

Submitter : Dr. Alan Shikoh
Organization : Digestive Disease Consultants
Category : Physician

Date: 11/06/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1506-P2-1079-Attach-1.DOC

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

Submitter : Ms. I. Naya Kehayes
Organization : MHC, LLC dba Eveia Health Consulting
Category : Individual

Date: 11/06/2006

Issue Areas/Comments

ASC Inflation

ASC Inflation

see attachment

ASC Office-Based Procedures

ASC Office-Based Procedures

see attachment

ASC Packaging

ASC Packaging

see attachment

ASC Payable Procedures

ASC Payable Procedures

see attachment

ASC Ratesetting

ASC Ratesetting

see attachment

GENERAL

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see attachment

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

Submitter : Dr. Kay Kirkpatrick
Organization : Resurgens Orthopaedics
Category : Physician

Date: 11/06/2006

Issue Areas/Comments

ASC Conversion Factor

ASC Conversion Factor

62 % conversion factor is unacceptable and often does not cover the cost of the procedure. 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

ASC Office-Based Procedures

ASC Office-Based Procedures

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.

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.

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

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 OPSS 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. Thomas Buckley
Organization : Naples Day Surgery, LLC
Category : Ambulatory Surgical Center

Date: 11/06/2006

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

I would like to request that surgery center reimbursement be made for the Interstim procedure which is used for overactive bladder and urgency symptoms. It is a fast procedure that can be done safely in an ASC, and it should be less expensive to CMS to have this procedure done in an ASC than in a hospital. Private insurers already reimburse for this procedure and enjoy high satisfaction from their insureds and experience less costs because the procedure is done in an ASC.

Submitter : Dr. Michael Setzen
Organization : American Rhinologic Society
Category : Physician

Date: 11/06/2006

Issue Areas/Comments

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See Attachment

CMS-1506-P2-1083-Attach-1.DOC

CMS-1506-P2-1083-Attach-2.DOC



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November 6, 2006

VIA ELECTRONIC SUBMISSION

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

**Re: Ambulatory Surgical Center Payment System and
 CY 2008 Payment Rates [CMS-1506-P]**

Dear Ms. Norwalk:

The American Rhinologic Society (ARS) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Ambulatory Surgical Center (ASC) payment system and calendar year 2008 payment rates (Proposed Rule).¹ ARS is a professional medical organization that was founded in 1954 in order to promote education and research for rhinologic diseases and conditions. We focus specifically on issues of conventional and endoscopic sinus surgery and work to promote excellence in clinical care and investigation in the field of rhinology and sinusology. By concentrating our efforts on these specific areas, we serve as an advocate for patients by ensuring that the latest research and technology are available for the advancement of clinical care.

¹ 71 Fed. Reg. 49506 (Aug. 23, 2006).

Toward this end, we are encouraged by CMS' efforts to reform the ASC payment system to help ensure that Medicare beneficiaries have improved access to surgeries performed in ASCs. ASCs are a convenient and cost-effective treatment setting for many procedures, including functional endoscopic sinus surgeries (FESS). We generally are in favor of basing the new ASC system on relative values established under the hospital outpatient prospective payment system (OPPS) and are hopeful that CMS' payment reforms will help ensure that Medicare beneficiaries have the same access to surgical procedures performed in ASCs as their private sector counterparts.

In these comments, we ask CMS to take the following actions regarding its proposal:

- CMS should finalize its proposal to base ASC payments on OPPS relative weights and to exempt procedures involving costly implanted devices from application of the multiple procedure reduction;
 - CMS should permit payment for three additional functional endoscopic sinus surgery procedures – Current Procedural Terminology (CPT) ² codes 31292, 31293, and 31294 – as these procedures meet CMS' criteria and can be performed safely in an ASC;
 - We applaud CMS for allowing ASC payment for CPT Code 61795 in 2007, and the agency should finalize its proposal to exclude this procedure from the multiple procedure reduction in 2008; and
 - CMS should establish a fair and reasonable ASC conversion factor and devise a means to ensure the availability of device-dependent procedures to patients in ASCs.
1. **CMS should finalize its proposal to base ASC payments on OPPS relative weights and to exempt procedures involving costly implanted devices from application of the multiple procedure reduction. (ASC Rate Setting—Multiple Procedures)**

ARS commends CMS for endeavoring to develop an accurate and appropriate ASC payment system. We believe the proposed reimbursement

² CPT is a trademark of the American Medical Association.

system will give Medicare beneficiaries greater access to important surgical services performed safely and cost-effectively in ASCs. We support the alignment of the payment systems for ASCs and hospital outpatient departments. The proposed ASC payment system can facilitate the performance of procedures, when clinically appropriate, in an efficient and cost-effective setting, resulting in greater convenience for patients and their physicians.

ARS also supports CMS' proposal to apply to ASCs the discounting method currently used in the outpatient hospital department context when a Medicare patient undergoes multiple surgical procedures in the same day. CMS has noted that for outpatient hospital departments discounting does not occur when a procedure requires use of costly implantable devices, even if the procedure is conducted the same day as other surgeries "because the cost of the implantable device does not change, so resource savings due to efficiencies would be minimal."³ We support CMS' position that reimbursement for device-dependent procedures performed in ASCs should not be decreased when conducted on the same day as other procedures. We also support CMS in applying similar packaging and payment rules to same set of multiple procedures in outpatient hospital departments and ASCs. CMS should finalize this proposal.

2. **CMS should permit payment for three additional functional endoscopic sinus surgery procedures – CPT codes 31292, 31293, and 31294 – as these procedures meet CMS' criteria and can safely be performed in an ASC. (ASC Payable Procedures)**

CMS has proposed to provide payment to an ASC for procedures within the surgical range of CPT codes that do not pose a safety risk to Medicare patients or require an overnight stay.⁴ CMS proposes to use the criteria currently set forth at proposed 42 C.F.R. § 416.66(c) to determine whether a procedure involves a safety risk.⁵ Accordingly, procedures resulting in extensive blood loss, requiring major or prolonged invasion of body cavities, directly involving major blood vessels, or posing threats to patients' lives are excluded from ASC payment in the 2008 system.

In light of the criteria set forth above, we urge CMS to allow payment for the following procedures for payment when performed in an ASC:

³ 71 Fed. Reg. at 49651.

⁴ Id. at 49637.

⁵ Id. at 49699.

<u>CPT Code</u>	<u>Procedure Description</u> ⁶
31292	Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression
31293	Nasal/sinus endoscopy, surgical; with medial and inferior orbital wall decompression
31294	Nasal/sinus endoscopy, surgical; with optic nerve decompression

Each of these functional endoscopic sinus surgeries is within the surgical range of CPT codes. CPT codes 31292, 31293 and 31294 are similar to several endoscopic sinus surgeries for which CMS already allows payment in the ASC setting, including CPT codes: 31233, 31235, 31237, 31238, 31239, 31240, 31254, 31255, 31256, 31267, 31276, 31287, and 31288.⁷ Similar to each of FESS already approved for ASC payment, CPT codes 31292, 31293, and 31294, typically involve the sinuses but do not involve major blood vessels and do not require major or prolonged invasion of any body cavities. Extensive blood loss typically does not occur during the performance of any of the three procedures nor are they life-threatening or emergent in nature. These procedures are currently safely performed in ASCs on patients with private insurance. In addition, they are minimally invasive. In order to provide Medicare beneficiaries access to these important services in a less costly and more convenient setting, we ask CMS to reimburse CPT codes 31292, 31293 and 31294 when such procedures are performed in an ASC.

