CMS-1506-P2-1 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. brian weiner** **Date & Time:** **08/10/2006**

Organization : **manalapan surgery center**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Regarding proposed cuts in fees to asc, please note that medicare is already our lowest payer, and is already being subsidized by private payors. A cut would be catastrophic, as private payors link their reimbursement to medicare. In fairness to patients and the general community, as well as to fulfill the moral requirement of keeping asc viable as a less expensive, more efficient alternative to hospital outpatient units, please do not allow us to become financially unstable. The cuts would not be in the interest of patients, doctors or the general public.

CMS-1506-P2-2 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Ronald E Feldman** **Date & Time:** **08/10/2006**

Organization : **Parkway Endoscopy Center**

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

Providers of care in ASCs that perform GI endoscopy have worked hard to assure high quality and efficient care to Medicare beneficiaries. Hospital outpatient depts. should be viewed separately from the emergency and inpatient care provided. Costs in ASCs in California are not low, and they are increasing. Punishing ASCs for the inherent inefficiencies of hospitals makes little sense. The impact of cuts in rates to 2/3 of HOPD will affect our ability to provide care to CMS beneficiaries and may reduce the high quality of service we provide to all patients. I urge you not to reduce ASC endoscopy rates to a lower percent of HOPD than currently.

CMS-1506-P2-3 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Jonathan Jensen** **Date & Time:** **08/10/2006**

Organization : **Colorado Center for Digestive Disorders**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Recent proposal for decreased reimbursement rates for ASC facility fees and professional fees to MC patients will result in decreased services to these individuals. In essence, you are penalizing physicians for being efficient. Hopsital based procedures are time consuming, fraught with scheduling issues and inefficient. Efficiency is the CORE reason for development of ASC's. Why are you penalizing provioders and, indirectly, your beneficiaries ? Physicians will simply drop MC patients and become "non par" MC providers. This will burden MC patients further. Your decision makes no sense. Why hinder the provision of medical care to deserving individuals by making reimbursement issues burdensome. Overhead costs have increased by some 37-40 % over the previous 10-15 years with similar decreases in MC reimbursements. This represents a net 75-80 % decrease in profit margins that had been, by most physicians, utilized to permit provision of care to uninsured patients. How far do you really think this is capable of going ? Continue with this line of thinking and action and you will be able to include "Beating a dead horse" into the congressional records.

Jonathan E. Jensen MD FACP FACG
Board Certified Gastroenterologist
Clinical Assistant Porfessor of Medicine
University of Colorado Health Science Center/ Denver VAMC- Volunteer Faculty

CMS-1506-P2-4 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. MIke Morelli** **Date & Time:** **08/10/2006**

Organization : **Indianapolis Gastroenterology and Hepatology**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The continued cut in pay will only lead to physicians declining to take part in the Medicare system and will also lead to further inefficiencies(and thus greater long term costs) in the adminstration of colon cancer screening

CMS-1506-P2-5 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Philip Dolan** **Date & Time:** **08/10/2006**

Organization : **The Portland Clinic**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Your proposal to reduce ASC payments to 62% of hospital payments is ill advised. The push for ASC's in the early 1980's was motivated exclusively by a desire to reduce the expenses of doing outpatient procedures in the hospital setting, and that has been accomplished. The current proposal will simply drive the procedures back in to the hospital outpatient arena, where line item billing can be done, and where costs are double to triple those in the ASC's. What are you thinking? PJ Dolan, MD

CMS-1506-P2-6 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Harvey Guttmann** **Date & Time:** **08/11/2006**

Organization : **Gastrointestinal Associates**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The provision of gastrointestinal endoscopic services in today's medical climate requires a complex and thus very costly approach. The requirements and appropriate necessity to insure patient safety and privacy cannot adequately be achieved at the proposed ASC rates for endoscopy. Equipment costs, sterilization procedures, and staffing needs and liability insurance are increasing at alarming rates. HOPDs do not have the capacity to accommodate the numbers of Medicare patients that require diagnostic and therapeutic colonoscopy in our area. I believe that these new rates will result in serious access difficulties to the Medicare population; ASCs will not be able to provide endoscopic services at these rates, while HOPDs will have insufficient space. At the end of the day, the cost of hospital care for Medicare patients will likey INCREASE, by the flow of these patients to hospital units (and thus a significantly higher paymaent for the same service by CMS), as well as added costs of building larger HOPDs to receive the extra volume. Because patients PREFER the ease and convenience of ASC treatment, they will be less satisfied to go to the hospital unit. Consequently, what CMS will accomplish is a more expensive, less patient friendly care, with immediate crowding and poor access within the HOPD, and longterm increased need to create capacity in the HOPD (at significant costs) when there is adequate current ASC space to allow for the care of the Medicare population. You will convert a flow that is working well currently into a broken system. It often seems, that in their haste to "save money" in the short term that CMS is doing a terrific job with this payment system of causing a more expensive and increasingly cumbersome bureaocracy fated NOT to serve our seniors in the manner that they require and deserve. I urge you to rethnk this unworkable payment system by correcting the flaws so apparant in the payment for endoscopic services.

CMS-1506-P2-7 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Tesu Lin** **Date & Time:** **08/11/2006**

Organization : **None**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The CMS reccomendation to link facility reimbursement rate for endscopic procedure to 68% that of the hospital is unfair. You will result in Gastorenterologist limiting the nos of medicare patients that we already see.If you want to increase hospital rates go ahead but don't cut asc rate. Thsi is a drastic cut!

CMS-1506-P2-8 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Muhammed Hiba** **Date & Time:** **08/11/2006**

Organization : **Premier Gastroenterology**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Dear Sir,
Even though I do not own or participate in an ambulatory surgical center, I can reassure you positively that the proposed payment rate at 62 % of the Hospital Outpatient.Prospective Payment rate is very unfair. I can not see how the ASC's are going to provide a similar service incurring similar cost to the hospital outpatient area; however, they get paid 62% of the hospital. There are - in my mind - only three possible explanations to this. The first is a very strong hospital politically active and effective committee. The second possible explanation is that the ASC's themselves have a weak lobby that is not active on their behalf. The third is that CMS is decisively trying to put ASC's out of business. I should not care, since I do not have a surgical center. However, I think that will drive the business back to the hospital outpatient center leading to significant increase in healthcare cost. Then I end up paying more taxes to cover for the same service that ASC's is providing efficiently at this time. The only beneficiary of this proposed rule would be the big hospital corporation getting stronger and wealthier. But, unfortunately, the track record of CMS is full of incidents where hard working people with less power get penalized with less payment in favor of big corporations.
Thanks

CMS-1506-P2-9 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. barry migicovsky** **Date & Time:** **08/12/2006**

Organization : **AGA**

Category : **Congressional**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

How do you expect us to continue to make a living if we continue to take all the risk, continue working long hours, face lower reimbursements and the cost of living for everything continues to rise. You ask us to keep the patients out of the hospital and manage them as an outpatient. Why should the hospitals benefit for these procedures that we finally found a way to compensate us for all our hard work.

CMS-1506-P2-10 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. david wexler** **Date & Time:** **08/14/2006**

Organization : **Dr. david wexler**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Your proposed payment cuts to ASCs are unacceptable. Medicare patients barely meet ASC costs and further payment cuts would make them charity care. There would be even less incentive for GI specialists to want to care for Medicare patients if futre trends continue. Linking ASC payments at 62 percent of the Hospital Outpatient Prospective Payment rate is unfair. Since currently, ASC payments for most endoscopic procedures are between 88 and 92 percent of hospital outpatient rates and you want to remain budget neutral, why not put all ASC and hospital out-patients in one large pool and then divide the pool equally. Otherwise you punish the more efficient ASC and reward the inefficient hospital.
Your policies are currently schizophrenic since they initially encouraged physicians to treat patients in a safe outpatient setting i.e. the ASC, yet now the proposed payment reductions destroy this option for Medicare patients. The out-patient hospital setting is neither truly out-patient or geared for out-patient,(since almost all hospitals use the same endofacility for in- and out-patients) and therefore inefficient and money wasting. The office setting has its own inherent difficulties e.g. quite limited due to safety issues.
Do not destroy medicare patients access to ASCs.

CMS-1506-P2-11 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. William Rowe** **Date & Time:** **08/14/2006**

Organization : **Endoscopy Center of Central Pennsylvania, LLC**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Medicare's current ASC reimbursement rates for endoscopic procedures (current level I and II) are very close to the break-even point for our ASC. Fortunately, private insurers do tend to pay more, but many of them link their payment schedules to the Medicare rate. The proposed rate reduction for endoscopic procedures will force us to shift these lower reimbursing cases to the hospital, resulting in:
1. Significant inconvenience to the patient;
2. Higher costs to Medicare, as the hospital reimbursement rate is substantially higher;
3. Probable loss of employment for at least several taxpaying employees as the volume that can be done to maintain a break-even financial viability of the ASC is threatened; if other insurers follow suit, the very viability of the endoscopy center is threatened.

This third concern is, of course, the goal of the hospital industry; unfortunately CMS has bowed to that political pressure from an industry that has demonstrated that it will only cost CMS more in the long run than will the same service provided by private, independent ASCs at the current reimbursement rates.

I strongly urge reconsideration of the reduction in ASC reimbursement rates for endoscopic procedures.

CMS-1506-P2-12 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Date & Time:** **08/14/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The proposed payment system is unfair for many physicians such as gastroenterologists. We are required to practice the best medicine possible, improve our knowledge, keep up with current standards and maintain an update in equipment use and function; and in return we will recive less money. The medical profesion is the only field that does not keep up with the reality of our economy. Every aspect of our life undergoes revision to increase according to inflation except reimbursement for physicians. THIS IS UNFAIR!! These measures need reconsideration.

CMS-1506-P2-13 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Alexander Lustberg** **Date & Time:** **08/16/2006**

Organization : **Alexander Lustberg**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

Endoscopic ambulatory surgical centers provide many cost efficiencies to the total cost of a procedure, for example, lower nursing costs, lower drug costs, and reduced recovery time. Patient experience is generally more favorable as well. The proposed cuts will serve to discourage use of ASC's. We should work together to continue to provide better care at a reasonable cost but at a price that is feasible for the continuation of ASC's. The proposed cuts will create disincentives to treat Medicare patients and once again may further limit these worthy beneficiaries to care.

CMS-1506-P2-14 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Prasad Podila** **Date & Time:** **08/18/2006**

Organization : **AGA**

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

It is very difficult to run the ASC with proposed cuts in 2008. The cost of running ASC's are going up every year. Salaries for nurses going up because of shortage of nursing. Please consider not to cut the ASC payments in 2008. If it is implemented, there will be closure of ASC's and cost will be high if we do proceudures in the hospital

CMS-1506-P2-15 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. Thomas Castellano** **Date & Time:** **08/18/2006**

Organization : **Dr. Thomas Castellano**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Reductions of the magnitude outlined in this proposal will force procedures out of the asc and back the the less efficient and more expensive hospital setting raising costs and decreasing both quality and service to our medicare beneficiaries. Testimonials from almost every patient we have served in our asc have clearly stated strong preferences for the asc over the hospital in terms of convenience, service and quality. These changes are a big step backward.

CMS-1506-P2-16 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Ms. melissa kemp** **Date & Time:** **08/18/2006**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Please do not support any current cuts to Medicare or Medicaid. Stop any movement to further stress and impoverish poor people and the government treasury in public service payments by making more people sick and refusing to provide them with free or reduced medical assistance. Put yourself and your family in their shoes. Would you like to be them simply because you do not have money, power or privilege? Protect all Americans; don't cut Medicare or Medicaid.

CMS-1506-P2-18 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Dr. robert hally** **Date & Time:** **08/22/2006**

Organization : **digestive disease physicians, PC**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The proposed decrease in ASC reiumbursement for GI procedures will adversely affect our ASC center, such that the center may need to close, given the high overhead assocated with these centers. Please reconsider the ASC reimbursement changes so that we may continue to offer our patients a viable alternative to tho HOPD.

