Submitter:

Ms. Patricia Aiken-O'Neill

Organization:

Eye Bank Association of America

Category:

Health Care Professional or Association

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

October 10, 2006

Mark McClellan, M.D., Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1478-P P.O. Box 8013 Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program HCAHPS Survey, SCIP, and Mortality)

[Comment: Table of Contents Section XV: Proposed OPPS Payment Status and Comment Indicators.

A. Proposed CY 2007 Status Indicator Definitions, 2. Proposed Payment Status Indicators to Designate Services that Are Paid under a Payment System other than OPPS.]

Dear Administrator McClellan:

On behalf of our more than 83 member eye bank organizations, the Eye Bank Association of America (EBAA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule which addresses payment policy and rates for services performed pursuant to the hospital outpatient prospective payment system for calendar year 2007. The adoption and implementation of an appropriate payment policy for the acquisition of corneal tissue for procedures provided in a hospital outpatient department (HOPD) setting is absolutely vital to the eye banking system, a network that was established for the single purpose of procuring and providing donated human eye tissue for sight restoring transplantation procedures.

The 83 eye bank members of the EBAA represent 99% of the entire U.S. eye banking community and provide 97% of all corneal tissue for transplantation. All eye banks are 501 (c)(3) organizations. The community supports the CMS proposal to pay for the acquisition of corneal tissue as a separate payment at reasonable cost, not payable under the Outpatient Prospective Payment System as outlined in Section XV, Proposed OPPS Payment Status and Comment Indicator, A. (2). Proposed Payment Status Indicators to Designate Services that Are Paid Under a Payment System Other than OPPS. Addendum D1 defines the acquisition of corneal tissue as Status Indicator F as an item/service not paid under OPPS and paid at reasonable cost.

This payment policy remains unchanged from the previous years as set forth in the April 7, 2000 final rule with comment period, which implemented OPPS. The factors included in the development of the payment policy for the acquisition of corneal tissue remain unchanged. The current payment system recognizes significant charitable contributions and allows for a successful community-based donation network.

In sum, the EBAA appreciates CMS payment direction for this service and categorization. We seek consistency in the adoption and implementation of payment policy for the acquisition of corneal tissue between providers in a Hospital Outpatient Department setting and an Ambulatory Surgical Center setting. The EBAA will provide further comment on the Ambulatory Surgical Center provisions by the November 6, 2006 Comment Close date.

Again, thank you for your direction and consistency in payment policy for this important public health service.

Sincerely,

Patricia Aiken-O Neill President Date: 10/10/2006

CMS-1506-P2-61-Attach-1.DOC



# **Via CMS Website**

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Sincerely,

Patricia Aiken-O'Neill President

Submitter:

Dr. Laurie Young

Organization:

Older Women's League

Category:

**Consumer Group** 

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

See Attachment

CMS-1506-P2-62-Attach-1.DOC

CMS-1506-P2-62-Attach-2.DOC

Page 63 of 63

October 11 2006 09:01 AM

Date: 10/10/2006

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Laurie Young, Ph.D.

Executive Director

October 10, 2006

The Honorable Mark B. McClellan, MD, PhD Administrator Centers for Medicare and Medicaid Services 200 Independence Avenue, SW Washington, DC 20201

RE: Physician Fee Schedule (CMS-1321-P)

Hospital Outpatient Prospective Payment System (CMS-1506-P)

Dear Administrator McClellan:

In my capacity as the Executive Director of the Older Women's League (OWL), I am writing today to express OWL's concern over proposed Medicare reimbursement cuts to an important breast cancer treatment option – partial breast irradiation. OWL's mission and daily work is focused on improving the status and quality of life of the more than 60 million women age 40 and over in America.

As you know, breast cancer takes an incredible toll on midlife and older women and their families. According to the American Cancer Society, in 2006, over 200,000 new cases of breast cancer are expected to occur among women in the United States, and over 40,000 women are expected to die from the disease. Breast cancer is the most frequently diagnosed cancer in women. Great advances have been made in recent years, but clearly more needs to be done to combat this deadly killer.

Unfortunately, the risk of being diagnosed with breast cancer increases with age. Because of this increasing incidence, women's access to safe, effective, and patient-friendly treatments is extremely important to our constituents. Far too many women diagnosed with breast cancer do not receive the standard of care.

The current standard of care for women with early-stage breast cancer is lumpectomy followed by radiation therapy. Whole breast radiation treatment takes 5-6 weeks, placing great demands upon women's time. According to the National Cancer Institute's 2005 Cancer Trends Progress Report, of the 123,000 women who received lumpectomies in 2005, 42,000 did not receive radiation therapy. These statistics are very troubling.

Partial breast irradiation is an easier treatment option that makes it possible for more women to choose to receive radiation therapy. With PBI, the radiation source is placed inside the lumpectomy cavity where the cancer is most likely to recur. This method limits radiation to healthy tissue and other organs such as the lungs and heart, and can be completed in 5 days. This shortened treatment time is particularly helpful to older women who might find it difficult to travel to a radiation treatment facility for a lengthy period of time, or who don't have state of the art cancer facilities in their communities. Most importantly, partial breast irradiation, which

has been in use for over a decade, has demonstrated 5-year recurrence rates comparable to whole breast radiation.