- 3. We applaud CMS for allowing ASC payment for CPT Code 61795 in 2007, and the agency should finalize its proposal to exclude this procedure from the multiple procedure reduction in 2008. (ASC Payable Procedures)**

We commend CMS for permitting ASC reimbursement for CPT code 61795, Stereotactic computer assisted volumetric (navigational) procedure,

⁶ CPT 2006, CURRENT PROCEDURAL TERMINOLOGY (American Medical Association ed., Professional Edition).

⁷ Id. By way of example the CPT descriptions for codes 31256, 31276 and 31288 are as follows: 31256 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy); 31276 (Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus); and 31288 (Nasal/sinus endoscopy, surgical, with sphenoidotomy, with removal of tissue from sphenoid sinus). Id.

intracranial, extracranial, or spinal, beginning in 2007.⁸ CPT code 61795 is used in conjunction with functional endoscopic sinus surgeries that were already on the ASC-approved procedures list, meets all CMS' criteria regarding covered surgical procedures in ASCs, and may be safely performed in an ASC. The addition of this procedure will improve the safety and outcomes of the underlying surgeries with which it is performed. CMS' decision to permit the performance of 61795 in ASCs will enhance patient care and allow Medicare beneficiaries to realize the same convenience and economic savings of treatment in an ASC as their private sector counterparts. Moreover, because 61795 is a service that is always conducted with a primary procedure that would otherwise always be subject to the 50 percent multiple procedure reduction, we also support CMS' application of the appropriate status indicator, "S", to the procedure beginning in 2008, exempting 61795 from that multiple procedure discount.

4. CMS should establish a fair and reasonable ASC conversion factor and devise means to ensure the availability of device-dependent procedures to patients in ASCs. (ASC Conversion Factor).

In order to help guarantee beneficiary access to surgeries performed the ASC setting when clinically appropriate, ARS strongly encourages CMS to adopt a fair and reasonable conversion factor to adequately pay ASCs for their services. We are concerned that CMS' proposal to reimburse procedures performed in an ASC at 62 percent of the hospital outpatient rate will be insufficient for ASC to offer certain surgical procedures in this economical and efficient setting.⁹ If ASCs are not adequately reimbursed, patients will have to seek certain surgical services in an hospital outpatient department instead. We believe a higher conversion factor is more likely to enable ASCs to provide beneficiary access to important surgical services in that setting.

We also urge CMS to devise methods to guarantee sufficient payment for device-dependent procedures. For procedures using or implanting medical devices, the devices costs usually are the same regardless of whether the procedure is performed in an hospital or in an ASC. If the CMS' payment rate is below the cost of the device, ASCs will not offer these important device-dependent procedures. If device-dependent surgical services are not offered in the ASC setting despite being clinically appropriate for that setting, beneficiaries will lose access to vital services in the most efficient and

⁸ See Final Changes to the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, page 764, available at <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage>

⁹ 71 Fed. Reg. at 49656.

economic clinical location. Moreover, CMS will pay more for procedures that could be performed more cost-effectively elsewhere. Accordingly, ARS encourages CMS to investigate mechanisms to provide sufficient reimbursement for the performance of device-dependent procedures in the ASC setting.

5. Conclusion

Thank you for this opportunity to comment on the Proposed Rule. If you have any questions or would like to discuss our comments further, please feel free to contact Dr. Michael Setzen at (516) 482 8778.

Sincerely,



Michael Setzen MD, FACS
Chair, Patient Advocacy Committee
American Rhinologic Society



Howard Levine, MD
President
American Rhinologic Society

Submitter : Dr. Mark J. Lema
Organization : American Society of Anesthesiologists
Category : Physician

Date: 11/06/2006

Issue Areas/Comments

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

Submitter : Dr. Lawrence Ross
Organization : American Urological Association
Category : Health Care Provider/Association

Date: 11/06/2006

Issue Areas/Comments

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CMS-1506-P2-1085-Attach-1.DOC



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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 that CMS sought input from the ASC community, including holding a listening session teleconference in August 2005 and 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 considers 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 an improvement over the current outdated and clinically irrelevant rules that govern the ASC list. However, we are concerned that CMS's proposed exclusion criteria would exclude many procedures that can be safely and appropriately performed in an ASC, and we offer the following comments on the 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 it would artificially restrict the natural migration of procedures among sites of service that technological developments and clinical experience 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.** Furthermore, 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. Therefore, a more viable criteria may be anesthesia risk as that could be more readily verified.

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 and patient preference is of the utmost importance. 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. However, we also urge CMS to include certain radiology procedures in the definition of surgery, as modern surgical techniques include a number of radiology procedures that are invasive in nature and that are integral to the performance of other surgical procedures.

Examples for urology include stone removal, balloon dilation of strictures and prostate biopsies. To allow for the efficient performance of these procedures in ASCs, we urge CMS to include x-ray, fluoroscopy or ultrasound 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.

These are the same definitions used in Medicare's physician self-referral regulations to identify radiology services that are carved out of the definition of radiology services that are subject to the self-referral prohibition. This 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.

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 OPSS, and 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

It is our understanding that currently the HCPCS panel does not include practicing physician representation or representation from the APC Advisory Panel. **To truly encourage active dialogue across all payment systems, we would strongly encourage that the Panel be expanded to include representation from these groups.**

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:

- C MS 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.
- C MS wants an ASC system that is as similar to OPPS as possible
- AS Cs 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.

ASC RATESETTING

CMS proposes to base ASC relative payment weights on Ambulatory Payment Classification (APC) groups and relative payment weights established under the OPPS. This is 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.

For many of these procedures, the facility fee is comprised almost entirely of the cost of the implant. However, hospitals and ASCs both pay the same amount for implants, meaning that application of a conversion factor that represents 62 percent of the OPPS conversion factor would result in large underpayment to the ASC. **Therefore, for procedures in which high-cost implants account for a significant percentage of the overall cost of furnishing the procedure, we urge CMS to continue to pay for these items separately outside the bundle of items included in the facility fee and to not include these procedures in the phase-in.** This proposal is consistent with the OPPS multiple procedure discount exemption for procedures involving high-cost implants (see section below titled "Payment policy for multiple procedure discounting").

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 indicates 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. As a result, 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. 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 capabilities 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 receive general anesthesia. 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. (see attachment regarding CPT codes 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 2004. 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 OPSS 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 OPSS 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 OPSS 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.

Alternate option for calculating the budget neutrality adjustment considered

According to the proposed rule, CMS considered an alternative approach to calculating the budget neutrality adjustment under the new payment system, which would take into account the effects of the migration of procedures between ASCs, offices, and HOPDs that might be attributable to the new ASC payment system. CMS assumed that 25 percent of HOPD utilization for new ASC procedures would migrate to the ASC and that 15 percent of the physician office utilization for new ASC procedures would migrate to the ASC.

The AUA disagrees with CMS's assumption that 15 percent of the new physician office utilization for new ASC procedures would migrate to the ASC, and urges CMS to revise these assumptions if this methodology is used to calculate the budget neutrality adjustment. Based on our attached analysis of Medicare data for three office-based urology procedures that have been on the ASC list for quite some time, it is not realistic to assume that physicians will move procedures that are commonly performed in an office to an ASC just because they are added to the ASC list. We suggest that CMS completely exclude office-based migration from this calculation until more data can be collected and that CMS use the phase-in period to collect data on this issue and, if necessary, adjust the calculations going forward.

