Submitter : **Dr. Thomas Dopson** **Date: 11/06/2006**

Organization : **Resurgens**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

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

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

Organization : **Cytyc Corporation**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

please see attachment

CMS-1506-P2-1024-Attach-1.DOC

#1024

CYTYC

November 6, 2006 ***Via Electronic Submission***

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

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

Dear Ms. Norwalk:

Cytyc welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ('CMS') Medicare Program Ambulatory Surgical Center Payment System and CY 2008 Payment Rates published in the Federal Register (Vol. 71, No.163) on August 23, 2006. In particular, we wish to express our concerns regarding CMS's proposal in the areas of breast cancer and gynecologic procedures. Specifically, we will address payment policy for the following items:

- Multiple Procedure Discounting
- Device Dependent Surgical Procedures
- New Technology
- Conversion Factor

Cytyc supports CMS in its endeavor to revise and develop a new ambulatory surgical center payment system under the requirement of the Medicare Modernization Act of 2003. Moreover a new ASC payment system modeled after the Hospital Outpatient Prospective Payment System (OPPS) seems to be the most appropriate and reasonable approach. However, as a company dedicated to women's health, we are quite concerned about certain areas in the proposed rule that we believe needs additional refinement and/or reform. Cytyc respectively requests CMS consider our comments and recommendations as presented below:

250 CAMPUS DRIVE • MARLBOROUGH, MA 01752 • TEL: (508) 263-2900 • FAX: (508) 229-2795

1. For breast brachytherapy codes; CPT 19296 and 19297, due to the high cost of this device, both CPT codes should be added to the list identified in Table 46 – Procedures Proposed for Exemption from Multiple Procedure Discounting, just as CPT 19298 is listed and the procedures are similar.

2. CMS should re-evaluate surgical services that require use of high-cost devices and ensure that procedures that are device-dependent are eligible for scheduling at an ASC.

3. CMS should consider how to address future technologies within the scope of the new ASC payment system allowing for payment under a New Technology APC and/or Pass-through type payment method for medical devices in the ASC setting.

4. CMS should establish a fair and reasonable ASC conversion factor.

   In addition, CMS should update the annual ASC conversion factor using the hospital market basket as opposed to the CPI-U to adjust for inflation.

Cytyc Corporation, a medical device company, provides therapeutic and screening technologies for multiple areas of women's health. In the area of therapeutics, Cytyc manufactures the MammoSite® Radiation Therapy System (RTS) the most widely used method of breast brachytherapy to treat breast cancer and the NovaSure® System, the most widely used method of second generation endometrial ablation to treat abnormal uterine bleeding.

Payment Policy for Multiple Procedure Discounting

The proposed rule indicates CMS is proposing to mirror the OPPS policy for discounting when a beneficiary has more than one surgical procedure performed on the same day at an ASC. The policy is based on a simple count of procedures wherein the most costly procedure is paid the full amount and all other procedures are discounted by half. Of note, certain surgical procedures are not subject to the discounting policy – those exempted are generally surgeries performed to implant costly devices. They are not discounted even when performed in association with other surgical procedures because the cost of the implantable devices does not change, so resource savings due to efficiencies would be minimal. Please note the similarity in definitions below.

19296: Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy

19297: Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy

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

CMS has proposed the Exemption List from Multiple Procedures Discounting to include CPT 19298; however, CPT codes 19296 and 19297 are unlisted. While we are uncertain to this exclusion being an oversight, it should be noted that descriptor similarities exist between the three codes.

Cytyc requests that CMS consider coherence and consistency to the clinical characteristics, resource use and code descriptions relevant to breast brachytherapy codes 19296, 19297 and 19298 exempting all three codes from the multiple procedure discount. Additionally, we ask CMS update Table 46 and add CPT 19296 and 19297 listing the procedures exempt from multiple procedure discounting.

Device Dependent Surgical Procedures

For surgical procedures that utilize high-cost devices, often described "device-dependent" procedures, it is necessary to offer to the ASC the same purchasing opportunity the HOPD experiences. There are a number of surgical procedures that may be provided safely in the ASC, however, to date because of the purchasing limitations experienced by the ASC, access and choice is minimal for Medicare beneficiaries and their surgeons.

There is evidence that the ASC offers cost-effective surgical care, thereby, when a facility is disadvantaged by its inability to purchase devices for surgical procedures simply due to payment rates set below the cost of a device, this contributes to limiting access and moving procedures to the HOPD, traditionally recognized as a higher cost setting.

Breast Cancer Radiation

Cytyc manufactures the MammoSite® Radiation Therapy System (RTS), the most widely used method of breast brachytherapy. Breast brachytherapy targets radiation therapy where the radiation source is placed inside the tumor cavity via a special balloon catheter (i.e., MammoSite® RTS) and only delivers radiation to the area where cancer is most likely to recur. This technique limits radiation to healthy tissue, lungs and heart, thus reducing the likelihood of the possible side effects experienced during whole beam radiation. Unlike whole beam radiation where the woman requires 5-6 weeks of radiation every day, breast brachytherapy is *completed in 5 days*.