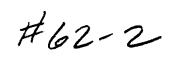
Although we know that the purpose of the proposed rules is not to limit women's access to partial breast irradiation, it is a likely outcome. It is a mystery to us why the patient-friendly method of partial breast irradiation should receive a disproportionate payment cut, while the more invasive procedures of whole breast radiation and mastectomy are slated for very significant increases.

In order to ensure the availability of the widest range of breast cancer treatment options, OWL urges CMS to maintain adequate Medicare reimbursement of partial breast irradiation by not moving forward with the proposed payment cuts included in the recently released Physician Fee Schedule and Outpatient Prospective Payment System rules.

Sincerely,

Laurie Young, Ph.D. Executive Director

Cc: Leslie Norwalk, Deputy Administrator, CMS
Kathleen Harrington, Director of External Affairs, CMS





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Cc: Leslie Norwalk, Deputy Administrator, CMS
Kathleen Harrington, Director of External Affairs, CMS

Submitter:

Dr. David George

Date: 10/11/2006

Organization:

Physicians Outpatient Surgery Center in Belpre Ohi

Category:

Physician

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

see attachment

October 23 2006 02:44 PM

Page 64 of 69

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:

Dr. David George

Organization:

Physicians Outpatient Surgery Center

Category:

Physician

Issue Areas/Comments

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**GENERAL** 

see attachment

CMS-1506-P2-64-Attach-1.DOC

Page 65 of 69

October 23 2006 02:44 PM

Date: 10/11/2006

### October 10, 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:

I am the Medical Director of Physicians Outpatient Surgery Center in Belpre, Ohio. Each year our surgery center provides about 2,500number of procedures and 70% of our patients are Medicare beneficiaries.. 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

I 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 insureds 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. I believe CMS is inappropriately limiting beneficiary site-of-service choices by continuing to make procedure list determinations 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. I 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.

Another consideration is whether other procedures are being performed at the same time. If a patient is having a procedure performed in an ASC and another procedure that can be performed in an office is also needed, the patient and the Medicare program benefit from having both procedures performed at the same time.

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.

<u>Medical Liability Policy Differences</u> – 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

I 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.

I am 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. <<I/We>> believe the HOPD data is a more reliable proxy for the cost of providing this service.

I aam 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 been 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. I 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. I am 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. <<I/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 and cost Pass Through for other devices

I am 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). I 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.

I think CMS should also recognize an increasing number of cataract surgeries are becoming more complex due to the Floppy Iris Syndrome induced by Flomax use for prostate disease in seniors. Such cases often require extra disposable devises such as iris retractors which cost over \$100 per use. The cost of these devices for complex cataract cases should be passed through just as it is done for the HOPD system. Additionally, a new CPT code for cataract surgery in a patient with Floppy Iris Syndrome should be entertained and it should have a higher reimbursement.

Cataract surgery is on of the most common procedures done in an ASC setting. CMS saves a great deal of money as HOPD rates are much higher for the same service. This savings should be considered when addressing the overall cost of the new ASC payment system.

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:".

I am 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 considering our comments. If you have any questions or need additional information, please do not hesitate to call me at 1-800-758-3937

Sincerely,

David S. George, MD

Submitter:

Ms. Lori Turk

Organization:

Ms. Lori Turk

Category:

Nurse

Issue Areas/Comments

**GENERAL** 

#### GENERAL

An ASC offers every patient access to affordable healthcare within their community. An ASC can efficiently and safely provide state-of-the art healthcare services to patients at a substantial saving to the consumer and insurance companies, including Medicare and Medicaid. This creates an opportunity to decrease the healthcare costs paid by the government.

Every effort should be made to remove the road blocks in place that hinder the progress of ASC development. Hospitals are trying to prevent ASC development and growth, especially in rural areas, by refusing to sign transfer agreements. Our government can prevent this attempt to deny access and choice to patients by allowing ASCs to transfer patients by following the EMTALA guidelines or the guidelines used for nursing home transfers. These guidelines protect the rights of patients to receive continuing healthcare if their medical condition warrants it.

Patients should have a choice when it comes to their healthcare, especially when it could mean substantial saving of their already limited financial resources.

ASCs are a win-win proposition. Patients will win with increased access to quality healthcare within their community and the Federal government will realize a substantial decrease in the costs related to outpatient surgery.