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

Medicare Site-of-Service Shifts for 3 Office-Based Urology Procedures: 1997 to 2004

52000																
	1997	1997%	1998	1998%	1999	1999%	2000	2000%	2001	2001%	2002	2002%	2003	2003%	2004	2004%
Total	790,876		806,964		811,299		835,669		829,281		871,051		954,983		952,641	
ASC	52,396	6.63%	63,504	7.87%	68,156	8.40%	79,116	9.47%	48,181	5.81%	50,608	5.81%	57,732	6.05%	63,065	6.62%
Office	581,810	73.57%	592,634	73.44%	563,709	69.48%	618,984	74.07%	659,030	79.47%	692,224	79.47%	759,279	79.51%	766,304	80.44%
Inpatient	38,296	4.84%	36,987	4.58%	32,374	3.99%	33,823	4.05%	30,352	3.66%	31,880	3.66%	36,032	3.77%	30,008	3.15%
Outpatient	116,359	14.71%	111,559	13.82%	99,082	12.21%	102,109	12.22%	90,972	10.97%	95,554	10.97%	101,157	10.59%	92,692	9.73%
52281																
	1997	1997%	1998	1998%	1999	1999%	2000	2000%	2001	2001%	2002	2002%	2003	2003%	2004	2004%
Total	129,620		122,616		114,848		112,756		109,994		129,777		144,779		138,688	
ASC	10,664	8.23%	11,638	9.49%	11,860	10.33%	13,089	11.61%	7,260	6.60%	8,565	6.60%	9,359	6.46%	9,431	6.80%
Office	83,192	64.18%	77,616	63.30%	67,807	59.04%	70,328	62.37%	77,084	70.08%	90,948	70.08%	101,844	70.34%	102,227	73.71%
Inpatient	9,429	7.27%	8,972	7.32%	7,755	6.75%	7,605	6.74%	7,040	6.40%	8,306	6.40%	9,529	6.58%	7,295	5.26%
Outpatient	25,941	20.01%	24,023	19.59%	21,636	18.84%	21,455	19.03%	18,435	16.76%	21,751	16.76%	23,642	16.33%	19,416	14.00%
55700																
	1997	1997%	1998	1998%	1999	1999%	2000	2000%	2001	2001%	2002	2002%	2003	2003%	2004	2004%
Total	278,630		259,791		268,025		270,189		262,209		268,779		255,205		233,082	
ASC	21,627	7.76%	25,122	9.67%	27,267	10.17%	31,244	11.56%	20,216	7.71%	20,723	7.71%	21,064	8.25%	19,905	8.54%
Office	200,233	71.86%	183,323	70.57%	178,468	66.59%	190,532	70.52%	197,312	75.25%	202,256	75.25%	192,138	75.29%	177,492	76.15%
Inpatient	7,158	2.57%	6,418	2.47%	5,286	1.97%	5,027	1.86%	4,379	1.67%	4,489	1.67%	4,631	1.81%	3,613	1.55%
Outpatient	48,914	17.56%	44,239	17.03%	41,705	15.56%	42,676	15.79%	39,961	15.24%	40,962	15.24%	37,075	14.53%	31,839	13.66%

Submitter : Dr. Michael Setzen
Organization : American Rhinologic Society
Category : Physician
Issue Areas/Comments

Date: 11/06/2006

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1086-Attach-1.DOC



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November 6, 2006

VIA ELECTRONIC SUBMISSION

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

**Re: Ambulatory Surgical Center Payment System and
CY 2008 Payment Rates [CMS-1506-P]**

Dear Ms. Norwalk:

The American Rhinologic Society (ARS) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Ambulatory Surgical Center (ASC) payment system and calendar year 2008 payment rates (Proposed Rule).¹ ARS is a professional medical organization that was founded in 1954 in order to promote education and research for rhinologic diseases and conditions. We focus specifically on issues of conventional and endoscopic sinus surgery and work to promote excellence in clinical care and investigation in the field of rhinology and sinusology. By concentrating our efforts on these specific areas, we serve as an advocate for patients by ensuring that the latest research and technology are available for the advancement of clinical care.

¹ 71 Fed. Reg. 49506 (Aug. 23, 2006).

Toward this end, we are encouraged by CMS' efforts to reform the ASC payment system to help ensure that Medicare beneficiaries have improved access to surgeries performed in ASCs. ASCs are a convenient and cost-effective treatment setting for many procedures, including functional endoscopic sinus surgeries (FESS). We generally are in favor of basing the new ASC system on relative values established under the hospital outpatient prospective payment system (OPPS) and are hopeful that CMS' payment reforms will help ensure that Medicare beneficiaries have the same access to surgical procedures performed in ASCs as their private sector counterparts.

In these comments, we ask CMS to take the following actions regarding its proposal:

- CMS should finalize its proposal to base ASC payments on OPPS relative weights and to exempt procedures involving costly implanted devices from application of the multiple procedure reduction;
 - CMS should permit payment for three additional functional endoscopic sinus surgery procedures – Current Procedural Terminology (CPT) ² codes 31292, 31293, and 31294 – as these procedures meet CMS' criteria and can be performed safely in an ASC;
 - We applaud CMS for allowing ASC payment for CPT Code 61795 in 2007, and the agency should finalize its proposal to exclude this procedure from the multiple procedure reduction in 2008; and
 - CMS should establish a fair and reasonable ASC conversion factor and devise a means to ensure the availability of device-dependent procedures to patients in ASCs.
1. **CMS should finalize its proposal to base ASC payments on OPPS relative weights and to exempt procedures involving costly implanted devices from application of the multiple procedure reduction. (ASC Rate Setting—Multiple Procedures)**

ARS commends CMS for endeavoring to develop an accurate and appropriate ASC payment system. We believe the proposed reimbursement

² CPT is a trademark of the American Medical Association.

system will give Medicare beneficiaries greater access to important surgical services performed safely and cost-effectively in ASCs. We support the alignment of the payment systems for ASCs and hospital outpatient departments. The proposed ASC payment system can facilitate the performance of procedures, when clinically appropriate, in an efficient and cost-effective setting, resulting in greater convenience for patients and their physicians.

ARS also supports CMS' proposal to apply to ASCs the discounting method currently used in the outpatient hospital department context when a Medicare patient undergoes multiple surgical procedures in the same day. CMS has noted that for outpatient hospital departments discounting does not occur when a procedure requires use of costly implantable devices, even if the procedure is conducted the same day as other surgeries "because the cost of the implantable device does not change, so resource savings due to efficiencies would be minimal."³ We support CMS' position that reimbursement for device-dependent procedures performed in ASCs should not be decreased when conducted on the same day as other procedures. We also support CMS in applying similar packaging and payment rules to same set of multiple procedures in outpatient hospital departments and ASCs. CMS should finalize this proposal.

2. **CMS should permit payment for three additional functional endoscopic sinus surgery procedures – CPT codes 31292, 31293, and 31294 – as these procedures meet CMS' criteria and can safely be performed in an ASC. (ASC Payable Procedures)**

CMS has proposed to provide payment to an ASC for procedures within the surgical range of CPT codes that do not pose a safety risk to Medicare patients or require an overnight stay.⁴ CMS proposes to use the criteria currently set forth at proposed 42 C.F.R. § 416.66(c) to determine whether a procedure involves a safety risk.⁵ Accordingly, procedures resulting in extensive blood loss, requiring major or prolonged invasion of body cavities, directly involving major blood vessels, or posing threats to patients' lives are excluded from ASC payment in the 2008 system.

In light of the criteria set forth above, we urge CMS to allow payment for the following procedures for payment when performed in an ASC:

³ 71 Fed. Reg. at 49651.

⁴ Id. at 49637.

⁵ Id. at 49699.