CPT 19296 and 19297

Breast brachytherapy codes 19296 and 19297 include a high-cost medical device and are bundled into the procedure payment, thus designating the surgical procedure device-dependent. The proposed payment methodology for a procedure that is device dependent will limit access in the ASC for procedures involving high-cost devices. Physicians and patients will be excluded from choosing the ASC as a preferred site of service for the catheter implant and will be forced to choose the HOPD due to reimbursement.

Abnormal Uterine Bleeding

Cytyc also manufactures the NovaSure® System which uses precisely controlled amounts of impedance controlled radio frequency energy to remove the endometrial lining of the uterus for abnormal uterine bleeding, also known as menorrhagia – a common disorder defined as excessive blood loss during menstruation. Women suffering from menorrhagia commonly use more than twenty sanitary napkins or tampons in a single day and often times miss work

and cannot participate in normal life activities such as caring for loved ones. The NovaSure® System, is approved to reduce or eliminate excessive menstrual bleeding due to benign causes in women who have completed childbearing. For women who have long suffered from menorrhagia, this next-generation option provides the possibility that their extreme symptoms will be relieved and their lifestyle improved, without a dramatic or extreme effect on their body. Second generation endometrial ablation technology provides alternatives to women who would typically undergo drug therapy, dilation & curettage (D&C), rollerball ablation, or hysterectomy. These second generation technologies provide a safe and less invasive alternative to treat this de-habilitating condition.

CPT 58563

Endometrial Ablation code 58563 also requires the use of a high-cost medical device bundled into the procedure payment, thereby categorizing the surgical procedure as device-dependent. The proposed payment methodology for a procedure that is device dependent will limit access in the ASC for procedures involving high-cost devices. Physicians and patients will be excluded from choosing the ASC as a preferred site of service for endometrial ablation, thus limiting access.

The Future in New Technology

As medical technology continues to evolve and develop, manufacturers will strive and continue to offer the health care delivery system new and innovative medical and surgical devices, as well as bringing to market diagnostic and therapeutic product advancements.

Bearing this in mind, we ask CMS to factor these certainties into the infrastructure of the new ASC Payment System so that payment to ASCs will continue to mirror that of the OPPS system inclusive of New Technology APCs and Pass-through payments.

ASC Conversion Factor

According to the Proposed Rule, CMS estimates a budget neutral ASC conversion factor for CY 2008 at $39.688 or approximately 62% of the CY 2008 estimated OPPS CF of $64.013.

While Cytyc acknowledges the final ASC CF may be higher or lower than $39.688 for a number of reasons as discussed in the Proposed Rule, our organization remains concerned that this proposed estimated conversion factor amount will further restrain ASC facilities from offering a full scope of available services to Medicare beneficiaries. We understand that some stakeholders may have found potential errors in the calculation of the conversion factor. If so, we ask that CMS carefully consider any recommended corrections that may be submitted by those stakeholders. If the ASC fee schedule consists of rates that do not adequately meet ASC expenditures, the possibility exists that surgeries will not be scheduled in an ASC simply because of financial reasons and not because the ASC cannot safely provide high-quality, efficient, cost-effective surgical care.

As described in the Proposed Rule, updates to the ASC payment rates in the past have been based on the Consumer Price Index for all urban consumers (CPI-U). Beginning in CY 2008, CMS proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. The CPI-U adjustment in CY 2008 and 2009 would equal zero.

We do not believe the statute requires the use of the CPI-U for future updates. We note that health spending has been increasing faster than inflation and that Congress found merit in linking the ASC payment system to the OPPS relative payment weights and APC groups. Therefore, adjustments of the ASC update based on the CPI are unreasonable and inconsistent with the update established for the OPPS. We believe the statutory language governing ASCs in the section 1833(i) of the Social Security Act provides the Secretary sufficient flexibility to permit the use of the hospital market basket to update the ASC payments and that the CPI-U is simply a default. Therefore, we recommend the use of the hospital market basket update for ASCs to provide consistent updates for both ASCs and hospital OPDs and better align the two payment systems.

Recommendations

CMS expects that a final rule implementing the revised ASC payment system will be published separately in the spring of 2007 with the revised payment system taking effect January 1, 2008.

Cytyc request that CMS consider posting another 'Proposed' Notice or Rule in the spring 2007 rather than a final rule. This would allow the public to further evaluate and provide comment of the CY 2008 ASC Payment system before the OPPS Final Rule is published on November 1, 2007 for CY 2008. It is our understanding CMS determined ASC services and the revised payment system would be brought in under and made part of the OPPS Rule combining and addressing both payment systems in one document with proposed and final updates. Alternatively should CMS decline our request, Cytyc would like to ask for a Town Hall Meeting sometime early 2007. The meeting would provide an opportunity for the public to hear from CMS as to the Agency's further refinement to the payment system based on comments received during this current comment period ending November 6, 2006.

Cytyc respectfully requests that CMS consider and implement the following recommendations:

1. For breast brachytherapy codes; CPT 19296 and 19297, due to the high cost of this device, both CPT codes should be added to the list identified in Table 46 – Procedures Proposed for Exemption from Multiple Procedure Discounting, just as CPT 19298 is listed and the procedures are similar.

2. CMS should re-evaluate surgical services that require use of high-cost devices and ensure that procedures that are device-dependent are eligible for scheduling at an ASC.

