Submitter : **Dr. Mark A. Mintz** **Date: 11/06/2006**

Organization : **Southwwest Florida Urologic Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

CMS-1506-P2-1037-Attach-1.DOC

#1037

November 6, 2006

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

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

Dear Ms. Norwalk:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed rule for reforming the Ambulatory Surgical Center (ASC) Payment System. The AUA understands that this reform proposal, as mandated by the 2003 Medicare Modernization Act (MMA) has been a huge undertaking for CMS and appreciates the time and effort CMS has put into development of the proposal. We also appreciate CMS holding a listening session teleconference in August 2005 and for meeting with the AUA and other groups that are interested in ASC payment reform over the past couple of years.

We understand that the MMA places certain limitations, the major one being a budget-neutrality requirement, on CMS's discretion in developing an ASC payment reform proposal. However, CMS does have a certain degree of discretion in how it implements the MMA, and we hope that CMS we consider suggestions that would improve the reform proposal to the extent that the suggestions are within CMS's discretion to implement them.

ASC PAYABLE PROCEDURES

Under the proposal, Medicare would allow payment of an ASC facility fee for any surgical procedure performed in an ASC, except those that CMS determines are not payable under the ASC benefit based on the principal clinical considerations of beneficiary safety and the need for an overnight stay. CMS also proposes to discontinue the current time-based criteria of procedures that exceed 90 minutes of operating time, 4 hours of recovery time or 90 minutes of anesthesia. The AUA applauds CMS for proposing these changes to the ASC list as they are a big improvement over some of the current outdated rules that govern the ASC list. We also offer the following comments regarding the specific criteria for defining a significant safety risk and the need for an overnight stay.

Procedures that could pose a significant safety risk

CMS proposes to define procedures that could pose a significant safety risk as:

- any procedure included on the OPPS inpatient-only list
- procedures performed 80 percent or more of the time in the hospital inpatient setting
- procedures that involve major blood vessels; prolonged or extensive invasion of body cavities; extensive blood loss or are emergent or life-threatening in nature

The AUA disagrees with the criteria of procedures performed 80 percent or more of the time in the hospital inpatient setting, and urges CMS to delete this as one of the criteria for procedures that could pose a significant safety risk. We feel that the 80 percent cut-off is arbitrary and we are concerned that this criterion could artificially restrict the natural movement of procedures among sites of service that technological developments may allow for. Also, because the determination of whether procedures meet the 80 percent cut-off would be based on Medicare site-of-service data, a lag in data collection could also artificially restrict the movement of procedures into the less-expensive ASC setting. Furthermore, use of Medicare data does not allow consideration of site-of-service trends in non-Medicare populations.

Overnight stay:
CMS is also proposing to exclude from payment any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. The AUA opposes this blanket criterion for excluding procedures from the ASC list, as many ASCs have the capability to deal with these types of situations and physicians would not choose to do procedures in an ASC if they felt there was a possibility of having to admit the patient to the hospital. Physicians make these decisions using their clinical judgment based on the patient's anesthesia risk as determined by the patients' score based on the American Society of Anesthesiologist's Physical Status Classification System.

Proposed definition of surgical procedures
CMS proposes to define surgical procedures as any procedure within the CPT code range of 10000 to 69999, but seeks comments on whether all services contained in this range are appropriately defined as surgery. For example, CMS asks whether office-based procedures or procedures that require relatively inexpensive resources to perform should be excluded from the ASC list. The ability of a physician to select the most appropriate site of service for their patients based on clinical considerations is extremely important. Therefore, the AUA agrees that any procedure within the "Surgery" section of CPT should continue to be defined as a surgical procedure eligible for payment under the revised ASC payment system, regardless of whether it is office-based or requires relatively inexpensive resources to perform.

We also note, however, that modern surgical techniques also include a number of radiology procedures that are invasive in nature and that are integral to the performance of other surgical procedures. Examples include stone removal, balloon dilation of strictures and prostate biopsies. To allow for the efficient performance of these procedures in ASCs, we believe the revised ASC payment system's definition of surgical procedure should be expanded to include invasive radiology procedures that require the insertion of a needle, catheter, tube or probe through the skin or into a body orifice and intraoperative radiology procedures that are integral to the

performance of a non-radiological surgical procedure and performed during the non-radiological surgical procedure or immediately following the surgical procedure to confirm placement of an item, such as ultrasound used to provide guidance for biopsies and major surgical procedures or to determine, during surgery, whether surgery is being conducted successfully. The physician self-referral regulations also carve out these invasive and intraoperative radiology services from the definition of "radiology" services subject to the law's self-referral prohibition. This Stark law exclusion is based "on the theory that the radiology services in these procedures are merely incidental or secondary to another procedure that the physician has ordered" and, thus, are less subject to abuse from overutilization. 63 Fed. Reg. 1645, 1676 (Jan. 9, 1998).

HCPCS and category III CPT codes
CMS also proposes to include within the scope of surgical procedures payable in an ASC certain HCPCS codes or CPT category III codes which directly crosswalk to or are clinically similar to procedures in the CPT surgical range. The AUA supports this proposal, as such codes are eligible for payment under the OPPS, thus should also be eligible for payment under the new ASC payment system. Examples for urology include 0135 T, *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy* and 0137T, *Biopsy, prostate, needle, saturation sampling for prostate mapping.*

Broaden representation on HCPCS panel
The AUA also urges CMS to broaden the representation on the HCPCS panel to include representatives who are familiar with the outpatient and ASC payment systems.

ASC UNLISTED PROCEDURES
CMS proposes to exclude unlisted procedure codes from the ASC list because of potential safety concerns in not knowing what the procedure involved and also to not make separate payment in an ASC for CPT codes in the surgical range that are packaged under the Outpatient Prospective Payment System (OPPS) (status indicator of N) for the following reasons:

- CMS would not be able to establish an ASC payment rate for packaged surgical procedures using the same method proposed for all other ASC procedures because packaged surgical codes have no relative payment weights under OPPS upon which to base an ASC payment.
- CMS wants an ASC system that is as similar to OPPS as possible
- ASCs would receive payment for these surgical procedures because their costs are already packaged into the APC relative payment weights for associated separately payable procedures

The AUA agrees that it is appropriate to exclude from the ASC list unlisted procedures as well as procedures that are packaged under the OPPS.

For urology, these codes are:

CPT/ HCPCS	Description	SI
50394	Injection for kidney x-ray	N

50684	Injection for ureter x-ray	N
50690	Injection for ureter x-ray	N
51600	Injection for bladder x-ray	N
51605	Preparation for bladder xray	N
51610	Injection for bladder x-ray	N
54230	Prepare penis study	N
55300	Prepare, sperm duct x-ray	N

ASC RATESETTING

CMS proposes to base ASC relative payment weights on Ambulatory Payment Classification (APC) groups and relative payment weights established under the OPPS based on the belief that the relative payment weights established under the OPPS for procedures performed in the outpatient hospital setting reasonably reflect the relative resources required for such procedures and do so with sufficient coherence to be applicable to other ambulatory sites of service. The AUA agrees that the OPPS APC groups are appropriate for use in the ASC payment system and that tying ASC payments to OPPS payments will create transparency and continuity across the continuum of ambulatory settings.

ASC PACKAGING

Proposed packaging policy
Under the current ASC payment system, CMS packages into a single facility fee the payment for a bundle of direct and indirect costs incurred by the facility to perform the procedure, including use of the facility, including an operating suite or procedure room and recovery room; nursing, technician and related services; administrative, recordkeeping and housekeeping items and services; medical and surgical supplies and equipment; surgical dressings; and anesthesia materials.

Currently, CMS determines payment for other items and services, including drugs, biologicals, contrast agents, implantable devices and diagnostic services such as imaging, differently in ASC and OPPS payment systems. CMS is proposing to continue the current policy of packaging into the ASC facility fee payment all direct and indirect costs incurred by the facility to perform a surgical procedure. This would include payment for all drugs, biologicals, contrast agents, anesthesia materials and imaging services, as well as the other items and services that are currently packaged into the ASC facility fee.

Separate payment for implantable prosthetic devices and DME
CMS proposes to continue to exclude from payment as part of the ASC facility fee items and services for which payment is made under other Part B fee schedules, with the exception of implantable prosthetic devices and implantable DME. CMS is proposing to cease making separate payment for implantable prosthetic devices and implantable DME inserted surgically at an ASC and instead to package them into the ASC facility fee payment. **The AUA strongly disagrees with CMS's proposal to package into the ASC facility fee payment the cost of**

implantable prosthetic devices and implantable DME inserted surgically at an ASC. The proposed conversion factor and phase-in would only exacerbate this problem.

ASC PAYMENT FOR OFFICE-BASED PROCEDURES

Proposed payment for office-based procedures

According to the proposed rule, CMS generally interprets office-based to mean a surgical procedure that the most recent Medicare Part B Extract Summary System (BESS) data available indicate is performed more than 50 percent of the time in the physician's office setting (even if the code lacks a nonfacility practice expense relative value unit under the Medicare physician fee schedule). According to CMS, an influx of high-volume, relatively low cost office-based procedures into the ASC setting under the revised payment system could lower the payment amounts for other procedures paid for in the ASC due to the statutory budget neutrality requirement, and CMS would have to scale down the ASC conversion factor to meet budget neutrality requirements.