<u>CPT Code</u>	<u>Procedure Description</u> ⁶
31292	Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression
31293	Nasal/sinus endoscopy, surgical; with medial and inferior orbital wall decompression
31294	Nasal/sinus endoscopy, surgical; with optic nerve decompression

Each of these functional endoscopic sinus surgeries is within the surgical range of CPT codes. CPT codes 31292, 31293 and 31294 are similar to several endoscopic sinus surgeries for which CMS already allows payment in the ASC setting, including CPT codes: 31233, 31235, 31237, 31238, 31239, 31240, 31254, 31255, 31256, 31267, 31276, 31287, and 31288.⁷ Similar to each of FESS already approved for ASC payment, CPT codes 31292, 31293, and 31294, typically involve the sinuses but do not involve major blood vessels and do not require major or prolonged invasion of any body cavities. Extensive blood loss typically does not occur during the performance of any of the three procedures nor are they life-threatening or emergent in nature. These procedures are currently safely performed in ASCs on patients with private insurance. In addition, they are minimally invasive. In order to provide Medicare beneficiaries access to these important services in a less costly and more convenient setting, we ask CMS to reimburse CPT codes 31292, 31293 and 31294 when such procedures are performed in an ASC.

- 3. We applaud CMS for allowing ASC payment for CPT Code 61795 in 2007, and the agency should finalize its proposal to exclude this procedure from the multiple procedure reduction in 2008. (ASC Payable Procedures)**

We commend CMS for permitting ASC reimbursement for CPT code 61795, Stereotactic computer assisted volumetric (navigational) procedure,

⁶ CPT 2006, CURRENT PROCEDURAL TERMINOLOGY (American Medical Association ed., Professional Edition).

⁷ *Id.* By way of example the CPT descriptions for codes 31256, 31276 and 31288 are as follows: 31256 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy); 31276 (Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus); and 31288 (Nasal/sinus endoscopy, surgical, with sphenoidotomy, with removal of tissue from sphenoid sinus). *Id.*

intracranial, extracranial, or spinal, beginning in 2007.⁸ CPT code 61795 is used in conjunction with functional endoscopic sinus surgeries that were already on the ASC-approved procedures list, meets all CMS' criteria regarding covered surgical procedures in ASCs, and may be safely performed in an ASC. The addition of this procedure will improve the safety and outcomes of the underlying surgeries with which it is performed. CMS' decision to permit the performance of 61795 in ASCs will enhance patient care and allow Medicare beneficiaries to realize the same convenience and economic savings of treatment in an ASC as their private sector counterparts. Moreover, because 61795 is a service that is always conducted with a primary procedure that would otherwise always be subject to the 50 percent multiple procedure reduction, we also support CMS' application of the appropriate status indicator, "S", to the procedure beginning in 2008, exempting 61795 from that multiple procedure discount.

4. **CMS should establish a fair and reasonable ASC conversion factor and devise means to ensure the availability of device-dependent procedures to patients in ASCs. (ASC Conversion Factor).**

In order to help guarantee beneficiary access to surgeries performed the ASC setting when clinically appropriate, ARS strongly encourages CMS to adopt a fair and reasonable conversion factor to adequately pay ASCs for their services. We are concerned that CMS' proposal to reimburse procedures performed in an ASC at 62 percent of the hospital outpatient rate will be insufficient for ASC to offer certain surgical procedures in this economical and efficient setting.⁹ If ASCs are not adequately reimbursed, patients will have to seek certain surgical services in an hospital outpatient department instead. We believe a higher conversion factor is more likely to enable ASCs to provide beneficiary access to important surgical services in that setting.

We also urge CMS to devise methods to guarantee sufficient payment for device-dependent procedures. For procedures using or implanting medical devices, the devices costs usually are the same regardless of whether the procedure is performed in an hospital or in an ASC. If the CMS' payment rate is below the cost of the device, ASCs will not offer these important device-dependent procedures. If device-dependent surgical services are not offered in the ASC setting despite being clinically appropriate for that setting, beneficiaries will lose access to vital services in the most efficient and

⁸ See Final Changes to the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, page 764, available at <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage>

⁹ 71 Fed. Reg. at 49656.

economic clinical location. Moreover, CMS will pay more for procedures that could be performed more cost-effectively elsewhere. Accordingly, ARS encourages CMS to investigate mechanisms to provide sufficient reimbursement for the performance of device-dependent procedures in the ASC setting.

5. Conclusion

Thank you for this opportunity to comment on the Proposed Rule. If you have any questions or would like to discuss our comments further, please feel free to contact Dr. Michael Setzen at (516) 482 8778.

Sincerely,



Michael Setzen MD, FACS
Chair, Patient Advocacy Committee
American Rhinologic Society



Howard Levine, MD
President
American Rhinologic Society

Submitter : Ms. Patricia Aiken-O'Neill
Organization : Eye Bank Association of America
Category : Health Care Professional or Association

Date: 11/06/2006

Issue Areas/Comments

ASC Payment for Corneal Tissue

ASC Payment for Corneal Tissue
Via CMS Website

November 6, 2006

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

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

ASC Payment for Corneal Tissue

Dear Administrator McClellan:

On behalf of our more than 83 member eye bank organizations, the Eye Bank Association of America (EBAA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule addressing the payment system for ambulatory surgical centers, and payment rates for calendar year 2008. The payment policy adopted for the acquisition of corneal tissue reflects the current eye banking system, which continues to work well.

The 83 eye bank members of the EBAA represent 99% of the entire U.S. eye banking community and provide 97% of all corneal tissue provided for transplantation. All eye banks are 501(c)(3) organizations whose mission is to recover and provide donated human eye tissue for sight restoring transplantation procedures. Currently, eye banks are able to provide sufficient corneal tissue to meet the need for sight restoring transplants, but the supply of human ocular tissue is dependent on the gift of sight, ie, donated ocular tissue.

The June 12, 1998 Federal Register publication of HCFA-1885-P proposed a payment policy to package or bundle a set payment for the acquisition of corneal tissue with the payment for the associated cornea transplant procedure rather than making separate payments. In response to the proposed rule, the EBAA contracted with an independent organization, the Lewin Group, to collect and analyze financial data from member eye banks. The final Lewin Report, attached, established a credible, representative sample of eye bank cost data, which demonstrated that the eye banking community relies on charitable-based, local donation networks to recoup the cost associated with the provision of tissue for transplant. Data from the 1998 study demonstrated the amount to which eye banks rely on fundraising revenue and donated services to subsidize their costs. The fees billed by eye banks for the acquisition of human eye tissue fell far short of the actual cost of providing the ocular tissue for transplant, but were subsidized to varying degrees by philanthropic revenue. This philanthropic revenue from fund-raising and in-kind services varied from community to community, and even from year to year within the same community. The Lewin report concluded that a fixed-rate system would make it economically unfeasible for many banks to continue operations, thus reducing access to corneal tissue in the United States.

The EBAA and its community of banks strongly supported the CMS conclusion, based on the materials provided to it: the eye banking community continues to rely, in part, on philanthropy, so that eye banking costs incurred are no less variable now than in 1998. The EBAA supports the proposed revised ASC payment system, which continues to pay ASCs separately, based on their invoiced costs, for the acquisition of corneal tissue.

Overall, operational costs have continued to increase, due to the current regulatory environment. On May 25, 2005, the Food and Drug Administration (FDA) implemented 21 CFR Part 1271 Subpart C- Donor Eligibility and Subpart D-Current Good Tissue Practices, which set stringent requirements for establishments involved in recovering, processing, testing, storing and distributing human cells and tissues, and tissue-based products (HCT/Ps), including the establishment of formal quality programs. These requirements include increased testing and screening, which further increases the cost of providing the tissue, reduces the donor pool, and thus, the availability of corneal tissue.

