Submitter : Dr. Keith Bruninga **Date:** 11/06/2006

Organization : Rush University Medical Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

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See Attachment

CMS-1506-P2-976-Attach-1.DOC

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November 1, 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, Maryland 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:
I am an academic practicing gastroenterologist who presently treats Medicare beneficiaries in my practice. I am writing to express my grave concern with CMS's recent proposal to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments.

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

Both the GAO and CMS itself have stated that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC has repeatedly endorsed the concept that medical procedures and services should be site neutral. So, on its face, a proposal such as this one, which institutionalizes the concept of paying significantly more to the hospital than to the ASC, and which will likely reduce the capacity to provide GI screening colonoscopies and other GI endoscopic procedures by forcing a significant number of ASCs to close their doors to Medicare beneficiaries, if not to all patients, because Medicare's payment level will drop so precipitously that these ASCs can no longer meet their expenses and render a reasonable return on investment, seems foolish and counterproductive.

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

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

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For the Medicare System:

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

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

So, the inevitable result of this proposed CMS action, if implemented will be: (a) total Medicare costs for GI facility fees will rise (although the per unit facility fee for decreased number of these performed in the ASC may well decline); (b) available access by Medicare beneficiaries for GI colonoscopies and other endoscopic procedures will decline; and (c) more Medicare beneficiaries will die unnecessarily from colorectal cancer will increase as screening rates decline.

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

Respectfully submitted,

Submitter : Dr. Mark DeMeo **Date:** 11/06/2006

Organization : Rush University Medical Center

Category : Ambulatory Surgical Center

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Respectfully submitted,

Submitter : Dr. Edward Kane **Date:** 11/06/2006

Organization : North Coast Surgery Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

We support retaining the Medicare beneficiary coinsurance for ASC services at 20 percent. For Medicare beneficiaries, lower coinsurance obligations will continue to be a significant advantage for choosing an ASC to meet their surgical needs. Beneficiaries will save significant dollars each year under the revised ASC payment system because ASC payments will in all cases be lower than the 20-40 percent HOPD coinsurance rates allowed under the OPPS.

ASC Conversion Factor

ASC Conversion Factor

62 % conversion factor is unacceptable and often does not cover the cost of the procedure. We understand that budget neutrality is mandated in the MMA of 2003; however, we believe that CMS made assumptions in order to reach budget neutrality with which we differ, most especially the migration of cases from and to the ASC. The ASC industry has worked together with our physicians and established a migration model that is being provided to CMS along with the data in an industry comment letter. We encourage CMS to accept this industry model.

ASC Office-Based Procedures

ASC Office-Based Procedures

We support CMS s proposal to extend the new ASC payment system to cover procedures that are commonly performed in physician offices. While physicians may safely perform many procedures on healthy Medicare beneficiaries in the office setting, sicker beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition.

ASC Payable Procedures

ASC Payable Procedures

We support CMS s decision to adopt MedPAC s recommendation from 2004 to replace the current inclusive list of ASC-covered procedures with an exclusionary list of procedures that would not be covered in ASCs based on two clinical criteria: (i) beneficiary safety; and (ii) the need for an overnight stay. However, the ASC list reform proposed by CMS is too limited. CMS should expand the ASC list of procedures to include any and all procedures that can be performed in an HOPD. CMS should exclude only those procedures that are on the inpatient only list and follow the state regulations for overnight stays.

ASC Phase In

ASC Phase In

Given the size of the payment cuts contemplated under the proposed rule for certain procedures and specialties; especially GI, pain and ophthalmology, one year does not provide adequate time to adjust to the changes. Thus, we believe the new system should be phased-in over several years.

ASC Ratesetting

ASC Ratesetting

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs.. These facilities exist in the same communities and often in partnership with the community hospital. 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.

ASC Unlisted Procedures

ASC Unlisted Procedures

At a minimum, when all the specific codes in a given section of CPT are eligible for payment under the revised ASC payment system, the associated unlisted code also should be eligible for payment.

ASC Updates

ASC Updates

We are pleased that CMS is committing to annual updates of the new ASC payment system, and agree it makes sense to do that conjunction with the OPPS update cycle so as to help further advance transparency between the two systems. Regular, predictable and timely updates will promote beneficiary access to ASCs as changes in clinical practice and innovations in technology continue to expand the scope of services that can be safely performed on an outpatient basis.

Submitter : Dr. Ashkan Farhadi **Date:** 11/06/2006

Organization : Rush University Medical Center

Category : Ambulatory Surgical Center

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GENERAL

See Attachment

CMS-1506-P2-980-Attach-1.DOC

#980

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Tanya Gilbert
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November 1, 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, Maryland 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:
I am an academic practicing gastroenterologist who presently treats Medicare beneficiaries in my practice. I am writing to express my grave concern with CMS's recent proposal to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments.

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

Both the GAO and CMS itself have stated that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC has repeatedly endorsed the concept that medical procedures and services should be site neutral. So, on its face, a proposal such as this one, which institutionalizes the concept of paying significantly more to the hospital than to the ASC, and which will likely reduce the capacity to provide GI screening colonoscopies and other GI endoscopic procedures by forcing a significant number of ASCs to close their doors to Medicare beneficiaries, if not to all patients, because Medicare's payment level will drop so precipitously that these ASCs can no longer meet their expenses and render a reasonable return on investment, seems foolish and counterproductive.