Therefore, CMS proposes to cap payment for office-based surgical procedures for which an ASC facility fee would be allowed under the new payment system at: the lesser of the Medicare physician fee schedule nonfacility practice expense payment or the ASC rate under the revised ASC payment system. CMS also proposes to exempt procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, from the payment limitation proposed for office-based procedures.

While the AUA appreciates CMS's concerns about potential migration of office-based procedures to the ASC setting, we disagree with the proposal to cap payment for office-based procedures to address this concern. For patients that require the extra resources or greater surgical capacity available in an ASC setting, a physician should be able to make the decision to perform these procedures in an ASC based on clinical considerations and should be reimbursed at a rate that accounts for the increased costs and complexities associated with performing procedures in an ASC setting.

If CMS adds office-based procedures to the ASC list, they are effectively indicating that Medicare beneficiaries should have the option of having these procedures performed in an ASC and CMS should therefore provide reasonable reimbursement for these procedures. Otherwise, ASCs will be effectively prohibited from performing these procedures because they will not be able to recoup their costs, and beneficiaries will not have the ASC as a viable site-of-service option. If the ASC is not an option for such patients, these procedures will then likely be performed in the hospital outpatient setting, resulting in higher costs to both beneficiaries and the Medicare program.

Usually, office-based procedures do not require the extra capacity of an ASC. However, the option should be available to physicians if they find it necessary for clinical reasons. For example, sometimes patients refuse to have a procedure performed unless they can be anesthetized. Also, urologists may choose to perform prostate biopsies on older patients or patients who require anesthesia in an ASC. Based on our analysis of Medicare data in the past

for urology office-based codes that have been on the ASC list for quite some time, CMS's migration assumptions are not realistic. (52000, 52281 and 55700).

The AUA strongly supports CMS's proposal to exempt from the office-based payment limitation procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, as there is no reason to assume these procedures would migrate further into an ASC setting. In fact, Medicare data shows that despite an increase in the number of ASCs in recent years, CPT codes 52000, 52281 and 55700 are performed no more in an ASC today than they were in 1997. These procedures have consistently been furnished in hospital or ASC settings in 25 to 28 percent of cases between 1997 and 2003. These patients will almost certainly be treated in a hospital environment if the ASC is no longer a financially viable option.

Payment policy for multiple procedure discounting

The AUA strongly supports CMS's proposal to mirror the OPPS policy for discounting when a beneficiary has more than one surgical procedures performed on the same day at an ASC. Under OPPS, procedures performed to implant costly devices are not subject to the discounting policy. For urology, the procedures to which this applies (listed below) involve expensive implantable devices, and physicians will not be able to perform these procedures in an ASC if the cost of these devices are not covered.

53440	Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)
53444	Insertion of tandem cuff (dual cuff)
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

ASC INFLATION

Proposed adjustment for inflation

Although the MMA froze ASC inflation updates until 2010, the current updates are based on the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. However, the OPPS is updated annually using the hospital inpatient market basket

percentage increase. Because CMS states multiple times in the proposed rule that they desire for the revised ASC payment system to reflect the OPPS as closely as possible, and because MMA does not mandate that any particular update system be used for the ASC payment system, the AUA urges CMS to use the same update method for both payment systems, which would achieve parity and transparency in the market and assure that site-of-service determinations are made based on clinical indications rather than economic considerations.

ASC PHASE IN

Proposal to phase in implementation of payment rates

CMS proposes to implement the revised ASC payment system in 2008 using transitional payment rates that would be based on a 50/50 blend of the payment rate for procedures on the 2007 list of approved ASC procedures and the payment rate for that procedure calculated under the revised payment methodology. Procedures added in 2008 would be paid the full amount calculated under the revised methodology, and new rates would be fully implemented in 2009. The AUA supports a two-year phase in for the new ASC payment rates.

ASC CONVERSION FACTOR

Based on CMS's proposed methodology for calculating the ASC payment system conversion factor, it would equate to 62 percent of the OPPS conversion factor, or $39.688. Although we understand that CMS must implement ASC payment reform in a budget-neutral fashion as required by Congress, it is completely unreasonable to assume that the cost of furnishing any given procedure in an ASC is only 62 percent of the cost of furnishing the same procedure in a hospital outpatient department. We urge CMS to use its discretion to institute changes in the methodology in order to reach a more reasonable and credible conversion factor.

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross, M.D.
President

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

Organization : American Medical Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1038-Attach-1.PDF

#1038

Michael D. Maves, MD, MBA, Executive Vice President, CEO

November 6, 2006

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

Re: *CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates*

Dear Administrator Norwalk:

The American Medical Association (AMA) appreciates the opportunity to provide its views on the Centers for Medicare and Medicaid Services' (CMS) proposed rules concerning Section XVIII, Proposed Revised Ambulatory Surgical Center (ASC) Payment System for Implementation January 1, 2008, that would make revisions to polices affecting ambulatory surgical centers for CY 2008.

The AMA commends CMS on its efforts to implement a new ASC payment system, as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. We are confident that a new payment system can help to ensure that Medicare beneficiaries have access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the Medicare program in containing health expenditures. We are hopeful that implementation of a new payment system will help to create a level playing field between ASCs and hospital outpatient departments so that facility determinations are based primarily upon what is best for the patient.

I. ASC Payable Procedures

The proposed rule adopts the recommendation of the Medicare Payment Advisory Commission (MedPAC), that the ASC procedures list be modified such that ASCs can receive Medicare facility payments for any surgical service, except those that the Secretary of Health and Human Services (HHS) designates as posing a significant risk to beneficiary safety when furnished in an ASC or that would require an overnight stay. CMS deviates from the MedPAC recommendation, however, and lists criteria that it will use as proxies for safety. Specifically, CMS proposes to exclude those procedures involving major blood vessels, major or prolonged invasion of body cavities, significant loss of blood, or procedures defined as inpatient-only services in the Outpatient Prospective Payment System.

Thus, the proposal defines safety using a set of criteria, rather than engaging in a meaningful dialogue with physicians, including those practicing in ASCs, about which procedures are safe in the ASC setting. Physicians are best equipped to determine the safest place to perform a procedure. They are most familiar with assessing anesthetic risk, expected duration and complexity of a procedure, the anticipated degree and duration of postoperative pain and discomfort, and the probability of peri- and post-operative complications. While an ASC may not always be the proper surgical setting, it may indeed be safe and appropriate for many patients undergoing procedures not typically performed in an ASC. And we believe that this determination should be made based on the expertise of the physician community.

We strongly believe that physicians, in consultation with their patients, are in the best position to determine the most appropriate site of service for a surgical procedure. For this reason, we strongly encourage CMS to establish a process to consult with national medical specialty societies and the ambulatory surgical community to develop and adopt a systematic and adaptable means of fairly reimbursing ASCs for all safe and appropriate services, allowing for changes in technology and current-day practices.

II. ASC Payment for Office-Based Procedures

CMS proposes to further expand the list of procedures by discontinuing the restriction on payment for procedures performed in an ASC that "are commonly performed, or that may be safely performed, in physicians' offices." However, CMS proposes to cap payments for these services at the lesser of the non-facility practice expense payment under Medicare's Physician Fee Schedule, or the ASC payment rate. This cap would result in reimbursement levels that make it economically infeasible for many ASCs to continue offering certain procedures—forcing patients who could be treated safely and more cost effectively in an ASC into a hospital outpatient department.

Although physicians may safely perform many procedures on Medicare beneficiaries in the office setting, certain beneficiaries will require additional infrastructure and safeguards. Eliminating ASCs as an option for such patients, by reducing ASC payments to such a level as to make their use infeasible, imposes unnecessary costs on both the Medicare program and individual beneficiaries.

For example, in the Hospital Outpatient Department (HOPD) setting, payment for CPT® 64555, Percutaneous implantation of neurostimulator electrodes, would be $3025.80, whereas payment for performing the procedure in an ASC, under the proposed rule, would be only $96.40. Similarly, the payment for performing CPT® 65210, Removal foreign body of the eye, in an ASC would amount to only $26.81; CPT® 53025, Incision of urethra, would be capped at $14.09; CPT® 56606, Biopsy of vulva, would amount to $33.54; and payment for CPT® 62368, Analyze spine infusion pump, would be only $21.90. As is clear from these examples, payment amounts for many services would be so low under the proposed rule that utilization of an ASC for these and other procedures would be impractical and unworkable.

CMS indicates that it is concerned that allowing payment for office-based procedures under the ASC benefit may create an incentive for physicians inappropriately to convert their offices into ASCs or move all of their office surgery to an ASC. However, we do not think that capping payments at a level that in many cases will not cover the cost of performing the procedure is a viable solution. Thus, we urge CMS to review carefully the costs related to these lower intensity services and develop a payment system that adequately covers such costs if performing the procedure in an ASC is indeed appropriate. Finally, in the interest of promoting a system whereby facility decisions are made based upon a patient's best interests rather than reimbursement rates, we urge CMS to apply any payment policies uniformly to both ASCs and hospital outpatient departments. CMS should recognize that if a payment would be unreasonably low for a service provided in a hospital outpatient department, then it is equally unreasonable in the ASC setting.