CMS-1506-P2-1087-Attach-1.DOC



**EYE BANK
ASSOCIATION
of AMERICA**

Via CMS Website

November 6, 2006

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

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

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charitable-based, local donation networks to recoup the cost associated with the provision of tissue for transplant. Data from the 1998 study demonstrated the amount to which eye banks rely on fundraising revenue and donated services to subsidize their costs. The fees billed by eye banks for the acquisition of human eye tissue fell far short of the actual cost of providing the ocular tissue for transplant, but were subsidized to varying degrees by philanthropic revenue. This philanthropic revenue from fund-raising and “in-kind” services varied from community to community, and even from year to year within the same community. The Lewin report concluded that a fixed-rate system would make it economically unfeasible for many banks to continue operations, thus reducing access to corneal tissue in the United States.

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The FDA’s proposed Donor Eligibility Guidance is not yet final, but is expected “at any time”. In the final Guidance document, specific testing requirements for relevant communicable diseases will be outlined. Additional testing requirements will most likely include testing for Hepatitis B core antibody, HIV-1 and HCV NAT testing, which will again increase eye banking costs, and further reduce the donor pool.

Recent scandals in the tissue banking industry have caused a public demand for an ever-increasing regulatory framework around donation. Although the FDA has only recently implemented the 1271 requirements, various state legislatures have drafted bills to increase regulation of tissue banks in their state. Eye banks will be affected as well, although no scandal has involved eye banks or corneas. If additional state regulations are implemented, variability among eye banking costs will only become more defined.

The present eye banking system works extremely well. A payment policy that continues making separate payments for the acquisition of corneal tissue, without bundling at a set-rate, is necessary in today’s dynamic regulatory environment, and is required in order for eye banks to continue its culture of community-based philanthropy. We heartily support CMS’s proposed ASC payment policy for the acquisition of corneal tissue, and thank you for considering the effects such a policy has on the provision of corneas for sight restoring procedures.

Sincerely,

[Faint, illegible signature]

Patricia Aiken-O'Neill, Esq.
President and CEO
Eye Bank Association of America

Submitter :

Date: 11/06/2006

Organization : American Burn Association

Category : Health Care Professional or Association

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

November 3, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS 1506 P
Medicare Program: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Ms. Norwalk,

The American Burn Association (ABA) sincerely appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System 2007 Proposed Rule. The American Burn Association represents the nation's burn surgeons, nurses, therapists, and other members of the burn team, and the nation's leading medical institutions with burn centers who together provide therapeutic and surgical services for burn patients and other patients diagnosed with extensive and/or life-threatening skin diseases.

ASC Payable Procedures

Thank you for the opportunity to comment on this issue, specifically in regard to the inclusion of HCPCS/CPT codes 15170-15176 in 71 FR, page 49643, Table 45.--CPT Surgical Procedure Codes Proposed for Exclusion from ASC Facility Fee Payment Because They Require an Overnight Stay, proposed to be effective January 1, 2008.

CPT Codes 15170-15176 represent the following procedures:

- 15170 Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children
- 15171 Acellular dermal replacement, trunk, arms, legs; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
- 15175 Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children
- 15176 Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

It should also be noted that the lead article in the October, 2006 edition of the AMA's CPT Assistant, entitled "Skin Replacement Surgery and Skin Substitutes," indicates that Integra® is one example of an acellular dermal replacement product.

Codes 15170-15176 Included in Procedures Eligible for Payment under HOPPS (Final Rule)

CMS has included all CPT skin substitute/replacement codes, including 15170-15176, in its list of procedures that are eligible for payment in the outpatient hospital setting according to the just published 2007 HOPPS Final Rule, indicating that CMS has determined that these procedures do not require an overnight stay, proposed by CMS to be defined as a stay beyond midnight of the day of the surgery. We agree with this decision.

ASC Payable Procedures

ASC Payable Procedures

Inconsistency Between Outpatient Hospital and ASC Allowed Procedures: Counter to CMS Intent to Align Both Payment Systems

CMS placement of procedures represented by codes 15170-15176 in Table 45, 71 FR, page 49643, CPT Surgical Procedure Codes Proposed for Exclusion from ASC Facility Fee Payment Because They Require an Overnight Stay, is inconsistent with the foregoing final HOPPS rule and with CMS stated intent to align ASC payment provisions with those of HOPPS.

CMS Includes All Remaining CPT Skin Substitute/Replacement Codes in Proposed ASC Approved List

CMS-1506-P2-1088

In addition, CMS includes all remaining CPT skin substitute/replacement codes/procedures, including autografts, in the procedures proposed for approval for ASC payment. We concur with this proposed placement.

Procedures 15170-15176 Are No Less Safe than Autografts

However, the ABA and its members believe that the procedures represented by codes 15170-15176 are inappropriately included in the proposed ASC excluded list for reasons of safety and need for medical monitoring.

1. We believe these procedures are no less safe than autografts, procedures which long have been included in the list of ASC approved procedures, going back at least as far as 1995. Autografts typically require a) excisional preparation of the wound or scar and b) creation of a second wound for harvest of the autograft. In contrast to autografts, which can be more extensive, procedures 15170-15176 require only excisional preparation of the wound or scar (represented by codes 15000-15001) and application of a product (e.g., Integra) to that wound (codes 15170-15176).

2. Thus we see that, historically for autografts and in the proposed rule, CMS has appropriately determined that autografts and the remaining CPT skin replacement codes would not require immediate access to the full resources of an acute care hospital or be included among those procedures where prevailing medical practice dictates the beneficiary will typically be expected to require active medical monitoring and care at midnight of the day on which the surgical procedure was performed. We believe that the same reasons clearly apply to procedures 15170-15176.

For all the above reasons--inconsistency with HOPPS, safety, and overnight stay requirements--the ABA respectfully requests that CMS delete codes 15170-15176 from the list of procedures excluded from ASC payment and that CMS move codes 15170-15176 to the list of ASC approved procedures effective for January 1, 2008.

Thank you for the opportunity to provide comments on the ASC provisions of this proposed rule. The ABA is pleased to be able to contribute its expertise to CMS in these important matters in order to promote appropriate payment for services provided to Medicare beneficiaries now and for the future. If you have any questions or need further information regarding the issues we have discussed, please contact us at any time.

Respectfully submitted,

John Krichbaum, JD
Executive Director
American Burn Association

CMS-1506-P2-1088-Attach-1.DOC

#1088



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November 3, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS—1506—P
Medicare Program: Hospital Outpatient Prospective Payment System and CY 2007
Payment Rates

Dear Ms. Norwalk,

The American Burn Association (ABA) sincerely appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System 2007 Proposed Rule. The American Burn Association represents the nation's burn surgeons, nurses, therapists, and other members of the burn team, and the nation's leading medical institutions with burn centers who together provide therapeutic and surgical services for burn patients and other patients diagnosed with extensive and/or life-threatening skin diseases.

ASC Payable Procedures

Thank you for the opportunity to comment on this issue, specifically in regard to the inclusion of HCPCS/CPT codes 15170-15176 in 71 FR, page 49643, "Table 45.--CPT Surgical Procedure Codes Proposed for Exclusion from ASC Facility Fee Payment Because They Require an Overnight Stay," proposed to be effective January 1, 2008.

