Submitter : Ms. Anna Weinstein **Date:** 11/06/2006

Organization : Susan G. Komen Foundation

Category : Consumer Group

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

ASC Payable Procedures

ASC Payable Procedures

2. ASC Payable Procedures (Exclusion Criteria)

CMS, in its revised CY 2008 ASC payment system, proposes to include all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay. Like MedPAC, the Komen Foundation endorses this policy proposal. We urge the agency to consistently evaluate procedures based on these two criteria, and do so through an open, public process.

We thank the agency for listening to those who commented on the CY 2007 Update to ASC Procedures List, and corrected the omission of CPT codes 19290 and 19291 (Preoperative placement of needle wire, breast), from the ASC-approved procedures list for CY 2007. We trust that the agency will make the same correction to the list of CY 2008 covered procedures. In addition, we are pleased that in CY 2008, CPT codes 19000 and 19001 (Puncture, aspiration of breast cyst), have been added to the list of ASC covered procedures. (We regret, however, that these procedures are not listed in the CY 2007 OPPS final rule as being covered by Medicare in CY 2007.)

Komen also extends our appreciation to the agency for adding CPT code 19297 (Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy), to the list of ASC approved procedures in CYs 2007 and 2008. However, we are extremely troubled by the drastic rate reduction from CY 2007 to CY 2008 proposed for a related procedure, CPT code 19298 (Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance) (88%). We are also concerned about the reductions for other procedures listed in the chart below, all of which are absolutely critical to the early detection of breast cancer and improving the quality of life for breast cancer survivors:

APC HCPCS/CPT Descriptor Percent Reduction From 2007 Rate to 2008 Proposed Rate
0005 19100 Biopsy of breast; percutaneous, needle core, not using imaging guidance (18%)
0005 19102 Biopsy of breast; percutaneous, needle core, using imaging guidance (18%)
0658 19103 Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance (18%)
0029 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (17%)
1524 19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance (88%)

3. Effect on Beneficiaries

Under the new methodology, CMS proposes to allow payment of an ASC facility fee for certain office-based procedures that have been, historically, excluded from the ASC-approved list because the agency agrees with commenters that these procedures do not pose a significant safety risk and do not require and overnight stay. However, CMS expresses concern that allowing office-based procedures to be performed in an ASC may provide incentives for physicians to convert their offices into ASCs or to move office based procedures to the ASC setting. While we understand CMS desire not to induce inappropriate shifts in site of services, we believe that for a given procedure, physicians must be able to determine what setting is most appropriate given the patient s specific condition. Although physicians may be able to perform a particular procedure in his/her office, some patients are sicker or more frail and may require the additional infrastructure and safeguards that an ASC can provide to help ensure safe and effective

ASC Ratesetting

ASC Ratesetting

Dear Acting Administrator Norwalk:

The Susan G. Komen Breast Cancer Foundation is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed changes to the Ambulatory Surgery Center (ASC) payment methodology for CY 2008.

The Komen Foundation is a global leader in the war against breast cancer. Founded in 1982, the Komen Foundation is now comprised of 121 Affiliates nationwide, three international Affiliates and 75,000 volunteers. Komen has invested more than $630 million dollars for breast cancer research, education, screening and treatment programs, and actively addresses the gaps and disparities in the needs of the medically underserved.

The Foundation appreciates the work CMS has done in the past to help ensure access to quality breast health care and breast cancer care. Our main points

pertaining to the CY 2008 proposal are the following:

" We fully support CMS s stated belief that the care setting (or place of service) should be the most clinically appropriate setting as determined by the doctor and patients in consultation.

" We strongly urge CMS to reassess the migration assumptions embedded in the new CY2008 revised ASC payment methodology. At a reimbursement rate of 62% of the hospital outpatient prospective payment (OPPS) rate, we believe there will be very little, if any, migration into the ASC setting.

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

" We request that the agency revise the ASC exclusion criteria to align more closely with the recommendations put forth by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. Specifically, we support the inclusion of all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay.