October 23 2006 02:44 PM

Date: 10/11/2006

Submitter:

Organization:

Category:

Other

Issue Areas/Comments

**ASC Payable Procedures** 

ASC Payable Procedures

Test

**ASC Payable Procedures** 

ASC Payable Procedures

Test

Date: 10/12/2006

Date: 10/19/2006

Submitter:

Ms. Patricia Lombardo

Organization:

Eastern Pennsylvania Endoscopy Center

Category:

**Ambulatory Surgical Center** 

Issue Areas/Comments

#### **ASC Ratesetting**

#### ASC Ratesetting

I have been a GI nurse for the past 14 years. I have worked in both the hospital and now the Ambulatory Surgical Facility (ASF) setting. I have seen many patients "eured" from colon cancer in my career. This happens every day that a polyp is removed or a patient is sent for a colon resection for a cancerous lesion. Patients who are cared for in an ASF are much happier and satisfied with their care. Their experience is professional, comfortable and satisfying. The availability of a timely appointment is very important to our patients. The efficiency of the Center is extremely important. All this is provided to these patients at a lesser reimbursement than the hospital. Medicare saves money every day because of the procedures that are done in an ASF vs. the hospital. My biggest fear is that countless lives will be lost and the already overburdened Medicare system will spend billions more if this proposed rate system goes into effect. In essence, this proposal will force single specialty ASF's to close their doors as 40% of the patients that come to the Center are Medicare beneficiaries. If these rates are reduced according to the proposed rule, the reimbursement will not cover the cost of the procedure. At present, a hospital colonoscopy is reimbursed approximately \$50 per procedure more than at an ASF. There are 15 million colonoscopies done in the United States per year. If all these procedures were forced into the hospitals, this would cost the Medicare system billions. If the proposed rates go into effect, the cost will increase even further. An added burden would be that patients would not be able to have colonoscopies in a timely manner and the likelihood of "cures" would decrease significantly. I urge to come up with a different "budget nuctral" equation so that we can help save our Medicare program instead of thwarting it.

October 23 2006 02:44 PM

Page 68 of 69

Submitter:

Dr. Mayank Modi

Organization:

Berks Cardiologists

Category:

Physician

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

This has the potentialto significantly impact level of care on a lot of medicare patients and our ability to provide timely and cost effective care to this patients.

Date: 10/19/2006

Submitter :

Anna Sokola

Organization:

Anna Sokola

Category:

Individual

Issue Areas/Comments

**ASC Office-Based Procedures** 

ASC Office-Based Procedures

Please allow these services in ASC office settings.

**ASC Office-Based Procedures** 

ASC Office-Based Procedures

Please allow these services in ASC office settings.

Date: 10/24/2006

Page 70 of 320

October 25 2006 09:40 AM

Submitter:

Ms. Elizabeth Zieienski

Organization:

Ms. Elizabeth Zielenski

Category:

**Ambulatory Surgical Center** 

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mr. Kevin Vest, RHIT,CCS

Date: 10/24/2006

Organization:

**US Medical Providers** 

Category:

**End-Stage Renal Disease Facility** 

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

Justr leave it alone! Keep it all the way it is!!! STOP wasting patients and providers time.... MEDICARE is not broken DONT try and FIX IT.... Politicians BACK OFF!!! Leave it alone unless you are trying to improve the Delivery of care to the patients and up the reimbursement to providers LEAVE IT ALONE!!!! Thanks!

Page 72 of 320 October 25 2006 09:40 AM

Submitter:

Kathy Fisne

Date: 10/24/2006

Organization:

DaVita Dialysis

Category:

Health Care Professional or Association

#### Issue Areas/Comments

#### **ASC Payable Procedures**

#### **ASC Payable Procedures**

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center settings

Incude angioplasty codes in the ASC setting to support CMS Fistula First initiative, permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes are allowed in the ASC setting.

October 25 2006 09:40 AM

Submitter:

**Brian Ernst** 

Date: 10/24/2006

Organization:

Brian Ernst

Category:

**Ambulatory Surgical Center** 

Issue Areas/Comments

#### **ASC Office-Based Procedures**

**ASC Office-Based Procedures** 

ASC's should remain able to do procedures to assist renal patients. They are capable and this saves much time and expence to the patient.

Page 74 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Ms. Jolene Parker

Organization: M

Ms. Jolene Parker

Category:

Individual

#### Issue Areas/Comments

#### **ASC Payable Procedures**

#### **ASC Payable Procedures**

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

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

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

#### **GENERAL**

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

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

Page 75 of 320 October 25 2006 09:40 AM

Submitter: Date: 10/24/2006

Organization:

Category: Physician

Issue Areas/Comments

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Page 76 of 320 October 25 2006 09:40 AM

Submitter:

Mr. Stephen Wolfe

Date: 10/24/2006

 ${\bf Organization:}$ 

DaVita

Category:

**Health Care Industry** 

Issue Areas/Comments

#### **ASC Payable Procedures**

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October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

**Ambulatory Surgical Center** 

Issue Areas/Comments

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Page 78 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

 ${\bf Organization:}$ 

Category:

Physician

Issue Areas/Comments

## **ASC Payable Procedures**

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Submitter:

Date: 10/24/2006

Organization:

Category:

Physician

**Issue Areas/Comments** 

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Submitter:

Ms. Revkah Balingit

Date: 10/24/2006

Organization:

DaVita

Category:

Nurse

Issue Areas/Comments

## **ASC Payable Procedures**

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October 25 2006 09:40 AM

Submitter:

Mrs. nancy quintero

Organization:

center for army lessons learned

Category:

Nurse

Issue Areas/Comments

**ASC Payable Procedures** 

ASC Payable Procedures

support the docket.