CPT Codes 15170-15176 represent the following procedures:

- 15170 Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children
- 15171 Acellular dermal replacement, trunk, arms, legs; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)



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- 15175 Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children
- 15176 Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

It should also be noted that the lead article in the October, 2006 edition of the AMA's *CPT Assistant*, entitled "Skin Replacement Surgery and Skin Substitutes," indicates that Integra® is one example of an acellular dermal replacement product.

Codes 15170-15176 Included in Procedures Eligible for Payment under HOPPS (Final Rule)

CMS has included all CPT skin substitute/replacement codes, including 15170-15176, in its list of procedures that are eligible for payment in the outpatient hospital setting according to the just published 2007 HOPPS Final Rule, indicating that CMS has determined that these procedures do not require an overnight stay, proposed by CMS to be defined as a stay beyond midnight of the day of the surgery. We agree with this decision.

Inconsistency Between Outpatient Hospital and ASC Allowed Procedures: Counter to CMS Intent to Align Both Payment Systems

CMS' placement of procedures represented by codes 15170-15176 in Table 45, 71 FR, page 49643, "CPT Surgical Procedure Codes Proposed for Exclusion from ASC Facility Fee Payment Because They Require an Overnight Stay," is inconsistent with the foregoing final HOPPS rule and with CMS' stated intent to align ASC payment provisions with those of HOPPS.

CMS Includes All Remaining CPT Skin Substitute/Replacement Codes in Proposed ASC Approved List

In addition, CMS includes all remaining CPT skin substitute/replacement codes/procedures, *including autografts*, in the procedures proposed for approval for ASC payment. We concur with this proposed placement.

Procedures 15170-15176 Are No Less Safe than Autografts

However, the ABA and its members believe that the procedures represented by codes 15170-15176 are inappropriately included in the proposed ASC excluded list for reasons of safety and need for medical monitoring.

1. We believe these procedures *are no less safe* than autografts, *procedures which long have been included in the list of ASC approved procedures*, going back at least as far as 1995. Autografts



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typically require a) excisional preparation of the wound or scar and b) creation of a second wound for harvest of the autograft. In contrast to autografts, which can be more extensive, procedures 15170-15176 require only excisional preparation of the wound or scar (represented by codes 15000-15001) and application of a product (e.g., Integra) to that wound (codes 15170-15176).

2. Thus we see that, historically for autografts and in the proposed rule, CMS has appropriately determined that autografts and the remaining CPT skin replacement codes *would not* require immediate access to the full resources of an acute care hospital *or* be included among those procedures where prevailing medical practice dictates the beneficiary will typically be expected to require active medical monitoring and care at midnight of the day on which the surgical procedure was performed. We believe that the same reasons clearly apply to procedures 15170-15176.

For all the above reasons--inconsistency with HOPPS, safety, and overnight stay requirements--the ABA respectfully requests that CMS delete codes 15170-15176 from the list of procedures excluded from ASC payment and that CMS move codes 15170-15176 to the list of ASC approved procedures effective for January 1, 2008.

Thank you for the opportunity to provide comments on the ASC provisions of this proposed rule. The ABA is pleased to be able to contribute its expertise to CMS in these important matters in order to promote appropriate payment for services provided to Medicare beneficiaries now and for the future. If you have any questions or need further information regarding the issues we have discussed, please contact us at any time.

Respectfully submitted,

John Krichbaum, JD
Executive Director
American Burn Association

Submitter : Mr. Terence Green

Date: 11/06/2006

Organization : MGI PHARMA

Category : Drug Industry

Issue Areas/Comments

ASC Packaging

ASC Packaging

CMS Should Provide Separate Payment for Certain Drugs and Biologicals

CMS is proposing major reforms to Medicare ASC payment policy. In short, beginning in 2008, revised Medicare ASC payment rates would be tied to the hospital outpatient prospective payment system (OPPS) ambulatory payment classification (APC) payment amounts. However, CMS would establish the ASC rate at a significantly reduced percentage of the OPPS rate. For 2008, CMS estimates that ASC rates would equal 62 percent of the corresponding OPPS payment rates. Despite CMS's plan to base ASC payment on the OPPS payment amount, CMS is proposing very different packaging rules for the two sites of service. In particular, CMS is proposing to include payment for all drugs and biologicals in the ASC payment rate, even though a number of drugs and biologicals are reimbursed separately in the OPPS context (that is, those with pass-through status and specified covered outpatient drugs that exceed a fixed packaging threshold). Thus, under CMS's proposal, Medicare reimbursement for ASC services would be less than the corresponding OPPS rate, yet the payment amount would be expected to cover a broader range of items, including expensive drugs and biologicals that are reimbursed separately under the OPPS system.

We are concerned that this proposal would not adequately compensate ASCs for their drug acquisition and pharmacy handling costs, which could threaten patient access to needed drugs. CMS itself acknowledges the need to guard against inadequate reimbursement for drug and biologicals in the OPPS setting, on which the proposed ASC payment system is based:

Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs, biologicals, and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services.

The same concerns certainly hold true in the ASC setting and points to the need to ensure that expensive drugs and biologicals are not packaged into ASC rates.

Moreover, bundling payment for all drugs and biologicals in the ASC setting while providing separate reimbursement in the outpatient hospital setting could create inappropriate incentives to base care decisions on payment considerations, contrary to CMS's oft-stated goal of decreasing such site-of-service differentials.

We agree with concerns raised by the Medicare Payment Advisory Commission (MedPAC) in its formal comments on the Proposed Rule submitted to CMS on October 10, 2006:

We support CMS's proposal to expand the ASC payment bundle but encourage the agency to make the payment bundles in the ASC and hospital outpatient settings even more comparable. . . . Different bundling policies may lead to different relative payment amounts in each setting, even if the base payment rates share the same relative values in both settings.

Such differentials would have a disproportionate impact on individuals undergoing cancer treatments and others needing expensive drug and biological products in conjunction with their care, since their site of service options could effectively be limited under this policy.

To prevent an inappropriate site-of-service differential between hospital outpatient and ASC setting and ensure beneficiary access to medically-necessary drugs and biologicals in ASCs, CMS should carve out payments for certain drugs and biologicals in the ASC setting from the facility fee. Specifically, we propose that CMS provide separate payments to ASCs for (1) those drugs and biologicals that qualify for pass-through status under the OPPS system, and (2) those drugs and biologicals whose costs exceed the OPPS packaging threshold (\$50 in 2006). CMS could adopt these provisions as a temporary policy for 2 to 3 years as the agency collects ASC drug cost data & develops rates

GENERAL

GENERAL

MGI PHARMA appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Rule on Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-4125-P) (the Proposed Rule), 71 Fed. Reg. 49,506 (August 23, 2006). MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi? (palonosetron hydrochloride) injection is one of MGI's products that is made available in the ambulatory surgical center (ASC) setting. It is a 5-HT3 anti-emetic used to treat chemotherapy-induced nausea and vomiting.

We appreciate CMS providing this early opportunity to comment on the agency's plans for the reform of ASC payment and coverage policies beginning in 2008. We believe this dialogue with the stakeholder community offers an important opportunity to develop a policy framework that is responsive to both to Medicare program objectives and the needs of Medicare beneficiaries served by ASCs.

MGI PHARMA seeks to ensure that Medicare reimbursement for oncology drugs and other innovative pharmaceutical products is adequate to support Medicare beneficiary access to these therapies in ASCs. Our comments therefore focus on the Proposed Rule's provisions addressing packaging for drugs and biologicals under the revised ASC payment system.