3. CMS should consider how to address future technologies within the scope of the new ASC payment system allowing for payment under a New Technology APC and/or Pass-through type payment method for medical devices in the ASC setting.

4. CMS should establish a fair and reasonable ASC conversion factor.

   In addition, CMS should update the annual ASC conversion factor using the hospital market basket as opposed to the CPI-U to adjust for inflation.

Should you have any questions or need additional information, please do not hesitate to contact me at 508-263-8958 or via email at margaret.eckenroad@ cytyc.com.

Sincerely,

Margaret Eckenroad
Senior Director, Women's Health
and Professional Relations

Submitter : **Dr. Reuben Sloan** **Date: 11/06/2006**

Organization : **Resurgens Orthopaedics**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P2-1025-Attach-1.DOC

CMS-1506-P2-1025-Attach-2.DOC

FF 1095

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
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Ms. Norwalk:

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

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

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

Sincerely,

Reuben Sloan, MD
Resurgens Orthopaedics
Atlanta, GA

Submitter : **Dr. William P. Evans** **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-P2-1026-Attach-1.DOC

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. Thomas Dopson** **Date: 11/06/2006**

Organization : **Resurgens**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

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

Submitter : **Dr. Thomas Dopson** **Date: 11/06/2006**

Organization : **Resurgens**

Category : **Physician**

Issue Areas/Comments

ASC Unlisted Procedures

ASC Unlisted Procedures

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

Submitter : **Dr. Paul R. Bretton** **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-P2-1029-Attach-1.DOC

#1029

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. Michael Ridgway **Date:** 11/06/2006

Organization : United Surgical Partners International

Category : Health Care Professional or Association

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

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

ASC Conversion Factor

ASC Conversion Factor

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

ASC Office-Based Procedures

ASC Office-Based Procedures

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

ASC Payable Procedures

ASC Payable Procedures

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

ASC Phase In

ASC Phase In

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

ASC Ratesetting

ASC Ratesetting

I urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs.
These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Unlisted Procedures

ASC Unlisted Procedures

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

ASC Updates

ASC Updates

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

Submitter : Mr. Gary Delhougne **Date:** 11/06/2006

Organization : Tyco Healthcare Valleylab

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1031-Attach-1.DOC

#1031

tyco / Healthcare / Valleylab

November 6, 2006

Submitted via www.cms.hhs.gov/eRulemaking

Leslie V. Norwalk, Esq.
Administrator, Centers for Medicare & 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

Dear Ms. Norwalk,

Valleylab, a division of Tyco Healthcare Group L P, is submitting these comments in response to the August 23, 2006 proposed rule: Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates. Valleylab is the world leader in the innovation and manufacture of advanced energy based medical systems including devices for the radiofrequency ablation of lesions and tumors. Valleylab is submitting comments specific to **"ASC Payable Procedures"** and **"ASC Packaging."**

Comment

Valleylab commends CMS for providing doctors and their patients more choice in deciding where to perform many medical procedures. Added choice for physicians and their patients is important for many procedures, Valleylab, however, is concerned that performing percutaneous radiofrequency ablation procedures (CPTs 20982, 47382, and 50592) in the ASC setting will be severely limited due to CMS's proposed payment rate and packaging policy.

Valleylab respectfully requests that CMS make a payment exception for procedures with packaged costs that do not change when care moves from the hospital outpatient department to Ambulatory Surgical Centers. More specifically, Valleylab requests the following:

1. **As the acquisition cost of radiofrequency electrodes are the same for ASCs as they are for hospital outpatient departments CMS should develop a payment**

exception that reimburses ASCs for the acquisition cost of radiofrequency electrodes; and

2. **CMS should allow the separate payment of RFA imaging guidance (76940, 77013, and 77022) because regardless of the severity of RFA cases that migrate to ASCs all RFA procedures, whether in an ASC or a hospital, require the use of imaging guidance.**

What is Radiofrequency Ablation?

Radiofrequency ablation involves the percutaneous, laparoscopic, or intraoperative insertion of a radiofrequency energy emitting electrode into a lesion or tumor with the assistance of imaging guidance. Radiofrequency (RF) energy is used to rapidly heat and destroy diseased tissue, leaving the surrounding healthy tissue unharmed. Protein denaturation and coagulation are the ultimate cause of cell death. This is an important new tool for clinicians to treat various forms of cancer and has been shown to significantly improve net health outcomes in patients who are not appropriate candidates for conventional surgery.

CMS RFA Proposed ASC Payable Procedures

CPT 20982	Ablation, bone tumor(s) (eg, Osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomographic guidance
CPT 47382	Ablation, one or more liver tumor(s), percutaneous, radiofrequency
CPT 50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency

Imaging Guidance Codes for RFA Procedures

CPT 76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
CPT 77013	Computerized tomography guidance for, and monitoring of, parenchymal tissue ablation
CPT 77022	Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation

Cost of Radiofrequency Ablation Electrodes

Radiofrequency ablation procedures utilize needle-like electrodes to deliver RF energy for the purpose of ablating tumors. The acquisition cost of electrodes for an ASC will be the same as a hospital purchasing units for inpatient and outpatient procedures. RF electrodes range in price from $900 to $2,500 and Valleylab's technology allows physicians to use multiple electrodes in a single procedure with each electrode costing approximately $900.