Medicare seems to be ignoring both the stated priorities of the current Administration as well as the lessons of cost management in the private sector. President Bush and his staff are on record, on multiple occasions, stating that ASCs are a more cost-effective environment than the hospital to receive key medical services. When private sector insurers have sought to reduce total health care costs, they have actively sought to encourage patients to receive

their services in the ambulatory surgery center, instead of in the hospital outpatient department. In a recent example, Blue Cross of California has announced that it will pay a 5% premium to physicians for every GI endoscopy that is performed in the ASC, rather than in the HOPD. This CMS proposal, which would always pay more to HOPDs and always pay less to ASCs, is directly antithetical to the direction adopted by the private sector insurers.

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

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

In the gastroenterology area, CMS's proposed policy virtually assures results inimical to the public health. Today, when a GI procedure, such as a screening colonoscopy is performed in an ASC, that ASC receives a facility fee which on the average amounts to 89% of the facility fee CMS pays to the HOPD if that same procedure is performed there. We need to provide a bit of background relating to the effectiveness of the Medicare colorectal cancer screening benefit. Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has done everything possible to emasculate the effectiveness and utilization of that benefit. Since 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction would almost certainly be in excess of 50%). According to information from the American College of Gastroenterology, no other Medicare service has been cut this much. Now, CMS issues a new proposal, which would further undercut and devastate the prospects for Medicare beneficiaries to receive a colorectal cancer screening colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS foolishly has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs, as by far the biggest potential loser, with the prospect of cuts from 89% of the HOPD payment to 62%.

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

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

For Patients:

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

For the Medicare System:

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

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

So, the inevitable result of this proposed CMS action, if implemented will be: (a) total Medicare costs for GI facility fees will rise (although the per unit facility fee for decreased number of these performed in the ASC may well decline); (b) available access by Medicare beneficiaries for GI colonoscopies and other endoscopic procedures will decline; and (c) more Medicare beneficiaries will die unnecessarily from colorectal cancer will increase as screening rates decline.

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

Respectfully submitted,

Submitter : Dr. John Losurdo **Date:** 11/06/2006

Organization : Rush University Medical Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

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CMS-1506-P2-981-Attach-1.DOC

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Respectfully submitted,

Submitter : **John Marasco** **Date: 11/06/2006**

Organization : **Marasco**

Category : **Individual**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

Please see my attached comments. Also attached is an article I have written regarding this subject.

John A. Marasco
Marasco & Associates
Principal & American Consumer

CMS-1506-P2-982-Attach-1.DOC

CMS-1506-P2-982-Attach-2.DOC

#952-1

THE REAL NUMBERS: How CMS Has Missed the Forest for the Trees

by John A. Marasco, AIA, NCARB
Principal
Marasco & Associates, Inc.

CMS's proposed rule to reimburse Ambulatory Surgery Centers (ASC's) at 62% of Hospital Outpatient Departments (HOPD's) is preposterous. Although comparing the two environments as they treat the same patient types makes perfect sense, the way they arrived at the 38% reduction is down right idiotic. The intent of creating an equitable, not equal, transparent playing field for both entities to compete on is a brilliant idea; to do so by overpaying HOPD's and underpaying ASC's is just downright lazy. How can CMS think that just because HOPD rates are set, in the name of "budget neutrality", ASC's should get the raw end of the deal? Although it might sound crazy to CMS, maybe the whole rate structure should be readjusted based on some sense of reality - not an unfair "budget neutral" approach. Lets look at the facts.

Over our 30+ year history Marasco & Associates, a healthcare architectural firm, has helped develop 300+ ASC's & 20+ hospitals. We have therefore helped prepare hundreds of feasibility analyses projecting actual overhead costs. Many of our clients have asked us to look at their proposed facility as both an ASC as well as a HOPD. They want to know the increase in costs to an ASC now, in order to convert it into a HOPD later. Their long term goal is obviously to turn their ASC into a surgical hospital - we have had several clients that have successfully done exactly that. Surgical hospitals are fully accredited, certified & licensed hospitals that specialize in handling surgical cases.

In order to find a fair and equitable reimbursement percentage reduction of HOPD payment rates for ASC's one needs to look carefully at a facilities total overhead. This overhead is broken into four major cost categories - staff, supplies, real-estate and equipment. As real-estate development is my expertise as well as being one of the largest cost differentials between a HOPD and an ASC, that is where I will begin.

REAL-ESTATE

One must keep in mind that each state has its own rules & regulations for the development of an ASC or a hospital and we simply don't have time to cover every situation. Most states however have at least partially adopted the American Institute of Architects, Guidelines for Design & Construction of Hospital & Health Care Facilities as a basis for the physical environment requirements of both an ASC as well as a HOPD. Of course other codes, like the International Building Code (IBC), National Fire Protection Agency (NFPA), American National Standards Institute (ANSI)..., are applied locally to ASC's and hospitals alike. This is therefore a general comparison, and as with most comparisons may not apply to every situation.