III. ASC Conversion Factor

The AMA is pleased that CMS is proposing to link ASC payments to the rates paid to HOPDs. We believe it is essential to revise payments for surgical procedures provided in ASCs so that they are aligned with surgical procedures provided in hospital outpatient departments. Such alignments would make payments more accurate and promote higher quality and value in outpatient care. We are concerned, however, with CMS' proposal that ASCs be paid based upon a methodology that results in ASCs being paid no more than 62 percent of the HOPD rates in 2008 and even less in 2009.

While we understand that this low percentage is driven by CMS's interpretation of the Medicare Modernization Act's requirement that the new system be implemented in a budget

neutral manner, we believe that CMS' interpretation is based upon unproven assumptions and is unduly narrow. There are a number of assumptions behind CMS' calculation that budget neutrality requires the new ASC rates to be set at 62 percent of the Outpatient Prospective Payment System (OPPS) rate for the same service. Although the 62 percent payment rate, as well as the expanded ASC coverage policy, will make it possible to provide some services in ASCs that are now commonly provided in hospital outpatient departments, this payment rate also represents a sharp reduction for a number of services that are already being frequently provided in ASCs.

In particular, many single-specialty ASCs that specialize in gastrointestinal, pain management, and ophthalmic procedures that provide critical care to Medicare beneficiaries may not be feasible at these rates. Patients could then be forced to obtain treatment in hospitals, which will increase costs to the program and limit physicians' ability to determine the most appropriate setting for their patients. To take procedures that are currently provided frequently in ASCs and revert back to providing them in a hospital setting would represent a major reversal of medical progress.

We encourage CMS to reconsider its assumptions about utilization rates under the new payment system and work to achieve the highest possible level of comparability between the ASC and OPPS rates in order to minimize the adverse impact on gastroenterology, pain management, and ophthalmic services facing steep reductions under the current proposal. For example, CMS should not assume migration of procedures that currently are provided in physician offices into ASCs. Many services defined as surgery, such as dermatological procedures, are highly unlikely to migrate from physician offices to ASCs. The services that are most likely to be done more frequently in ASCs under the new payment system are those that are primarily done in hospitals currently due to significant underpayment in ASCs.

We also urge CMS to interpret broadly the budget neutrality requirement. Providing Medicare beneficiaries with access to ASCs offers them more choices and enhances their access to services in a timely manner. In addition, it provides significant economic savings to the Medicare program and its beneficiaries. Maintaining ASC access, however, requires reasonable payment rates, and since current ASC rates are based upon 20-year old data and a 6-year freeze, a broad interpretation of budget neutrality is necessary to establish such rates and allow Medicare and its beneficiaries to take advantage of the myriad benefits of ASCs.

Furthermore, like hospitals, ASCs should be updated based upon the hospital market basket rather than the Consumer Price Index for all urban Consumers (CPI-U).
The hospital market basket more appropriately reflects inflation in providing surgical services. Moreover, alignment with hospital updates would achieve parity and transparency in the market and assure that facility decisions are made based upon what is best for the patient, rather than the economic strength of the facility.

Finally, under the proposed rule, the new payment rates would be phased in over a two-year period. For 2008, CMS would pay a blended amount equal to 50 percent of the rate under the existing payment system and 50 percent of the rate under the new system. Starting in 2009, payment rates would be tied entirely to the new methodology. The AMA is concerned that such a short transition period could threaten the viability of many centers and recommends that CMS provide more time for phasing in the new methodology.

We are pleased that CMS is moving forward with adoption of a new ASC payment system and we support CMS in this effort. We appreciate the opportunity to provide our views on the implementation of the proposed rule and look forward to working further with CMS on this important matter.

Sincerely,

Michael D. Maves, MD, MBA

Submitter : Mr. Keener Lynn **Date:** 11/06/2006

Organization : Southern Surgery Center, LLC

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

My general comments focus on payment reform and the procedure list.

As the Administrator of a freestanding multispecialty surgery center in Georgia, 62% of the HOPD rate is just not an adequate reimbursement rate. I strongly recommend that the reimbursement rate approach more closely the initial request of 75% of HOPD. CMS is enjoying considerable savings at ASCs currently and I am certain that CMS wishes for surgery centers to continue participating and providing quality, cost effective medical care.

The ASC list reform proposed by CMS is too limited. This list should parallel the list of procedures that can be performed in an HOPD. Only those procedures that require an overnight stay in a hospital should be excluded. Such a move will allow CMS to conduct quality and cost studies to determine outcomes for patients.

Let's close the gap in payment rates and payment structures so that clinical outcomes can be compared between HOPDs and ASCs. Without a parallel payment structure, it is extremely difficult to analyse specific types of care provided and quality of care issues between HOPDs and ASCs. More unified alignment is the least complicated way of determining quality of care issues.

Thank you for your consideration of my comments.

Submitter : Mr. Stephen Harwell **Date:** 11/06/2006

Organization : Healthcare Association of New York State

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachement

CMS-1506-P2-1040-Attach-1.DOC

#1090

Healthcare Association
of New York State

November 6, 2006

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

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

Dear Ms. Norwalk:

The Healthcare Association of New York State (HANYS), on behalf of our more than 550 hospitals, nursing homes, home health agencies, and other health care providers, welcomes the opportunity to comment on the proposed rule related to the Ambulatory Surgical Center (ASC) Payment System and Calendar Year 2008 Payment Rates. Below are our comments, arranged by topic area.

The Centers for Medicare and Medicaid Services (CMS) is required by statute to specify surgical procedures that are appropriately and safely performed on an ambulatory basis in an ASC. In doing so, CMS must review and update the list of ASC procedures no less often than every two years, in consultation with appropriate trade and professional associations. The current process adds a procedure to the list of those payable under the ASC fee schedule only after it has been individually reviewed and it is determined that the procedure may be safely performed on an ambulatory basis.

CMS proposes to replace the existing review process with a policy that allows payment under the ASC facility fee for any surgical procedure, except those surgical procedures that CMS determines are not payable under the ASC benefit. In effect, this proposal reverses the review framework, eliminating a process that adds specific procedures when it is proved that they may be safely performed in an ASC and substituting a process that includes all procedures and then removes specific procedures when it is proved that they cannot be safely performed in an ASC. **We object to this change and urge CMS to continue the current policy of adding procedures on an individual basis only after it is determined that they can be safely performed on an ambulatory basis in an ASC.**

CMS proposes to exclude those procedures that pose a significant beneficiary safety risk when performed in an ASC and procedures that ordinarily require an overnight stay. However, CMS proposes not to continue applying current time-based prescriptive criteria that exclude from the ASC list procedures that

exceed 90 minutes of operating time or four hours of recovery time or 90 minutes of anesthesia. CMS states that "[w]e believe these criteria are no longer clinically appropriate for purposes of defining a significant safety risk for surgical procedures."

HANYS opposes the proposal to discontinue use of the current time-based prescriptive criteria. CMS has provided no evidence to support its belief that these criteria are no longer clinically appropriate for purposes of defining a significant safety risk. These criteria are indicative of more complex procedures that inherently involve a higher risk of complication and should continue to be applied in CY 2008.

We share the concern expressed by the American Hospital Association (AHA) that the proposed broad expansion of the number and types of services that may be performed in ASCs could jeopardize patient safety and quality of care. The regulations and facility standards to which ASCs are subject fall far short of the requirements hospitals and their outpatient departments must meet with regard to patient safety, patient rights, quality assurance, and operating standards. It also is not clear that either federal or state oversight would be rigorous enough to ensure patient safety if the volume of services and complexity of procedures furnished in ASCs were to increase, as would happen if this rule were finalized.

We join AHA in urging that CMS defer implementing any changes to the current criteria for determining ASC payable procedures until the Medicare conditions of participation for ASCs and/or hospital outpatient departments are revised to ensure comparable patient protections for comparable services in these settings. In addition, ASCs should be required to report quality data to the same extent as hospital outpatient departments before any major expansion of the ASC procedures list.

HANYS appreciates having the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please contact Stephen Harwell, Director, Economic Analyses, at (518) 431-7777 or at sharwell@hanys.org, or me at (518) 431-7704 or at jchang@hanys.org.

Sincerely,

Ju-Ming Chang
Vice President
Economics, Finance, and Information

Submitter : Gary Janko **Date:** 11/06/2006

Organization : Pain Solutions Management Group, LLC

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

Pain Solutions Management Group, LLC
280 Main Street, Suite 330
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October 31, 2006

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

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

Dear Ms. Norwalk:

As a concerned citizen, I am writing to express my alarm at CMS s proposed rule for ambulatory surgery centers payment system. This rule will create significant inequities between hospitals, ASCs, and ultimately will harm beneficiary access. While this may be good for some specialties, it is clear that interventional pain management will suffer substantially - approximately 20% in 2008 and approximately 30% in 2009 and thereafter. At these reduced reimbursement rates, physicians will not be adequately reimbursed for the services they provide to their Medicare patients and consequently, because nearly all major payers follow Medicare, this reduction in ASC reimbursements will affect not only patient access for Medicare patients but all interventional pain management patients.