CMS-1506-P2-19 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : **Mrs. Aimee Bissonette** **Date & Time:** **08/22/2006**

Organization : **Great Lakes Mobile PET**

Category : **Health Care Professional or Association**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

CMS-1506-P - Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates

I am a PET technologist working on a mobile unit in Northern Michigan. Our unit travels long distances to reach the surrounding areas. Since Michigan is a CON state it makes it difficult to have an in house unit at any of the Northern Hospitals - therefore that is why we have a mobile unit. I see that these changes could drastically affect the way things are ran for us. 1st the cost of gas has sky rocketed since we started this mobile unit which affects our bottom line, 2nd our doses come from a distance and with the cost of gas as for the company that provides our doses they in return fold it into the cost of our FDG. I am not for the changes and I believe that they need to be reviewed for special situations as the one I have just described. It is critical that this service is offered to our area. Our residents of this area should not have to travel 4 hours for a PET scan.

Submitter : **Dr. Frank Jackson** **Date: 08/24/2006**

Organization : **Wesr Shore Endoscopy Center**

Category : **Physician**

Issue Areas/Comments

ASC Updates

ASC Updates

I strongly object to the proposed severe reductions in the facility fee payments for ambulatory surgical centers. These changes will simply and markedly reduce the number of Medicare patients that we will be able to see. It will dramatically reduce the colon cancer screening program for the elderly that all health organizations, including the federal government,have and even now are promoting. ASCs have been a remarkable success story and Medicare deserves much of the credit for it. These regulations would reverse all of the work and effort that Medicare and the various health organizations have exerted over the years. We need to have 75% of the payment made to hospitals for the same outpatient procedures. Thank you for your consideration of these comments.

Frank W Jackson MD
West Shore Endoscopy Center
Camp Hill PA 17011

Submitter : **Dr. Shirley Harris** **Date: 08/28/2006**

Organization : **Gastroenterology Specialist of Dekalb**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The proposed significant cutting of rates for ASC will likely to be counterproductive.Rather than a cost saving it will likely drive up the cost of care.
At the current rate for out patient surgery most ASC are able to cover cost and see a small profit. If that reimbursement is cut drasically as proposed I see several things happening.
1. ASC's will be shutting down and shifting their cases to the hospital.
2. ASC's being considered will be abandoned since the costs involved in setting up, especially with new requirements will make it prohibitive. Since costs cannot be cut by being at an ASC the cost for endoscopy will remain high.
3. ASC's to stay profitable will treat their patient like cattle and move them in and out therefore affecting quality and possibly patient comfort.
4. ASC's will utilize Anesthesiologists more for sedation to enable patient's to move in and out more quickly. This will drive up the overall cost of the procedure. Frankly since the Anesthesilogist is paid more than the Gastroenterologist for the procedure this is really an unfair process.
I am sure if I put more thought to this I can come up with more reasons why cutting the reimbursement will be a bad reason but these are what comes to mind quickly

Submitter : **Dr. Sandeep Sherlekar** **Date: 08/30/2006**

Organization : **CAPMA**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Please increase payments as the payments do not match what the hospital get paid and the cost of delivering the service has gone up

Submitter : **Dr. Frederick Weber** **Date: 09/04/2006**

Organization : **Endoscopy center of Coastal Georgia**

Category : **Physician**

Issue Areas/Comments

ASC Ratesetting

ASC Ratesetting

Our ASC provides a much higher quality of care (by almost any definition) than any any of the local hospital-based endoscopy units and already does it with lower reimbursements. Shrinking freestanding ASC fees will only serve to lower the quality of services an area can provide and inadvertantly rewards hospitals for inefficiency and lower quality. Doesn't CMS wish to improve the care that is delivered to patients? If so, it should pay for the service provided and not overreimburse hospitals at the expense of the higher quality freestanding ASCs.

Submitter : **Dr. D. Louis Kennedy MD,FACC** **Date: 09/06/2006**

Organization : **Cardiology Associates of No Ky**

Category : **Physician**

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

Proposed cuts to outpatient cardiac catheterization are draconian and will severely limit access to this important procedure for our burgeoning group of patients with cardiac disease. Please reconsider the cuts as you are cutting muscle, not fat.

Submitter : **Dr. Robert Jaffe** **Date: 09/07/2006**

Organization : **Dr. Robert Jaffe**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The proposal to reduce PET reimbursement further will put an end to the availability of PET CT to our patients. We are already facing a cut of 50% in reimbursement based on previous legislation. This further cut will reduce payment to 1/3 of what we are being payed now. We simply can't afford to do PET CT at this level of reimbursement.

Submitter : **Dr. Neil Green** **Date: 09/08/2006**

Organization : **Mary Washington Hospital**

Category : **Radiologist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P2-26-Attach-1.RTF

CMS-1506-P2-26-Attach-2.RTF

HHAC n IT
26

RADIOLOGIC ASSOCIATES OF FREDERICKSBURG

September 8, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Mary Washington Hospital to address an issue of great importance to Medicare beneficiaries with cancer. Mary Washington Hospital] is a leading oncologic treatment center, and treats many cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth on the proposed hospital outpatient rule will seriously underpay hospitals, and could compromise beneficiary access to this vital technology.

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

CMS proposes to reduce the Medicare payment rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. Based on my experience, I believe that $865 is far below the true cost to our hospital outpatient department of providing PET/CT services, and that such a reduction would significantly underpay Mary Washington Hospital. The proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Mary Washington Hospital of acquiring, maintaining, and operating a

PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Further, CMS bases the proposed rate reduction on only nine months of hospital claims data from 2005. This is inconsistent with the fact that hospitals typically do not update their charge masters frequently enough to account for new CPT codes that are first implemented mid-way through a calendar year. At Mary Washington Hospital, for example, we typically update our charge masters annually. Claims data from 2005 therefore does not reflect the current cost to our outpatient department of providing PET/CT.

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

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

Sincerely,

Neil B. Green, MD
Physician Director, Nuclear Medicine
Mary Washington Hospital
Fredericksburg, VA 22401

Submitter : **Date: 09/12/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

With significant arbitrary cuts in ASC reimbursement, reasonable services may become unavailable to covered participants. Private ASC facilities will always provide more cost effective and efficient services to members than competing hospitals which historically are cumbersome and inefficient. Removing privates from the competition will increase the cost of care for subscribers. Competition is the key to keeping costs down. Cutting reimbursements when costs are rising, guarantees a decrease in patient choices. ASC facilities will be forced to limit services. Implementing a policy for published rates by all ASC's, including hospital owned, would be more effective in reducing costs, because patients could then shop for the best rates. That's market driven and forces prices where they belong. That is superior to arbitrary cuts. I am strongly against this new policy, and you should be too.

Submitter : **Dr. Jeffrey Falk** **Date: 09/13/2006**

Organization : **Magee-Womens Surgical Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-28-Attach-1.DOC

Attach H
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Magee-Womens Hospital

of University of Pittsburgh Medical Center

Magee-Womens Surgical Associates

September 12, 2006

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

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting treatment access for this deadly disease for Medicare patients.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Jeffrey Falk, MD, FACS
Pittsburgh, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. David Neiblum** **Date: 09/14/2006**

Organization : **West Chester Endoscopy**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

The proposed drastic cuts in ASC reimbursement rates for GI endoscopic procedures will effectively kill our newly-opened center, and will entail dramatic increases in wait times for such procedures, as we start doing them at the hospital. Our staff costs have doubled, our reimbursements shrunk. We've already cut staff and doctor salaries. Please do not go ahead with these cuts; the people that stand to lose the most is the patients, who will wait much longer, and be inconvenienced much more. Staff will be let go as well.
Thank you,
David Neiblum, MD

Submitter : **Dr. Howard Mertz** **Date: 09/15/2006**

Organization : **Dr. Howard Mertz**

Category : **Physician**

Issue Areas/Comments

ASC Ratesetting

ASC Ratesetting

To Whom It May Concern:

The August 8, 2006 CMS proposed rules on Ambulatory Surgical Centers proposed a dramatic reduction in payments to ASC s. Currently ASC payment rates vary between 88 and 92% of hospital fees. The proposed reduction reduces ASC payment to 62% of hospital fees.

This proposal is unfair to Medicare and Medicaid patients, as well as to ASC owners and operators. I believe any reductions in payment to ASC s will ultimately increase cost to CMS.

It is unfair to penalize ASC s, which already provide better services than hospitals and a significant cost savings to CMS. There is scant justification to support these proposed reductions. I suspect the hospital lobby in some way has influenced this proposal.

The scheduled payment reduction would dramatically reduce the profitability of ASC s such that many centers, including ours, would stop serving Medicare and Medicaid patients. These patients would then be treated in hospitals, which would increase the cost to CMS. It is doubtful that hospitals have enough access to provide for the large and growing number of Medicare and Medicaid patients. There is likely to be a significant delay in treatment of these patients, ultimately leading to some type of rationing.

I propose that payment to ASC s be kept where it is to allow ongoing care of the poor and elderly without rationing or net cost increases to CMS.

Sincerely yours,

Dr. Howard Mertz
Clinical Associate Professor
Vanderbilt University

Submitter : **Dr. Alan Chang** **Date: 09/15/2006**

Organization : **Northwest Gastroenterology**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

The proposal to drastically reduce ASC reimbursement (CMS-1506-P2) in comparison to hospital payments does not make sense to me. I think that patients are cared for in a much more efficient manner in the ASC/AEC setting than the hospital, which allows for greater ability to perform procedures such as screening colonoscopy for the population. By drastically lowering the ASC/AEC reimbursement rate, servicing patients in that setting will no longer be financially feasible, driving more and more procedures to the hospital setting. This, in turn, will lead to longer waiting lists to get the procedures complete due to the decreased efficiency of hospital-based procedures. (For example, in our community we can only complete 4 colonoscopies in a half day at the hospital. In our AEC, with two doctors working the same half day time slot, at least 12 colonoscopies can be completed.)

Therefore, I would implore you to reconsider this proposed change, which ultimately would be a disservice to patient care. It would result in greatly reduced access of a much needed service.

Sincerely,

Alan Chang, MD

Submitter : **Mr. Bradley Schmidt** **Date: 09/15/2006**

Organization : **Inglewood Imaging Center, LLC**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

September 15, 2006

Medicare:

The reason for my request is probably a little more self-serving. I am opening a new outpatient imaging center in Inglewood, CA later this year and Medicare is threatening the project by reducing the payment rates by almost 70% from this year fee schedule to next years by assuming a single payment standard for hospitals and outpatient imaging centers. Therefore I wanted to go directly to THE healthcare source and express my frustration with Medicare proposed payment changes and give you an overview of what IDTF s face in opening up a non-referral diagnostic center

FINANCIAL IMPACT OF START UP
Opening as an IDTF, was a very difficult decision. For starters, Medicare puts undo regulations on an IDTF s mandating a supervision to be onsite (costing an additional $1,000/day to have a radiologist onsite). Second, IDTF s don t have a guarantee of securing payor contracts as is the case with medical practices. So it is totally possible all local payors will not contract services with our IDTF as their network might be full. Third, I was actually planning for a drop in reimbursement by discounting 25% from current Medicare rates. Medicare was communicating they wanted to drop rates, earlier this year so I felt the 25% was a worst case scenario. Forth, to make these numbers work I had to buy a used MRi (very good technology) and negotiate very hard with our vendor to bring our PET/CT price down to $1,688,000. I honestly would have loved to buy a new MRi but the decrease in reimbursement would not allow this luxury. Finally, I had to reduce the center s personnel. It would have been great to hire a phlebotomist, sales representative, and an IT manager, but because of the decrease in reimbursement I will be assuming their roles.