1. ASC Reimbursement Rates

Congress has given the Department of Health and Human Services (HHS) broad authority to develop a new Medicare payment system for ambulatory surgical centers. We support CMS proposal to replace the current ASC system with one based on OPPS procedure groups (APCs) and relative weights, so that procedures provided in ASCs are more closely aligned with those provided in hospital outpatient departments. The Komen Foundation is concerned, however, with CMS proposal to set ASC payment at no more than 62 percent of the OPPS rates in 2008, and even less in 2009. This payment rate represents a sharp reduction for numerous breast health services that are currently being safely provided in ASCs. We strongly believe the agency has a responsibility to make sure that any changes to the ASC system do not have an adverse impact on patient access or physician ability to choose appropriate sites of service for patient care.

A. Migration Assumptions/Budget Neutrality: We understand that the Medicare Modernization Act of 2003 (MMA) dictates that changes to the ASC payment system must be made in a budget neutral manner. CMS interprets this to mean that spending on ASC services remains the same under the revised system as it would have without the changes. To achieve this, CMS proposes to multiply the hospital outpatient conversion factor by a budget neutrality adjustment of 0.62. We believe that the assumptions used to arrive at that figure should be re-examined. It is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from any shift of services currently performed in hospital outpatient departments (HOPDs) to ASCs following the implementation of the new payment system. Otherwise, if budget neutrality is applied only to ASC services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the ab

CY 2008 ASC Impact

CY 2008 ASC Impact

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GENERAL

GENERAL

See attachment

Submitter : Ms. Linda Taibel **Date:** 11/06/2006

Organization : Dermsurgery Associates

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P2-1107-Attach-1.PDF

#1107

November 6, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
ATTN: CMS-1506-P or CMS-4125-P
PO BOX 8011
Baltimore, MD 21244-1850

To whom it may concern,

I agree that the list of procedures that are eligible for payment in an ASC facility should be expanded.

I oppose the proposed rule for the revised payment system for Ambulatory Surgery Centers scheduled for implementation on January 1 2008 for the following reasons:

- Physicians must retain the ability to choose which type of facility best meets their patients' needs clinically.
- Patients should not be forced to limit their choices of procedure facilities.
- In order for ASC's to survive they must be adequately compensated for their services, comparable to hospital reimbursement, not 38% less.
- ASC's have proven to be more economical for the patient due to the higher charge for the same procedure performed in a hospital setting.
- ASC's are more convenient for patients, and safer due to documented lower infection rates compared to hospitals.
- These proposed changes would force smaller ASC's to close. This would further limit patient choices and adversely impact the lives of the health care employees in those facilities.

Sincerely yours,

Linda Taibel
Business Manager
DSA Surgery Center
7515 Main Street Suite 240
Houston TX 77030

Submitter : **Dr. Paul Friedman** **Date: 11/06/2006**

Organization : **DermSurgery Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

November 6, 2006

To whom it may concern:

I am writing to express my concern about the proposed changes to the ASC payment schedule. I feel that the changes regarding ASC costs and payment are based on inaccurate assumptions. As it stands, inaccurate rates in hospital outpatient methodology are being carried into ASC payment schedules. Site of service decisions should not be forced to be based on financial factors rather than clinical appropriateness. These proposed payment changes would limit the transition of procedures associated with ASC settings and also limit beneficiary access. Please consider these points in your review of the proposed changes to the ASC payment system.

Sincerely,

Paul M. Friedman, MD
DermSurgery Associates
7515 Main Street, Suite 240
Houston, Texas 77030
713-791-9966

Submitter : Dr. Eric Zelnick **Date:** 11/06/2006

Organization : Berks Center for Digestive Health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P2-1109-Attach-1.DOC

To whom it may concern:

I am a partner at Digestive Disease Associates LTC (my practice) and part owner of Berks Center For Digestive Health, L.P. where I perform the majority of the outpatient procedures on my patients. The Berks Center for Digestive Health is an important part of the high quality health care I am able to provide in Berks County. I perform over 10,000 procedures on an outpatient basis each year. There is no way that the hospitals in this area would be able to perform the amount of procedures that are currently performed in our community without the Berks Center. Further our commitment to quality care and service excellence can be demonstrated through quality measures and patient satisfaction surveys. Below I have included some of the history of ASCs, why I believe that they represent a very positive development for patients and physicians in this country and what my concerns are with the proposed Medicare payment system. I hope you will take the time to read these comments.