Every credible health care provider recognizes pain as the fifth vital sign. The CMS proposed rule will have a very negative effect on the 65% to 80% of Americans who will experience chronic pain at some point in their lives. Failing to adequately pay for and provide accessibility to skilled clinicians specializing in pain management will only add to the current estimated $90 billion a year in medical expenses, lost productivity, and legal costs associated with this growing epidemic.

Given the impact this proposed rule would have on interventional pain physicians practicing in ASCs and their ability to provide services to Medicare patients, I ask that CMS reverse the proposal and that a means be established where surgery centers are reimbursed at least at the present rate and will not go below that rate. If no realistic proposal can be achieved at this time, Congress should repeal the previous mandate and leave the system alone as it is now, with inflation adjustments immediately reinstated.

On behalf of all the patients in the United States and especially the elderly, I thank you for your consideration.

Sincerely,

Gary M. Janko
Chief Operating Officer

CMS-1506-P2-1041-Attach-1.DOC

#1041

Pain Solutions Management Group, LLC
280 Main Street, Suite 330
Nashua, NH 03060

October 31, 2006

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

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

Dear Ms. Norwalk:

As a concerned citizen, I am writing to express my alarm at CMS's proposed rule for ambulatory surgery centers payment system. This rule will create significant inequities between hospitals, ASCs, and ultimately will harm beneficiary access. While this may be good for some specialties, it is clear that interventional pain management will suffer substantially - approximately 20% in 2008 and approximately 30% in 2009 and thereafter. At these reduced reimbursement rates, physicians will not be adequately reimbursed for the services they provide to their Medicare patients and consequently, because nearly all major payers follow Medicare, this reduction in ASC reimbursements will affect not only patient access for Medicare patients but all interventional pain management patients.

Every credible health care provider recognizes "pain" as the fifth vital sign. The CMS proposed rule will have a very negative effect on the 65% to 80% of Americans who will experience chronic pain at some point in their lives. Failing to adequately pay for and provide accessibility to skilled clinicians specializing in pain management will only add to the current estimated $90 billion a year in medical expenses, lost productivity, and legal costs associated with this growing epidemic.

Given the impact this proposed rule would have on interventional pain physicians practicing in ASCs and their ability to provide services to Medicare patients, I ask that CMS reverse the proposal and that a means be established where surgery centers are reimbursed at least at the present rate and will not go below that rate. If no realistic proposal can be achieved at this time, Congress should repeal the previous mandate and leave the system alone as it is now, with inflation adjustments immediately reinstated.

On behalf of all the patients in the United States and especially the elderly, I thank you for your consideration.

Sincerely,

Gary M. Janko
Chief Operating Officer

Submitter : Dr. Vladimir Fiks **Date:** 11/06/2006

Organization : Advanced Pain Management Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

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

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

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

Submitter : **Dr. Omar Benitez** **Date: 11/06/2006**

Organization : **Southwest Florida Urologic Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

CMS-1506-P2-1043-Attach-1.DOC

#1043

November 6, 2006

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

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

Dear Ms. Norwalk:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed rule for reforming the Ambulatory Surgical Center (ASC) Payment System. The AUA understands that this reform proposal, as mandated by the 2003 Medicare Modernization Act (MMA) has been a huge undertaking for CMS and appreciates the time and effort CMS has put into development of the proposal. We also appreciate CMS holding a listening session teleconference in August 2005 and for meeting with the AUA and other groups that are interested in ASC payment reform over the past couple of years.

We understand that the MMA places certain limitations, the major one being a budget-neutrality requirement, on CMS's discretion in developing an ASC payment reform proposal. However, CMS does have a certain degree of discretion in how it implements the MMA, and we hope that CMS we consider suggestions that would improve the reform proposal to the extent that the suggestions are within CMS's discretion to implement them.

ASC PAYABLE PROCEDURES

Under the proposal, Medicare would allow payment of an ASC facility fee for any surgical procedure performed in an ASC, except those that CMS determines are not payable under the ASC benefit based on the principal clinical considerations of beneficiary safety and the need for an overnight stay. CMS also proposes to discontinue the current time-based criteria of procedures that exceed 90 minutes of operating time, 4 hours of recovery time or 90 minutes of anesthesia. The AUA applauds CMS for proposing these changes to the ASC list as they are a big improvement over some of the current outdated rules that govern the ASC list. We also offer the following comments regarding the specific criteria for defining a significant safety risk and the need for an overnight stay.

Procedures that could pose a significant safety risk

CMS proposes to define procedures that could pose a significant safety risk as:

- any procedure included on the OPPS inpatient-only list
- procedures performed 80 percent or more of the time in the hospital inpatient setting
- procedures that involve major blood vessels; prolonged or extensive invasion of body cavities; extensive blood loss or are emergent or life-threatening in nature

The AUA disagrees with the criteria of procedures performed 80 percent or more of the time in the hospital inpatient setting, and urges CMS to delete this as one of the criteria for procedures that could pose a significant safety risk. We feel that the 80 percent cut-off is arbitrary and we are concerned that this criterion could artificially restrict the natural movement of procedures among sites of service that technological developments may allow for. Also, because the determination of whether procedures meet the 80 percent cut-off would be based on Medicare site-of-service data, a lag in data collection could also artificially restrict the movement of procedures into the less-expensive ASC setting. Furthermore, use of Medicare data does not allow consideration of site-of-service trends in non-Medicare populations.

Overnight stay:
CMS is also proposing to exclude from payment any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. The AUA opposes this blanket criterion for excluding procedures from the ASC list, as many ASCs have the capability to deal with these types of situations and physicians would not choose to do procedures in an ASC if they felt there was a possibility of having to admit the patient to the hospital. Physicians make these decisions using their clinical judgment based on the patient's anesthesia risk as determined by the patients' score based on the American Society of Anesthesiologist's Physical Status Classification System.

Proposed definition of surgical procedures
CMS proposes to define surgical procedures as any procedure within the CPT code range of 10000 to 69999, but seeks comments on whether all services contained in this range are appropriately defined as surgery. For example, CMS asks whether office-based procedures or procedures that require relatively inexpensive resources to perform should be excluded from the ASC list. The ability of a physician to select the most appropriate site of service for their patients based on clinical considerations is extremely important. Therefore, the AUA agrees that any procedure within the "Surgery" section of CPT should continue to be defined as a surgical procedure eligible for payment under the revised ASC payment system, regardless of whether it is office-based or requires relatively inexpensive resources to perform.

We also note, however, that modern surgical techniques also include a number of radiology procedures that are invasive in nature and that are integral to the performance of other surgical procedures. Examples include stone removal, balloon dilation of strictures and prostate biopsies. To allow for the efficient performance of these procedures in ASCs, we believe the revised ASC payment system's definition of surgical procedure should be expanded to include invasive radiology procedures that require the insertion of a needle, catheter, tube or probe through the skin or into a body orifice and intraoperative radiology procedures that are integral to the

performance of a non-radiological surgical procedure and performed during the non-radiological surgical procedure or immediately following the surgical procedure to confirm placement of an item, such as ultrasound used to provide guidance for biopsies and major surgical procedures or to determine, during surgery, whether surgery is being conducted successfully. The physician self-referral regulations also carve out these invasive and intraoperative radiology services from the definition of "radiology" services subject to the law's self-referral prohibition. This Stark law exclusion is based "on the theory that the radiology services in these procedures are merely incidental or secondary to another procedure that the physician has ordered" and, thus, are less subject to abuse from overutilization. 63 Fed. Reg. 1645, 1676 (Jan. 9, 1998).

HCPCS and category III CPT codes
CMS also proposes to include within the scope of surgical procedures payable in an ASC certain HCPCS codes or CPT category III codes which directly crosswalk to or are clinically similar to procedures in the CPT surgical range. The AUA supports this proposal, as such codes are eligible for payment under the OPPS, thus should also be eligible for payment under the new ASC payment system. Examples for urology include 0135 T, *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy* and 0137T, *Biopsy, prostate, needle, saturation sampling for prostate mapping.*

Broaden representation on HCPCS panel
The AUA also urges CMS to broaden the representation on the HCPCS panel to include representatives who are familiar with the outpatient and ASC payment systems.

ASC UNLISTED PROCEDURES
CMS proposes to exclude unlisted procedure codes from the ASC list because of potential safety concerns in not knowing what the procedure involved and also to not make separate payment in an ASC for CPT codes in the surgical range that are packaged under the Outpatient Prospective Payment System (OPPS) (status indicator of N) for the following reasons:

- CMS would not be able to establish an ASC payment rate for packaged surgical procedures using the same method proposed for all other ASC procedures because packaged surgical codes have no relative payment weights under OPPS upon which to base an ASC payment.
- CMS wants an ASC system that is as similar to OPPS as possible
- ASCs would receive payment for these surgical procedures because their costs are already packaged into the APC relative payment weights for associated separately payable procedures

The AUA agrees that it is appropriate to exclude from the ASC list unlisted procedures as well as procedures that are packaged under the OPPS.