A HOSPITAL FEE SCHEDULE SHOULD NOT BE THE SAME AS AN IDTF
Hospital services generate additional fees that are not found at IDTF s. Patients are referred for one scan and one cost so the expense of service was a lot less than found at hospitals. Yet, the current landscape may show IDTF s to be paid at the same rate of hospitals which doesn t make sense since the hospital charges for so many extra tests. Also if the hospital fee schedule is passes, it will reduce our outpatient revenue by upwards of 70%! This drop in reimbursement will surly hurt many more facilities.

POTENTIAL ALTERNATIVES TO REDUCE COSTS
I understand Medicare need to reduce costs, but they are going about it in the wrong way. I would recommend the following solutions:
1. Mandate a certain technology requirement in order to be paid for imaging tests - such as 5 onsite modalities. This would curb the incentive for self-referral and reduce costs.
2. Maintain the existing IDTF fee schedule separate from a hospitals fee schedule.
3. Understand technology changes and pay a reimbursement premium for such.
4. Refer patients to the best modality possible for specific diseases. The current rules mandate many unnecessary test prior to getting the best test.
5. Increase the payment rates to Hospitals for services performed. It would be great if they were not in this situation.

CONCLUSION
Medical technologies reduce unnecessary medical procedures, pin-point diseases faster; offer an improved course of treatment, and save costs. Yet, the change in Medicare payment structure and rates will kill the industry (for lack of a better word).

I know that I am biased, but diagnostic imaging tests are THE FUTURE of healthcare. I would love to sit and discuss.

Sincerely,

Bradley Schmidt
CEO, Inglewood Imaging Center LLC
415-710-7070 (mobile)

Submitter : **Dr. Stephen Levinson** **Date: 09/18/2006**

Organization : **Digestive Health Consultants**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

I am very concerned about your propsed decrease in payment rates for GI procedures performed in ASC's. The current proposal to reimburse at 62% of the HOPD rate will result in financial collapse of my ASC. This proposed payment reduction will not come close to covering the fixed and variable expenses associated with performing GI procedures. My colleagues and I created our ASC as a business, with the hope of realizing some profit and with the hope of broadening access of patients to outpatient procedures. All of the hospitals in our area are hopelessly overcrowded and very limited in their capacity to handle outpatients. Your proposed payment reductions will eliminate our ASC as a GI procedure center and will reduce patient access to colonoscopy and other procedures.

Submitter : **Mr. Shane Cohen** **Date: 09/18/2006**

Organization : **Strategic Outpatient Services, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-34-Attach-1.DOC

Attach 34

Strategic Outpatient Services, Inc.

70 Grand Avenue · Suite 101
River Edge, NJ 07661
Phone: 201.488.7996 · Fax: 201.488.7919
www.sosinc.biz

September 18, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Strategic Outpatient Services, Inc. (SOS) to address an issue of great importance to Medicare beneficiaries with cancer. SOS operates six (6) outpatient diagnostic imaging centers, which provide PET/CT imaging services to over 10,000 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay outpatient imaging centers, and will compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by doctors offices traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS has proposed to reduce the hospital outpatient rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. For outpatient imaging centers that represents a cut of up to 60% to 70% in one year from current carrier based prices. More shocking however, is that the proposed combined reimbursement for PET/CT's technical component, professional component and allowable reimbursement for FDG will be almost 20% below SOS's cost of providing these services *excluding* an allowance for a return on invested capital. How can this

possibly be? Especially given that in today's managed care environment, what CMS does, Aetna, United Healthcare, Blue Cross Blue Shield, Cigna, etc. are all sure to follow.

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

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

Many cancer patients live far from hospitals, and rely on outpatient imaging centers for oncologic imaging. The proposed payment rate reduction for PET/CT would seriously underpay outpatient diagnostic imaging centers, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of $1,250. Furthermore, since the vast majority of PET/CT scans are presently performed in outpatient imaging centers, CMS should rapidly work to develop a payment methodology that takes the costs of operating in this very different environment into account and factor that into its "hospital" outpatient rates. <u>It makes no sense to have a cost-based reimbursement methodology based on the costs of less than half of the entities providing a given service.</u>

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

Sincerely,

Shane Cohen
Corporate Controller
Strategic Outpatient Services, Inc.
Office: 201-488-7996
Cell: 201-362-6910
www.sosinc.biz

Submitter : **Dr. Donald Lurye** **Date: 09/19/2006**

Organization : **Welborn Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

First, let me say that I am trained in family medicine and do not do surgical procedures.

Freestanding ambulatory surgery centers (ASCs) have been a boon to the US health care system. They easily fit within the Institute of Medicine's quality framework - the care they give is timely, efficient, effective, patient-centered, equitable and safe. As the population ages and technology drives more care to the outpatient arena, it is critical that ASCs remain viable. In particular, if such centers are degraded, the US will simply lack the capacity to deliver screening colonoscopy according to well researched, evidence based guidelines. Surely CMS has no desire to add to the already large national burden of colon cancer diagnosed too late.

Thus, I find unfathomable the sharp inequity in CMS reimbursement proposed for ASCs going forward. It seems clear they are to be penalized for their history of efficient, high quality care. I could accept a modest tilt in favor of hospital based surgery centers if it is proven that their case mix is more severe. However, the current plan for ASC reimbursement goes much too far in this direction.

President Bush advocates an "ownership society". He openly promotes entrepreneurial activity. I doubt very much he cares to see his administration backing an initiative such as this which, to be blunt, openly punishes achievement.

Quality health care begins with access. Please think first of the needs of the public and abandon this ill-advised proposal.

Submitter : **Mr. Richard Bittler** **Date: 09/21/2006**

Organization : **Oregon Endoscopy Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

The proposed ASC payment system scheduled to take affect in CY 2008 is adaquate in some areas and inadaquate in other areas. Linking ASC payment rates to the HOPD rates is a good idea. I foresee many positives to the proposaled use of HOPD rates and allowable CPT list as a basis for setting ASC rates.. I have significant concerns regarding the proposed ASC payment rate of 62% of HOPD rates. I am an administrator for a GI single specialty ASC. Currently our reimbursement rate from CMS for GI specific CPT codes is closer to the FASA proposed ASC rate of 75% of HOPD rates. We currently recieve an average of $468.37 from the CMS for our highest volume CPT codes. Our per case cost is averaging $375.50. The margin of 'profit' is not adaquate to maintain high quality equipment and/ or advanced modalities of care. Approximately 50% of our patient population is covered by Medicare/Medicaid. Reducing the payment rate for GI specific CPT codes to 62% of HOPD rates, will significantly impact our ability to purchase new capital equipment and/or add new treatment modalities for our patients. We are currently an accredited ASC, and staff all our procedures with an RN and GI tech. To maintain this high level of care and continue to improve the quality of our unit I urge you to reconsider the 62% of HOPD rates for the proposed ASC payment rates. I do feel the FASA proposed rate of 75% of HOPD is closer to what we as a high quality ASC need to maintain high quality service to our patients. Thank you for the opportunity to submit my comments.

Submitter : **Ms. Sandra Berreth** **Date: 09/22/2006**

Organization : **Brainerd Lakes Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

It is imperative that CMS understands that there are many provisions in its proposed rule that will hurt ASCs and the patients that use them.

The proposed rule includes several key differences between the HOPD and the ASC payments that will perpetuate the unnecessary use of higher cost settings and may make it impossible for ASCs to offer surgical services.

In regards to the Rate-setting Methodology: There has not been sufficient time since the proposed rule was released to adequately study the methodology used and the possible impact of slight changes. This fact alone will have a 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 will force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government.

CMS should pay ASCs a set percentage of HOPD rates that has been suggested by the proponents of ASCs. The ASC industry had suggested a 75% of HOPD rates. We, in the ASC world, believe that we provide the most efficient, safest, and cost-effective care. We feel that we can save the Medicare program significant money, but Medicare must be willing to help us do that, by suggesting adequate reimbursements. Unfortunately, this 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 the 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, and this won't happen with the new rule.

CMS needs to understand that the modest update to the list of payable procedures continue to 'cost' the Medicare beneficiaries and the government more dollars; there are established criteria for ambulatory cases, if the patients 'fall-out' of the set criteria that should have their procedure at the more expensive hospital setting.

It is difficult to understand how CMS would think that an ASC could provide care at a 38% discount to the higher cost center [hospital].

Thank you for your time and attention.
Sandy Berreth, RN, MM, CASC

Submitter : **Dr. Shouwen Wang** **Date: 10/01/2006**

Organization : **Arizona Kidney Disease and Hypertension Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I support the position as outlined by the American Society of Diagnostic and Interventional Nephrology (ASDIN).

Submitter : **Dr. Kelly Carson** **Date: 10/02/2006**

Organization : **Metro Atlanta Endoscopy, LLC**

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

I am a gastroenterologist in Atlanta. The largest portion of my practice and largest number of patients seen in my endoscopy center are Medicare patients. The proposed change to the ASC payment system in regards to a further reduction in ASC payment rates would actually result in an increase in program expenditures. My specialty of Gastroenterology would no longer be able to keep their ASC doors open to Medicare beneficiaries. It's a clear case of "false savings" as patients would then have to have their colorectal cancer screenings, as well as their diagnostic colonoscopies and endoscopies, at HOPD's resulting in an increase instead of a decrease in expenditures.

Submitter : **Dr. John Horney** **Date: 10/02/2006**

Organization : **Metro Atlanta endoscopy**

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

I am a gastroenterologist in Atlanta. The largest portion of my practice and largest number of patients seen in my endoscopy center are Medicare patients. The proposed change to the ASC payment system in regards to a further reduction in ASC payment rates would actually result in an increase in program expenditures. My specialty of Gastroenterology would no longer be able to keep their ASC doors open to Medicare beneficiaries. It's a clear case of "false savings" as patients would then have to have their colorectal cancer screenings, as well as their diagnostic colonoscopies and endoscopies, at HOPD's resulting in an increase instead of a decrease in expenditures.

CMS-1506-P2-41

Submitter : Dr. Thomas McGahan **Date:** 10/02/2006

Organization : Metro Atlanta Endoscopy, LLC

Category : Physician

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

I am a gastroenterologist in Atlanta. The largest portion of my practice and largest number of patients seen in my endoscopy center are Medicare patients. The proposed change to the ASC payment system in regards to a further reduction in ASC payment rates would actually result in an increase in program expenditures. My specialty of Gastroenterology would no longer be able to keep their ASC doors open to Medicare beneficiaries. It's a clear case of "false savings" as patients would then have to have their colorectal cancer screenings, as well as their diagnostic colonoscopies and endoscopies, at HOPD's resulting in an increase instead of a decrease in expenditures.

Submitter : **Mr. Bill Davis** **Date: 10/03/2006**

Organization : **Digestive Disease Specialists, Inc.**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

COMMENT Regarding Section 5103 Proposed Revised Ambulatory Surgical Center Payment System for Implementation January 1, 2008

The calculation described in the proposed rule to achieve budget neutrality, which results in a factor of .62 -- payment to an ASC for a procedure will be 62% of a hospital s OPPS payment -- is an oversimplified solution. The proposed reduction in payment is not related to any current cost data of ambulatory surgery centers and hospitals and docs not differentiate among the costs associated with different procedures. The proposed methodology will have the following unintended consequences:

(1) Payment to an ASC for procedures for which current payment to a hospital and an ASC are similar, will be drastically reduced, solely as a result of the application of the .62 factor with no relationship to costs.
(2) Payment to an ASC for procedure for which current payment to a hospital is much higher, will be increased solely as a result of the application of the .62 factor with no relationship to costs.
(3) Ambulatory surgery centers that provide low-paying procedures will not permit physicians to perform such procedures, and physicians will be forced to perform those procedures in the hospital at a higher cost to Medicare.
(4) The overall result will be a shift to more procedures being performed in a hospital a result that is contrary to the fundamental role of an ASC a health care facility that staffed and equipped to safely and effectively provide certain surgical procedures at a lower cost.