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

Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room

turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices. In the ASC setting, physicians are able to schedule procedures more conveniently, are able to assemble teams of specially-trained and highly skilled staff, are able to ensure the equipment and supplies being used are best suited to their technique, and are able to design facilities tailored to their specialty. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Overview

The broad statutory authority granted to the Secretary to design a new ASC payment system in the Medicare Modernization Act of 2003 presents the Medicare program with a unique opportunity to better align payments to providers of outpatient surgical services. Given the outdated cost data and crude payment categories underlying the current ASC system, I welcome the opportunity to link the ASC and hospital outpatient department (HOPD)

payment systems. Although the HOPD payment system is imperfect, it represents the best proxy for the relative cost of procedures performed in the ASC.

In the comments to follow, I focus on three basic principles:

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

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

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

Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost data used to evaluate outpatient surgical services for Medicare beneficiaries. The benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law. While I appreciate the many ways in which the agency proposes to align the payment system, I am concerned that the linkage is incomplete and may lead to further distortions between the payment systems. Many policies applied to payments for hospital outpatient services were not extended to the ASC setting, and these inconsistencies undermine the appropriateness

of the APC relative weights, create disparities in the relationship between the ASC and HOPD payment rates, and embed in the new payment system site of service incentives that will cost the taxpayer and the beneficiary more than necessary.

There are many components of the regulation where a more complete alignment of the ASC and HOPD payment systems is appropriate. Below is an overview of the major areas where further refinement of the proposed rule is warranted. These issues are discussed in greater detail under the relevant section heading in the text to follow.

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

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

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

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

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

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

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

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

Ensuring Beneficiaries' Access to Services

Ambulatory surgery centers are an important component of beneficiaries' access to surgical services. As innovations in science and technology have progressed, ASCs have demonstrated tremendous capacity to meet the growing need for outpatient surgical services. In some areas and specialties, ASCs are performing more than 50% of the volume for

certain procedures. Sudden changes in payments for services can have a significant effect on Medicare beneficiaries' access to services predominantly performed in ASCs.

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

Establishing Reasonable Reimbursement Rates

Medicare payment rates for ASC services have remained stagnant for nearly a decade. Over time, the industry has identified which services it can continue to offer to Medicare

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

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

- Budget Neutrality: Adopt an expansive, realistic interpretation of budget neutrality. The new payment system and the expansion of the ASC list will result in migration of services from one site of service setting to another. CMS has the legal authority and the fiduciary responsibility to examine the consequences of the new ASC payment system on all sites of care – the physician office, ASCs, and HOPD.

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

- By setting rates this low, CMS would force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government. Rather than paying

ASCs a set percentage of HOPD rates, the proposed rule establishes a complicated formula to link ASC payment to HOPD payment but does not link payment in a uniform manner. This will impede Medicare beneficiaries' ability to understand their real costs in alternative settings. In the words of President Bush, Medicare beneficiaries need to be able to make "apples to apples" comparisons in order to increase transparency in the health care sector.

- CMS failed to include on the procedure list many higher complexity services that have for years been safely and effectively performed in ASCs throughout the country. By not creating a truly exclusionary list, CMS is losing an opportunity to increase patient choice and rely on the clinical judgment of the surgeon.

Eric Zelnick, MD
Berks Center for Digestive Health
Wyomissing PA 19610

Submitter : **Dr. Bhupinder Saini** **Date: 11/06/2006**

Organization : **Advanced Pain Management**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 31, 2006

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

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

Dear Ms. Norwalk:

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

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

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

Sincerely,

Bhupinder Saini, MD

Submitter : **Dr. Saleem Awan** **Date: 11/06/2006**

Organization : **Advanced Pain Management**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 31, 2006

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

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

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

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

Sincerely,
Saleem Awan,MD

Submitter : **Mr. Max Gill** **Date: 11/06/2006**

Organization : **Cyberonics**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

November 6, 2006

Honorable 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-P2 - Medicare Program; The Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Dr. McClellan:

As the sole manufacturer of the VNS Therapy System, Cyberonics, Inc. is pleased to submit these comments regarding the August 23, 2006 proposed rule to revise the ASC facility payment system and update the payment rates for CY 2008.
The VNS Therapy implant procedure is typically performed on an outpatient basis. Surgery is performed under general anesthesia and lasts approximately 1 to 2 hours. Historically, neurosurgeons, otolaryngologists, and general and vascular surgeons have been trained and competently performed the implant procedure. No special operating room equipment is required.
This procedure can easily be performed in an outpatient department or an ambulatory surgical center. Based on reimbursement, ASCs are currently providing this procedure for private-pay patients only.
We would like to offer comments on the following provisions of the proposed rule:

" The 62% conversion percentage will be a particular problem for ASCs performing device implantation procedures for APC Codes 0039 and 0225. While the hospital OPPS payment weights include an allowance for the cost of implanted devices, this cost provision is known to be inadequate even when hospitals are paid 100% of the OPPS rate.