For urology, these codes are:

CPT/ HCPCS	Description	SI
50394	Injection for kidney x-ray	N

50684	Injection for ureter x-ray	N
50690	Injection for ureter x-ray	N
51600	Injection for bladder x-ray	N
51605	Preparation for bladder xray	N
51610	Injection for bladder x-ray	N
54230	Prepare penis study	N
55300	Prepare, sperm duct x-ray	N

ASC RATESETTING

CMS proposes to base ASC relative payment weights on Ambulatory Payment Classification (APC) groups and relative payment weights established under the OPPS based on the belief that the relative payment weights established under the OPPS for procedures performed in the outpatient hospital setting reasonably reflect the relative resources required for such procedures and do so with sufficient coherence to be applicable to other ambulatory sites of service. The AUA agrees that the OPPS APC groups are appropriate for use in the ASC payment system and that tying ASC payments to OPPS payments will create transparency and continuity across the continuum of ambulatory settings.

ASC PACKAGING

Proposed packaging policy
Under the current ASC payment system, CMS packages into a single facility fee the payment for a bundle of direct and indirect costs incurred by the facility to perform the procedure, including use of the facility, including an operating suite or procedure room and recovery room; nursing, technician and related services; administrative, recordkeeping and housekeeping items and services; medical and surgical supplies and equipment; surgical dressings; and anesthesia materials.

Currently, CMS determines payment for other items and services, including drugs, biologicals, contrast agents, implantable devices and diagnostic services such as imaging, differently in ASC and OPPS payment systems. CMS is proposing to continue the current policy of packaging into the ASC facility fee payment all direct and indirect costs incurred by the facility to perform a surgical procedure. This would include payment for all drugs, biologicals, contrast agents, anesthesia materials and imaging services, as well as the other items and services that are currently packaged into the ASC facility fee.

Separate payment for implantable prosthetic devices and DME
CMS proposes to continue to exclude from payment as part of the ASC facility fee items and services for which payment is made under other Part B fee schedules, with the exception of implantable prosthetic devices and implantable DME. CMS is proposing to cease making separate payment for implantable prosthetic devices and implantable DME inserted surgically at an ASC and instead to package them into the ASC facility fee payment. **The AUA strongly disagrees with CMS's proposal to package into the ASC facility fee payment the cost of**

implantable prosthetic devices and implantable DME inserted surgically at an ASC. The proposed conversion factor and phase-in would only exacerbate this problem.

ASC PAYMENT FOR OFFICE-BASED PROCEDURES

Proposed payment for office-based procedures

According to the proposed rule, CMS generally interprets office-based to mean a surgical procedure that the most recent Medicare Part B Extract Summary System (BESS) data available indicate is performed more than 50 percent of the time in the physician's office setting (even if the code lacks a nonfacility practice expense relative value unit under the Medicare physician fee schedule). According to CMS, an influx of high-volume, relatively low cost office-based procedures into the ASC setting under the revised payment system could lower the payment amounts for other procedures paid for in the ASC due to the statutory budget neutrality requirement, and CMS would have to scale down the ASC conversion factor to meet budget neutrality requirements.

Therefore, CMS proposes to cap payment for office-based surgical procedures for which an ASC facility fee would be allowed under the new payment system at: the lesser of the Medicare physician fee schedule nonfacility practice expense payment or the ASC rate under the revised ASC payment system. CMS also proposes to exempt procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, from the payment limitation proposed for office-based procedures.

While the AUA appreciates CMS's concerns about potential migration of office-based procedures to the ASC setting, we disagree with the proposal to cap payment for office-based procedures to address this concern. For patients that require the extra resources or greater surgical capacity available in an ASC setting, a physician should be able to make the decision to perform these procedures in an ASC based on clinical considerations and should be reimbursed at a rate that accounts for the increased costs and complexities associated with performing procedures in an ASC setting.

If CMS adds office-based procedures to the ASC list, they are effectively indicating that Medicare beneficiaries should have the option of having these procedures performed in an ASC and CMS should therefore provide reasonable reimbursement for these procedures. Otherwise, ASCs will be effectively prohibited from performing these procedures because they will not be able to recoup their costs, and beneficiaries will not have the ASC as a viable site-of-service option. If the ASC is not an option for such patients, these procedures will then likely be performed in the hospital outpatient setting, resulting in higher costs to both beneficiaries and the Medicare program.

Usually, office-based procedures do not require the extra capacity of an ASC. However, the option should be available to physicians if they find it necessary for clinical reasons. For example, sometimes patients refuse to have a procedure performed unless they can be anesthetized. Also, urologists may choose to perform prostate biopsies on older patients or patients who require anesthesia in an ASC. Based on our analysis of Medicare data in the past

for urology office-based codes that have been on the ASC list for quite some time, CMS's migration assumptions are not realistic. (52000, 52281 and 55700).

The AUA strongly supports CMS's proposal to exempt from the office-based payment limitation procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, as there is no reason to assume these procedures would migrate further into an ASC setting. In fact, Medicare data shows that despite an increase in the number of ASCs in recent years, CPT codes 52000, 52281 and 55700 are performed no more in an ASC today than they were in 1997. These procedures have consistently been furnished in hospital or ASC settings in 25 to 28 percent of cases between 1997 and 2003. These patients will almost certainly be treated in a hospital environment if the ASC is no longer a financially viable option.

Payment policy for multiple procedure discounting

The AUA strongly supports CMS's proposal to mirror the OPPS policy for discounting when a beneficiary has more than one surgical procedures performed on the same day at an ASC. Under OPPS, procedures performed to implant costly devices are not subject to the discounting policy. For urology, the procedures to which this applies (listed below) involve expensive implantable devices, and physicians will not be able to perform these procedures in an ASC if the cost of these devices are not covered.

53440	Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)
53444	Insertion of tandem cuff (dual cuff)
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

ASC INFLATION

Proposed adjustment for inflation

Although the MMA froze ASC inflation updates until 2010, the current updates are based on the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. However, the OPPS is updated annually using the hospital inpatient market basket

percentage increase. Because CMS states multiple times in the proposed rule that they desire for the revised ASC payment system to reflect the OPPS as closely as possible, and because MMA does not mandate that any particular update system be used for the ASC payment system, the AUA urges CMS to use the same update method for both payment systems, which would achieve parity and transparency in the market and assure that site-of-service determinations are made based on clinical indications rather than economic considerations.

ASC PHASE IN

Proposal to phase in implementation of payment rates

CMS proposes to implement the revised ASC payment system in 2008 using transitional payment rates that would be based on a 50/50 blend of the payment rate for procedures on the 2007 list of approved ASC procedures and the payment rate for that procedure calculated under the revised payment methodology. Procedures added in 2008 would be paid the full amount calculated under the revised methodology, and new rates would be fully implemented in 2009. The AUA supports a two-year phase in for the new ASC payment rates.

ASC CONVERSION FACTOR

Based on CMS's proposed methodology for calculating the ASC payment system conversion factor, it would equate to 62 percent of the OPPS conversion factor, or $39.688. Although we understand that CMS must implement ASC payment reform in a budget-neutral fashion as required by Congress, it is completely unreasonable to assume that the cost of furnishing any given procedure in an ASC is only 62 percent of the cost of furnishing the same procedure in a hospital outpatient department. We urge CMS to use its discretion to institute changes in the methodology in order to reach a more reasonable and credible conversion factor.

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross, M.D.
President

Submitter : Mr. Daniel Winkler **Date:** 11/06/2006

Organization : HCA Ambulatory Surgery Division

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1044-Attach-1.DOC

#1044

HCA Ambulatory Surgery Division

RE: CMS Proposed Rule Remarks

CMS Proposed Rule: Revised Payment System for Ambulatory Surgery Centers for Implementation January 1, 2008

Background

As a result of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Congress mandated a revised payment system for Ambulatory Surgery Centers (ASC) to be implemented no later than January 1, 2008.

Current Situation

The proposed rule, as published by The Centers for Medicare and Medicaid Services (CMS)[1], includes the following proposed changes to the ASC payment system:

I. Expand the current list of procedures that are eligible for payment in an ASC facility.

- Allow payment for any surgical procedure (CPT Codes 10000-69999) except those that require an overnight stay or could pose a safety risk to Medicare beneficiaries (extensive blood loss, procedures involving a major blood vessel, etc.).
- Allow payment for surgical procedures that are commonly and safely performed in a physician office setting more than 50% of the time. Payment for these procedures would be limited to the non-facility Medicare Physician Fee Schedule.