With electrode costs alone of $900 to $2,500 it is apparent that a Medicare payment system that does not recognize this significant cost may inhibit a procedures adoption in an ASC. CMS is proposing to base payments to ASCs on a percentage of the OPPS rate, the effect of which means an ASC is proposed to receive only $994.58 for percutaneous

bone RFA procedures and $1,548.77 for percutaneous liver and renal RFA procedures. The proposed rates barely cover the cost of the RF electrodes let alone the remaining supplies, personnel, and other costs inherent in an RFA procedure.

Valleylab recommends the CMS explore developing a method to reimburse ASCs for procedures with costs that do not change, regardless of severity, when cases migrate to the ASC setting.

Packaging Policy

Whether it is performed in the hospital or in an ASC the use of imaging guidance is absolutely necessary to perform an RFA procedure. The use of imaging guidance is not impacted by the lower case severity typically experienced in an ASC. Physicians use Ultrasound, CT, and MRI technologies to help them guide the needle-like electrode to the diseased tissue and into the tumor's core. The OPPS system separately reimburses imaging guidance for the percutaneous liver and renal procedures. (The bone procedure is inclusive of CT guidance.)

Coupling CMS's proposal to base ASC payment on a percentage of the OPPS rate and its determination to package imaging costs, RFA procedures are effectively priced out of the ASC setting. Valleylab recommends that CMS reimburse ASCs separately for imaging guidance as is the case in OPPS.

Conclusion

Valleylab commends CMS on offering more choice to physicians and their patients for many new procedures destined to populate the ASC payable list for 2008. Valleylab respectfully requests that CMS re-evaluate its packaging policy and consider developing a mechanism to appropriately reimburse ASCs the cost of RF electrodes in RFA procedures.

Sincerely,

~s~

Gary V. Delhougne
Tyco Healthcare Valleylab
675 McDonnell Blvd, 10-3-C
St. Louis, MO 63134
314-654-7238
314-654-3099 fax
Gary.Delhougne@tycohealthcare.com

Submitter : Dr. Thomas Dopson **Date:** 11/06/2006

Organization : Resurgens

Category : Physician

Issue Areas/Comments

ASC Office-Based Procedures

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

Submitter : Mrs. Dale Bowman **Date:** 11/06/2006

Organization : San Fernando Valley Surgery Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

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ASC Updates

ASC Updates

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

CY 2008 ASC Impact

CY 2008 ASC Impact

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

These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

Submitter : Mrs. Rena Courtay **Date:** 11/06/2006

Organization : HCA Healthcare

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

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, pharmaceutical 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,

Rena M. Courtay RN, BSN, MBA, CNOR, CASC
VP of Operations, Gulf Coast Division
HCA Healthcare

Submitter : **Dr. Jasper J. Rizzo** **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-P2-1035-Attach-1.DOC

#1025

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 : Ms. PATRICIA ANDERSEN **Date:** 11/06/2006

Organization : Oklahoma Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED LETTER AND ATTACHMENT TO LETTER

CMS-1506-P2-1036-Attach-1.DOC

CMS-1506-P2-1036-Attach-2.DOC

November 6, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
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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 Oklahoma Hospital Association, representing over 140 hospitals in the State of Oklahoma, appreciates the opportunity to comment on the proposed rule related to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates. Our comments follow.

ASC PAYABLE PROCEDURES

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 ambulatory surgery center (ASC.) In doing so, CMS must review and update the list of ASC procedures at a minimum of 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 the individual procedures has been 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.

The OHA objects to this change and urges 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 those procedures that ordinarily require an overnight stay. However, CMS proposes not to continue applying current time-based prescriptive criteria which exclude from the ASC list procedures that exceed 90 minutes of operating time or four hours of recovery time or

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Leslie Norwalk
Detailed AHA Comments on 2008 ASC Payment System
Supported by the Oklahoma Hospital Association
November 6, 2006

The American Hospital Association's
Detailed Comments on the Proposed Rule
Revising the Ambulatory Surgical Center Payment System in 2008

In the *Medicare Modernization Act of 2003* (MMA), Congress mandated that the Centers for Medicare & Medicaid Services (CMS) create a new ambulatory surgical center (ASC) payment system no later than January 1, 2008, and that the revised system be budget neutral in 2008. Consistent with this mandate, the proposed ASC rule for 2008 includes significant revisions to the criteria for excluding services from ASC coverage and an entirely new payment structure based primarily upon the hospital outpatient prospective payment system (PPS) payment weights and policies.

ASC PAYABLE PROCEDURES

Proposed Payable Procedures

CMS proposes significant changes to its criteria for determining the procedures for which Medicare will pay an ASC. Consistent with Section 1833(i)(1) of the *Social Security Act*, CMS currently publishes a list of nearly 2,500 surgical procedures that can be safely performed in an ASC. For 2008 and beyond, CMS plans to replace the current "inclusive" list of procedures for which Medicare allows payment of an ASC facility fee with an "exclusionary" list. Beginning January 1, 2008, ASCs would be paid for any surgical procedures allowed to be performed in a hospital outpatient department, except those surgical procedures that CMS determines are not payable under the ASC benefit. CMS proposes to exclude from coverage only those surgical procedures that could pose a significant safety risk when performed in an ASC, procedures that require an overnight stay and unlisted surgical current procedural terminology (CPT) procedure codes. These proposed policy changes would expand the ASC-allowed list by more than 750 procedures.