" We would like to recommend that Medicare reimburse the ASCs 100% of the device acquisition rate portion of the APC rates and apply 62% to the procedure portion of the APC rates. The only efficiencies will be achieved in the procedure costs, and not in the acquisition cost.

We appreciate the considerable effort CMS has put into these proposals to ensure that patients have equal access to care in the setting that best serves the patient. Inappropriate reimbursement will definitely hinder access to the facilities.

Sincerely,

Max Gill

Senior Director, Reimbursement
Cyberonics, Inc.

Submitter : Dr. Seth Rosenzweig **Date:** 11/06/2006

Organization : Berks Center For Digestive Health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1113-Attach-1.DOC

#1113

To whom it may concern:

I am a partner at Digestive Disease Associates LTC (my practice) and part owner of Berks Center For Digestive Health, L.P. where I perform the majority of the outpatient procedures on my patients. The Berks Center for Digestive Health is an important part of the high quality health care I am able to provide in Berks County. I perform over 10,000 procedures on an outpatient basis each year. There is no way that the hospitals in this area would be able to perform the amount of procedures that are currently performed in our community without the Berks Center. Further our commitment to quality care and service excellence can be demonstrated through quality measures and patient satisfaction surveys. Below I have included some of the history of ASCs, why I believe that they represent a very positive development for patients and physicians in this country and what my concerns are with the proposed Medicare payment system. I hope you will take the time to read these comments.

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Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room

turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices. In the ASC setting, physicians are able to schedule procedures more conveniently, are able to assemble teams of specially-trained and highly skilled staff, are able to ensure the equipment and supplies being used are best suited to their technique, and are able to design facilities tailored to their specialty. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

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payment systems. Although the HOPD payment system is imperfect, it represents the best proxy for the relative cost of procedures performed in the ASC.

In the comments to follow, I focus on three basic principles:

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

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Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost data used to evaluate outpatient surgical services for Medicare beneficiaries. The benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law. While I appreciate the many ways in which the agency proposes to align the payment system, I am concerned that the linkage is incomplete and may lead to further distortions between the payment systems. Many policies applied to payments for hospital outpatient services were not extended to the ASC setting, and these inconsistencies undermine the appropriateness

of the APC relative weights, create disparities in the relationship between the ASC and HOPD payment rates, and embed in the new payment system site of service incentives that will cost the taxpayer and the beneficiary more than necessary.

There are many components of the regulation where a more complete alignment of the ASC and HOPD payment systems is appropriate. Below is an overview of the major areas where further refinement of the proposed rule is warranted. These issues are discussed in greater detail under the relevant section heading in the text to follow.

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

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

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Ensuring Beneficiaries' Access to Services

Ambulatory surgery centers are an important component of beneficiaries' access to surgical services. As innovations in science and technology have progressed, ASCs have demonstrated tremendous capacity to meet the growing need for outpatient surgical services. In some areas and specialties, ASCs are performing more than 50% of the volume for

certain procedures. Sudden changes in payments for services can have a significant effect on Medicare beneficiaries' access to services predominantly performed in ASCs.

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

Establishing Reasonable Reimbursement Rates

Medicare payment rates for ASC services have remained stagnant for nearly a decade. Over time, the industry has identified which services it can continue to offer to Medicare

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

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

- Budget Neutrality: Adopt an expansive, realistic interpretation of budget neutrality. The new payment system and the expansion of the ASC list will result in migration of services from one site of service setting to another. CMS has the legal authority and the fiduciary responsibility to examine the consequences of the new ASC payment system on all sites of care – the physician office, ASCs, and HOPD.