II. Change the ASC facility payment methodology and the payment rates.

- Base the new payment system on the Hospital Outpatient Prospective Payment System (HOPPS).
- Move from a limited fee schedule based on 9 groups to a payment system incorporating relative payment weights and Ambulatory Payment Classification (APC) groups which are key elements of the hospital outpatient payment system.
- The MMA imposed a budget neutrality condition on the new system. This requires that expenditures in the new payment system result in the same aggregate expenditure that would be made if the revised system was not implemented.
- Payments in the ASC setting would be 38% lower than payments in the hospital outpatient setting for the same procedure. This reduction is necessary to meet the budget neutrality requirement.
- Payment rates for ASCs will change from a range of $331-$1,399 to a range of $4-$16,146.
- Discontinue separate payment for surgically implanted devices. These will be packaged into the payment rate as they are under the hospital outpatient payment methodology.
- A 2-year transition is proposed. In 2008 the payment would be a 50/50 blend of the current ASC payment methodology and the revised payment methodology. Starting in 2009, ASC payment would be based entirely on the new payment methodology.
- Beneficiaries will continue to have a 20% co-insurance.
- Beginning CY2010, the ASC conversion factor would be updated annually for inflation.

---

[1] CMS-1506-P: Medicare Program: Proposed Changes to the Hospital Outpatient PPS and CY2007 Rates; Proposed CY2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY2008 Payment Rates, Federal Register, Volume 71, Number 163, August 23, 2006.

Comments regarding the proposed rule:

1) It is inaccurate to assume that ASC costs are on average 38% less than that of hospital outpatient departments, especially in the case of high cost implantable devices. ASC cost for an implant is identical to that of a hospital outpatient department for the same device as are the ASC costs for all supplies and medications used for any given surgical procedure.
2) One of the most important shortcomings in the hospital outpatient payment methodology is the known phenomenon of charge compression. It underestimates the cost of more expensive items such as medical devices, and high cost supplies, resulting in payment rates that do not reflect true costs. CMS should remedy this issue by applying a decompression factor or other methodology rather than allowing inaccurate rates to be carried over to the revised ASC payment system.
3) The proposed transition payments appear to include errors in the calculations for implantable devices for which separate payment has historically been made. Device costs appear to have been inadvertently omitted from the calculation.
4) The proposed payment methodology will inappropriately impact site of service decisions. These decisions should be based on clinical considerations. Payment accuracy should be included as a goal of any new payment system to avoid site of service decisions based on financial factors rather than clinical appropriateness. However, setting rates so low at 62% of HOPD, CMS would force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government.
5) These payment issues will impede the transition of procedures associated with devices or other technologies to the ASC setting when appropriate and will limit beneficiary access to needed procedures because ASCs will not receive adequate payment to cover their costs.
6) ASC's should receive the same annual price updates as hospitals. Staffing costs, medical device costs, pharmaceautical costs, etc. affect ASC's the same way as hospitals. ASC's have not had a rate increase since 2003, already making it extremely difficult to be competitive for labor or to cover the increasing cost of supplies and medications.
7) The transition time of 2 years for implementation is not sufficient for ASC's as they are small businesses with most having 20 or fewer full-time employees. Certain types of ASC's (GI centers and ophthalmology centers) will be disproportionately impacted by the new payment rates, which make it imperative to phase in the new system over several years.
8) When determining what procedures get reimbursed in an ASC, CMS should eliminate the use of specific ASC list criteria and use only safety and the lack of need for an overnight stay as the criteria to determine what is reimbursable in an ASC setting.
9) Not allowing procedures that are performed more than 80% of the time on an inpatient basis does not make sense since CMS is already reimbursing those procedures 20% of the time on an outpatient basis. These criteria will also quickly become outdated as technology improves and medical advances occur. This will prevent CMS from gaining cost savings as many of these procedures could transfer to the less expensive ASC environment.

Thank you in advance for consideration of these comments. We do not want to limit the ASC's role in meeting the surgical needs of CMS beneficiaries going forward.

Sincerely,

Daniel C. Winkler, MBA
VP of Operations, Tennessee/Louisiana Markets
HCA Ambulatory Surgery Division

Submitter : **Dr. Melanie Firmin** **Date: 11/06/2006**

Organization : **Firmin Pain Consultants**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

As a practicing interventional pain physician, I am having difficulty locating facilities eager to accept my medicare patients. The hospitals haven't been interested for a few years now because I am told that the reimbursement is so low. Now, I understand that the ASC rates are to be a fraction of the HOPD rates. As ASC reimbursement decreases, I will have less available time to work in the ASC as my time is redistributed to better reimbursed specialities such as orthopedics.

My practice includes elderly patients that have no other alternatives offered to them and wish to function independently as long as possible. If you wish to limit the number of pain procedures performed on medicare patients, limit that performance to physicians who have demonstrated skills and education in interventional pain procedures. A substantial number of these procedures are being performed by non-pain physicians and CRNAs with no formal pain medicine education or demonstration of qualifications.

Please allow quality venues for my patients to receive care.

Thank you,

Melanie Firmin, M.D.

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

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

ASC List Reform

Submitter : Dr. Michael G. Strickland **Date:** 11/06/2006

Organization : Southwest Florida Urologic Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

CMS-1506-P2-1047-Attach-1.DOC

#1067

November 6, 2006

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

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

Dear Ms. Norwalk:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed rule for reforming the Ambulatory Surgical Center (ASC) Payment System. The AUA understands that this reform proposal, as mandated by the 2003 Medicare Modernization Act (MMA) has been a huge undertaking for CMS and appreciates the time and effort CMS has put into development of the proposal. We also appreciate CMS holding a listening session teleconference in August 2005 and for meeting with the AUA and other groups that are interested in ASC payment reform over the past couple of years.

We understand that the MMA places certain limitations, the major one being a budget-neutrality requirement, on CMS's discretion in developing an ASC payment reform proposal. However, CMS does have a certain degree of discretion in how it implements the MMA, and we hope that CMS we consider suggestions that would improve the reform proposal to the extent that the suggestions are within CMS's discretion to implement them.

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Overnight stay:
CMS is also proposing to exclude from payment any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. The AUA opposes this blanket criterion for excluding procedures from the ASC list, as many ASCs have the capability to deal with these types of situations and physicians would not choose to do procedures in an ASC if they felt there was a possibility of having to admit the patient to the hospital. Physicians make these decisions using their clinical judgment based on the patient's anesthesia risk as determined by the patients' score based on the American Society of Anesthesiologist's Physical Status Classification System.

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We also note, however, that modern surgical techniques also include a number of radiology procedures that are invasive in nature and that are integral to the performance of other surgical procedures. Examples include stone removal, balloon dilation of strictures and prostate biopsies. To allow for the efficient performance of these procedures in ASCs, we believe the revised ASC payment system's definition of surgical procedure should be expanded to include invasive radiology procedures that require the insertion of a needle, catheter, tube or probe through the skin or into a body orifice and intraoperative radiology procedures that are integral to the

performance of a non-radiological surgical procedure and performed during the non-radiological surgical procedure or immediately following the surgical procedure to confirm placement of an item, such as ultrasound used to provide guidance for biopsies and major surgical procedures or to determine, during surgery, whether surgery is being conducted successfully. The physician self-referral regulations also carve out these invasive and intraoperative radiology services from the definition of "radiology" services subject to the law's self-referral prohibition. This Stark law exclusion is based "on the theory that the radiology services in these procedures are merely incidental or secondary to another procedure that the physician has ordered" and, thus, are less subject to abuse from overutilization. 63 Fed. Reg. 1645, 1676 (Jan. 9, 1998).

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Broaden representation on HCPCS panel
The AUA also urges CMS to broaden the representation on the HCPCS panel to include representatives who are familiar with the outpatient and ASC payment systems.

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- CMS wants an ASC system that is as similar to OPPS as possible
- ASCs would receive payment for these surgical procedures because their costs are already packaged into the APC relative payment weights for associated separately payable procedures

The AUA agrees that it is appropriate to exclude from the ASC list unlisted procedures as well as procedures that are packaged under the OPPS.

For urology, these codes are:

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ASC RATESETTING

CMS proposes to base ASC relative payment weights on Ambulatory Payment Classification (APC) groups and relative payment weights established under the OPPS based on the belief that the relative payment weights established under the OPPS for procedures performed in the outpatient hospital setting reasonably reflect the relative resources required for such procedures and do so with sufficient coherence to be applicable to other ambulatory sites of service. The AUA agrees that the OPPS APC groups are appropriate for use in the ASC payment system and that tying ASC payments to OPPS payments will create transparency and continuity across the continuum of ambulatory settings.

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Proposed packaging policy
Under the current ASC payment system, CMS packages into a single facility fee the payment for a bundle of direct and indirect costs incurred by the facility to perform the procedure, including use of the facility, including an operating suite or procedure room and recovery room; nursing, technician and related services; administrative, recordkeeping and housekeeping items and services; medical and surgical supplies and equipment; surgical dressings; and anesthesia materials.

Currently, CMS determines payment for other items and services, including drugs, biologicals, contrast agents, implantable devices and diagnostic services such as imaging, differently in ASC and OPPS payment systems. CMS is proposing to continue the current policy of packaging into the ASC facility fee payment all direct and indirect costs incurred by the facility to perform a surgical procedure. This would include payment for all drugs, biologicals, contrast agents, anesthesia materials and imaging services, as well as the other items and services that are currently packaged into the ASC facility fee.