The AHA is concerned that, in moving from a framework of an "inclusive" list of procedures to a system in which *any* procedure may be done that is not specifically excluded, CMS has given inadequate consideration to all of the factors that must be considered to reasonably assure that the expanded services can be provided safely in the ASC setting. CMS has proposed the use of a limited number of procedure-specific factors to determine which services will be paid for in ASCs. Procedure-specific factors alone are inadequate to protect beneficiaries. Research suggests that patient outcomes are a function of three kinds of factors: (1) procedure-specific factors; (2) patient-specific factors; and (3) organization-specific factors.[1,2] These factors are inter-related with regard to their impact on risk and patient outcomes.

The AHA believes that, in addition to procedure-specific factors, CMS should develop exclusion criteria for patient-specific and organization-specific factors, such as those outlined in our Table 1 on page 10. In the absence of such additional considerations, CMS has an inadequate basis upon which to draw to determine whether services may be safely performed in an ASC. In addition, organizations and surgeons must clearly understand what is meant by each term that is used in the defining criteria. In the proposed rule, CMS used ambiguous terms such as "major blood vessel." We recommend definitions for several of CMS' proposed procedure-specific clinical criteria, as well as two additional procedure-specific criteria for consideration.

Furthermore, the regulations and facility standards to which ASCs are subject fall short of the standards that hospitals and their outpatient departments must meet in areas such as patient safety, patient rights, quality assurance and operations (e.g., facilities, equipment, staffing, etc.). ASCs have fewer and often lesser standards, with infrequent compliance surveys, and are not

required to report detailed cost and quality data to Medicare. State licensing requirements vary in the degree to which these gaps are filled.

CMS should defer implementing any changes to the current criteria for determining ASC payable procedures until and unless the Medicare conditions of coverage for ASCs and/or hospital outpatient departments' conditions of participation regarding patient safety, patient rights, quality assurance and operating standards are revised to ensure comparable patient protections for comparable services. We are aware of major differences between the safeguards currently in place for hospital outpatient surgical departments and those required for ASC and are concerned that these differences would place ASC patients undergoing some of the more difficult or hazardous procedures at unnecessary risk.

For example, in our review, we found critical gaps in the conditions of participation for ASCs relative to hospitals, including:

- No infection control standard exists in the ASC conditions of coverage that requires the presence of an infection control officer who develops and implements policies governing infections. Hospitals are required to have an infection control officer as part of their effective infection prevention programs.

- ASCs have no requirement for a facility-wide quality assurance and training program, as hospitals do.

- ASCs have no patients' rights standards. Hospital conditions of participation require them to comply with patients' rights requirements, such as establishing a process to promptly resolve grievances and the requirement that hospitals comply with patient advance directives.

- In hospitals, an experienced nurse or physician must supervise the operating room, the hospital must maintain a roster of practitioners, specifying the surgical privileges of each, and a complete history and physical workup must be included in the patient's chart prior to surgery (with the exception of emergencies). None of these requirements apply to ASCs.

It is of special concern that the public is unaware of these differences in standards and assumes a greater degree of facility oversight and patient protection than exists.

In addition, a study on quality oversight of ASCs by the Department of Health and Human Services' Office of the Inspector General (OIG) found that the ability of states to oversee ASCs on behalf of Medicare is eroding because of the growth in the number of ASCs and states' limited resources. Of state-surveyed ASCs, one-third (872) had not undergone a recertification survey in over five years. The OIG also found that CMS gives little oversight to ASC surveys and accreditation and does not make findings readily available to the public, as it does for hospitals and other types of providers.[3]

The AHA believes that comparable standards and oversight should be applied to providers of comparable services. That is, health care standards should be service-specific, not setting-specific. Under CMS' proposal, 99 percent (in terms of both number of services and payment) of hospital outpatient department surgical services would be payable in the ASC setting. Achieving comparability should be driven by what is reasonably needed, regardless of setting, to ensure patient safety and quality. This ensures that patients have the same quality protections for similar services in every care setting.

In addition, we believe that ASCs should report quality data to the same extent as hospital outpatient departments. In other parts of the proposed rule, CMS proposes linking the receipt of a full outpatient payment update in 2007 and 2008 with the reporting of inpatient hospital quality measures. CMS further signals its intention to require reporting of outpatient-specific quality measures for purposes of determining the outpatient PPS update as early as 2009. Similar quality reporting requirements have not been proposed for ASCs.

The public deserves accountability for quality from all providers. It would not be prudent to expand the ASC procedures list so significantly in the absence of both comparable standards and quality reporting requirements. **We again recommend, as we did in our October 10 comment letter on the outpatient PPS, that CMS continue to work with the Hospital Quality Alliance (HQA) and AQA (formerly known as the Ambulatory Quality Alliance) to identify and implement measures that truly assess aspects of care quality across all ambulatory care settings. In the case of ASCs, we believe that the Surgical Care Improvement Project (SCIP) measures should be considered for their applicability to the ambulatory care setting.** Not all may be appropriate, but it is likely that many would be, and this program, which already makes use of scientifically sound measures that have been, or are in the process of being, endorsed by the National Quality Forum, would make it possible to rapidly embrace transparency on quality of care in the ambulatory setting.