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

- By setting rates this low, CMS would force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government. Rather than paying

ASCs a set percentage of HOPD rates, the proposed rule establishes a complicated formula to link ASC payment to HOPD payment but does not link payment in a uniform manner. This will impede Medicare beneficiaries' ability to understand their real costs in alternative settings. In the words of President Bush, Medicare beneficiaries need to be able to make "apples to apples" comparisons in order to increase transparency in the health care sector.

- CMS failed to include on the procedure list many higher complexity services that have for years been safely and effectively performed in ASCs throughout the country. By not creating a truly exclusionary list, CMS is losing an opportunity to increase patient choice and rely on the clinical judgment of the surgeon.

Seth Rosenzweig, MD
Berks Center for Digestive Health
Wyomissing PA 19610

Submitter : **Dr. Hany Nosir** **Date: 11/06/2006**

Organization : **Advanced Pain Management**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 31, 2006

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

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

Dear Ms. Norwalk:

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

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

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

Sincerely,

Hany Nosir, MD

Submitter :

Date: 11/06/2006

Organization : **Susan G. Komen**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1506-P2-1116-Attach-1.DOC

#1114

The Susan G. Komen Breast Cancer Foundation

5005 LBJ Freeway
Suite 250
Dallas, Texas 75244
Tel: 972.855.1600
Fax: 972.855.1605
Helpline: 1.800 I'M AWARE®
www.komen.org

Headquarters

November 6, 2006

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

Re: CMS-1506-P; CMS-4125-P (The Ambulatory Surgical Center Payment System and CY2008 Payment Rates)

Dear Acting Administrator Norwalk:

The Susan G. Komen Breast Cancer Foundation is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed changes to the Ambulatory Surgery Center (ASC) payment methodology for CY 2008.

The Komen Foundation is a global leader in the war against breast cancer. Founded in 1982, the Komen Foundation is now comprised of 121 Affiliates nationwide, three international Affiliates and 75,000 volunteers. Komen has invested more than $630 million dollars for breast cancer research, education, screening and treatment programs, and actively addresses the gaps and disparities in the needs of the medically underserved.

The Foundation appreciates the work CMS has done in the past to help ensure access to quality breast health care and breast cancer care. Our main points pertaining to the CY 2008 proposal are the following:

- We fully support CMS's stated belief that the care setting (or place of service) should be the most clinically appropriate setting as determined by the doctor and patients in consultation.
- We strongly urge CMS to reassess the migration assumptions embedded in the new CY2008 revised ASC payment methodology. At a reimbursement rate of 62% of the hospital

outpatient prospective payment (OPPS) rate, we believe there will be very little, if any, migration into the ASC setting.

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

- We request that the agency revise the ASC exclusion criteria to align more closely with the recommendations put forth by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. Specifically, we support the inclusion of all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay.

1. ASC Reimbursement Rates

Congress has given the Department of Health and Human Services (HHS) broad authority to develop a new Medicare payment system for ambulatory surgical centers. We support CMS' proposal to replace the current ASC system with one based on OPPS procedure groups (APCs) and relative weights, so that procedures provided in ASCs are more closely aligned with those provided in hospital outpatient departments. The Komen Foundation is concerned, however, with CMS' proposal to set ASC payment at no more than 62 percent of the OPPS rates in 2008, and even less in 2009. This payment rate represents a sharp reduction for numerous breast health services that are currently being safely provided in ASCs. We strongly believe the agency has a responsibility to make sure that any changes to the ASC system do not have an adverse impact on patient access or physician ability to choose appropriate sites of service for patient care.

A. *Migration Assumptions/Budget Neutrality:* We understand that the Medicare Modernization Act of 2003 (MMA) dictates that changes to the ASC payment system must be made in a budget neutral manner. CMS interprets this to mean that spending on ASC services remains the same under the revised system as it would have without the changes. To achieve this, CMS proposes to multiply the hospital outpatient conversion factor by a budget neutrality adjustment of 0.62. We believe that the assumptions used to arrive at that figure should be re-examined. It is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from any shift of services currently performed in hospital outpatient departments (HOPDs) to ASCs following the implementation of the new payment system. Otherwise, if budget neutrality is applied only to ASC services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the ability of ASCs to serve as an alternative site of service, and more importantly, will likely have a negative impact beneficiary access to care. CMS should examine the consequences of the new ASC payment system on all sites of care and adopt alternative methodologies to determine the conversion factor.