For this article I have compared a 4 operating & 2 procedure room ASC to a like HOPD within a hospital. Although this article does not permit me the space to show you the actual comparison, we have posted it on our website at www.marasco-associates.com for your review. In a nut shell our findings indicate that it takes ~10% more square footage to build a HOPD than a comparable ASC. Most of this increase comes from the required larger corridor widths, "circulation", as well as larger distances between gurneys and obstructions throughout a HOPD. There are also some minor requirement differences for scrub facilities as well as specimen and blood storage areas. The other large difference comes in the form of non-usable square footage like mechanical & electrical rooms. Typically the capabilities of an integrated HOPD's heating, ventilation and air conditioning system as well as its electrical and medical gas systems are required to be higher than those of an ASC. This doesn't mean that an ASC's environment is unsafe; it simply means that as part of a globally more complex facility, i.e. a hospital, an integrated HOPD is typically required to meet higher standards. In fact many states allow free standing HOPD's to meet ASC standards. However for arguments sake lets assume a worse case scenario of an integrated HOPD. In addition to the higher capability level of these systems, by being part of a hospital a HOPD is considered an Institutional or "I" occupancy under the IBC & NFPA..., while an ASC can often be classified as a Business or "B" occupancy. An "I" occupancy requires a fire rated building type while a "B" occupancy typically does not. In addition an "I" occupancy has stricter fire partition standards, shorter exit corridor lengths.... Because of these reasons the construction cost of a HOPD is ~25% more than an ASC. We get this cost figure from RSMeans "CostWorks" program, which is the construction industries most used, quoted, and respected construction and facility management cost guide. We have used these figures to accurately estimate costs on over 500 projects and can assure you they are accurate.

When you compound the 10% increase in size with the 25% increase in construction costs you get a net 38% increase in total real-estate costs. Although this 38% increase sounds right in line with CMS's proposed 38% decrease to HOPD payment rates for ASC's, it actually couldn't be farther from the truth. When you take this 38% increase and apply it to real-estate costs, which account for no more than 15% of the total facility overhead, the total facility overhead is increased by only 6%. Of course there are an infinite number of smaller items one can nit pick about, but in a best case scenario the increased real-estate costs of providing a HOPD environment over an ASC environment will net a maximum **10% total facility overhead cost gain for the HOPD**.

STAFF

Given an ASC's ability to offer more consistent hours to their non-union staff than a hospital typically can, one can argue that the ASC has the advantage on this overhead cost component. Due to market conditions we typically do not see this competitive edge exceeding 15%. When you take this 15% increase and apply it to staffing costs, which account for no more than 45% of the total facility

overhead, the total facility overhead is increased by only 7%. Once again there are of course an infinite number of smaller items one can nit pick about, but in a best case scenario the increased staffing costs of providing a HOPD environment over an ASC environment will net a maximum **10% total facility overhead cost gain for the HOPD**.

SUPPLIES, EQUIPMENT & MISCELANEOUS

As each facility is treating a like patient, the supplies, equipment & miscellaneous (insurance, management, marketing...) costs for either an ASC or a HOPD to service that patients' needs should be the same. In fact a hospital, with its globally larger purchasing budget, should actually have a competitive advantage over an ASC and should be paying less for these overhead costs. However for arguments sake let's say that these overhead costs are a push and will net a **0% total facility overhead cost gain for the HOPD**.

Of course there are numerous other costs that can be nit picked. The hospitals tout that ASC's don't need to be accredited or collect & submit annual financial & quality data like they do and that this costs them additional money. Most of the nations ~5,000 Medicare certified ASC's are also accredited by AAAASF, AAAHC and/or JCAHO even though they are not required to be and although currently not a requirement for ASC's, CMS is already talking about making data collection & submittal one. Many ASC's already provide AAASC, FASA and/or OOSS with similar data in order to better serve their industry and patients. This just goes to show how dedicated the ASC industry is to quality patient care. Making ongoing accreditation and data collection & submittal a requirement in order to compete equitably with HOPD's will not pose a problem to the vast majority of the nations ASC's. However for arguments sake let's say that these requirements are not applied to ASC's. As this overhead cost component accounts for no more than 10% of the total facility overhead, a best case scenario for providing a HOPD environment over an ASC environment will net a maximum **5% total facility overhead cost gain for the HOPD**.

Ultimately when you add it all up even in a very conservative setting, providing a HOPD environment over an ASC environment to provide services on a like patient should cost no more than 20-25% of the facilities total overhead. Therefore for CMS to pay ASC's anything less than 75-80% of HOPD payment rates is simply unfair . Again to maintain this "budget neutrality" by overpaying HOPD's and underpaying ASC's is just wrong. All the ASC industry is asking for is the chance to compete on an equitable transparent playing field, just like the FTC, GAO & OIG would want. CMS has the opportunity to create this field once and for all; I just hope they can find a way to pull it off.