CMS should delay implementation of any change in the payment methodology until it can properly analyze and compare cost data of ambulatory surgery centers and hospitals and develop a methodology that is consistent with costs, rather than an implementing a quick fix that will have dire consequences for many ambulatory surgery centers.

Submitter : **Mrs. Catherine Morris** **Date: 10/03/2006**

Organization : **Diomed, Inc.**

Category : **Nurse**

Issue Areas/Comments

ASC Ratesetting

ASC Ratesetting

CMS-1506-P2

Policy and Recommendation: Comment
Ambulatory Surgical center (ASC)
Proposal dated September 21, 2006

The proposed ASC payment published August 10, 2006 moved codes 36478, 36479, into group 9, with a 2006 payment rate of $1,339.

The proposal published on September 21, 2006 has placed codes 36478 and 36479, into Group 8, with payment of $973.The data file, published September 21, 2006 identifies 2007 ASC payment at $510 (the Group 3 payment).

Provision of cndovenous laser ablation in the ASC is cost prohibitive. The 2005 CMS data clearly illustrate the low number (105) of patients treated in the ASC. Acquisition cost of laser equipment is $37,900 with a per patient supply cost of approximately $360. It is financially impossible to provide endovenous laser ablation the ASC setting within the Group 3 payment.

We are requesting that codes 36478 and 36479 be moved to Group 9, as originally identified in the August 10th proposal.

Submitter : **Mrs. Catherine Morris** **Date: 10/03/2006**

Organization : **Diomed, Inc.**

Category : **Nurse**

Issue Areas/Comments

ASC Phase In

ASC Phase In

CMS-1506-P2

Policy and Recommendation: Comment
Ambulatory Surgical center (ASC)
Proposal dated September 21, 2006

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Provision of endovenous laser ablation in the ASC is cost prohibitive. The 2005 CMS data clearly illustrate the low number (105) of patients treated in the ASC. Acquisition cost of laser equipment is $37,900 with a per patient supply cost of approximately $360. It is financially impossible to provide endovenous laser ablation the ASC setting within the Group 3 payment.

We are requesting that codes 36478 and 36479 be moved to Group 9, as originally identified in the August 10th proposal.

Submitter : **Dr. Richard Neville** **Date: 10/03/2006**

Organization : **Richard Neville, M.D.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS-1506-P2

Policy and Recommendation: Comment
Ambulatory Surgical center (ASC)
Proposal dated September 21, 2006

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We are requesting that codes 36478 and 36479 be moved to Group 9, as originally identified in the August 10th proposal.

Submitter : **Dr. Martin Smith** **Date: 10/04/2006**

Organization : **Virginia Skin and Vein LLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Ambulatory Surgical center (ASC)
Proposal dated September 21, 2006

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We are requesting that codes 36478 and 36479 be moved to Group 9, as originally identified in the August 10th proposal.

Submitter : **Dr. DONALD SCHON** **Date: 10/04/2006**

Organization : **AKDHC**

Category : **Physician**

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

TABLE 45 EXCLUDED PROCEDURES
The proposed list of procedures prohibited from reimbursement in an ASC includes 35475 and 37206. 35475 is the code used by interventional physicians performing pro-cedures (i.e. balloon angioplasty or PTA) at the arterial anastomosis of a fistula or graft and the proximate feeding artery. When applied to the repair and maintenance of vas-cular access for dialysis, these procedures are very safely performed in an ASC. In-deed, they are currently frequently performed safely in POS 11. Data from three sources is provided. The first is an ASC setting with low volume of procedures coding 35475. The second is a single Access Center which performs greater than 3,000 proce-dures per year all on dialysis vascular access. The third is a large number of proce-dures from multiple access centers all functioning as POS 11 and managed by a com-mon entity.
no. proc. /% major complica-tions
14 / 0%
455 /0%
1,968 / <0.3%

In each case the number of major complications is miniscule and well within the profes-sional guidelines for each center and the national guidelines published by the Society for Interventional Radiology. Thus, excluding procedures performed on dialysis vascular access which would be coded as 35475 would be inappropriate as well as counterpro-ductive. These procedures can be safely and effectively performed in an outpatient set-ting. Prohibiting this code would also have the affect of limiting access to care for ESRD patients as these patients would have to have a second procedure and anesthesia to open these lesions at a separate time. Since they would need a way to achieve dialysis access in the meantime, a large number of otherwise unnecessary catheter insertion procedures would be necessitated and the cost to the Medicare program from both ad-ditional procedures would go up significantly.
37206 is the code utilized by interventional physicians for placement of additional vas-cular stents in the venous system. These procedures have been safely performed in the outpatient setting for years. In addition, the initial placement of a stent in the venous system, coded 37205, is not on the list of excluded procedures. In our opinion, this pro-hibition is logically inconsistent, not medically indicated and would necessitate repeat and additional procedures which could otherwise be avoided.
We recommend and request that 35475 and 37206 both be removed from the list of ex-cluded services when applied to dialysis access.

Submitter : **jyl bradley** **Date: 10/05/2006**

Organization : **dunning st ambulatory care center, llc**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Camille White** **Date: 10/05/2006**

Organization : **Central GA Head & Neck Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

We disagree with not allowing payment on procedures that can be done in an outpatient setting simply because they are more frequently done inpatient.

Submitter : **Dr. FREDERICK ELMORE** **Date: 10/05/2006**

Organization : **ELMORE MEDICAL VEIN**

Category : **Physician**

Issue Areas/Comments

ASC Ratesetting

ASC Ratesetting

CMS-1506-P2

Policy and Recommendation: Comment
Ambulatory Surgical center (ASC)
Proposal dated September 21, 2006

The proposed ASC payment published August 10, 2006 moved codes 36478, 36479, into group 9, with a 2006 payment rate of $1,339.

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We are requesting that codes 36478 and 36479 be moved to Group 9, as originally identified in the August 10th proposal.

Submitter : **Mr. Jared Leger** **Date: 10/05/2006**

Organization : **Stonegate Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

To whom it may concern:

I am the Director of Stonegate Surgery Center in Austin, TX. Each year, our surgery center provides a large number of procedures to Medicare beneficiaries. Medicare patients represent 33% percent of our business and ensuring appropriate payment for their services is vital to our ability to serve our community. Please allow modification to be made to the proposed 2007-2008 changes that will impact ASC's. These proposed changes threaten our ability to deliver quality care and also save CMS real dollars. We deliver better care for less money. This is a win-win for everyone.

Thanks for your attention,

Jared Leger
Stonegate Surgery Center
Austin, TX
512-439-7300

Submitter : **Dr. Ara Deukmedjian** **Date: 10/05/2006**

Organization : **Dr. Ara Deukmedjian**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Spinal surgery should be allowed to be performed in the ambulatory surgery setting at the disgression of the treating physician. There are many patient care advantages to providing these services in the ASC setting including:
1. Lower risk of infection. Hospitals are where highly sick and infected patients go for treatment(pneumonia, Staph, MRSA,etc) and invariably post op spine patients are exposed to greater risk of infection as inpatients even with the best measures implemented (hand washing). Lower risk of infection is particularlt important because post op spinal infections are notoriously difficult to treat with metallic foreign bodies implanted.
2. No hospitalization required.
3. Lower complication rate of procedures performed in outpatient setting.
4. Higher patient satisfaction.
5. Lower cost to health care system compared to same procedure performed in hospital.
6. Higher physician satisfaction because of more efficient use of time in OR, shorter turnovers,shorter operative days hence physician less fatigued at end of operative day and less likely to make mistake in the OR.

Thank you

Ara Deukmedjian MD
321-383-8092 office
Florida Neurosurgical & Spinal Rehab Center

Submitter : **Dr. Ara Deukmedjian** **Date: 10/05/2006**

Organization : **Dr. Ara Deukmedjian**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Spinal surgery should be allowed to be performed in the ambulatory surgery setting at the disgression of the treating physician. There are many patient care advantages to providing these services in the ASC setting including:
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2. No hospitalization required.
3. Lower complication rate of procedures performed in outpatient setting.
4. Higher patient satisfaction.
5. Lower cost to health care system compared to same procedure performed in hospital.
6. Higher physician satisfaction because of more efficient use of time in OR, shorter turnovers,shorter operative days hence physician less fatigued at end of operative day and less likely to make mistake in the OR.

Thank you

Ara Deukmedjian MD
321-383-8092 office
Florida Neurosurgical & Spinal Rehab Center

Submitter : **Mr. Steven Pimental** **Date: 10/06/2006**

Organization : **Same Day Surgicare of N.E.**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

See Attached

ASC Unlisted Procedures

ASC Unlisted Procedures

See attached

GENERAL

GENERAL

See Attachment

CMS-1506-P2-54-Attach-1.DOC

SAME DAY SURGICARE OF N.E.
272 Stanley Street
Fall River, MA 02720
Telephone: 508-672-2290 ♦ Fax 508-674-8419

October 6, 2006

Mark B. McClellan, M.D., Ph.D., 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; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

As the **Business Manager** and **Clinical Administrator** of **Same Day Surgicare of N.E.** in **Fall River, Massachusetts,** we are concerned about the proposed rule referenced above. Each year, our surgery center provides over **2,200** procedures to Medicare beneficiaries. Medicare patients represent **twenty six** percent of our business and ensuring appropriate payment for their services is vital to our ability to serve our community.

Please accept the following comments regarding Section XVII of the proposed rule, which would make revisions to policies affecting ambulatory surgical centers for CY 2007. 71 Fed. Reg. 49505 (August 23, 2006).

I. Proposed ASC List Update Effective for Services Furnished On or After January 1, 2007

A. Criteria for Additions to or Deletions from the ASC List

We commend CMS for proposing to update the ASC list for CY 2007, but believe the update falls short by not making extensive revisions to the criteria used to determine which procedures may be reimbursed in the ASC setting. As a result, beneficiary access to ASC services will continue to be limited by arbitrary criteria in CY 2007.

1. The inclusionary ASC list should be abandoned.

The limited, inclusionary list of covered ASC procedures is no longer the best way to address the safety and appropriateness of ASC services. Within currently accepted standards of medical practice - in which vast numbers of procedures may performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient procedural services.

First, and most importantly, the ASC list limits the ability of physicians to select the site of service they believe is most clinically appropriate for their patients. A physician's assessment of the medical needs of the patient and the capabilities of the facility should determine whether a patient receives care in the ASC setting.

Second, the list limits Medicare beneficiaries' access to procedures that many other patients routinely receive in ASCs. Private payers do not restrict the access of their insured members to ASC services. Decisions regarding the site of service are recognized to be the province of the insured's physician. As a result, several minimally invasive procedures not available to Medicare patients in the ASC setting, such as spinal disc decompression and laparoscopic cholecystectomy, are commonly performed for selected privately insured patients at significant savings to the patient and to the insurer. As long as CMS continues to maintain an ASC list, Medicare beneficiaries' access to appropriate services will always lag behind that of the private sector.

The ASC list should be abandoned. In its place, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and develop a list of services specifically excluded from coverage. In fact, CMS already has such an exclusionary list; for purposes of hospital outpatient payment under the Outpatient Prospective Payment System, CMS has developed and uses an "inpatient only" list. Because Medicare-certified ASCs have proven over the past two decades that they are capable of safely performing the same scope of services provided in hospital outpatient departments, this list may also be used to identify procedures excluded from coverage in ASCs.

Alternatively, if CMS develops a separate exclusionary list for ASCs, then that list should be based on the criteria identified by MedPAC in their March 2004 report. Specifically, MedPAC recommended the current list of ASC approved procedures by replaced "with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay".

2. The criteria used to revise the Medicare list of procedures that may be performed in an ASC are outdated and do not serve the interest of the Medicare program or its beneficiaries.

Section 1833(i)(1) of the Social Security Act requires CMS to determine which surgical services are safely and appropriately offered in an ASC. CMS selects the services represented on the current list of approved procedures based on criteria outlined in the Code of Federal Regulations at §416.65. We believe CMS is inappropriately limiting beneficiary site-of-service choices by continuing to make procedure list det erminations using obsolete and outdated criteria that CMS itself previously proposed to substantially revise (63 Fed. Reg. at 32298).

a. Requirement that procedures be commonly performed in an inpatient setting.