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Date: 10/24/2006

Organization:

Category:

**End-Stage Renal Disease Facility** 

Issue Areas/Comments

### **ASC Payable Procedures**

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Page 83 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Dr. Thomas Amato

Organization: Inland Nephrology

Category:

Physician

Issue Areas/Comments

### **ASC Payable Procedures**

## **ASC Payable Procedures**

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Page 84 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Sandra Cortez

Date: 10/24/2006

Organization:

**DaVita** 

Category:

Nurse

Issue Areas/Comments

## **ASC Payable Procedures**

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Page 85 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mrs. Melissa Yousett

 ${\bf Organization:}$ 

Mrs. Melissa Yousett

Category:

Individual

#### Issue Areas/Comments

#### ASC Addenda

ASC Addenda

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

#### ASC Coinsurance

ASC Coinsurance

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

### **ASC Conversion Factor**

**ASC Conversion Factor** 

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

### **ASC Inflation**

**ASC Inflation** 

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

#### **ASC Office-Based Procedures**

ASC Office-Based Procedures

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

### **ASC Packaging**

ASC Packaging

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

### **ASC Payable Procedures**

**ASC Payable Procedures** 

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

# **ASC Payment for Corneal Tissue**

ASC Payment for Corneal Tissue

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

## **ASC Payment for Office-Based**

#### **Procedures**

ASC Payment for Office-Based Procedures

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

## ASC Phase In

ASC Phase In

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

### **ASC Ratesetting**

ASC Ratesetting

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

### **ASC Unlisted Procedures**

**ASC Unlisted Procedures** 

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

## **ASC Updates**

ASC Updates

Page 86 of 320 October 25 2006 09:40 AM

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

# ASC Wage Index

ASC Wage Index

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

# CY 2008 ASC Impact

CY 2008 ASC Impact

Anything that will help make it easier for me and others like me who are on dialysis or have kidney troubles is a great idea.

Page 87 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Other

Issue Areas/Comments

**ASC Payable Procedures** 

**ASC Payable Procedures** 

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting.

Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Submitter:

Ms. Karen Strayer

Date: 10/24/2006

 ${\bf Organization:}$ 

Davita Healthcare, Inc.

Category:

Nurse

### Issue Areas/Comments

### **ASC Payable Procedures**

#### **ASC Pavable Procedures**

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

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

### **ASC Payable Procedures**

## **ASC Payable Procedures**

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

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

Page 89 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mr. Kevin Burkett

Organization:

Mr. Kevin Burkett

Category:

Individual

#### Issue Areas/Comments

#### **ASC Payable Procedures**

### **ASC Payable Procedures**

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## GENERAL

### **GENERAL**

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Page 90 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Shelley Purifoy

Date: 10/24/2006

Organization:

grant co organ transplant support group

Category:

Nurse

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

I feel there is a great need for easy access to care for the patient on dialysis. Be that the initial preparation or the actual treatment itself. As a life long kidney patient I know the hardships of getting treatment and care. The easier for the care/treatment is to access the more the patient will and can comply.

Page 91 of 320 October 25 2006 09:40 AM

Submitter:

Gale Schulke, RN

Date: 10/24/2006

Organization:

DaVita at Home

Category:

**Ambulatory Surgical Center** 

# Issue Areas/Comments

### **ASC Payable Procedures**

## **ASC Payable Procedures**

I am a nurse with over 10 years experience in the OR. I currently am working as a manager for DaVita at Home. From experience, there are few procedures involving fistula/graft/catheter that cannot be done in the Outpatient Setting. I worked in ASC at Stanford University Medical Center, one of the most prestigious hospitals in the country. We did all of our fistulas, grafts, catheters in the Ambulatory Surgery Center. We did declottings and fistulagrams in the outpatient setting as well. Using my experience as a guide, there are very few reasons to do any of these procedures inpatient. Most of them can be done under either a light general, IV conscious sedation, regional block, or even a local anesthetic. the cost is much less than in-hospital. The staff are just as well trained and educated as the in-center staff. I strongly urge the use of Ambulatory Surgery Centers as first choice for these procedures,

### **GENERAL**

#### **GENERAL**

Ambulatory Surgery is under-utilized as an option for many surgery procedures, particularly those that do not require a general anesthetic and intubation. If the procedure can be done under a light general, IV conscious sedation, regional block, or local anesthetic, it should be done in the Ambulatory Setting. To use an expensive in-hospital surgery room is not necessary.

Any procedure that does not require hospitalization should be considered as well. Ambulatory Surgery Centers can do general anesthesia if needed. They have fully qualified RNs, Surgical Techs, and Anesthesiologists/Nurse Anesthetists just as the in hospital settings do. If something happens during the procedure that requires hospitalization, the patient can be transported to the hospital.

Page 92 of 320

Having worked in ASC for several years, I can attest to the fact that few patients required transportation to the hospital.

October 25 2006 09:40 AM

Submitter:

Mr. Daniel Rueda Posada

Date: 10/24/2006

Organization:

**DaVita** 

Category:

Individual

Issue Areas/Comments

**GENERAL** 

GENERAL

There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.