Strangely enough the biggest looser of this whole situation would be CMS themselves. If passed at the proposed 62% rate this ruling will at a minimum discourage the development of new ASC's and at a maximum cause at least some existing ones to stop taking Medicare patients or go out of business

altogether. Even at a more equitable 75-80% of HOPD payment rates for ASC's, CMS is getting equal if not better care for their patients at a 20-25% discount over HOPD's – why would they want to mess with that kind of success? ASC's already save CMS over a billion dollars a year by using them over hospitals, eliminating that savings does not sound like a "budget neutral" situation to me. Another response to the proposed rate would be the very reason I know so much about these cost differences in the first place – surgical hospitals! The 62% rate will force surgeons to upgrade their ASC's to surgical hospitals in order to survive by taking advantage of CMS's infinite, "budget neutral" wisdom. By taking this approach to setting the percentage reduction rate, CMS will ultimately do more harm than good to themselves as well as us, the tax payers.

We need to convince the powers that be, your Representatives & Senators, that they shouldn't cut off their nose to spite their face. They need to help create an equitable payment differential between ASC's and HOPD's, keep that differential tied to the same inflation factor and move forward.

982-2

MARASCO & ASSOCIATES, INC.
HEALTHCARE ARCHITECTS AND CONSULTANTS

October 30, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and 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

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

Dear Ms. Norwalk:

I am the owner of Marasco & Associates, an architectural firm located in Denver which specializes in healthcare. My firm has helped develop over 300 ASC's and hospitals all across the USA. In doing so I have seen first hand the benefit ASC's bring to the people who work and the patients that are treated in them.

The experience of ASCs is a rare example of a successful transformation in health care delivery. Thirty years ago, virtually all surgery was performed in hospitals. Waits of weeks or months for an appointment were not uncommon, and patients typically spent several days in the hospital and several weeks out of work in recovery. In many countries, surgery is still like this today, but not in the United States.

Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices. In the ASC setting, physicians are able to schedule procedures more conveniently, are able to assemble teams of specially-trained and highly skilled staff, are able to ensure the equipment and supplies being used are best suited to their technique, and are able to design facilities tailored to their specialty. Simply stated, physicians are striving for, and have found in ASCs,

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the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Overview

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 outdated 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, 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 the alignment of the ASC and HOPD payment systems eliminate distortions between the payment systems that could inappropriately influence site of service selection,

- ensuring beneficiary access to a wide 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.

Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost data used to evaluate outpatient surgical services for Medicare beneficiaries. 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 disparities 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 a more complete alignment of the ASC and HOPD payment systems is appropriate. Below is an overview of the major areas where further refinement of the proposed rule is warranted. These issues are discussed in greater detail under the relevant section heading in the text to follow.

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

- **Treatment of unlisted codes:** Providers occasionally perform services or procedures for which CPT does not provide a specific code and therefore use an unlisted procedure code identify the service. HOPDs receive payment for such unlisted codes under OPPS; ASCs should also be eligible for payment of selected unlisted codes.

- **Different payment bundles:** Several of the policies for packaging ancillary and other procedure costs into the ASC payment bundle result in discrepancies between service costs represented in the APC relative weight. For example, when HOPDs perform services outside the surgical range that are not packaged, they receive additional payments for which ASCs should also be eligible.

- **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.

- **Different measures of inflation:** CMS updates the OPPS conversion factor for annual changes in inflation using the hospital market basket; however, the agency proposes to update ASC payments using the consumer price index for all urban consumers. The market basket is a better proxy for the inflationary pressures faced by ASCs, as it is the measure used by the agency to update payments to hospitals providing the same services.

- **Secondary rescaling of APC relative weights:** CMS applies a budget neutrality adjustment to the OPPS relative weight values after they are recalibrated with new cost data each year. The agency proposes a secondary recalibration of the relative weights before they are used by ASCs. This secondary recalibration will result in annual and potentially cumulative variation between ASC and HOPD payments without any evidence that the cost of providing services has further diverged between settings.

- **Non-application of HOPD policies to the ASC.** Over the years, CMS has implemented through statutory or administrative authority numerous policies to support services in the HOPD, including additional payment for high-cost outliers, transitional corridor and hold-harmless payments to rural and sole-community hospitals, and payments for new technologies. While not all of these policies are appropriate for the ASC, surgery centers should be eligible to receive new technology pass-through payments.

- **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 ASCs to submit claims using the UB-92, and the Medicare program should likewise align the payment system at the claim level.

Ensuring Beneficiaries' Access to Services

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.

The implementation of the revised payment system proposed by Medicare will result in significant redistribution of payments for many specialties. Because ASCs are typically focused on a narrow spectrum of services that require similar equipment and physician expertise, they have a limited ability to respond to changes in the payment system other than to adjust their volume of Medicare patients. On the one hand, for procedures such as ophthalmology, there is a limited market for these services in the non-Medicare population. If the facility fee is insufficient to cover the cost of performing the procedure in an ASC, responding to the change may mean relocating their practice to the HOPD. Such a decision would increase expenditures for the government and the beneficiary. On the other hand, the demand for services such as diagnostic colonoscopies is extremely high in the non-Medicare population. If ASCs determine that the payment rates for such services are too low, they may be able to decrease the proportion of Medicare patients they see without reducing their total patient volume. In that case, beneficiaries may experience significant delays accessing important preventive services or treatment. Neither outcome is optimal for the beneficiary of the Medicare program.