2. ASC Payable Procedures (Exclusion Criteria)

CMS, in its revised CY 2008 ASC payment system, proposes to include all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay. Like MedPAC, the Komen Foundation endorses this policy proposal. We urge the agency to consistently evaluate procedures based on these two criteria, and do so through an open, public process.

We thank the agency for listening to those who commented on the CY 2007 Update to ASC Procedures List, and corrected the omission of CPT codes 19290 and 19291 (Preoperative placement of needle wire, breast), from the ASC-approved procedures list for CY 2007. We trust that the agency will make the same correction to the list of CY 2008 covered procedures. In addition, we are pleased that in CY 2008, CPT codes 19000 and 19001 (Puncture, aspiration of breast cyst), have been added to the list of ASC covered procedures. (We regret, however, that these procedures are not listed in the CY 2007 OPPS final rule as being covered by Medicare in CY 2007.)

Komen also extends our appreciation to the agency for adding CPT code 19297 (Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy), to the list of ASC approved procedures in CYs 2007 and 2008. However, we are extremely troubled by the drastic rate reduction from CY 2007 to CY 2008 proposed for a related procedure, CPT code 19298 (Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance) (88%). We are also concerned about the reductions for other procedures listed in the chart below, all of which are absolutely critical to the early detection of breast cancer and improving the quality of life for breast cancer survivors:

APC	HCPCS/CPT	Descriptor	Percent Reduction From 2007 Rate to 2008 Proposed Rate
0005	19100	Biopsy of breast; percutaneous, needle core, not using imaging guidance	(18%)
0005	19102	Biopsy of breast; percutaneous, needle core, using imaging guidance	(18%)
0658	19103	Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance	(18%)
0029	19297	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial	(17%)

		mastectomy	
1524	19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance	(88%)

3. Effect on Beneficiaries

Under the new methodology, CMS proposes to allow payment of an ASC facility fee for certain office-based procedures that have been, historically, excluded from the ASC-approved list because the agency agrees with commenters that these procedures do not pose a significant safety risk and do not require and overnight stay. However, CMS expresses concern that allowing office-based procedures to be performed in an ASC may provide incentives for physicians to convert their offices into ASCs or to move office based procedures to the ASC setting. While we understand CMS' desire not to induce inappropriate shifts in site of services, we believe that for a given procedure, physicians must be able to determine what setting is most appropriate given the patient's specific condition. Although physicians may be able to perform a particular procedure in his/her office, some patients are sicker or more frail and may require the additional infrastructure and safeguards that an ASC can provide to help ensure safe and effective outcomes. We do not believe it is CMS' intent to decrease or limit Medicare eligible patients access to and choice of various surgical sites of service when such patients are faced with a diagnosis of breast cancer. However, if ASC reimbursement rates are economically unsustainable, physicians' ability to provide care for their patients in the most appropriate setting could be seriously impacted.

4. Conclusion

The Komen Foundation appreciates the opportunity to comment on the proposed regulations. We strongly believe that physicians, in consultation with their patients, are in the best position to determine the most appropriate site of service for a surgical procedure. For this reason, we urge CMS to establish a process to consult with national medical specialty societies and the ambulatory surgical community to develop and adopt a systematic and adaptable means of fairly reimbursing ASCs for all safe and appropriate services, allowing for changes in technology and current-day practices. We hope that our letter highlights our sincere interest in continuing to work with CMS to make breast health services cost effective, properly reimbursed and readily accessible. Please do not hesitate to contact me at 972-855-4315 if you have any questions regarding these comments.

Sincerely,

Diane L. Balma

Diane Balma
Public Policy Director

Submitter : **Dr. Daniel Blecker** **Date: 11/06/2006**

Organization : **Berks Center For Digestive Health**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P2-1117-Attach-1.DOC

#1117

To whom it may concern:

I am a partner at Digestive Disease Associates LTC (my practice) and part owner of Berks Center For Digestive Health, L.P. where I perform the majority of the outpatient procedures on my patients. The Berks Center for Digestive Health is an important part of the high quality health care I am able to provide in Berks County. I perform over 10,000 procedures on an outpatient basis each year. There is no way that the hospitals in this area would be able to perform the amount of procedures that are currently performed in our community without the Berks Center. Further our commitment to quality care and service excellence can be demonstrated through quality measures and patient satisfaction surveys. Below I have included some of the history of ASCs, why I believe that they represent a very positive development for patients and physicians in this country and what my concerns are with the proposed Medicare payment system. I hope you will take the time to read these comments.