When the Medicare ASC benefit was originally implemented in the 1980s, most surgical procedures were performed in an inpatient setting. In the intervening decades, the outpatient setting has become the accepted setting for many types of surgical procedures. As new clinical approaches to surgery, anesthesia and pain management have been incorporated into standard medical practice, certain procedures have moved almost exclusively to the outpatient environment. New procedures have evolved that were never commonly performed in an inpatient setting. Examples include newer arthroscopic and endoscopic interventions, and surgical treatments using laser or radiofrequency instrumentation. These procedures were

developed predominately in an outpatient setting and are performed safely and cost-effectively on thousands of commercial insurance and self-pay patients each year.

To continue to require that a procedure be commonly performed in the inpatient setting before it can be deemed appropriate for the ambulatory surgery setting is no longer consistent with current standards of practice. We recommend general standard (1) "Covered surgical procedures are those surgical and other medical procedures that are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC" be eliminated as obsolete. This recommendation is also supported by MedPAC's 2004 report which specifically states, "it no longer makes sense to consider inpatient volume when updating the ASC list."

c. Requirement that a procedure not be commonly performed in physicians' offices

Current CMS guidelines provide that a procedure performed 50 percent or more of the time in a physician's office cannot be reimbursed in an ASC. In effect, this limits a physician's options to an inpatient or HOPD setting for patients for whom an office setting would be inappropriate. The higher costs generally associated with inpatient and HOPD reimbursement as compared to ASC reimbursement rates have been well documented by the OIG and MedPAC. Eliminating ASCs as an option for procedures which can be safely performed in the outpatient setting imposes unnecessary costs on both the Medicare program and individual beneficiaries. Conversely, allowing ASCs to serve as a site-of-service option to HOPDs for care has allowed the Medicare program to achieve significant cost savings.

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. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. A brief summary of these factors follows.

<u>Patient Characteristics</u> – Patient characteristics affect the selection of the appropriate site of service. Factors such as body habitus, comorbid conditions and even the patient's ability to lie in certain positions or hold still for long periods of time may affect whether a procedure can or should be performed in a physician office.

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Additionally, a procedure may be scheduled for a facility when the physician thinks it likely that a diagnostic procedure will result in the need for a therapeutic intervention. For example, a diagnostic cystoscopy (CPT code 52000) may be scheduled at an ASC because the physician thinks it likely that a cystoscopy with biopsy (CPT code 52204), requiring instruments and cautery not available in the office, will be necessary.

<u>Procedure Differences</u> –Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The

number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12-20 biopsies. Due to the more invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

Office Differences – Physician offices vary greatly in terms of equipment and personnel. To a great extent, this varies based upon the volume in the office. A small office may simply not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

State Laws and Regulations – State laws and regulations impose limitations on what can be done in offices. To be able to perform certain types of procedures, these state provisions may require specific equipment, staff or even accreditation. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

As was noted in the preamble to the interim final rule of May 2005, the rate of performance in ASCs of the physician office procedures originally proposed for deletion has remained relatively stable over the past 10 years. In other words, the inclusion of these procedures on the ASC list has not induced substantial shifts in sites of service, which suggests site-of-service selection is being driven by clinical need. If CMS remains concerned about the potential for financial incentives to improperly influence site-of-service selection, then the logical solution is to address any unjustified payment variations in the new payment system, rather than denying ASC coverage for procedures commonly performed in physician offices.

MedPAC has also recommended that CMS abandon the requirement that procedures be performed less than 50 percent of the time in physician offices to be added to the list. The Commission has specifically stated, "Physicians should have the discretion to decide which setting is most clinically appropriate for individual patients."

c. Operating and recovery time limits are unnecessary.

The ASC industry supported CMS's 1998 proposal (63 Fed. Reg. at 32298) to discontinue using the time limits on operating, anesthesia, and recovery time currently defined under 42 C.F.R. § 416.65(b), which are used as a basis for determining whether a procedure should be added to or deleted from the ASC List. The numeric threshold rules presently employed by CMS are obsolete and too often result in the exclusion of procedures that are entirely appropriate for the ASC setting. The current rule that the ASC List should be restricted to procedures that generally do not require more than 90 minutes operating time or 4 hours recovery time is outdated. This standard was developed in the early 1980s and predates

numerous technological advances that are now standard in the ASC setting. Both thresholds are arbitrary and without clinical significance.

As MedPAC has observed, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting. With the development of short-acting general anesthetics, the length of operating time is immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Moreover, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours.

B. Procedures Proposed for Addition to the ASC List

We commend CMS for updating the ASC list again for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clearly clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. **We** believe the HOPD data is a more reliable proxy for the cost of providing this service.

We are also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339.00) and Group 1 ($333.00), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no real opportunity for ASCs to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should add the procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in the physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service; significant error rates (80 % and higher) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe continued reliance on this data is appropriate.

As noted above, there is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to overutilization of those procedures in the ASC setting. CMS itself has acknowledged that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696).

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must be seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also costs both the program and its beneficiaries significantly more. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment, the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a humane examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. Now, these procedures are commonly performed for non-Medicare patients in the ASC setting. Although CMS has not included these procedures on the ASC list to date, CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures were being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. We recognize an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. We are aware of just one recent study which exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of

Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an ambulatory elective laparoscopic cholecystectomy, the surgeon may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CMS should also add G0289, which describes a knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

There are several procedures that are appropriate additions to the ASC list. **We** believe that CMS should add these procedures to the list with an effective date of January 1, 2007.

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

II. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

We are supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). We also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes

accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:".

We are also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is our belief that the items CMS finds necessary for review should be published in the Federal Register, as any change in regulation should be open to review and comment by the public before being implemented.

* * * * *

Thank you for your time and consideration of our comments. If you have any questions or need additional information, please do not hesitate to call us at 508-672-2290 and/or email to spimental.sds@verizon.net and pkeegan.sds@verizon.net.

Sincerely,

Steven Pimental, CASC
Business Manager

Margaret E. Keegan, BSN, RN
Clinical Administrator

Submitter : **Ms. Margaret Keegan** **Date: 10/06/2006**

Organization : **Same Day Surgicare of N.E.**

Category : **Nurse**

Issue Areas/Comments

GENERAL

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See Attachment

CMS-1506-P2-55-Attach-1.DOC

SAME DAY SURGICARE OF N.E.
272 Stanley Street
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October 6, 2006

Mark B. McClellan, M.D., Ph.D., 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

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Additionally, a procedure may be scheduled for a facility when the physician thinks it likely that a diagnostic procedure will result in the need for a therapeutic intervention. For example, a diagnostic cystoscopy (CPT code 52000) may be scheduled at an ASC because the physician thinks it likely that a cystoscopy with biopsy (CPT code 52204), requiring instruments and cautery not available in the office, will be necessary.

Procedure Differences –Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The

number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12-20 biopsies. Due to the more invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

Office Differences – Physician offices vary greatly in terms of equipment and personnel. To a great extent, this varies based upon the volume in the office. A small office may simply not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

State Laws and Regulations – State laws and regulations impose limitations on what can be done in offices. To be able to perform certain types of procedures, these state provisions may require specific equipment, staff or even accreditation. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

As was noted in the preamble to the interim final rule of May 2005, the rate of performance in ASCs of the physician office procedures originally proposed for deletion has remained relatively stable over the past 10 years. In other words, the inclusion of these procedures on the ASC list has not induced substantial shifts in sites of service, which suggests site-of-service selection is being driven by clinical need. If CMS remains concerned about the potential for financial incentives to improperly influence site-of-service selection, then the logical solution is to address any unjustified payment variations in the new payment system, rather than denying ASC coverage for procedures commonly performed in physician offices.

MedPAC has also recommended that CMS abandon the requirement that procedures be performed less than 50 percent of the time in physician offices to be added to the list. The Commission has specifically stated, "Physicians should have the discretion to decide which setting is most clinically appropriate for individual patients."

c. Operating and recovery time limits are unnecessary.

The ASC industry supported CMS's 1998 proposal (63 Fed. Reg. at 32298) to discontinue using the time limits on operating, anesthesia, and recovery time currently defined under 42 C.F.R. § 416.65(b), which are used as a basis for determining whether a procedure should be added to or deleted from the ASC List. The numeric threshold rules presently employed by CMS are obsolete and too often result in the exclusion of procedures that are entirely appropriate for the ASC setting. The current rule that the ASC List should be restricted to procedures that generally do not require more than 90 minutes operating time or 4 hours recovery time is outdated. This standard was developed in the early 1980s and predates

numerous technological advances that are now standard in the ASC setting. Both thresholds are arbitrary and without clinical significance.

As MedPAC has observed, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting. With the development of short-acting general anesthetics, the length of operating time is immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Moreover, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours.

B. Procedures Proposed for Addition to the ASC List

We commend CMS for updating the ASC list again for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clearly clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. **We** believe the HOPD data is a more reliable proxy for the cost of providing this service.

We are also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339.00) and Group 1 ($333.00), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no real opportunity for ASCs to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should add the procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in the physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service; significant error rates (80 % and higher) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe continued reliance on this data is appropriate.

As noted above, there is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to overutilization of those procedures in the ASC setting. CMS itself has acknowledged that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696).

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must be seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also costs both the program and its beneficiaries significantly more. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment, the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a humane examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. Now, these procedures are commonly performed for non-Medicare patients in the ASC setting. Although CMS has not included these procedures on the ASC list to date, CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures were being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. We recognize an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. We are aware of just one recent study which exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of

Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an ambulatory elective laparoscopic cholecystectomy, the surgeon may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CMS should also add G0289, which describes a knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

There are several procedures that are appropriate additions to the ASC list. **We** believe that CMS should add these procedures to the list with an effective date of January 1, 2007.

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

II. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

We are supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). We also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes

accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:".

We are also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is our belief that the items CMS finds necessary for review should be published in the Federal Register, as any change in regulation should be open to review and comment by the public before being implemented.

* * * * *

Thank you for your time and consideration of our comments. If you have any questions or need additional information, please do not hesitate to call us at 508-672-2290 and/or email to spimental.sds@verizon.net and pkeegan.sds@verizon.net.

Sincerely,

Steven Pimental, CASC
Business Manager

Margaret E. Keegan, BSN, RN
Clinical Administrator

Submitter : **Date: 10/09/2006**

Organization :

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-56-Attach-1.DOC

#56

October 9, 2006

Dear Congresswoman Wasserman Schultz,

I am a licensed mental health counselor working for a community mental health center which provides partial hospitalization program services to a wide range of individuals in need in the south Florida area. Our job and the services we provide are critical and the proposed rate cut for CMS would significantly impact our community needs.

I am therefore opposing this proposal to lower rates. Please take the voice of our patients and those who provide an important service into consideration. Do not cut CMS rates.

Thank you,

Naiyana Chantarabunchorn, LMHC

Submitter : **Mrs. Isabel Soler** **Date: 10/09/2006**

Organization : **American Therapeutic Corporation**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

I write you in order to request that medicare payments for services in the mental health field, particularly with chronic patients, be reconsidered as it would detrimentally impact the quality and efficacy of services to one of our neediest populations.

Submitter : **Dr. stanley satz** **Date: 10/09/2006**

Organization : **Bio-Nucleonics, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

"Scc Attachmcnt".

CMS-1506-P2-58-Attach-1.TXT

#5 3

βIO-NUCLEONICS PHARMA, INC.