Establishing Reasonable Reimbursement Rates

Medicare payment rates for ASC services have remained stagnant for nearly a decade. Over time, the industry has identified which services it can continue to offer to Medicare beneficiaries through reductions in cost and improvements in efficiency. In the Medicare Payment Advisory Commission's first review of ASC payments in 2003, ASCs were paid more than the HOPD for eight of the top ten procedures most frequently performed in the ASC. One suggestion by the commission was that services migrated to the ASC because the payment rate was higher than the HOPD. However, a multi-year payment freeze on ASC services has turned the tables and now the HOPD rate in 2007 will be higher (or the same) for eight of the same ten ASC procedures. The continued growth of ASCs during the payment freeze is a strong testament to their ability to improve their efficiency and the preference of physicians and beneficiaries for an alternative to the hospital outpatient surgical environment.

The impact of HOPD payments eclipsing the ASC rates has had the perverse effect of increasing the "cost" of the budget neutrality requirement imposed by the Medicare Modernization Act on the future conversion factor for ASC payments. The Lewin Group estimates that the inflation updates applied to the HOPD rates since passage of the MMA account for 40 percent of the discount required to achieve budget neutrality under the agency's proposed rule. This, combined with the agency's narrow interpretation of budget neutrality, produce an unacceptably low conversion factor for ASC payments.

- Budget Neutrality: Adopt an expansive, realistic interpretation of budget neutrality. 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.

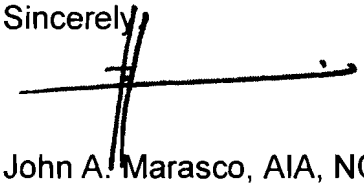
- ASCs should comment on the possible negative effect on access to services, since the methodology proposed results in ASC payments equaling only 62% of HOPD.

- By setting rates this low, CMS would force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government. Rather than paying ASCs a set percentage of HOPD rates, the proposed rule establishes a complicated formula to link ASC payment to HOPD payment but does not link payment in a uniform manner. This will impede Medicare beneficiaries' ability to understand their real costs in alternative settings. In the words of President Bush, Medicare beneficiaries need to be able to make "apples to apples" comparisons in order to increase transparency in the health care sector.

- 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. 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.

Attached is a paper I recently authored detailing why the 62% of HOPD payment rates has no bearing on the real cost structures existing between ASC's and HOPD's. In the name of fairness I implore you to read this paper carefully and do the right thing.

Sincerely,



John A. Marasco, AIA, NCARB
Principal and American Consumer

Submitter : **Dr. Ece Mutlu** **Date: 11/06/2006**

Organization : **Rush University Medical Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-983-Attach-1.DOC

#983

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November 1, 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, Maryland 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:
I am an academic practicing gastroenterologist who presently treats Medicare beneficiaries in my practice. I am writing to express my grave concern with CMS's recent proposal to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments.

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

Both the GAO and CMS itself have stated that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC has repeatedly endorsed the concept that medical procedures and services should be site neutral. So, on its face, a proposal such as this one, which institutionalizes the concept of paying significantly more to the hospital than to the ASC, and which will likely reduce the capacity to provide GI screening colonoscopies and other GI endoscopic procedures by forcing a significant number of ASCs to close their doors to Medicare beneficiaries, if not to all patients, because Medicare's payment level will drop so precipitously that these ASCs can no longer meet their expenses and render a reasonable return on investment, seems foolish and counterproductive.

Medicare seems to be ignoring both the stated priorities of the current Administration as well as the lessons of cost management in the private sector. President Bush and his staff are on record, on multiple occasions, stating that ASCs are a more cost-effective environment than the hospital to receive key medical services. When private sector insurers have sought to reduce total health care costs, they have actively sought to encourage patients to receive

their services in the ambulatory surgery center, instead of in the hospital outpatient department. In a recent example, Blue Cross of California has announced that it will pay a 5% premium to physicians for every GI endoscopy that is performed in the ASC, rather than in the HOPD. This CMS proposal, which would always pay more to HOPDs and always pay less to ASCs, is directly antithetical to the direction adopted by the private sector insurers.

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

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

In the gastroenterology area, CMS's proposed policy virtually assures results inimical to the public health. Today, when a GI procedure, such as a screening colonoscopy is performed in an ASC, that ASC receives a facility fee which on the average amounts to 89% of the facility fee CMS pays to the HOPD if that same procedure is performed there. We need to provide a bit of background relating to the effectiveness of the Medicare colorectal cancer screening benefit. Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has done everything possible to emasculate the effectiveness and utilization of that benefit. Since 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction would almost certainly be in excess of 50%). According to information from the American College of Gastroenterology, no other Medicare service has been cut this much. Now, CMS issues a new proposal, which would further undercut and devastate the prospects for Medicare beneficiaries to receive a colorectal cancer screening colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS foolishly has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs, as by far the biggest potential loser, with the prospect of cuts from 89% of the HOPD payment to 62%.

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

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

For Patients:

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

For the Medicare System:

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

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

So, the inevitable result of this proposed CMS action, if implemented will be: (a) total Medicare costs for GI facility fees will rise (although the per unit facility fee for decreased number of these performed in the ASC may well decline); (b) available access by Medicare beneficiaries for GI colonoscopies and other endoscopic procedures will decline; and (c) more Medicare beneficiaries will die unnecessarily from colorectal cancer will increase as screening rates decline.