Proposed Procedure-specific Criteria under a Revised ASC System

As noted earlier, CMS proposes to exclude from coverage in an ASC setting surgical procedures that could pose a significant safety risk when performed in an ASC or that require an overnight stay. To identify procedures that pose a significant safety risk, CMS proposes revised criteria that would exclude:

- procedures currently included on the outpatient PPS inpatient-only list;
- procedures that are performed 80 percent or more of the time in a hospital inpatient setting; and
- procedures that directly involve major blood vessels, result in extensive blood loss, require major or prolonged invasion of body cavities or are generally emergency or life-threatening in nature.

Finally, CMS proposes to no longer use certain other "time-based" criteria currently used to define surgical procedures that pose a significant safety risk. For instance, CMS proposes to no longer consider – for purposes of excluding procedures from the ASC coverage list – whether a procedure exceeds 90 minutes of operating time, four hours of recovery time or 90 minutes of anesthesia.

Several of these procedure-specific exclusionary factors, such as "major blood vessel," "extensive blood loss" and "major or prolonged invasion of body cavities," are not further defined within the scope of the ASC regulation and, as such, are largely subjective in nature. As noted earlier, given the differences in standards between the hospital outpatient and ASC settings, and the fact that these clinical criteria will be used in the absence of any more objective numeric criteria that exist under current regulation, establishing clear definitions of these terms is an important step toward ensuring the safety and quality of care for Medicare beneficiaries. Therefore, as CMS seeks to expand access to procedures in ASCs, it is more important than ever to define parameters and criteria that clearly distinguish procedures that are appropriate or inappropriate for this alternative care site.

We recommend clarifications to the definitions of several current exclusion criteria, as well as additions to the current list of exclusion criteria. Specifically, the AHA recommends the following definitions for current clinical criteria.

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Detailed AHA Comments on 2008 ASC Payment System
Supported by the Oklahoma Hospital Association
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"Major Blood Vessels." The AHA recommends that CMS adopt the definition of "major blood vessel" advanced by Seeley, Stephens and Tate in their medical textbook, *Essentials of Anatomy & Physiology, 6th Edition.*[4] This list includes not only the heart and the aorta, but also vessels providing primary blood supply to major limbs and organs, including the legs and the kidneys.

Please note that because procedures involving some of the vessels defined as "major" by Seeley, *et al.*, are already performed safely in ASCs (e.g., thrombectomy, percutaneous, arteriovenous fistula), we have omitted these vessels from the list. As a result, the following vessels should be included in the definition of "major blood vessels" and should, in general, be excluded from the ASC list:

- Heart
- Divisions and Branches of the Aorta
    - Ascending aorta
    - Aortic arch
    - Descending aorta (thoracic and abdominal aorta)
- Arteries of the Shoulder and Upper Limb
    - Right and left subclavian arteries
    - Axillary arteries
- Arteries of the Head and Neck
    - Common, external and internal carotid arteries
    - Vertebral arteries
- Major Branches of the Abdominal Aorta
    - Celiac trunk
    - Superior and inferior mesenteric arteries
    - Renal arteries (supplier of blood to kidneys)
    - Gonadal arteries
    - Common iliac arteries (at L_5 level; sole supply of blood to legs)
- Arteries of the Pelvis and Lower Limb
    - Right or left common iliac artery
    - Femoral artery
    - Posterior tibial artery
    - Anterior tibial artery
- Veins Entering the Right Atrium
    - Coronary sinus veins
    - Superior and inferior vena cava
- Veins of the Head and Neck
    - External and internal jugular veins
    - Vertebral vein
- Veins of Abdomen and Pelvis
    - Hepatic veins
    - Renal veins
    - Gonadal veins
    - Right and left common iliac veins

- Veins of Lower Limb
    - Anterior and posterior tibial veins
- Hepatic Portal System
    - Hepatic portal vein
    - Mesenteric veins
    - Gastric veins
    - Cystic vein[5]

The clarification of these definitions is intended to help appropriately limit the expansion of procedures to the ASC setting. Exceptions would be made for procedures involving these vessels that are safely performed in ASCs today.

"Extensive Blood Loss." We recommend that CMS further define the term "extensive blood loss" to refer to procedures that typically result in the loss of 15 percent or more of total blood volume during the routine performance of the procedure (excluding any peri-procedural complications). According to the American College of Surgeons, the loss of less than 15 percent of total blood volume typically results in no change in vital signs, and fluid resuscitation is usually unnecessary.[6] Therefore, a patient losing less than 15 percent of total blood volume could reasonably be managed in an ASC.

"Major or Prolonged Invasion of Body Cavities." The AHA recommends that CMS define "prolonged" invasion as referring to any procedure in which the patient is under anesthesia for a period of 90 minutes or longer, since there is a correlation between a higher rate of adverse events and prolonged anesthesia time. We also propose that CMS expand this definition to include not only major body cavities, but also major blood vessels.