Submitter:

Mr. LARRY MCDONALD

Organization:

**SMOKIN JOES** 

Category:

Other Government

Issue Areas/Comments

**GENERAL** 

GENERAL

its great

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Date: 10/24/2006

Organization:

Category:

Health Care Industry

Issue Areas/Comments

**GENERAL** 

### **GENERAL**

When I can work, Medicare is taken out of my check. I'm not supposed to work according to doctors. I have epilepsy and have had seizures on the job or fallen putting my students at risk. I've been sent home obviously for that. Doctors say don't work but Social Security refuses to help me. I am told that I can get Social Security in up to two years, provided I go to counseling. I can have counseling free at a place if I had Medicare. I don't have it but it has been taken out of my check. What takes Social Security so long? There should be something to help people out while they're waiting for their money. I want to work so I can eat but when I try to work, I get sent home. Social Security doesn't seem to care about that.

Date: 10/24/2006

Submitter:

Miss. Kendra Pomeroy

Organization:

DaVita Inc. Yuba City Dialysis

Category:

Social Worker

**Issue Areas/Comments** 

**GENERAL** 

## **GENERAL**

I am in favor of kidney/dialysis patients being able to have access surgeries in an outpatient setting. Our patients spend upwards of 25 hours per week in dialysis centers and hospitals. Being able to access an outpatient surgery center for access care and surgery will have a significant impact on quality of life for dialysis/kidney patients.

Page 96 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mrs. Alison Kelly

 ${\bf Organization:}$ 

Mrs. Alison Kelly

Category:

Other Association

Issue Areas/Comments

**ASC Payable Procedures** 

**ASC Payable Procedures** 

I am yet another supporter of the CMS practices and recommendations by MedPAC. The conclusion of the report that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list needs to be addressed.

Please support patient choices. There is scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center settings. Patients are satisfied with having an option. The inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascualr access procedures to be performed in an ASC setting. It is less expensive and more accessible than the current hospital settings. Please treat End Stage Renal Disease patients fairly by ensuring angioplasty codes, including CPT 35476 are allowed in the ASC setting.

Page 97 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mrs. Cherry Alexander

Organization:

Mrs. Cherry Alexander

Category:

Individual

#### Issue Areas/Comments

## **ASC Payable Procedures**

## **ASC Payable Procedures**

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

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting.

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Page 98 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Kathleen Cole

Date: 10/24/2006

 ${\bf Organization:}$ 

: Ms. Kathleen Cole

Category:

**End-Stage Renal Disease Facility** 

Issue Areas/Comments

## **ASC Payable Procedures**

## ASC Payable Procedures

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

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

Page 99 of 320 October 25 2006 09:40 AM

Submitter:

Mrs. Carole Elliott

Date: 10/24/2006

Organization:

Davita, Inc.

Category:

Social Worker

**Issue Areas/Comments** 

**GENERAL** 

## **GENERAL**

As a clinical social worker, I see first hand how difficult obtaining transportation to and from a hospital that is 45 minutes away. Perhaps access to vascular surgeons would improve if physicians could set up their own centers. Many of our patients require multiple trips to address fistula problems which is just not feasible. The consequences are clear, increased infection, lowered kt/v and shortened life span.

Page 100 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Gina Scroggins

Organization:

**Bradford Dialysis** 

Category:

Nurse

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

placement of vascular access in an outpatient setting should be available. These are safe procedures to be performed outpatient.

Page 101 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Lori Ridge

Date: 10/24/2006

Organization:

Davita

Category:

Nursing Aide

**Issue Areas/Comments** 

**GENERAL** 

**GENERAL** 

Docket: CMS-1506-P2 - Medicare Program; The Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

I have worked for a dialysis company for 5 years and we use this system all the time. This is a life line and they are efficient in getting the patients cared for and back to the dialysis facility to receive their life saving treatments quickly and efficiently. I think this is an important service to continue for our patients.

Page 102 of 320

October 25 2006 09:40 AM

Submitter:

Mr. Harlan Cleaver

Date: 10/24/2006

Organization:

DaVita

Category:

**End-Stage Renal Disease Facility** 

Issue Areas/Comments

# **ASC Payable Procedures**

## **ASC Payable Procedures**

As CIO for DaVita I strongly support providing vascular access procedures in an ambulatory setting for ESRD patients. The data that we collect on our patients clearly supports this as a better way to treat patients. Patients who receive treatmeent for access problems in an ambulatory setting instead of the ER generally can return to the dialysis center the same day and complete their dialysis treatment. Many who clot during treatment and have to go to the ER do not return for treatment and some get admitted and treated in the hospital. This is not good for the patient, or the taxpayer.

Page 103 of 320 October 25 2006 09:40 AM

Submitter:

**Deborah Evans** 

Date: 10/24/2006

 ${\bf Organization:}$ 

Davita

Category:

Social Worker

Issue Areas/Comments

**ASC Payable Procedures** 

ASC Payable Procedures

I am in favor of supporting legislation to allow for vascular access to performed in ambulatory surgery centers and supporting Medicare payment of such services. This is very important for continuity of care and decrease in hospitalizations, infection and missed treatments for outpatient dialysis patients across the country. As long as the outpatient centers follow strict standards there should be no reason to disallow or limit this practice.