Submitter : Dr. John Culclasure
Organization : Neurological Surgeons
Category : Physician

Date: 11/06/2006

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

ASC's provide safe, efficient care in a pleasant setting for patients. CMS should cover surgical procedures (CPT Codes 10000-69999) when performed in an ASC. Exceptions would include those procedures that require an staying overnight or those that could pose a safety risk(extensive blood loss, procedures involving a major blood vessel, etc.).

ASC Ratesetting

ASC Ratesetting

Changes proposed assume that ASC costs are 38% less than costs for hospital outpatient departments, and this is not accurate. This is especially true regarding implantable devices.

Using the technique of "compression" results in payments to ASC's that underestimate the cost of implantable devices. This should be corrected by selecting a methodology that results in appropriate reimbursement, especially for implantable devices.

The calculations for transition payments for implantable devices appear to have errors. It appears that device costs were not included in the calculations.

Medicare patients will lose access to ASC's for procedures that are not reimbursed properly. The ASC setting is an excellent location for patient procedures and ASC's are favored by many patients for their procedures.

Implantable devices should be reimbursed at the same rate whether implanted in an ASC or a hospital outpatient department. The costs of operation are similar therefore reimbursement should reflect this.

Submitter : Mr. Mark Leahey

Date: 11/06/2006

Organization : Medical Device Manufacturers Association

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment. Thank you.

CMS-1506-P2-1091-Attach-1.PDF



MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care TomorrowSM

November 6, 2006

VIA ELECTRONIC SUBMISSION

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

Re: Ambulatory Surgical Center Payment System and CY 2008 Payment Rates [CMS-1506-P2]

Dear Ms. Norwalk:

I am submitting these comments regarding the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Ambulatory Surgical Center (ASC) payment system and calendar year 2008 payment rates (Proposed Rule)¹ of behalf of the Medical Device Manufacturers Association (MDMA), a national trade association, representing over a hundred innovative medical device companies. Our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

MDMA commends CMS for its efforts to develop a new ASC payment system for implementation in 2008. We particularly appreciate the prompt release of the Proposed Rule, giving stakeholders almost 90 days to comment and putting providers on notice of the changes the agency is contemplating. Good policy takes time and thoughtful input, and we appreciate the agency's efforts to facilitate this process.

That said, we are pleased with certain aspects of the Proposed Rule, yet are concerned by others. Overall, we support CMS' aim to establish an accurate ASC payment system to improve Medicare beneficiary access to procedures performed in ASCs. We agree that the alignment of the payment systems for ASCs and hospital outpatient departments is appropriate; however, if this alignment is not coupled with an alignment of safety standards and quality reporting, full transparency will not be afforded to stakeholders including the government, patients, and providers. We hope the new ASC reimbursement system will encourage medical innovation and enable procedures to be performed faster, more accurately, and with less invasion in order to minimize patient risk and recovery times.

¹ 71 Fed. Reg. 49506 (Aug. 23, 2006).

We also believe it is critical that patient care only migrate from a hospital outpatient department to an ASC when that shift is clinically appropriate and in the interest of Medicare beneficiaries. Therefore, it is imperative that the new ASC payment system ensure that procedures only are available in an ASC when that setting is safe and clinically appropriate for most Medicare beneficiaries.

Payment rates under the new system should be appropriate to ensure beneficiary access to procedures performed in ASCs. Moreover, the new payment system should ensure that Medicare beneficiaries have access to new technologies and medical advances. For these reasons, our comments recommend the following improvements to CMS' proposal:

- CMS should further define certain criteria used to exclude procedures from payment when provided in an ASC setting and adopt additional exclusionary criteria;
- CMS should establish a fair and reasonable ASC conversion factor;
- Because the new ASC payment system is based on the weights established in the Medicare hospital outpatient prospective payment system (OPPS), the rate-setting methodology for device-dependent procedures in the OPPS must require the use of C-codes, ensure stable payment rates, and account for charge compression to ensure that, when the ASC conversion factor is applied, the resulting payment is appropriate;
- CMS should continue the current ASC policy of separate payment for items and services paid under the Medicare Part B Physician Fee Schedule, including brachytherapy sources and diagnostic and therapeutic imaging not directly related to performance of the surgical procedure. These medical devices and service would not be packaged in the ASC facility fee.
- CMS should ensure Medicare beneficiary access to new technologies meeting the criteria for payment in an ASC by extending the use of new technology ambulatory payment classifications (APCs) and device pass-through payments to the ASC setting; and
- CMS should use the market basket to update the ASC conversion factor for annual changes in inflation rather than the consumer price index for all urban consumers (CPI-U).

I. In order to ensure that patients receive care in the safest and most appropriate clinical setting, CMS should further define certain criteria used to exclude procedures from payment when provided in the ASC setting and adopt additional exclusionary criteria. (ASC PAYABLE PROCEDURES)

In determining which procedures will be covered by Medicare when provided in an ASC under the system for 2008 and beyond, CMS proposes to allow payment of an ASC facility fee for all procedures within the surgical range of current procedural terminology (CPT)² codes that do not pose a safety risk to Medicare beneficiaries or require an overnight stay.³ To evaluate safety risk, CMS proposes retaining the same specific criteria set forth in the current regulations at 42 C.F.R. § 416.65(b)(3). Accordingly, procedures that meet the following criteria would be excluded from the ASC payment in 2008 and beyond:

- Directly involve major blood vessels;

² CPT is a trademark of the American Medical Association.
³ 71 Fed. Reg. at 49637.

- Require major or prolonged invasion of body cavities;
- Generally result in extensive blood loss; or
- Are generally emergent or life-threatening in nature.⁴

The ASC regulation does not define the terms “major blood vessel,” “extensive blood loss,” and “major or prolonged.”

Although we support the expansion of beneficiary access to procedures in non-hospital settings when clinically appropriate, MDMA believes patient safety and quality of care are of utmost importance. We are very concerned about the absence of clear definitions for the criteria that establish whether a procedure is inappropriate for performance in the ASC setting, particularly as the list of ASC-covered procedures shifts from an inclusionary list to an exclusionary one. That silence, in conjunction with the fact that ASCs are not required to satisfy the same patient safety and quality reporting standards as hospital settings in which the same procedures are performed, could substantially compromise patient safety.

The exclusionary factors above parallel those established for the hospital outpatient setting. Generally, we support the alignment of the payment systems for ASCs and hospital outpatient departments; however, we believe the exclusionary factors require further clarification with respect to ASCs. Hospitals can address complications that may arise during surgical procedures in a manner that non-hospital settings cannot. ASCs only should perform those surgical services for which there is not a significant safety risk. Thus, as the new ASC payment system increases the availability of ASCs for surgical services, it is vital that the exclusionary criteria are defined clearly and carefully to ensure procedures are performed outside the hospital setting only when safe and clinically appropriate. Those procedures that pose a significant risk to patient safety should be limited to performance in a hospital setting. In addition, safety and quality reporting standards should be aligned across treatment settings.

a. Definitions for Exclusionary Criteria

In order to help ensure patient safety, MDMA strongly encourages CMS to adopt definitions to clarify the meaning of the following exclusionary criteria:

1. “Major Blood Vessels”

CMS should adopt a detailed definition of “major blood vessel.” In particular, we recommend that CMS define “major blood vessels” consistent with the definition provided by Seeley, Stephens and Tate in their medical textbook, *Essentials of Anatomy & Physiology*, 6th Edition.⁵ Procedures involving major blood vessels inherently increase the risk to patient safety. Accordingly, such procedures should be conducted in a hospital setting, where vital assistance is available should complications arise. Without clarification, patient safety could be jeopardized if risky procedures are conducted in inappropriate clinical environments. By adopting the Seeley, Stephens and Tate definition of “major blood vessels,” CMS would ensure that procedures

⁴ Proposed 42 C.F.R. § 416.166(c).