We also recommend that the following three criteria be added as factors that would exclude a procedure from payment in an ASC.

Access Methodology Exclusion. Interventional procedures requiring puncture of the femoral artery to gain access should be excluded from payment in an ASC. The rationale for this recommendation is related to the risks associated with transporting patients that have complications involving these types of interventional procedures. When complications necessitating hospital-based management arise in a physician office or ASC setting, they require transport to a hospital for further management while maintaining open femoral access. Transporting a patient with an open femoral puncture can result in dissection or infection. Interventional procedures involving femoral artery access are associated with a significant rate of peri-procedural complications. For example, in one study of 97 patients [112 interventions], 3 percent of patients had to be admitted to hospitals due to complications related to femoral puncture. These complications included a major puncture site hematoma requiring blood transfusion.[7] In another study of 197 interventional procedures, 177 of which were balloon dilations requiring femoral access, there were 68 complications (35 percent), including five patients (2.5 percent) who had significant problems that required admission and active therapy.[8] Waugh and Sacharias described a significant complication rate of 3.6 percent among patients undergoing peripheral interventional procedures (63 percent of which were balloon angioplasty procedures).[9]

Lytic Therapy Exclusion. The AHA recommends excluding from payment in an ASC procedures involving blood vessels where, if occluded, inpatient lytic therapy would be required. Occlusion is commonly found in, or may be a complication of, peripheral vascular interventions, and is often

managed with inpatient lytic therapy. In one study of 181 lesions in 166 vessels, 55 percent of lesions were either occluded or stenosed and occluded.[10] In another study of 23 patients with critical limb ischemia, patients typically presented with combined stenoses and occlusions in 15 (60 percent) limbs, stenoses alone in four (16 percent), and occlusions alone in six (24 percent).[11] Lytic therapy is administered on an inpatient basis typically via intra-arterial catheters. It would therefore necessitate transfer with an open catheter site from an ASC or physician office to a hospital. Movement associated with transfer could result in dissection/perforation. Moreover, transfer involves movement of the patient in non-sterile environments, increasing the risk of infection.

Using the exclusionary procedure-based criteria above, we recommend that the following procedures be removed from the list of ASC-approved procedures:

- CPT 32002 Thoracentesis with insertion of tube with or without water seal (eg, for pneumothorax);
- CPT 35473 Transluminal balloon angioplasty, percutaneous; iliac;
- CPT 35474 Transluminal balloon angioplasty, percutaneous; femoral-popliteal;
- CPT 35476 Transluminal balloon angioplasty, percutaneous; venous;
- CPT 35492 Transluminal peripheral atherectomy, percutaneous; iliac;
- CPT 35761 Exploration (not followed by surgical repair), with or without lysis of artery; other vessels;
- CPT 37205 Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel;
- CPT 37206 Transcatheter placement of an intravascular stent(s), (except coronary, carotid and vertebral vessel), percutaneous; each additional vessel;
- CPT 37250 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel; and
- CPT 37251 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel.

Patient-specific and Organization-specific Criteria. The AHA believes that, while procedure-specific clinical criteria are important, these criteria alone are insufficient to determine which services can be safely furnished in an ASC setting. Research indicates that risk is a multivariate phenomenon in which patient outcomes also are a function of patient-specific and organization-specific factors, such as those listed in Table 1. We recommend that CMS consider these factors in determining what services are excluded from payment in ASCs.

Table 1

Additional Factors to be Considered	Rationale
Patient-specific Factors	
Age 85 or greater	Patients of advanced age are more likely to develop complications and need the emergency back-up services available in hospitals.[12]
Prior inpatient hospital admission within six months	According to Fleisher LA, *et al.*, "The strongest predictor of inpatient hospital admission [following an outpatient surgical procedure] was the inpatient hospitalization history."[13]
Morbid obesity (for instance, a body mass index (BMI) greater than 39)[14]	This patient population is subject to a greater number of complications with greater frequency. According to Starnes, *et al.*, "The capability for expeditious open femoral arterial repair is mandatory."[15]
Patients in American Society of Anesthesiology (ASA) Physical Status Classification[16] level 3 or	Patients in these classification levels have one or more severe comorbid conditions that may lead to complications during or after an ASC procedure and the need for rescue or emergent hospital admission.

above	
Comorbid condition exclusion	CMS should consider excluding more complex and invasive procedures from coverage in an ASC if they involve patients with specific comorbidities that are shown to place the patient at higher risk, even if the procedure itself is generally allowable in the ASC. Comorbidities such as poorly controlled diabetes, uncontrolled hypertension, significant renal insufficiency, cardio-pulmonary failure and coagulopathy[17] should be considered.
Patients with implanted cardiac defibrillators (ICD)	If cardiac complications arise for a patient with an ICD, the ASC is not likely to have the technology to address it.
Organization-specific Factors	
Factors supporting the ability to rescue the patient in event of a life- or limb-threatening complication	Organizational factors that should be considered include: • distance to the hospital with which the ASC has arrangements for admission; • availability of blood and transfusion services; • ready availability of ambulance transport services for higher-risk patients (anesthesia level risk 3 or above) • post-anesthesia care unit factors, including qualifications and staffing appropriate for higher risk patients; and • availability of life-saving technology (e.g., automated external defibrillator).