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

Respectfully submitted,

Submitter : Dr. Carline Quander **Date:** 11/06/2006

Organization : Rush University Medical Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-984-Attach-1.DOC

#7584

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November 1, 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, Maryland 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

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Respectfully submitted,

Submitter : Dr. Michael Verdolin **Date:** 11/06/2006

Organization : Pain Control Associates, Inc

Category : Physician

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

Without a doubt, these drastic cuts proposed will do irreperable harm to availability and access to needed pain management for medicare and tricare beneficiaries. These cuts clearly do not take into account the practice management costs for individual, board certified, highly trained pain physicians who perform procedures in the office. These cuts appear to benefit hospitals and large ASC and hurt individual office based practitioners. The cost benefit in maintaining the status quo with payments as they are is clearly realized in keeping patients OUT of hospitals where fees are astronomically higher. The individually practicing physician has HUGE overhead in the form of rent, supplies, machinery, and personnel costs. This DRASTIC, unprecedented cut in reimbursement will destroy practices and significantly reduce access to eare; the very thing CMS is pledged to prevent. Please reconsider this unsustainable course of action before our patients bear the consequences (ie pain physicians may refuse to treat medicare recipients)

Submitter : Dr. Peter Zimmerman **Date:** 11/06/2006

Organization : Dr. Peter Zimmerman

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-986-Attach-1.DOC

#9186

October 31, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and 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

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

Dear Ms. Norwalk:

As a practicing interventional pain physician, I am disappointed at CMS's proposed rule for ASC payments. This rule will create significant inequities between hospitals, ASCs, and beneficiaries' access will be harmed. While this may be good for some specialties, interventional pain management will suffer substantially (approximately 20% in 2008 and approximately 30% in 2009 and after). The various solutions proposed in the rule with regards to mixing and improving the case mix, etc., are not really feasible for single specialty centers. CMS should also realize that in general healthcare uses, the topdown methodology or bottom-up methodology used by Medicare is the primary indicator for other payers - everyone following with subsequent cuts. Using this methodology, Medicare will remove any incentive for other insurers to pay appropriately.

Based on this rationale, I suggest that the proposal be reversed and a means be established where surgery centers are reimbursed at least at the present rate and will not go below that rate. We understand there are multiple proposals to achieve this. If none of these proposals are feasible, Congress should repeal the previous mandate and leave the system alone as it is now. However, inflation adjustments must be immediately reinstated.

I hope this letter will assist in coming with appropriate conclusions that will help the elderly in the United States.

Sincerely,

October 31, 2006

Leslie V. Norwalk, Esq., Acting Administrator

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Department of Health and Human Services
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Sincerely,

Peter A. Zimmerman, MD
Fellow Interventional Pain/Spine
Georgia Pain Physicians
Department of Physical Medicine & Rehabilitation
Emory University/Robert W. Woodruff Health Sciences Center

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Submitter : Mrs. Andrea Fann **Date:** 11/06/2006

Organization : Orthopaedic South Surgical Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

We support retaining the Medicare beneficiary coinsurance for ASC services at 20 percent. For Medicare beneficiaries, lower coinsurance obligations will continue to be a significant advantage for choosing an ASC to meet their surgical needs. Beneficiaries will save significant dollars each year under the revised ASC payment system because ASC payments will in all cases be lower than the 20-40 percent HOPD coinsurance rates allowed under the OPPS.

ASC Conversion Factor

ASC Conversion Factor

A 62 % conversion factor is unacceptable and often does not cover the cost of the procedure potentially forcing facilities not to perform these procedures forcing the Medicare patient back into the more expensive hospital setting. We understand that budget neutrality is mandated in the MMA of 2003; however, we believe that CMS made assumptions in order to reach budget neutrality with which we differ, most especially the migration of cases from and to the ASC. The ASC industry has worked together with our physicians and established a migration model that is being provided to CMS along with the data in an industry comment letter. We encourage CMS to accept this industry model of a 73% conversion factor

ASC Office-Based Procedures

ASC Office-Based Procedures

I support CMS proposal to extend the new ASC pymt system to cover procedures that are commonly performed in physicians office. For a given procedure, the appropriate site of service is dependent on the individual patient and specific condition.

ASC Packaging

ASC Packaging

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. 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 aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Payable Procedures

ASC Payable Procedures

ASC list reform proposed by CMS is too limited. CMS should expand ASC list of procedures to include any and all procedures that can be performed in HOPD. CMS should exclude only those that are inpatient only list and follow the state regulations for overnight stays.

ASC Payment for Office-Based Procedures

ASC Payment for Office-Based Procedures

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. 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 aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Phase In

ASC Phase In

Given the size of the payment cuts contemplated under the proposed rule for certain procedures and specialties; especially GI, pain and ophthalmology, one year does not provide adequate time to adjust to the changes. Thus, we believe the new system should be phased-in over several years

ASC Ratesetting

ASC Ratesetting

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. 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 aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Unlisted Procedures

ASC Unlisted Procedures

At a minimum, when all specific codes in a given section of cpt are eligble for payment under revised asc pymt system, the associated unlisted code also should be eligible for payment.

