in the office. Physicians should be allowed the option of performing a procedure in an ASC when they believe it is medically necessary for the procedure to be performed there rather than the office. We do not foresee this shifting from the office setting to an ASC occurring to any extent that would require CMS to make an adjustment to the ASC conversion factor. If this venue shifting does occur in great volume, then CMS should revisit this issue.

Multiple Procedure Discounting

CMS is proposing to adopt for the ASC setting the hospital outpatient policy of reducing payment for multiple procedures performed on the same patient on the same day. Under the hospital outpatient prospective payment system, certain surgical procedures, such as those involved with the implantation of an expensive device, are exempt from the multiple procedure reduction. Under current ASC policy, multiple procedures are also reduced, with the most costly procedure paid in full and the other procedures reimbursed at 50 percent. There are no exceptions to this policy, particularly since implantable devices are currently reimbursed in an ASC separately.

We support the CMS proposal to exempt certain multiple procedures from this reduction under the new ASC payment methodology.

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We appreciate this opportunity to comment on the proposed changes to the ASC payment methodology and look forward to working with CMS staff towards implementation of a more equitable payment system for January 1, 2008.

Respectfully submitted by,

Guy D. Beaumont, Jr.
ACOS Executive Director

Morton Morris, D.O, J.D.
AOAO Executive Director