Utilizing Radiation to Improve Human Health

October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05; Att: CMS-1506P2
7500 Security Blvd.
Baltimore, MD 21244-1850 By Fedex and e mail to: http:www.cms.hhs.gov/erulemaking

In Re: File Code CMS-1506-P2, CY 2007. Payment Rates Proposed Rule For 78492, (APC 0307), Myocardial Positron Emission Tomography (PET) Scan RHQDAPU

Dear Sir/Madam:

This is a formal submission of comments regarding a proposed payment decrease by combining single and multiple cardiac PET imaging (APC307) studies into one. Bio-Nucleonics is a small business that focuses on innovative solutions utilizing radiation to improve human health.

According to the American Heart Association, in 2006, more than 1.5 million Americans will have a first or recurrent coronary attack, and 600,000 will die. Cardiovascular disease is the nation's single largest cause of death, and more women die of the disease than of cancer. Around 7.2 million Americans age 20 and older have survived a heart attack, and 13% of middle-aged men have coronary arteriosclerosis, most of it clinically silent. Some 6.6 million have angina pectoris. Cardiac PET is a solution to the major question for cardiac care providers of how to detect and identify silent coronary artery disease in specific individuals, and how to define its severity in either the symptomatic or asymptomatic patient.

Bio-Nucleonics respectfully requests a payment rate review (Payment Rates Proposed Rule For 78492 and APC 307), myocardial PET scan, and upward readjustment for 2007 by the Centers for Medicare and Medicaid Services from the proposed cost rate of $721.26 to $2,484.88 in order to accurately reflect the real cost of providing a multiple study myocardial positron emission tomography (PET) scan. The rationale for this request follows.

A drastic decrease by more than two-thirds in the payment rate for a multiple cardiac PET procedure, caused by "bundling" single procedures and multiple procedures will serve to drive the underutilization of myocardial PET. The CMS is using a fundamentally flawed methodology for setting a payment rate, biased against a proven diagnostic tool, ultimately costing the CMS hundreds of millions of dollars of excess reimbursements for unnecessary invasive procedures. If the proposed reduced reimbursement goes into effect, CMS could see an increase in cardiac catheterizations, bypass surgery and heart transplantations resulting from false positive and false negative misdiagnosis or prognosis, leading to undesirable therapeutic approaches.

The level of reimbursement for a cardiac PET perfusion procedure was appropriately set by local Medicare providers for a rest/stress procedure. While these were acceptable payment rates, hospitals may soon experience a change in the way they are reimbursed for outpatient procedures performed on Medicare beneficiaries, and that change threatens to erode payment levels impacting the most needy of patients. The potentially negative impact on cardiovascular healthcare in America and taxpayers is all too obvious.

Bio-Nucleonics Pharma, Inc. · 1 N.E. 19th Street · Miami, Florida 33132 · Tel: 305 576-0996 · ssatz@bionucleonics.com

The Reimbursement History of Cardiac PET

Cardiac PET has been validated by the Centers for Medicare and Medicaid Services (CMS) with coverage as a primary or initial diagnostic study for determining myocardial viability in patients with ischemic heart disease, and increased PET reimbursement by the CMS and private insurers reflects a growing understanding of its clinical value. Such changes encouraged physicians to use PET imaging to detect cardiovascular disease earlier, contributing to an overall improvement in patient outcomes. For 2006, the CMS appropriately increased the reimbursement for myocardial PET perfusion imaging involving multiple studies at rest and/or stress to $2,484.88. CMS came up with the new figure by analyzing claims data and splitting the ambulatory payment classification (APC) into single studies and multiple studies, similar to how SPECT myocardial perfusion imaging procedures are handled. The Society of Nuclear Medicine, the Academy of Molecular Imaging, the American Society of Nuclear Cardiology, and the CMS APC panel were among the proponents advocating the level splitting.

Historically, the FDA approved a PET radiotracer, as a cardiac perfusion agent in 1989, and HCFA afforded coverage for Medicare patients in 1994. It was unfortunate that because of insufficient reimbursement, the diagnostic advantages of cardiac PET languished for more than a decade. Payment rate is a critical component of coverage and has been the subject of much attention. Historically, In 1998 HCFA accorded 53.96 relative value units (RVUs) for oncologic PET studies, which equated to an average payment rate of $1,980. This RVU assignment was to reflect the total technical reimbursement for the procedure, including both the actual scan fee and the radiopharmaceutical charge. It is unfortunate that cardiac PET was treated much less favorably.

While there has been exponential growth in PET camera installations in the U.S. during the past decade, and in 2005, over 1 million mostly oncological and neurological PET scans were performed, cardiac PET has languished, becoming the "orphan" brother of oncological PET because reimbursement does not economically justify the purchase of a dedicated scanner. In facilities where there is no scanner time available because of oncological, neurological and research workloads, there is no coronary PET.

For 2007, however, the CMS proposes to "bundle" single and multiple myocardial PET Scans under one code, APC 0307, (CPT Codes 78459, 78491, 78492 and under the OPPS) and to reduce the payment rate for a heart image (PET) multiple study to $721.26, a catastrophic reduction that if enacted would essentially eliminate the delivery of cardiac PET diagnostic procedures to Medicare beneficiaries.

Rationale For Not "bundling" Single and Multiple Myocardial PET Scans Under One Code

1. The CMS is proposing "bundling" lower cost single studies with multiple studies into a single new code based upon the CY 2004 claims from a single hospital (See Page 196, Line 21). Contrary what the CMS states on Page 198 of its current proposal, hospital resources to perform single and multiple studies are not similar. A multiple study takes more time, requires the multiple administration of injectable drugs and radiopharmaceuticals, takes longer to read, reduces patient throughput (adding to the amortization cost of the scanner per study), and adds to the amount of administrative time required per patient.

2. CMS stated that "we now have more data to support our proposed payment rates... based on almost 1,500 single claims for both single and multiple scans and that this should be more reflective of the hospital resources required to provide the service to beneficiaries in the outpatient setting—and that based on this data, the differential median costs of single and multiple studies procedures do not support the present 2-level APC payment structure". In fact, only a very few hospitals perform over a thousand cardiac PET studies a year (Cleveland Clinic, Brigham and Woman's and Mount Sinai of New York). Thus the CMS data relied upon was only for one or two hospitals and continues to be flawed, skewing to single scans.

3. The new rate for a multiple cardiac PET study is based on a statistically insignificant small number of claims, wherein there is confusion on the part of billing clerks between single and multiple scans. This has unfortunately resulted in a skewing; using the cost of a single scan to also cover more costly multiple scans.

4. We have surveyed the five leading hospitals performing cardiac PET and spoken to the billing clerks, administrative personnel and nuclear cardiologists. The results of these finding is that in four of these institutions the persons that enter in the data that is transmitted to CMS did not know that a multiple scan could be billed separately! Instead, in error, they were entering multiple studies as single ones. The result is that underreporting and "averaging" skews the figure that CMS has arrived at in its conclusion to eliminate reimbursement for multiple scans and pay for a multiple scan at the single scan rate.

5. For example, Brigham and Women's Hospital is participating in a multicenter clinical study to compare the diagnostic accuracy, cost-effectiveness, and prognosis of PET, and SPECT in coronary angiography. This medical center and other participants in a NIH funded study are appropriately reporting to the CMS at zero or near zero dollars because the expenses are being covered under a multi-year grant.

6. Nuclear cardiologists report that the majority of cardiac PET scans being performed are multiple studies, not single ones.

7. If enacted, the proposed cut is extreme and will unquestionably change how, where and if Medicare patients get the imaging services they need. The CMS cannot simply cut cardiac PET scan reimbursement radically without affecting patients. The cut is based upon a statistically insignificant data. A survey of reporting hospitals has shown that the persons responsible for data input confused single studies for multiple studies and, in fact, did not know how to distinguish between a single study and a multiple study.

8. CMS examined only 296 claims for single scans and 1,150 claims for multiple images. In fact, based upon a population of about sixty radionuclide generators, about 60,000 cardiac PET scans were performed in 2005 (4 scans per day X 60 sites X 250 days). Therefore, even when those scans paid for by private insurers are removed, the number of claims analyzed by CMS is simply statistically insignificant and the number of "so-called" single and multiple procedures used by CMS is unreliable and does not reflect the actual multiple studies that were performed.

9. If this proposed reimbursement elimination for multiple scans and resulting reduction is allowed to stand, it will result in the underutilization of PET cameras, which could be used to detect cardiovascular disease. An example is "hibernating" heart muscle, which results in equivocal results if a SPECT scan is utilized. The potential impact would be a disservice to Americans and increased treatment costs of invasive therapy (i.e. coronary artery bypass graft), paid for by CMS.

10. Unlike MRI, Cardiac PET is not a high volume procedure and is not widely used by Medicare patients.

11. Therefore, proposed new and the assignment of a single APC 0307 and HCPCS Code 78492, and a single reimbursement rate and the methodology utilized is simply flawed. The result will be that the proposed rate will be inadequate to ensure appropriate access for Medicare beneficiaries.

12. The decrease proposed simply does reflect the actual costs that are associated with providing patient care and the impact of this would be catastrophic for cardiac patients and their families,

nuclear cardiologists and technicians, hospitals, the small businesses that provide mobile cardiac PET and pharmaceutical and medical device companies. The potential result upon the CMS and the taxpayer would be a greatly increased financial burden and the substitution of more costlier and invasive medical procedures such as cardiac catheterizations.

13. Myocardial PET is an unusual case, specifically a low volume procedure. It is requested that special consideration be given in accordance with CMS reimbursement policy.

14. Fluctuation may have resulted in CMS utilizing erroneous or skewed cost data.

15. The median cost of this drug was not taken into account by CMS.

16. CMS does not base the payment rate on accurate claims data as required by statute. In accordance with the Regulatory Flexibility Act (RFA) as relates to underpayment the verifiable information presented herein reflects the actual, widely available, market-based pricing of mobile cardiac PET or the short-term rental or lease of a Rubidium-82 generator and infusion cart.

17. There has been massive underreporting of consumption and data corruption in the CMS-1506-P, CMS-4125-P HOPPS CY 2007 Payment Rates Proposed Rule.

18. The RFA requires Federal agencies to consider alternatives to their rules to ease the burden on small businesses.

19. Protections granted under the Administrative Procedures Act are being violated.

20. Bio-Nucleonics seeks redress in accordance with the Federal Advisory Committee Act.

21. Bio-Nucleonics respectfully requests that the CMS abide by own proposal on Pages 144 and 145 and to exempt Myocardial PET, also granting an exception to the 2 times rule limit on the variation of costs as Myocardial PET is an unusual case consisting of a low-volume item in terms of the number of procedures performed consisting of 2,979 claims as shown in the CMS-1506 P Document, Page 195, and the number of doses of the radionuclide (A9555) consisting of 3,837 units utilized in 2005 X$239.83, as shown in the CMS-1506 P Document, Page 283.

22. Decreasing reimbursement does not follow the spirit of CMS's own policy, or the recommendation of the APC Panel. The CMS specifically stated the following in the Federal Register, "In cases where costs show significant fluctuation, we believe it is appropriate to mitigate the potential for underpayment". It is requested that this objective be implemented for multiple study myocardial PET reimbursement.

23. The Regulatory Flexibility Act requires agencies to consider alternatives to their rules to ease the burden on small businesses. Our sales price is determined in great part by what the U.S. Department of Energy and the Federal laboratories charge for radioisotope feedstocks. The cost of a radionuclide and processing are much higher than conventional drugs and the profit margin is much less. If we discontinue production of any radiopharmaceutical (the likely result of decreased reimbursement) oncological and cardiac care costs will be driven up even higher, the quality of healthcare will be decreased and there is no assurance that we will be able to economically produce other radiopharmaceuticals; products that could save CMS many millions of dollars each year. This will further exacerbate a difficult state of affairs for us as an already disadvantaged small business and manufacturer of proven cost–effective radiopharmaceuticals.