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

Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room

turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices. In the ASC setting, physicians are able to schedule procedures more conveniently, are able to assemble teams of specially-trained and highly skilled staff, are able to ensure the equipment and supplies being used are best suited to their technique, and are able to design facilities tailored to their specialty. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Overview

The broad statutory authority granted to the Secretary to design a new ASC payment system in the Medicare Modernization Act of 2003 presents the Medicare program with a unique opportunity to better align payments to providers of outpatient surgical services. Given the outdated cost data and crude payment categories underlying the current ASC system, I welcome the opportunity to link the ASC and hospital outpatient department (HOPD)

payment systems. Although the HOPD payment system is imperfect, it represents the best proxy for the relative cost of procedures performed in the ASC.

In the comments to follow, I focus on three basic principles:

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

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

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

Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost data used to evaluate outpatient surgical services for Medicare beneficiaries. The benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law. While I appreciate the many ways in which the agency proposes to align the payment system, I am concerned that the linkage is incomplete and may lead to further distortions between the payment systems. Many policies applied to payments for hospital outpatient services were not extended to the ASC setting, and these inconsistencies undermine the appropriateness

of the APC relative weights, create disparities in the relationship between the ASC and HOPD payment rates, and embed in the new payment system site of service incentives that will cost the taxpayer and the beneficiary more than necessary.

There are many components of the regulation where a more complete alignment of the ASC and HOPD payment systems is appropriate. Below is an overview of the major areas where further refinement of the proposed rule is warranted. These issues are discussed in greater detail under the relevant section heading in the text to follow.

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

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

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

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Daniel Blecker, MD
Berks Center for Digestive Health
Wyomissing PA 19610

Submitter : **Dr. Roman Berezovski** **Date: 11/06/2006**

Organization : **Advanced Pain Management**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 31, 2006

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

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

Dear Ms. Norwalk:

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

Sincerely,

Roman Berezovski, MD

Submitter : **Dr. Luciana Berceanu** **Date: 11/06/2006**

Organization : **Advanced Pain Management**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 31, 2006

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Department of Health and Human Services
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Sincerely,

Luciana Berceanu, MD

Submitter : Ms. Karen Jefferson **Date:** 11/06/2006

Organization : Dialysis Access Center of Southeasast Michigan

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I HAVE BEEN A DIALYSIS (HEMO AND PERITONEAL)NURSE FOR 12 YEARS; IN ADDITION TO THAT, FOR THE LAST YEAR AND A HALF I HAVE BEEN WORKING AT AN ACCESS CENTER. WE HAVE PERFORMED ANGIOPLASTIES, DECLOTS, CATHETER PLACEMENTS AND EXCHANGES. GIVEN OUR PATIENT SATISFACTION RECORDS (ALWAYS GREATER THAN 90%)THIS CENTER WAS NEEDED AND, ACCORDING TO MOST PATIENTS, MORE ARE NEEDED CLOSER TO THEIR HOME. THEY LIST THEIR REASONS: EASIER ACCESS AND SCHEDULING TIMES, STAFF THAT KNOWS THEM AND THEIR SPECIAL REQUIREMENTS, NEPHROLOGISTS THAT ARE AWARE OF THEIR PROBLEMS AND ARE ABLE TO FOLLOW UP, SAFE PROCEDURES THAT ALLOWS THEM, TO BE CONTINUE WITH THEIR LIFE... THE LIST GOES ON. PLEASE SUPPORT VASCULAR ACCESS CENTERS AND PATIENTS' CHOICE!

Submitter : **Dr. Douglas Keehn** **Date: 11/06/2006**

Organization : **Advanced Pain Management**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

October 31, 2006

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
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200 Independence Avenue, SW
Washington, DC 20201

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

Dear Ms. Norwalk:

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

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

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

Sincerely,

Douglas Keehn, DO

Submitter : **jamie platt** **Date: 11/06/2006**

Organization : **jamie platt**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

I believe vascular access centers provide a valuble option for patients when selecting caregivers for their dialysis needs.I think all angioplasty codes(including CPT 35476). should be allowed in the ASC setting.