ASC Updates

ASC Updates

8. ASC Updates (Section XVIII.C.12)
We are pleased that CMS is committing to annual updates of the new ASC payment system, and agree it makes sense to do that conjunction with the OPPS update cycle so as to help further advance transparency between the two systems. Regular, predictable and timely updates will promote beneficiary access to ASCs as changes in clinical practic and innovations in technology continue to expand the scope of services that can be safely performed on an outpatient basis

ASC Wage Index

ASC Wage Index

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. 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 aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

Submitter : Mr. James T. Kirkpatrick **Date:** 11/06/2006

Organization : Massachusetts Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-988-Attach-1.DOC

#988

MHA

Massachusetts Hospital Association

November 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS–1506–P2, Medicare Program; Ambulatory Surgical Center Payment System Proposed Changes for 2008

Dear Dr. McClellan:

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the proposed changes for the Ambulatory Surgical Center (ASC) payment system for 2008.

Proposed Payable Procedures: Criteria for Inclusion and Expansion of List

As a basic principle, we believe that all providers of surgical services should meet comparable patient safety, patient rights, quality assurance, staffing, infection control, anesthesiology and other relevant standards. ASCs have fewer and often lesser standards, with infrequent compliance surveys, and are not required to report detailed cost and quality data to Medicare. Furthermore, state licensing requirements vary in the degree to which these gaps are filled. It is of special concern that the public is unaware of these differences in standards and assumes a greater degree of facility oversight and patient protection than exists.

The proposed 2008 broad expansion of the number and types of services that may be performed in ASCs could jeopardize patient safety and quality of care. We recommend that CMS defer implementing any changes to the current criteria for determining ASC payable procedures until the **Medicare conditions of participation for ASCs** are revised to ensure comparable patient protections for comparable services in hospital outpatient and ASC settings.

As CMS seeks to expand access to procedures in ASCs, it is more important than ever to define parameters and criteria that clearly distinguish procedures that are appropriate or inappropriate for this alternative care site. We recommend **clarifications to the definitions of several current exclusion criteria**, to help appropriately limit the expansion of procedures to the ASC setting. Such clarifications should include the following:

- A clear definition of the term: "Major Blood Vessel."

- "Extensive Blood Loss." We recommend that CMS further define the term "extensive blood loss" to refer to procedures that typically result in the loss of a *clearly defined percentage* or more of total blood volume during the routine performance of the procedure
- "Major or Prolonged Invasion of Body Cavities." We join the AHA in recommending that CMS define "prolonged" invasion as referring to any procedure in which the patient is under anesthesia for a period of 90 minutes or longer, since there is a correlation between a higher rate of adverse events and prolonged anesthesia time.

- Another shortcoming of the proposed criteria is the ambiguity surrounding the definition of "inpatient". CMS states when describing what would constitute an overnight stay that they are "proposing to exclude from payment of an ASC facility fee any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure." This definition could also describe a patient who is in observation status. When determining whether a procedure is performed at least 80% of the time in an inpatient setting, the cases where the patient is placed in observation status rather than admitted would be categorized as "outpatient" even though the case may meet the definition of an "overnight" stay as described above.

In addition to stressing the need for clarification of the above, MHA opposes the proposal to discontinue use of the current time-based prescriptive criteria. CMS has provided no evidence to support their belief that these criteria are no longer clinically appropriate for purposes of defining a significant safety risk. T hese criteria are indicative of more complex procedures that inherently involve a higher risk of complication and should continue to be applied in CY 2008.

Furthermore, while procedure-specific clinical criteria are important, these alone are insufficient to determine which services can be safely furnished in an ASC setting. Patient outcomes are also a function of ***patient-specific*** **and** ***organization-specific*** **factors**. Before CMS subjects beneficiaries to an unacceptable level of risk, it needs to conduct more research in these areas in order to determine which procedures can be done in an ASC, and *under what combination of patient and organizational factors.* If the research indicates a significant degree of inter-relatedness between these factors and patient safety and outcomes, CMS should consider incorporating patient specific and organization specific criteria into the ASC payment system.

Payment Rates:

We agree that it is appropriate that CMS has proposed a conversion factor for ASC services that is less than that in the hospital outpatient department setting. The rates for services provided in hospital-based settings ***should*** be set at a higher level in order to reflect their higher costs due to additional regulatory requirements, 24/7 availability, EMTALA-related costs, a more acutely ill population with more co morbidities and higher uncompensated care rates.

Also, in order to allow for future validation of the relative appropriateness of ASC payment weights and rates, CMS should seek congressional authority to require ASCs to report cost data. In addition, CMS should monitor how the significant revisions in its payment policies will impact the volume and types of services that migrate from one ambulatory setting to another, as well as trends in the acuity of patients undergoing similar procedures in hospital outpatient departments versus ASCs. CMS

would need to evaluate the effect on procedure median costs in hospitals and how the conversion factor is calculated in an ASC.

If I can provide you with any additional information regarding our comments, please do not hesitate to contact me at (781) 272-8000, ext. 173.