24. In accordance with the RFA as relates to underpayment the verifiable information presented herein reflects the actual, widely available, market-based pricing for the rental of a Rubidium-82

Generator and Infusion Cart, for the time needed to perform a PET Scan, for nuclear medicine technician time, for disposables (catheters and the disposable tubing and valves that need to be replaced daily) and for interpretation of the scan by a nuclear cardiologist. CMS's payment rate simply does not reflect the inherent costs and at which a broadly based, national sample are routinely able to procure this radiopharmaceutical. Respectfully, we ask the CMS to comply with its stated objective of "We believe it is appropriate to mitigate the potential for underpayment" as stated in the August 12, 2003 Federal Register.

The Economics of Cardiac PET

1. Using PET scanning rather than other types of imaging as the first tool to diagnose heart-vessel blockages is more accurate, less invasive and saves dollars, a study by University at Buffalo researchers has shown.

2. The broad-based Moran Study using 2006 Medicare claims data contradicts the view that imaging payments under HOPPS accurately reflects actual costs of performing a procedure. In fact, what would be paid is below the cost of performing a multiple study cardiac PET procedure.

3. The cost-savings that PET offers in being able to divert normal patients from receiving coronary angiography studies are considerable. The average cost of a PET study is about $1,480 (including Medicare patient and co-pay rates and technical and professional fees), compared to $3,270 for a cardiac catheterization.

4. By extrapolating these costs of one study's 233-person population, sending these patients for cardiac catheterization would have cost a total of $762,000. But by using PET instead after nondiagnostic SPECT, the cost would only be $528,000, even if 25% of the abnormal patients also went on to receive coronary angiography.

5. 890 sites reported they utilize a mobile service to provide PET or PET/CT imaging capability, resulting in a total of 1,400 sites offering PET imaging services. The 890 sites using mobile PET report using the mobile service for an average of 1.2 days per week per site. Assuming that the mobile vans are scheduled with no downtime between sites, an estimated 210 mobile vans serve these 890 sites. In 2001, the estimated average annual volume of clinical PET procedures per site was 385. Fixed PET sites conducted an average of 860 procedures per site in 2001, while mobile PET sites logged an average of 190 per site, and sites with gamma cameras that have coincidence-detection upgrades (NM-CD) performed 195 procedures per site. Currently, providers can offer PET procedures using a fixed PET scanner, a PET scanner in a mobile van. An estimated only 4 to 5% of PET scans were cardiac exams.

6. CMS pays separately for drugs on the basis of "the average acquisition cost of the drug". In fact, the average acquisition cost of the radionuclide is considerably more than what is reimbursed, (A9555, $239.83 a unit) because unlike most other radiopharmaceuticals, it is generator derived. Generators must be replaced at a cost of $28,500 a month, so if the patient load decreases, the cost per procedure increases dramatically. Many hospitals where myocardial PET is practiced utilize a mobile PET generator for a half a day or a day at a fixed cost. Therefore a multiple study takes more PET scanner time, more nuclear medicine technician time, longer scan and set-up time, more rental time, more supplies, more time to interpret the scan, and certainly costs more than a single study.

7. The radionuclide generator used to deliver a short-lived dose of the radionuclide used for myocardial PET costs about $500 an hour to rent, usually from a small business, and there is usually a minimum rental time, which is 4 hours or a full day. In some locations a mobile PET camera is utilized which can cost around $70,000 a month to rent. Typically, at most facilities only one to four cardiac PET scans are performed. The proposed CY 2007 payment rate of $721.26 for a

multiple procedure is woefully inadequate to cover even a portion of these costs. At the 2007 proposed reimbursement rate, it is estimated that a hospital would have to perform more than eight myocardial PET scans a week to break even, not including compensation for the nuclear medicine technologist, nuclear cardiologist, nurse or physician's assistant and an administrator.

8. Another potential consequence of the proposed CMS' rule will be increasing numbers of hospitals may substitute expensive but more highly reimbursable cardiac catheterization procedures, costing American taxpayers and the CMS hundreds of millions of dollars more for the treatment of cardiovascular disease than is already being spent. It is not known how the reimbursement figure was arrived at, what the relevant weight was or how the reduction was derived, but it certainly does not reflect the real acquisition cost of this drug. Clearly, this situation is untenable and needs to be expeditiously readjusted. The decreased usage of cardiac PET stress tests to detect cardiovascular disease will likely result in CMS paying at least $200 million more each year for cardiac catheterizations, balloon angioplasties and stenting, coronary artery bypass surgery and hear transplantations than it did in 2005, (10,000 patients at a $20,000 savings per patient), resulting from additional costs for procedures, supplies, hospital visits, CT Scans and tertiary care.

<u>About Cardiac PET</u>

Cardiac PET (positron emission tomography) is the newest and most powerful modality for detection and treatment of cardiovascular disease. PET is the newest, most powerful and accurate noninvasive test available to reveal or rule out the presence of coronary disease facilitating the most effective course of treatment. It not only provides an accurate assessment of blood flow to the heart, it indicates whether the appropriate treatment lies in transplant or bypass surgery. The advantage of the technology is that unlike SPECT, Cardiac PET enables evaluation of both myocardial perfusion and viability, delivering rapid patient throughput and superb image quality. The combination of PET and a diagnostic radiopharmaceutical enables delivery of the benefits of advanced cardiac PET stress testing to patients. This provides cardiologists with a new tool more sensitive and specific to cardiac disease than other imaging modalities, reducing equivocal results, saving the CMS and private insurers costs associated with invasive cardiac catheterization procedures, costly bypass surgery and non-beneficial drugs, shortened examination times, patient comfort, enables diagnosis of obese patients, delivers less than one tenth the radiation exposure of any other modality, and does not require additional technical training for physicians.

PET can more accurately define a host of disease processes that conventional, anatomic-based imaging alone (CT, X-Ray or MRI), oftentimes before symptoms appear. It traces molecular and functional processes in the body. PET can compliment any oncology, neurology or cardiology service, providing a non-invasive analytical tool for coronary artery disease, cancer and neurological conditions. Only PET delivers diagnostic performance in a fraction of the time that it takes for a conventional stress test. A myocardial perfusion study can be performed in only 40 minutes or less, compared to 2 to 3 hours for SPECT. This translates into added patient comfort, convenience and high throughputs.

The broader availability of PET imaging enhances diagnostic capabilities of patients that have or are suspected of having cardiovascular disorders or at-risk situations, early enough to make a difference. The clinical value of cardiac PET to deliver superb image quality is proven and well accepted. Regional myocardial perfusion can be evaluated to determine the presence and severity of coronary artery disease and impaired blood flow, response to treatment can be monitored and significant prognostic value has been demonstrated for predicting cardiac events including death and myocardial infarction.

Cardiac PET metabolic imaging PET can differentiate viable from nonviable myocardium in patients with ischemia is helpful in patient selection of those benefiting from revascularization, and can also identify "hibernating" tissue that may recover function after a procedure. Mismatch between blood flow and radionuclide uptake can predict post revascularization improvement, symptomatic relief and survivals. The information obtained can help avoid unnecessary and costly invasive procedures.

PET can be used to pinpoint the appropriate form of intervention, reducing the potential for equivocal results that may lead to high-risk procedures such as cardiac catheterization, transplantation and bypass surgery.

Unlike any other imaging modality, PET perfusion stress testing is more specific than SPECT, giving rise to few false negatives, and is more sensitive, resulting in fewer false positives. Unlike PET, SPECT studies are oftentimes compromised due to poor image quality or attenuation artifacts. PET can be used with improved diagnostic confidence in patients after an inconclusive SPECT scan. With PET there is considerably lower radiation exposure to patients and medical staff than SPECT.

Myocardial perfusion PET is both useful and prognostically predictive in a heterogeneous patient population with challenging SPECT scans. Cardiac PET following nondiagnostic SPECT resolved all of the patients except five, and these findings influence the coronary arteriogram rates. The majority of the patients in the study had a normal PET and were associated with a low likelihood of short-term events, obviating unnecessary coronary angiography.

If the proposed procedural "bundling" allowed to pass, this will further exacerbate a difficult state of affairs for us and others as already disadvantaged small businesses and manufacturers of cost–effective radiopharmaceuticals as well as the small businesses that provide mobile PET services. Please keep in mind that the RFA requires Federal agencies to consider alternatives to their rules to ease the burden on small businesses.

A reimbursement reduction by CMS in 2007, for multiple study myocardial PET could be an unfortunate one for the many thousands of Medicare recipients with cardiovascular symptoms or disease. The fact is that the drastic decrease in the payment rate proposed by CMS will result in the underutilization of a cost effective, proven diagnostic that needs to be expeditiously adjusted in order to accurately reflect the actual cost of a multiple scanning procedure.

CMS would be "shooting itself in the foot" and being "penny-wise and pound foolish" by setting the reimbursement rate for a dose of Strontium-89 so low that many hospitals, which are bottom line driven, will gravitate to procedures or to products where they can make a substantial profit.

As a potential result of this flawed CMS reimbursement proposed policy for myocardial PET for 2007, more and more Americans with heart disease or those suspected may be misdiagnosed needlessly, and their care and well being will be affected. With the CMS setting the standard, insurance companies are likely to follow suit, thus inflating the number of patients not receiving treatment. This flawed policy will result in increased costlier cardiac catheterization procedures, a decrease in quality-of-life and a dramatic rise in the cost of health care.

Also, what could be attributable to reduced CMS reimbursement for myocardial PET is that the uninsured will probably not be receiving this form of treatment at public hospitals, and the policy could also carry over to Medicaid patients. Since the number of uninsured is increasing nationwide, Medicaid costs are expected to increase even more dramatically and will be even further impacted unfavorably by the underutilization of this important diagnostic.

Through the use of myocardial PET, the CMS could achieve a substantial savings in health care treatment costs, at the same time through high specificity and accuracy only available with PET, decreasing the need for more invasive interventional procedures and improve the quality-of-life of patients suffering from cardiovascular disease. Pharmacoeconomic data supports this assumption.

Cardiac PET stress tests are used to check the health of the coronary arteries for functionally significant obstructions (narrowing), which can reduce blood flow to heart muscle and lead to the heart muscle becoming "starved" of oxygen. This condition is called coronary artery disease. Symptoms can include chest pain and shortness of breath. With coronary artery disease there is an increase in the possibility of a myocardial infarction (heart attack). PET cardiac scans are more accurate than other cardiac stress tests such as Thallium-201 SPECT (Single Photon Emission Computed Tomography) in the detection of heart disease and provide enhanced quantification. Because of this increase in accuracy, invasive catheterizations

can often be avoided in those patients who do not need it. Knowing about these obstructions can help the physician decide the best course of further diagnostic tests and treatment, such as catheterization, when necessary.

Because the radionuclides used in cardiac PET are so short lived, the patient must undergo pharmacological stress, and the radioisotope must be injected at peak stress through an infusion system. Clinical data show that cardiac PET's almost instantaneous ability to image a patient provides very high accuracy in identification of ischemia. In addition, it reduces a stress and rest test to 45 minutes, compared with routine SPECT myocardial stress imaging, which takes place over three to four hours.

Cardiac PET has also proven beneficial for difficult-to-image patients. Because of the limitations of SPECT, obese patients generally cannot be imaged. Those patients who need to undergo pharmacological stress are those who are usually the sickest; those are the patients for whom cardiac PET provides a significant advantages.

In one study, PET was able to resolve 98% of the nondiagnostic SPECT studies, reclassifying patients as either normal or abnormal. PET scans were normal in 170 patients (73%), and only 58 patients (25%) were reclassified as abnormal. Only three patients in the normal group went on to have coronary angiography within 60 days of PET (none of whom turned out to have significant coronary disease). Of the 58 abnormal patients, 29 were referred to coronary angiography within 60 days of PET and 18 had revascularization. Of the 29 patients who received angiography, 20 had significant coronary disease.