Thank you,
Jamie Platt

Submitter : **Dr. Anirudh Masand-Rai** **Date: 11/06/2006**

Organization : **Berks Center for Digestive Health**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P2-1123-Attach-1.DOC

To whom it may concern:

I am a partner at Digestive Disease Associates LTC (my practice) and part owner of Berks Center For Digestive Health, L.P. where I perform the majority of the outpatient procedures on my patients. The Berks Center for Digestive Health is an important part of the high quality health care I am able to provide in Berks County. I perform over 10,000 procedures on an outpatient basis each year. There is no way that the hospitals in this area would be able to perform the amount of procedures that are currently performed in our community without the Berks Center. Further our commitment to quality care and service excellence can be demonstrated through quality measures and patient satisfaction surveys. Below I have included some of the history of ASCs, why I believe that they represent a very positive development for patients and physicians in this country and what my concerns are with the proposed Medicare payment system. I hope you will take the time to read these comments.

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

Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room

turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices. In the ASC setting, physicians are able to schedule procedures more conveniently, are able to assemble teams of specially-trained and highly skilled staff, are able to ensure the equipment and supplies being used are best suited to their technique, and are able to design facilities tailored to their specialty. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Overview

The broad statutory authority granted to the Secretary to design a new ASC payment system in the Medicare Modernization Act of 2003 presents the Medicare program with a unique opportunity to better align payments to providers of outpatient surgical services. Given the outdated cost data and crude payment categories underlying the current ASC system, I welcome the opportunity to link the ASC and hospital outpatient department (HOPD)

payment systems. Although the HOPD payment system is imperfect, it represents the best proxy for the relative cost of procedures performed in the ASC.

In the comments to follow, I focus on three basic principles:

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

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

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

Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost data used to evaluate outpatient surgical services for Medicare beneficiaries. The benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law. While I appreciate the many ways in which the agency proposes to align the payment system, I am concerned that the linkage is incomplete and may lead to further distortions between the payment systems. Many policies applied to payments for hospital outpatient services were not extended to the ASC setting, and these inconsistencies undermine the appropriateness

of the APC relative weights, create disparities in the relationship between the ASC and HOPD payment rates, and embed in the new payment system site of service incentives that will cost the taxpayer and the beneficiary more than necessary.

There are many components of the regulation where a more complete alignment of the ASC and HOPD payment systems is appropriate. Below is an overview of the major areas where further refinement of the proposed rule is warranted. These issues are discussed in greater detail under the relevant section heading in the text to follow.

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

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

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

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

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

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

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

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

Ensuring Beneficiaries' Access to Services

Ambulatory surgery centers are an important component of beneficiaries' access to surgical services. As innovations in science and technology have progressed, ASCs have demonstrated tremendous capacity to meet the growing need for outpatient surgical services. In some areas and specialties, ASCs are performing more than 50% of the volume for

certain procedures. Sudden changes in payments for services can have a significant effect on Medicare beneficiaries' access to services predominantly performed in ASCs.

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

Establishing Reasonable Reimbursement Rates

Medicare payment rates for ASC services have remained stagnant for nearly a decade. Over time, the industry has identified which services it can continue to offer to Medicare

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

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

- Budget Neutrality: Adopt an expansive, realistic interpretation of budget neutrality. The new payment system and the expansion of the ASC list will result in migration of services from one site of service setting to another. CMS has the legal authority and the fiduciary responsibility to examine the consequences of the new ASC payment system on all sites of care – the physician office, ASCs, and HOPD.

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

- By setting rates this low, CMS would force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government. Rather than paying

ASCs a set percentage of HOPD rates, the proposed rule establishes a complicated formula to link ASC payment to HOPD payment but does not link payment in a uniform manner. This will impede Medicare beneficiaries' ability to understand their real costs in alternative settings. In the words of President Bush, Medicare beneficiaries need to be able to make "apples to apples" comparisons in order to increase transparency in the health care sector.

- CMS failed to include on the procedure list many higher complexity services that have for years been safely and effectively performed in ASCs throughout the country. By not creating a truly exclusionary list, CMS is losing an opportunity to increase patient choice and rely on the clinical judgment of the surgeon.

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