Page 104 of 320 October 25 2006 09:40 AM

Submitter:

Mrs. Lennie Jo Barnes

Organization:

Mrs. Lennie Jo Barnes

Category:

Individual

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

October 24, 2006

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

Dear Sirs:

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

#### General Comments

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

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

### ASC Payable Procedures (Exclusion Criteria)

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

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

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

Thank you.
Sincerely,
Lennie Jo Barnes
8007 SE Otty St
Milwaukie, OR
artbylen@comcast.net

Page 105 of 320

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:
Organization:

Mrs. Susan Griffith

Davita Mechanicsville Virginia

Date: 10/24/2006

Category:

Nurse

Issue Areas/Comments

**GENERAL** 

### **GENERAL**

Dialysis patients need to be seen in ambulatory surgical setting for vascular access to get them out of the long tedious procedure in the hospital. They miss their treatment times and wait long hours to be seen. They often are sent home late at night because their procedures are performed at the end of the regular surgery schedule. To reduce hospital costs these patients could be seen and the problem corrected in a timely manner and then sent back to their chronic care unit for their renal therapy.

I have been caring for these patients for 25 years and this process has gotten worse instead of improving, radiology and surgery do not want to deal with these unscheduled patients and they become caught in the middle.

Our area surgeons try their best to accommodate us but the hospital admission and rigidity of their times and what to do with the patient after the procedure presents the greatest hurdle that we face.

We are trying diligently to improve patient outcomes and vascular access is our first area that we must get right in order to perform this life saving procedure. We need to make it more accessible, cost effective and efficient for the patient.

Page 106 of 320

October 25 2006 09:40 AM

Submitter:

Maria Beitia

Date: 10/24/2006

Organization:

DaVita Inc

Category:

Individual

Issue Areas/Comments

**GENERAL** 

## **GENERAL**

The clinical benefits of permorming routine non-invasive studies on vascular access sites have been proven, but providers have no way to cover the costs associated with providing the tests. Providers should be fairly compensated for the costs associated with the tests, which will reduce costs that result from not performing these preventative tests, or the composite rate needs to be increased to cover the real cost of conducting the tests.

Page 107 of 320

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:
Organization:

Ms. Robin Bane

Ms. Robin Bane

Category:

Individual

Issue Areas/Comments

**GENERAL** 

## **GENERAL**

I have a kidney problem that is slowly shutting my kidneys down if any funding is taken away people like me and others wont have a chance to live because we wont be able to pay for it, all we have is medicaid and medicare. Please leave them alone you dont understand what you do and who's lives you affect when you mess with these programs.

Page 108 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Erin Lee

Organization:

DaVita

Category:

Individual

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

I am a contractor so this doesn't apply to me at this time

Page 109 of 320

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Ms. Vicki Kording

Date: 10/24/2006

Organization:

**DaVita** 

Category:

Nurse

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

October 24, 2006

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

Dear Sirs:

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

## General Comments

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

Thank you. Sincerely, Vicki Kording 3275 Stagecoach Rd Colorado Springs, Colorado 80921

Page 110 of 320 October 25 2006 09:40 AM

Submitter:

Mrs. Norma Gomez

Date: 10/24/2006

Organization:

daVita

Category:

Nurse

**Issue Areas/Comments** 

### **ASC Payable Procedures**

### **ASC Payable Procedures**

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### **GENERAL**

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Page 111 of 320 October 25 2006 09:40 AM

Submitter:

Miss. Michelle Castellani

Date: 10/24/2006

Organization:

Davita

Category:

Social Worker

Issue Areas/Comments

ASC Payment for Office-Based Procedures

ASC Payment for Office-Based Procedures

It is imperative that CMS pay for fistula/graft's in the ambulatory surgical centers! It is hard enough to get patients to agree to have a procedure, but if they are forced to have it done in the hospital setting, it is going to be even tougher. They will fear being admitted and not coming home that same day and justify it in their minds in this way. We need to continue to educate/support the patients regarding fistula first program and this is one way to do that. I see so much non-compliance with patients and this will give them an easy out to get out of moving forward with access placement/revision.

Page 112 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Kathleen Madsen

Organization:

Kathleen Madsen

Category:

Individual

**Issue Areas/Comments** 

# **ASC Payable Procedures**

# **ASC Payable Procedures**

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

Page 113 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mrs. Anita Daraska

Organization: Fi

Freeport Dialysis

Category:

Nurse

Issue Areas/Comments

## **ASC Payable Procedures**

## **ASC Payable Procedures**

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Page 114 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Nurse

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

I believe vascular access procedures should be included in the approved ASC billing codes. The procedures done in the ASC setting also save CMS money.