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CMS proposes to continue to exclude from payment as part of the ASC facility fee items and services for which payment is made under other Part B fee schedules, with the exception of implantable prosthetic devices and implantable DME. CMS is proposing to cease making separate payment for implantable prosthetic devices and implantable DME inserted surgically at an ASC and instead to package them into the ASC facility fee payment. **The AUA strongly disagrees with CMS's proposal to package into the ASC facility fee payment the cost of**

implantable prosthetic devices and implantable DME inserted surgically at an ASC. The proposed conversion factor and phase-in would only exacerbate this problem.

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Proposed payment for office-based procedures

According to the proposed rule, CMS generally interprets office-based to mean a surgical procedure that the most recent Medicare Part B Extract Summary System (BESS) data available indicate is performed more than 50 percent of the time in the physician's office setting (even if the code lacks a nonfacility practice expense relative value unit under the Medicare physician fee schedule). According to CMS, an influx of high-volume, relatively low cost office-based procedures into the ASC setting under the revised payment system could lower the payment amounts for other procedures paid for in the ASC due to the statutory budget neutrality requirement, and CMS would have to scale down the ASC conversion factor to meet budget neutrality requirements.

Therefore, CMS proposes to cap payment for office-based surgical procedures for which an ASC facility fee would be allowed under the new payment system at: the lesser of the Medicare physician fee schedule nonfacility practice expense payment or the ASC rate under the revised ASC payment system. CMS also proposes to exempt procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, from the payment limitation proposed for office-based procedures.

While the AUA appreciates CMS's concerns about potential migration of office-based procedures to the ASC setting, we disagree with the proposal to cap payment for office-based procedures to address this concern. For patients that require the extra resources or greater surgical capacity available in an ASC setting, a physician should be able to make the decision to perform these procedures in an ASC based on clinical considerations and should be reimbursed at a rate that accounts for the increased costs and complexities associated with performing procedures in an ASC setting.

If CMS adds office-based procedures to the ASC list, they are effectively indicating that Medicare beneficiaries should have the option of having these procedures performed in an ASC and CMS should therefore provide reasonable reimbursement for these procedures. Otherwise, ASCs will be effectively prohibited from performing these procedures because they will not be able to recoup their costs, and beneficiaries will not have the ASC as a viable site-of-service option. If the ASC is not an option for such patients, these procedures will then likely be performed in the hospital outpatient setting, resulting in higher costs to both beneficiaries and the Medicare program.

Usually, office-based procedures do not require the extra capacity of an ASC. However, the option should be available to physicians if they find it necessary for clinical reasons. For example, sometimes patients refuse to have a procedure performed unless they can be anesthetized. Also, urologists may choose to perform prostate biopsies on older patients or patients who require anesthesia in an ASC. Based on our analysis of Medicare data in the past

for urology office-based codes that have been on the ASC list for quite some time, CMS's migration assumptions are not realistic. (52000, 52281 and 55700).

The AUA strongly supports CMS's proposal to exempt from the office-based payment limitation procedures that are on the ASC list as of January 1, 2007 that meet the criterion for designation as office-based, as there is no reason to assume these procedures would migrate further into an ASC setting. In fact, Medicare data shows that despite an increase in the number of ASCs in recent years, CPT codes 52000, 52281 and 55700 are performed no more in an ASC today than they were in 1997. These procedures have consistently been furnished in hospital or ASC settings in 25 to 28 percent of cases between 1997 and 2003. These patients will almost certainly be treated in a hospital environment if the ASC is no longer a financially viable option.

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The AUA strongly supports CMS's proposal to mirror the OPPS policy for discounting when a beneficiary has more than one surgical procedures performed on the same day at an ASC. Under OPPS, procedures performed to implant costly devices are not subject to the discounting policy. For urology, the procedures to which this applies (listed below) involve expensive implantable devices, and physicians will not be able to perform these procedures in an ASC if the cost of these devices are not covered.

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53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
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54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

ASC INFLATION

Proposed adjustment for inflation
Although the MMA froze ASC inflation updates until 2010, the current updates are based on the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. However, the OPPS is updated annually using the hospital inpatient market basket

percentage increase. Because CMS states multiple times in the proposed rule that they desire for the revised ASC payment system to reflect the OPPS as closely as possible, and because MMA does not mandate that any particular update system be used for the ASC payment system, the AUA urges CMS to use the same update method for both payment systems, which would achieve parity and transparency in the market and assure that site-of-service determinations are made based on clinical indications rather than economic considerations.

ASC PHASE IN

Proposal to phase in implementation of payment rates

CMS proposes to implement the revised ASC payment system in 2008 using transitional payment rates that would be based on a 50/50 blend of the payment rate for procedures on the 2007 list of approved ASC procedures and the payment rate for that procedure calculated under the revised payment methodology. Procedures added in 2008 would be paid the full amount calculated under the revised methodology, and new rates would be fully implemented in 2009. The AUA supports a two-year phase in for the new ASC payment rates.

ASC CONVERSION FACTOR

Based on CMS's proposed methodology for calculating the ASC payment system conversion factor, it would equate to 62 percent of the OPPS conversion factor, or $39.688. Although we understand that CMS must implement ASC payment reform in a budget-neutral fashion as required by Congress, it is completely unreasonable to assume that the cost of furnishing any given procedure in an ASC is only 62 percent of the cost of furnishing the same procedure in a hospital outpatient department. We urge CMS to use its discretion to institute changes in the methodology in order to reach a more reasonable and credible conversion factor.

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross, M.D.
President

Submitter : Mr. Kent Thiry **Date:** 11/06/2006

Organization : Kidney Care Partner

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1048-Attach-1.DOC

#1018

KIDNEY CARE
PARTNERS

November 6, 2006

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

Re: **CMS-1506-P2** Medicare Program: The Ambulatory Surgical Center Payment System and CY 2008 Payment Rates)

Dear Administrator Norwalk,

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the proposed revised ASC payment system and the related regulatory changes described in the Proposed Rule for Hospital Outpatient Prospective Payment System (Proposed Rule).[1] KCP is an alliance of members of the kidney care community, including renal patient advocates, dialysis care professionals, providers, and suppliers who work together to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2]

We are pleased that in the Final Rule for the Hospital Outpatient Prospective Payment System (HOPPS) released on November 1 CMS recognizes the importance of expanding the types of procedures performed in the ambulatory surgical center (ASC) setting to include those related to the maintenance of fistula and graft maintenance. Given the importance of allowing these procedures to be performed in the ASC setting, we encourage CMS to ensure that for CY 2008 and beyond the payment structure allows for the performance of vascular access-related procedures in the ASC setting.

[1] 71 *Fed. Reg.* 49506 (August 23, 2006).

[2] A list of Kidney Care Partner coalition members is included in Attachment A.

I. Dialysis Background: Why vascular access maintenance is important.

Most patients with kidney failure typically receive hemodialysis to replace the blood cleaning functions of their diseased kidneys three-to-four times each week. Each dialysis session lasts for three-to-four hours, depending upon each patient's needs. Through the End Stage Renal Disease (ESRD) program, Medicare covers about 93 percent of the cost of the dialysis patients either as a primary or secondary payer.[3]

The blood cleaning process of dialysis requires an "access" to the patient's bloodstream to carry blood from the patient's body, through the artificial kidney (or dialyzer), and then back to the patient. There are three types of access – arteriovenous (AV) fistulas, synthetic grafts, and catheters. The clinically superior and, therefore, most desirable access for most patients is the AV fistula, which requires the surgical joining of a vein and an artery. The resultant flow of blood from the high pressure in the artery to the lower pressure in the vein, causes expansions along the vein that support the dialysis process. In most cases, the AV fistula is created in a patient's forearm. As CMS recognizes through the Fistula First ESRD quality initiative,[4] AV fistulas are the "gold standard" for establishing access for dialysis. Because fistulas involve the patient's native blood vessels, they last longer and require fewer repairs. This is related to the fact that fistulas have the body's normal defense against infection and normal clotting mechanisms. Therefore, patients with fistulas are less likely to develop either infections that lead to hospitalization or death or clots that require interventional procedures to declotting.

Each type of vascular access requires maintenance to ensure the continued flow of blood to enable the dialysis process. For example, angioplasty allows physicians to "open" a narrowed fistula or graft by cannulating the access at the point of the stenosis. After cannulation, an initial angiogram is performed. Next, a guidewire is inserted. The angioplasty balloon is inserted and dilatation is affected using a syringe. A recent study found that interventional nephrologists performed this procedure with a 96.58 percent success rate with a median procedure time of 33 minutes.[5] Given current technology, this and similar maintenance procedures can safely be performed with minimal blood loss and few complications.

II. CMS should ensure for CY 2008 and beyond that the payment structure allows for the performance of vascular access-related procedures to be performed in the ASC setting.

Given this critical relationship between the access to the bloodstream and the ability to keep patients alive through hemodialysis, these procedures are of great importance to the KCP member

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[3]MedPAC, "Report to the Congress" 109 (March 2006).