Sincerely,

James T. Kirkpatrick
Vice President, Health Care Finance and Managed Care

Submitter : **Ms. Irene Plenefisch** **Date: 11/06/2006**

Organization : **SonoSite, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see SonoSite comment in attached letter.

CMS-1506-P2-989-Attach-1.DOC

CMS-1506-P2-989-Attach-2.DOC

#989

SonoSite

November 3, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1506-P; Comments on Proposed Revised Ambulatory Surgical Center Payment System for Implementation January 1, 2008 (Section XVIII)

Dear Administrator Norwalk:

SonoSite, Inc., appreciates the opportunity to comment on the Proposed Payment System for ASCs for Implementation in January 1, 2008 (CMS-1506-P). SonoSite is a manufacturer of high quality portable ultrasound systems located in Bothell, Washington. SonoSite manufactures and markets ultrasound systems that provide full diagnostic ultrasound studies and are optimized for use at the point of care. SonoSite's products are used in ambulatory surgery centers, physician offices, hospitals and free-standing imaging centers, to provide a wide variety of diagnostic and guidance ultrasound services.

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ASC Packaging

I. Issue – Proposal to Package Payment for Imaging Guidance into the ASC Facility Fee.

In the proposal for revising the payment system for Ambulatory Surgical Centers for 2008, the Centers for Medicare and Medicaid Services (CMS) states that it intends to package the payment for imaging services that are directly related to the performance of a surgical procedure into the ASC facility fee. CMS also proposes to use the Hospital Outpatient Prospective Payment System (HOPPS) "APCs as a 'grouper' and the APC relative payment weights as the basis for ASC relative payment weights and for calculating ASC payment rates." The combination of these two proposals will result in no payment for the use of such imaging services in the ASC, cause a lack of payment parity across sites of service and result in reduced access to image-guided, minimally-invasive surgical services in the ASC setting.

This lack of payment for the imaging service will result from the fact that under the hospital outpatient prospective payment systems (HOPPS), imaging guidance of surgical procedures is, in most cases, provided separate payment. So payments under HOPPS for surgical procedures performed under imaging guidance do not reflect the costs of providing the imaging guidance; those services are reported and paid under a separate APC. As an example, an ultrasound-guided, core-needle breast biopsy is reported by the hospital outpatient department using CPT codes 19102 and 76942. CPT code 19102 is assigned to APC 0005 and CPT code 76942 is assigned to APC 0268 for separate payment. Thus, the payment associated with APC 0005 does not include the costs of providing the imaging guidance of the procedure. Yet CMS proposes to use the relative weights from APC 0005 only for calculating the ASC payment rates for both the biopsy procedure and its imaging guidance. By disallowing separate payment for imaging that is used to guide surgical procedures, CMS will be providing provider incentive not to perform this service when it is medically indicated.[1]

II. Recommendation

To ensure that Medicare beneficiaries have access to safe, high quality care, SonoSite recommends that CMS allow for separate payment of imaging services when those services are directly related to the performance of a surgical procedure and paid separately under the Hospital Outpatient Prospective Payment System.

III. Supporting Information

CMS has previously considered packaging radiologic guidance of surgical procedures under HOPPS and decided to maintain separate payment status for those services. We support this decision and believe it results in more accurate payment for these services. Clinical circumstances determine whether imaging guidance for a given surgical procedure is needed, and if so, whether the imaging modality used should be ultrasound, fluoroscopy or some other imaging technology. With such great variation in the way in which such procedures can be conducted, it is not possible to package the costs of the imaging guidance and accurately reflect the costs of providing these procedures in the resulting payment.

[1] Federal Register, Vol. 67, No. 212, Friday, November 1, 2002, pg. 66724

ASC Conversion Factor

I. Issue – Proposal to Base Budget Neutrality Formula on Aggregate ASC Facility Expenditures Only, Excluding Implantables Previously Billed Under Another Fee Schedule.

CMS has stated that it intends to aggregate only those expenditures that were previously paid under the ASC facility fee for the purposes of determining the budget neutral conversion factor for ASC payment. Those aggregate expenditures do not include payment for prosthetic implants and implantable DME as those items are paid separately. CMS has also stated that it intends to discontinue separate payment for those implantables under the revised payment system. This combination of policies will result in an overall reduction in aggregate payments to ASCs, an outcome which is in conflict with Section 1833(i)(2)(D)(ii) of the Act which requires that the revised ASC payment system be designed to result in the same aggregate amount of expenditures for surgical services furnished in ASCs the year the system is implemented as would be made if the new system did not apply.

II. Recommendation

To ensure that Medicare beneficiaries have access to surgical services that are appropriately provided in the ASC site of service, SonoSite recommends that CMS include payments made previously for prosthetic implants and implantable DME under the DMEPOS fee schedule in the aggregate expenditures used to calculate the ASC conversion factor.

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SonoSite, Inc. appreciates the opportunity to provide comments on this proposed rule. If SonoSite can provide CMS with additional information regarding this matter, please do not hesitate to contact me at 425-951-1205 or irene.plenefisch@sonosite.com.

Sincerely,

Irene Plenefisch
Director, Payer and External Relations