October 25 2006 09:40 AM

Submitter:

Kathleen Madsen

Date: 10/24/2006

Organization:

Kathleen Madsen

Category:

Individual

Issue Areas/Comments

**GENERAL** 

## **GENERAL**

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

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October 25 2006 09:40 AM

Page 116 of 320

Submitter:

Mrs. Cecily Sherlock- Huizing

Date: 10/24/2006

Organization:

DaVita Dialysis

Category:

Social Worker

**Issue Areas/Comments** 

**GENERAL** 

## **GENERAL**

It is imperative that dialysis patients be allowed to receive surgical access intervention in ambulatory care centers. Not only would this greatly decrease the time that patients wait between treatment (thus decreasing their hospitalization and morbidity risks), it would also assist patients in their emotional and psychological adjustment to this disease and the required treatment. In our area, there are very limited resources available to assist patients with access intervention. Therefore, patients may have to wait days in order to receive the treatment that they require, also prolonging the time between treatment. We provide so much education to patients regarding the necessity of compliance with treatment, knowing that compliance reduces their risk of illness or hospitalization. Therefore, it would only make sense for us to make the system easier for them.

October 25 2006 09:40 AM

Submitter:

Mrs. Christy Munoz

Date: 10/24/2006

Organization: Category:

Davita

Other Health Care Professional

#### Issue Areas/Comments

## **ASC Payable Procedures**

## ASC Pavable Procedures

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

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

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

#### **GENERAL**

## **GENERAL**

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

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

Submitter:

Mrs. Barbara McCarthy

Organization:

Mrs. Barbara McCarthy

Category:

Individual

**Issue Areas/Comments** 

## **ASC Payable Procedures**

#### **ASC Payable Procedures**

Not every patient who has kidney failure and a fistula will keep the fistula forever. Fistulas are certainly a preferred method of providing access for dialysis however a fistula can collapse suddenly. A dialysis patient still will need to receive dialysis even if the fistula has collapsed. This scenario usually requires an expensive trip via ambulance to the nearest hospital in order to receive a vascular access. This is a totally unneccessary trip and a waste of money and time (especially since they do this access in the emergency room at my local hospital). Vascular access procedures are safe and can be performed in an Ambulatory setting. Please support the patient's right to choose whether or not to go to the hospital for the procedure or to have it done in the ASC setting. Including angioplasty codes in the ASC setting would support CMS' 'Fistula First' initiative by permitting a full range of vasular procedures to be performed in an ASC setting. This, in itself, is a less expensive and more accessible option that the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by including CPT 35476 in the list of angioplasty procedures that are allowed in the ASC setting.

## **GENERAL**

## **GENERAL**

Including CPT codes 35475, 35476, 36205, and 37206 to list of Medicare approved abulatory surgical center procedures would provide Medicare the opportunity to reduce the cost care for end stage renal disease patients. In the end, the most important criteria should be a quality outcome for the patient. I believe including these codes to the list of reimbursable Medicare codes at an ASC facility will assist in providing a quality outcome for ESRD patients.

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Mrs. Monica Yost

Organization:

Davita Dialysis

Category:

**End-Stage Renal Disease Facility** 

Issue Areas/Comments

## **ASC Unlisted Procedures**

#### ASC Unlisted Procedures

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

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

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

October 25 2006 09:40 AM

Date: 10/24/2006

Submitter: Date: 10/24/2006

Organization:

Category: Nurse

Issue Areas/Comments

**ASC Payable Procedures** 

**ASC Payable Procedures** 

I support CMS' practice of re-examining its policies as the technology improves and practice patterns change. The report made by MedPAC in March 2004 report to Congress concluded taht clinical safety standards and the need for an overnight staybe the only criteria excluding a procedure from the approved list. Please support patient choice. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center settings. Patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in the out patient setting. The inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a LESS expensive and more accessible option than the current prevalent hospital setting.

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

Page 121 of 320 October 25 2006 09:40 AM

Submitter:

Mrs. Lori Harris

Date: 10/24/2006

Organization:

**DaVita** 

Category: End-Stage Renal Disease Facility

Issue Areas/Comments

## **ASC Payable Procedures**

**ASC Payable Procedures** 

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

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

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

October 25 2006 09:40 AM

Submitter:

Mrs. Shirley Miller

Date: 10/24/2006

Organization:

Davita

Category: Nurse

DAVILA

Issue Areas/Comments

**GENERAL** 

## **GENERAL**

This is a good program providing the patient is in stable condition. My father is on dialysis and I know from first hand experience the time it takes to get to the hospital and then have the access declotted or a temporary access placed. One thing I would love to see is that if a patient is going to be on dialysis then the patient should have a temporary access placed and at the same time have a permanent access(preferably a fistula) done during that hospital stay. That is not happening here and it is causing more infections due to having to keep the catheter in longer to get the permanent access placed and to mature if it is a fistula. Thank you for letting my voice be heard.

October 25 2006 09:40 AM

Page 123 of 320

Submitter:

Mrs. Melissa Fouts

Date: 10/24/2006

Organization:

DaVita

Category:

**End-Stage Renal Disease Facility** 

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

Please allow this to go through for ASC settings to be able to place accesses for dialysis patients.