[4]See www.cms.hhs.gov/ESRDQualityImprovementInit/04_FistulaFirstBreakthrough.asp#TopOfPage).

[5]Gerald A. Beathard, Terry Litchfeld, & Physician Operations Forum of RMS Lifeline, Inc., "Effectiveness and Safety of Dialysis Vascular Access Procedures Performed by Interventional Nephrologists" 66 *Kidney International* 1622-32 (2004).

organizations. As we noted in our letter submitted on October 10, 2006, commenting on the CY 2007 procedure list, allowing these procedures to be performed in the ASC setting will provide greater convenience for patients and reduce costs for the Medicare program.

CMS should ensure that the vascular access procedures incorporated into the CY 2007 procedures list may also be performed in the ASC setting in CY 2008 and beyond. As CMS shifts toward the MedPAC recommendation of allowing payments to ASCs for any surgical procedure,[6] except those that are explicitly excluded, we urge the Agency to allow the vascular access-related codes to be reimbursed as well. Specifically, we reiterate our comment to include CPT codes 37205 and 37206 within the ASC setting. In reviewing the FY 2008 ASC payment system, we encourage CMS to reconsider incorporating these codes into the new payment system. There is strong evidence of their safety and efficacy. We also encourage CMS to recognize stent procedures performed for hemodialysis vascular access care in the ASC setting.

In addition, the reimbursement rates established for the vascular access procedures under the new payment system for 2008 is also of critical importance. To the extent that the rates for vascular access procedures are reduced, that would likely result in more procedures being done in the more extensive hospital setting, increasing the amount of money paid by both Medicare beneficiaries and the government. We also support lengthening the transition period to provide sufficient time to adjust to the proposed changes. Therefore, we encourage CMS to ensure that once shifted to the ASC setting that these procedures are reimbursed appropriately. We would welcome the opportunity to work with the Agency as it develops the appropriate rates for these procedures.

III. Conclusion

KCP supports the Agency's efforts to reimburse appropriate vascular access procedures to be performed in the ASC setting. Not only will this allow patients with better access to these maintenance procedures, but it will also result in important savings for the Medicare program. We appreciate the opportunity to work with CMS on this issue welcome the opportunity to discuss these procedures with you in detail. Please do not hesitate to contact Kathy Lester at (202) 457-6562 if you have comments or questions.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

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[6] 71 *Fed. Reg.* at 49636.

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

Submitter : Dr. Veronique Fernandez-Salvador **Date:** 11/06/2006

Organization : Southwest Florida Urologic Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I have reviewed the comments submitted by the AUA with regard to CMS-1506-P and I concur with them in their entirety. Your consideration of these comments will be greatly appreciated. See Attachment.

CMS-1506-P2-1049-Attach-1.DOC

1049

November 6, 2006

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

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

Dear Ms. Norwalk:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the Centers for Medicare & Medicaid Service's (CMS) proposed rule for reforming the Ambulatory Surgical Center (ASC) Payment System. The AUA understands that this reform proposal, as mandated by the 2003 Medicare Modernization Act (MMA) has been a huge undertaking for CMS and appreciates the time and effort CMS has put into development of the proposal. We also appreciate CMS holding a listening session teleconference in August 2005 and for meeting with the AUA and other groups that are interested in ASC payment reform over the past couple of years.

We understand that the MMA places certain limitations, the major one being a budget-neutrality requirement, on CMS's discretion in developing an ASC payment reform proposal. However, CMS does have a certain degree of discretion in how it implements the MMA, and we hope that CMS we consider suggestions that would improve the reform proposal to the extent that the suggestions are within CMS's discretion to implement them.

ASC PAYABLE PROCEDURES

Under the proposal, Medicare would allow payment of an ASC facility fee for any surgical procedure performed in an ASC, except those that CMS determines are not payable under the ASC benefit based on the principal clinical considerations of beneficiary safety and the need for an overnight stay. CMS also proposes to discontinue the current time-based criteria of procedures that exceed 90 minutes of operating time, 4 hours of recovery time or 90 minutes of anesthesia. The AUA applauds CMS for proposing these changes to the ASC list as they are a big improvement over some of the current outdated rules that govern the ASC list. We also offer the following comments regarding the specific criteria for defining a significant safety risk and the need for an overnight stay.

Procedures that could pose a significant safety risk

CMS proposes to define procedures that could pose a significant safety risk as:

- any procedure included on the OPPS inpatient-only list
- procedures performed 80 percent or more of the time in the hospital inpatient setting
- procedures that involve major blood vessels; prolonged or extensive invasion of body cavities; extensive blood loss or are emergent or life-threatening in nature

The AUA disagrees with the criteria of procedures performed 80 percent or more of the time in the hospital inpatient setting, and urges CMS to delete this as one of the criteria for procedures that could pose a significant safety risk. We feel that the 80 percent cut-off is arbitrary and we are concerned that this criterion could artificially restrict the natural movement of procedures among sites of service that technological developments may allow for. Also, because the determination of whether procedures meet the 80 percent cut-off would be based on Medicare site-of-service data, a lag in data collection could also artificially restrict the movement of procedures into the less-expensive ASC setting. Furthermore, use of Medicare data does not allow consideration of site-of-service trends in non-Medicare populations.

Overnight stay:
CMS is also proposing to exclude from payment any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. The AUA opposes this blanket criterion for excluding procedures from the ASC list, as many ASCs have the capability to deal with these types of situations and physicians would not choose to do procedures in an ASC if they felt there was a possibility of having to admit the patient to the hospital. Physicians make these decisions using their clinical judgment based on the patient's anesthesia risk as determined by the patients' score based on the American Society of Anesthesiologist's Physical Status Classification System.

Proposed definition of surgical procedures
CMS proposes to define surgical procedures as any procedure within the CPT code range of 10000 to 69999, but seeks comments on whether all services contained in this range are appropriately defined as surgery. For example, CMS asks whether office-based procedures or procedures that require relatively inexpensive resources to perform should be excluded from the ASC list. The ability of a physician to select the most appropriate site of service for their patients based on clinical considerations is extremely important. Therefore, the AUA agrees that any procedure within the "Surgery" section of CPT should continue to be defined as a surgical procedure eligible for payment under the revised ASC payment system, regardless of whether it is office-based or requires relatively inexpensive resources to perform.

We also note, however, that modern surgical techniques also include a number of radiology procedures that are invasive in nature and that are integral to the performance of other surgical procedures. Examples include stone removal, balloon dilation of strictures and prostate biopsies. To allow for the efficient performance of these procedures in ASCs, we believe the revised ASC payment system's definition of surgical procedure should be expanded to include invasive radiology procedures that require the insertion of a needle, catheter, tube or probe through the skin or into a body orifice and intraoperative radiology procedures that are integral to the

performance of a non-radiological surgical procedure and performed during the non-radiological surgical procedure or immediately following the surgical procedure to confirm placement of an item, such as ultrasound used to provide guidance for biopsies and major surgical procedures or to determine, during surgery, whether surgery is being conducted successfully. The physician self-referral regulations also carve out these invasive and intraoperative radiology services from the definition of "radiology" services subject to the law's self-referral prohibition. This Stark law exclusion is based "on the theory that the radiology services in these procedures are merely incidental or secondary to another procedure that the physician has ordered" and, thus, are less subject to abuse from overutilization. 63 Fed. Reg. 1645, 1676 (Jan. 9, 1998).

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ASC INFLATION

Proposed adjustment for inflation

Although the MMA froze ASC inflation updates until 2010, the current updates are based on the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. However, the OPPS is updated annually using the hospital inpatient market basket

percentage increase. Because CMS states multiple times in the proposed rule that they desire for the revised ASC payment system to reflect the OPPS as closely as possible, and because MMA does not mandate that any particular update system be used for the ASC payment system, the AUA urges CMS to use the same update method for both payment systems, which would achieve parity and transparency in the market and assure that site-of-service determinations are made based on clinical indications rather than economic considerations.

ASC PHASE IN

Proposal to phase in implementation of payment rates

CMS proposes to implement the revised ASC payment system in 2008 using transitional payment rates that would be based on a 50/50 blend of the payment rate for procedures on the 2007 list of approved ASC procedures and the payment rate for that procedure calculated under the revised payment methodology. Procedures added in 2008 would be paid the full amount calculated under the revised methodology, and new rates would be fully implemented in 2009. The AUA supports a two-year phase in for the new ASC payment rates.

ASC CONVERSION FACTOR

Based on CMS's proposed methodology for calculating the ASC payment system conversion factor, it would equate to 62 percent of the OPPS conversion factor, or $39.688. Although we understand that CMS must implement ASC payment reform in a budget-neutral fashion as required by Congress, it is completely unreasonable to assume that the cost of furnishing any given procedure in an ASC is only 62 percent of the cost of furnishing the same procedure in a hospital outpatient department. We urge CMS to use its discretion to institute changes in the methodology in order to reach a more reasonable and credible conversion factor.

Thank you for considering our comments. If you have any questions or need additional information, contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Lawrence S. Ross, M.D.
President