Conaway calculated the cost-savings that PET offers in being able to divert normal patients from receiving coronary angiography studies. The average cost of a PET study is about $1,480 (including Medicare patient and co-pay rates and technical and professional fees), compared to $3,270 for a cardiac catheterization. By extrapolating these costs to the study's 233-person population, Conaway said that sending all the patients to cardiac cath would have cost a total of $762,000. But by using PET instead after nondiagnostic SPECT, the cost would only be $528,000, even if 25% of the abnormal patients also went on to receive coronary angiography.

Rubidium-82 myocardial perfusion PET is both useful and prognostically predictive in a heterogeneous patient population with challenging SPECT scans. PET following nondiagnostic SPECT is resolute and these findings influence the coronary arteriogram rates. The majority of these patients had a normal PET and were associated with a low likelihood of short-term events, obviating unnecessary coronary angiography.

Cardiac PET specificity is 95% or greater versus 45% for SPECT and sensitivity for PET is 95% versus 88% for SPECT meaning a much lower incidence of false negatives and false positives, that can result in unnecessary but costly invasive procedures being performed. With cardiac PET, there is the potential to reduce cardiac care costs by 20% to 50%.

In a patient with symptoms suggestive of coronary artery disease, a central clinical issue is to determine whether a coronary angiogram is necessary for further work-up. A variety of non-invasive imaging tests, including PET and SPECT scans, have been investigated as a means of identifying reversible perfusion defects, which may reflect coronary artery disease, and thus identify patients who may benefit from further work-up with an angiogram.

The ACC/AHA guidelines note that PET imaging "appears to have better overall accuracy for predicting recovery of regional function after revascularization in patients with left ventricular (LV) dysfunction than single photon techniques (i.e., SPECT scans)."

PET has been most thoroughly researched as a technique to assess myocardial viability to determine candidacy for a coronary revascularization procedure. For example, a patient with a severe stenosis

identified by coronary angiography may not benefit from revascularization if the surrounding myocardium is non-viable. A fixed perfusion defect, as imaged on SPECT scanning or stress thallium echocardiography, may suggest nonviable myocardium. However a PET scan may reveal metabolically active myocardium, suggesting areas of "hibernating" myocardium that would indeed benefit from revascularization. The most common PET technique for this application consists of a perfusion tracer and a metabolic marker of glucose utilization. A pattern of uptake in areas of hypoperfusion (referred to as blood flow mismatch) suggests viable, but hibernating myocardium. The ultimate clinical validation of this diagnostic test is the percentage of patients who experience improvement in left ventricular dysfunction after revascularization of hibernating myocardium, as identified by PET scanning.

I share in the CMS objective of reducing the cost of healthcare, and am aware that under CMS reimbursement, hospitals sometimes get less than the actual cost for some products, irrespective of the impact of cost of living adjustments. However, the profit margin to hospitals, radiopharmacies and especially to us for a Myocardial PET Procedure, (78492), not a high volume procedure, saves money for CMS and the taxpayer.

Respectfully, we also ask the CMS to comply with its objective as stated in Section 1833(t) (9) (A) of the Act requiring the Secretary to revise the relative payment weights taking into account new cost data and other relative information and factors, in the Federal Register, wherein the CMS states that "we believe it is appropriate to mitigate the potential for underpayment", and in an 8/15/03 press release, quoting former Former Administrator Scully, "We want to make certain that Medicare pays for the drugs and services it covers..."

To reiterate, as of August, 2006, reimbursement is $2484, so that if the proposed 2007 Medicare reimbursement reduction is enacted, patient, hospitals and clinics would lose money on procedure. If the HOPPS reimbursement rate stands, hospitals will receive much less than the actual cost of providing the service including all discounts and rebates, even after patient co-pay. Medicare reimbursement will further exacerbate a difficult state of affairs for us as a small business manufacturer of radiopharmaceuticals. Bio-Nucleonics' suggests a proposed solution for reimbursement readjustment; an equitable and fair reimbursement rate of $2,484, reestablishing the 2006 rate for this procedure.

The CMS needs to reevaluate the potential impact on patients and take patient access into account when developing regulations to implement the proposed reduction. CMS should conduct a detailed analysis of offsetting savings and efficiencies brought about by the substitution of imaging for more invasive and costly procedures that do not reduce cost or improve quality. Early diagnosis saves money and lives. This is especially where cardiac PETcomes into play.

This is to thank the CMS staff in advance for taking the time to investigate this matter, for the opportunity of presenting a suggested solution for this problem to CMS and hopefully, to resolve this situation. Should you have any questions, please contact me at your convenience at 305 576-0996 or by e-mail at ssatz@bionucleonics.com.

Sincerely,

Stanley Satz

Stanley Satz
President

Submitter : **Ms. Lourdes Rodriguez** **Date: 10/09/2006**

Organization : **Dade Family Counseling Community Mental Health Ctr**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P2-59-Attach-1.DOC

#5-9

Opposition to Medicare PHP Rate Cut

Millions of Americans of all ages experience psychiatric and substance use disorders every year, but access to necessary services is becoming an increasing challenge for many. The pressure on essential behavioral healthcare providers continues to diminish the services that are offered to those in need. Overall funding for behavioral health has been reduced dramatically. While overall health spending has generally increased, mental health and substance abuse spending continues on a decline. One can only imagine the correlation between the lack of services to people in need and the images we endure on the nightly news about increased school shootings, the mentally ill populations in our prison systems and our forgotten citizens, the elderly, many living in sub-human conditions. An administrative decision at the government level affects the providers, no doubt, but in the end the real victims are those in need of treatment. Access to acute psychiatric care has been strained by psychiatric hospital closures and bed reductions nationwide. Between 1992 and 1999, the number of beds in state psychiatric hospitals declined 32% and beds in private psychiatric hospitals decreased 23%. Between 1992 and 2000, the number of beds in general hospital psychiatric units declined an estimated 15.6%. Rising demand (as seen in historically high occupancy rates) and constrained capacity have overburdened emergency departments. Children and adolescents with behavioral healthcare disorders have been particularly hard-hit by access challenges. The cost of care continues to grow. Workforce shortages, skyrocketing professional liability costs, increasing pharmaceutical costs, and the ever-growing and

frustrating impact of the fraud and abuse is destroying the healthcare delivery system as we know it.

As a legitimate CMHC provider in the fraud infested *Miami-Dade County*, a change in our 2007 reimbursement rates is a chokehold on our ability to provide quality care. To the questionable providers that service only Medicare beneficiaries with the intent of financial gain, this will only provoke more creative ways to pay beneficiaries kickbacks in order to compensate the reduction. While we struggle to do the right thing, the system in order to calculate appropriately a true reimbursement rate for CMHC's, uses inflated cost reports from hundreds of providers who daily proceed to defraud the United States government by violating the anti-kickback statute and by other means to abuse federal dollars for their personal gain.

In the end, the patient always loses. Providers will come and go.

Our CMHC strives daily to protect the integrity of Medicare and its beneficiaries. We do not view a patient as a means to reimbursement, we view our services a means to well being. Our community is rich in Medicare beneficiaries. It is rich in Medicaid as well. So how many legitimate providers in this county have attempted to diversify their payor source? They can probably be counted on one hand in this community. The *FBI, OIG*, and state and local agencies bust the ones they can get their hands on. How many get through the legal and financial hurdles only to bill millions and abuse the system that was put in place to provide quality healthcare services to all Americans. It is a disgrace to the system. It is a disgrace to the hardworking Americans who contribute daily by their sweat. It is time for reform to the OPPS, we agree, but let's not throw the baby out with the bathwater. We feel our society and those in it who need the mental health services will be the ones who pay dearly.

Now for the meat of the issue, a reduction in payments for the serious provider translates to a change in the manner we can deliver the treatment. CMHC's depend on the client getting to the

facility. In a small geographic area, this may not be a concern. In *Miami-Dade County*, many do not drive or have the means to access their care. Our transport system is not perfect and does not reach every citizen. The elderly cannot withstand 90-degree temperatures to wait for a city or county bus on a daily basis. Many do not eat well-balanced meals and yet we prescribe psychotropic medications on empty stomachs. Therefore, we fill that burden and provide the hot meals although transportation and meals are not line items considered reimbursable on CMHC costs reports. Psychotherapists are all licensed with years of experience; a reduction would mean hiring green newly graduated therapists with hit or miss results. Psychiatrists, enduring their own falling reimbursements, are less interested in treating the acuity of care in the CMHC, remember inpatient beds have declined and the impetus in managed care era of healthcare is to use less restrictive care for psychiatric patients. So every facet of quality mental health services is impacted with less revenue. Even the bad debt reimbursements which provided the CMHC's with a year-end boost to enhance the quality of services provided to the patients has now been taken away as of *FY2004*.

In reality, the future of CMHC's appears bleak. If the trend continues with annual decreases, outpatient mental health will be nothing more than survival of the fittest. Survival of the providers that can out wit the system in order to line their pockets and survival of the clients that have the means and fortitude to overcome the obstacles to initiating and maintaining their care.

How depressing!

Thank you for your consideration of this matter.

Lourdes M. Rodriguez,
Director of Business Development

Submitter : **Miss. Millicent Gorham** **Date: 10/10/2006**

Organization : **National Black Nurses Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-60-Attach-1.DOC

#60

October 10, 2006

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

RE: Rule: Physician Fee Schedule (CMS-1321-P); and

Rule: Hospital Outpatient Prospective Payment System (OPPS) (CMS-1506-P)

Dear Administrator McClellan:

On behalf of the National Black Nurses Association (NBNA), I am writing to request that CMS refrain from instituting severe reimbursement cuts for breast brachytherapy (also known as partial breast irradiation (PBI)). NBNA is concerned that the cuts proposed in the Medicare Physician Fee Schedule and OPPS proposed rules would deny a greater number of African American women access to this important, patient-friendly, proven breast cancer treatment.

The National Black Nurses Association represents approximately 150,000 African American nurses, and has 76 chartered chapters nationwide. Our mission is to improve the health status of all people, particularly African Americans and other minority consumers.

Breast cancer is the most common cancer among African American women, and the second most common cause of death, surpassed only by lung cancer. African American women experience a greater delay between the time of breast cancer diagnosis and treatment than white women. In addition, poor or minority women tend to get less than optimal therapy for breast cancer, including surgery, chemotherapy, or radiation. Taken together, these factors contribute to African American women having death rates twice as high for all stages of breast cancer diagnosis compared to white women. Prevention, early detection, and access to the broadest range of breast cancer treatment options are critical for African American women.

Given our interest in this issue, we were distressed to realize that despite the availability and proven effectiveness of breast conservation therapy - a lumpectomy followed by radiation - fewer than 40% of eligible patients choose this treatment. This underutilization is likely due in no small part to the difficulties women, particularly low-income, minority women, have in complying with a 5-6 week radiation treatment course. A recent GAO report confirmed that "lengthy travel distances may especially pose an access barrier for medically underserved women."

Fortunately, with partial breast irradiation, the course of radiation treatment is reduced to 5 days. This increases the likelihood that eligible women will be able to take advantage of breast conservation therapy.

It is our understanding that under the proposed rules, Medicare reimbursement for partial breast irradiation would decrease by more than 50% by 2010, whereas payment for whole breast radiation would increase by over 60% in the same time period. These proposed Medicare cuts threaten to hinder African American women's access to partial breast irradiation post lumpectomy, while encouraging whole breast radiation and/or mastectomies, even if those treatments are not the preferred option of the patient and her health care provider.

The National Black Nurses Association urges CMS to reconsider the proposed reimbursement cuts to partial breast irradiation, and not force patients and health care providers to make critical treatment decisions based upon reimbursement considerations. Thank you in advance for your consideration of our views.

Sincerely,

Millicent Gorham
Executive Director

Cc: U.S. Representative Donna Christian Christensen, Chair, Congressional Black Caucus Health Braintrust
Leslie Norwalk, Deputy Administrator, CMS

Herb Kuhn, Director, Center for Medicare Management, CMS
Albert Morris, Jr., M.D., President, National Medical Association
Eleanor Hinton Hoyt, Interim CEO, Black Women's Health Imperative

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