Before CMS subjects beneficiaries to an unacceptable level of risk, it needs to conduct more research in these three areas in order to determine which procedures can be done in an ASC and under what combination of patient and organizational factors. This would involve some exploration of the inter-relatedness between these factors. For instance, while it may be safe to perform a minimally invasive procedure on a Medicare beneficiary with an ASA 3 classification, it may not be safe to perform a more invasive procedure due to potential complications that the ASC would be unable to handle.

CMS needs to monitor whether the expansion of procedures allowable in ASCs subjects beneficiaries to additional risk. Available research suggests that an excellent measure would be to track the extent to which beneficiaries undergoing procedures in ASCs are subsequently admitted to a hospital or are treated in an emergency department within seven days of the ASC procedure.[18,19]

ASC RATE-SETTING AND CONVERSION FACTOR

CMS proposes replacing the current ASC payment system, which consists of nine payment groups with rates based on 1986 ASC cost data updated for inflation, with a new system that would use the outpatient PPS' Ambulatory Payment Classifications (APC) groups. Outpatient hospital surgical APCs would serve as the basis for the ASC payment groups and relative payment weights. The conversion factor would be based on a budget-neutral adjustment designed to keep total payments under the new ASC payment system equal to those under the old ASC system.

We are concerned that while the rate-setting methodology based on the existing nine ASC payment groups is clearly outdated and should be replaced, there is no actual ASC cost data that CMS or interested stakeholders can use to validate whether this proposed policy is appropriate. We recommend, and Congress intended, that CMS ensure that Medicare payment weights and rates for ASC services reflect underlying costs and the types of patients served. It is critical that CMS get the payment system weights and rates right; otherwise, payment variations could create financial incentives to inappropriately shift services from one outpatient setting to another.

Leslie Norwalk
Detailed AHA Comments on 2008 ASC Payment System
Supported by the Oklahoma Hospital Association
November 6, 2006

Section 626 of the MMA mandated that CMS implement a new ASC payment system by January 1, 2008, taking into account the recommendations of a study conducted by the Government Accountability Office (GAO). The GAO was required to conduct a study, using data submitted by ASCs, comparing the relative costs of procedures furnished in ASCs to those furnished in hospital outpatient departments under the outpatient PPS, including an examination of the accuracy of the APC categories with respect to the procedures furnished in ASCs. The GAO was required to submit its report to Congress by January 2005, with recommendations regarding: (1) the appropriateness of using groups and relative weights established for the outpatient PPS as the basis of the new ASC payment system; (2) if such weights are appropriate, whether the ASC payments should be based on a uniform percentage of such weights, whether the percentages should vary, or whether the weights should be revised for certain procedures or types of services; and (3) the appropriateness of a geographic adjustment in the ASC payment system and, if appropriate, the labor and non-labor shares of such payment. *This GAO report has never been issued.*

In the absence of this study and its recommendations, it is nearly impossible for stakeholders to provide informed comment. More importantly, without any current ASC cost data, it is difficult to determine the validity of the proposal and its use of the hospital outpatient APC groupings and relative weights, the proposed geographic adjustment and the proposed ASC payment rates.

All that we can say with assurance is that it is appropriate that CMS has proposed a conversion factor for ASC services that is less than that in the hospital outpatient department setting. The rates for services provided in hospital-based settings should be set at a higher level in order to reflect their higher costs due to additional regulatory requirements, 24/7 availability, EMTALA-related costs, a more acutely ill population with more comorbidities and higher uncompensated care rates. This is consistent with the Medicare Payment Advisory Commission's (MedPAC) findings in its 2003 and 2004 reports that "outpatient departments are subject to additional regulatory requirements, which are likely to increase their overhead costs, and treat patients who are more medically complex. Thus, outpatient departments probably incur higher costs than ASCs for similar procedures."[20]

It is unfortunate that the GAO has not met its mandate from Congress to provide the data needed to set appropriate payment rates in ASCs. **In order to allow for future validation of the appropriateness of ASC payment weights and rates, CMS should seek congressional authority to require reporting of cost data in ASCs.** This could be accomplished through implementing an ASC cost-reporting system or, as MedPAC recommended in its March 2004 report, the periodic collection of ASC cost data at the procedure level.

CMS also should monitor how the significant revisions in its payment policies will impact the volume and types of services that migrate from one ambulatory setting to another, as well as trends in the acuity of patients undergoing similar procedures in hospital outpatient departments versus ASCs. These proposed changes could lead to a migration of lower-acuity patients to ASCs, which would leave hospital outpatient departments with an even higher proportion of sicker patients. While this migration may be appropriate based on the capabilities of these settings, hospitals would see higher costs due to the increased volume and intensity of services provided to sicker patients undergoing the same procedures and increased time per patient (resulting in reduced throughput in outpatient departments). CMS would need to evaluate the effect on procedure median costs in hospitals and how the conversion factor is calculated in an ASC. Because ASC payment groups and weights are proposed to be identical to the hospital outpatient PPS, a significant trend of this sort could misalign the ASC and the outpatient PPS, resulting in additional financial incentives to inappropriately shift services between settings.

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