October 25 2006 09:40 AM

Submitter :

Mrs. Lilly Alaggia

Date: 10/24/2006

Organization:

Retiree with Chronic Kidney Disease

Category:

Individual

#### Issue Areas/Comments

# ASC Payable Procedures

ASC Payable Procedures

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

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

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

#### **GENERAL**

## **GENERAL**

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

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

Page 125 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Jennifer Opincar

Date: 10/24/2006

Organization:

DaVita

Category:

Individual

**Issue Areas/Comments** 

## **ASC Payable Procedures**

#### **ASC Payable Procedures**

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

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

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

#### **GENERAL**

#### **GENERAL**

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

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

Page 126 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Ms. Marie Signorile

Organization:

Ms. Marie Signorile

Category:

Individual

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

See Attachment

CMS-1506-P2-125-Attach-1.WPD

Page 127 of 320 October 25 2006 09:40 AM

{October 24, 2006}

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

Dear Sirs:

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

# **General Comments**

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

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

# **ASC Payable Procedures (Exclusion Criteria)**

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

**Please support patient choice!** There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular

access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

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

Thank you.

Sincerely,

{Marie Signorile

8256 Creek Hollow Court

Jacksonville, FL 32244}

Date: 10/24/2006

Submitter:

**Chad Lennox** 

Chad Lennox

Organization: Category:

Individual

**Issue Areas/Comments** 

## **ASC Payable Procedures**

## ASC Payable Procedures

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

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

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

Page 128 of 320 October 25 2006 09:40 AM

Submitter:

Mrs. Stacy Coolbaugh

Date: 10/24/2006

Organization:

Category:

Dietitian/Nutritionist

Issue Areas/Comments

# **ASC Payable Procedures**

**ASC Payable Procedures** 

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

## **GENERAL**

## **GENERAL**

Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.

> Page 129 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Nurse

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

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

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

Page 130 of 320 October 25 2006 09:40 AM

Date: 10/24/2006

Submitter:

Ms. Sharon Gatch

Organization:

Ms. Sharon Gatch

Category:

Individual

**Issue Areas/Comments** 

**GENERAL** 

## **GENERAL**

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

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

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

Sample for CMS Online Comment Section titled "General Comments"

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

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

Page 131 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Individual

Issue Areas/Comments

## **ASC Payable Procedures**

## **ASC Payable Procedures**

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

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular

## **GENERAL**

## **GENERAL**

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

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

Page 132 of 320 October 25 2006 09:40 AM

Submitter:

Mr. Richard Turner

Date: 10/24/2006

Organization:

**DaVita** 

Category:

Health Care Professional or Association

Issue Areas/Comments

## **ASC Payable Procedures**

## **ASC Payable Procedures**

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

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

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

Page 133 of 320 October 25 2006 09:40 AM

Submitter:

Ms. Victoria Hazlett

Date: 10/24/2006

Organization:

Ms. Victoria Hazlett

Category:

Individual

**Issue Areas/Comments** 

## **ASC Office-Based Procedures**

**ASC Office-Based Procedures** 

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

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

Page 134 of 320

October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Dietitian/Nutritionist

Issue Areas/Comments

## **ASC Payable Procedures**

## **ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list. Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS. Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting. Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

## **GENERAL**

## **GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae. The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

Page 135 of 320 October 25 2006 09:40 AM

Submitter: Date: 10/24/2006

Organization:

Category: Social Worker

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

It would benefit patients to have increased access to vascular accesses through ASCs. Please consider supporting the current legislation to allow for this.

Page 136 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Dietitian/Nutritionist

**Issue Areas/Comments** 

## **ASC Payable Procedures**

#### **ASC Pavable Procedures**

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

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

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

#### **GENERAL**

## **GENERAL**

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

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

Page 137 of 320 October 25 2006 09:40 AM

Submitter:

Date: 10/24/2006

Organization:

Category:

Individual

Issue Areas/Comments

**ASC Payable Procedures** 

ASC Payable Procedures

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

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

Submitter:

Mrs. Pat Morgan

Date: 10/24/2006

Organization:

Davita

Category:

Nurse

Issue Areas/Comments

**ASC Payable Procedures** 

ASC Payable Procedures

I feel that the outpatient surgical producedure for dialysis patients should be such that there would be enough to encourage surgeons to participate in this program.

October 25 2006 09:40 AM

Submitter:

morgan

Organization:

morgan

Category:

Individual

Issue Areas/Comments

GENERAL

GENERAL

I watch you site for infomation only, i am a heamo patient in the UK

October 25 2006 09:40 AM

Date: 10/24/2006

Page 140 of 320

Submitter:

Date: 10/24/2006

Organization:

Category:

Individual

Issue Areas/Comments

## **ASC Payable Procedures**

**ASC Payable Procedures** 

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

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

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

**ASC Payable Procedures** 

**ASC Payable Procedures** 

Page 141 of 320 October 25 2006 09:40 AM

Submitter:

Mr. Carlos Jacobs

Date: 10/24/2006

Organization:

**DaVita** 

Category:

Nurse

Issue Areas/Comments

# **ASC Payable Procedures**

# **ASC Payable Procedures**

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

## **ASC Payable Procedures**

# **ASC Payable Procedures**

Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.

Page 142 of 320 October 25 2006 09:40 AM

Submitter:

Mrs. Tracy Rickels

Date: 10/24/2006

Organization:

**DaVita** 

Category:

Health Care Professional or Association

Issue Areas/Comments

## **ASC Payable Procedures**

## ASC Payable Procedures

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

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Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

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

Page 143 of 320 October 25 2006 09:40 AM