⁵ Seeley RR, Stephens TD, and Tate P. *Essentials of Anatomy & Physiology*, 6th Edition. McGraw-Hill. 2007: Chapter 21, Cardiovascular System: Peripheral Circulation and Regulation.

involving the heart and the aorta, and vessels providing primary blood supply to major limbs and organs are performed in a hospital setting.

Specifically, we believe that the following vessels should be considered “major blood vessels,” and procedures involving these vessels should not be added to those that receive Medicare payment if performed in an ASC:⁶

- 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 and axillary arteries);
- arteries of the head and neck (common, external and internal carotid arteries and vertebral arteries);
- major branches of the abdominal aorta (celiac trunk, superior and inferior mesenteric arteries, renal arteries (supplier of blood to kidneys), gonadal arteries, and common iliac arteries (at L₅ 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, and anterior tibial artery);
- veins entering the right atrium (coronary sinus veins and superior and inferior vena cava); veins of the head and neck (internal jugular vein and vertebral vein);
- veins of abdomen and pelvis (hepatic veins, renal veins, gonadal veins and right and left common iliac veins);
- veins of lower limb (anterior and posterior tibial veins); and
- hepatic portal system (hepatic portal vein, mesenteric veins, gastric veins, and cystic vein).⁷

We believe the exclusion of procedures involving these vessels is critical to ensuring patient safety and quality of care.

2. “Major or Prolonged Invasion of Body Cavities”

We also ask CMS to continue to define “prolonged” to include any procedure requiring the patient be under anesthesia for a period of 90 minutes or longer because a higher rate of adverse events is correlated with prolonged anesthesia time. In addition, “body cavities” should be defined to encompass major blood vessels. Such limitations will help ensure patients are treated in the environment most able to address their clinical needs and will further facilitate patient safety. Because procedures requiring anesthesia for more than 90 minutes and involving invasion of the body cavities or major blood vessels place patients at increased risk of adverse events, we believe CMS should limit the performance of such procedures to the hospital setting, where emergency support can be provided to patients if necessary. To date, there has not been

⁶ Procedures involving some of the vessels defined as “major” by Seeley, et al. currently are performed safely in ASCs (e.g., thrombectomy, percutaneous, arteriovenous fistula), therefore such vessels are not included in this list.

⁷ Seeley RR, Stephens TD, and Tate P. *Essentials of Anatomy & Physiology*, 6th Edition. McGraw-Hill. 2007: Chapter 21, Cardiovascular System: Peripheral Circulation and Regulation.

sufficient evidence to support the removal of the 90 minute threshold.

3. “Extensive Blood Loss”

We are concerned that without greater specificity regarding the meaning of extensive blood loss, beneficiaries could receive inappropriate procedures in ASCs. Therefore, we urge CMS to define the term “extensive blood loss” to include procedures that cause 15 percent or greater loss of total blood volume during the routine performance of the procedure. The American College of Surgeons has found that a loss less than 15 percent of total blood volume usually does not affect a patient’s vital signs, and fluid resuscitation usually is not necessary.^x An ASC typically can manage a patient who has lost 15 percent or less of total blood volume because such loss generally does not affect a patient’s vital signs. However, an ASC is not the appropriate or best setting to address complications impacting vital signs that can arise during procedures in which the routine performance results in greater than 15 percent total blood volume loss. Accordingly, CMS should clarify that extensive blood loss means a total blood volume loss of 15 percent so that procedures that routinely result in such loss are not performed in the ASC setting, and beneficiaries receive care in a safer environment.

b. Additional Exclusionary Criteria:

In addition, MDMA asks CMS to adopt the additional factors discussed below as exclusionary criteria, rendering a procedure inappropriate for the ASC setting. Each results in increased risk of complications to patients that could be better addressed in a hospital outpatient setting.

1. Interventional Procedures Involving Puncture of the Femoral Artery

We request that CMS exclude from payment in an ASC interventional procedures requiring puncture of the femoral artery. While these procedures are generally extremely safe, if complications do arise in an ASC setting requiring hospital care following puncture of the femoral artery, transport to a hospital would be required while maintaining open access to the femoral artery. This can cause infection or dissection due to motion. Interventional procedures involving femoral artery access are associated with a significant rate of peri-procedural complications.^y Because of the increased risk to patient safety, we strongly encourage CMS to exclude interventional procedures involving puncture of the femoral artery from coverage in the new ASC payment system.

2. Procedures Involving a Risk of Occlusion

Similarly, CMS should exclude procedures that involve a risk of occlusion from being paid in an ASC. Because lytic therapy is performed on an inpatient basis, a patient requiring lytic therapy

^x American College of Surgeons' Advanced Trauma Life Support (ATLS) as defined at <http://en.wikipedia.org/wiki/Hemorrhage>.

^y See Archbold, et. al, Radial Artery Access for Coronary Angiography and Percutaneous Coronary Intervention, *BMJ* (Aug. 21, 2004) available at <http://bmj.bmjournals.com/cgi/content/full/329/7463/443>; Vascular Complications of Cardiac Catheterization, *American Family Physician* (March 1993) available at http://www.findarticles.com/p/articles/mi_m3225/is_n4_v47/ai_13664785.

due to occlusion who is located in an ASC will require transfer to a hospital. Transfer with an open catheter site jeopardizes patient safety by increasing the risk of dissection, perforation, and infection. In light of the compromise to patient safety inherent in transferring patients with open catheter sites, we believe Medicare should not pay for procedures with a risk of blood vessel occlusion when provided in the ASC setting.

3. Certain Comorbidities

Procedures performed on patients with comorbidities lead to increased risk for patient complications and the need for interventions. Because patients with such comorbidities bear an increased risk of complication when they undergo surgical procedures, the immediate support of a hospital setting is necessary to help ensure beneficiary safety and quality of care. Therefore, we believe procedures involving patients with certain comorbidities should not be covered in the new ASC payment system, even if the procedure typically can be safely conducted in the ASC setting.

Comorbidities that should render a procedure inappropriate for the ASC setting include poorly controlled diabetes, uncontrolled hypertension, significant renal insufficiency, cardio-pulmonary failure, and coagulopathy. In addition, morbidly obese patients are at an increased risk for complications. Therefore, CMS also should require such patients to undergo surgical services in a hospital setting and not in an ASC. We strongly encourage CMS to exclude from ASC payment surgical services when performed on patients with such comorbidities in order to ensure the safety of such patients.

This prohibition should not apply to office-based surgical procedures performed in an ASC. Indeed, it is precisely patients with these types of comorbidities who could benefit from the additional safeguards present in an ASC that typically are not available in a physician office.

We recognize that the comorbidities exclusion is specific to the patient rather than to the procedure. Medicare has established precedents for exclusion from coverage of procedures based on comorbidities in other areas (e.g., the carotid stenting NCD), however. The comorbidities exclusion could potentially be enforced through the audit process or through edits to the diagnosis code reporting section of ASC claims forms.

c. Procedures Proposed for Exclusion in 2008

We urge CMS to exclude the following procedures from payment when performed in an ASC under the new system because they pose a safety risk to Medicare patients both under CMS' existing exclusionary criteria and the more detailed definitions for that criteria we proposed above (Even though CPT codes 33212 and 33213 were added as of 2005, we are drawing attention to these procedures as well as we do not feel they should be added given our patient safety concerns for cardiac rhythm management procedures.):

<u>CPT Code</u>	<u>Procedure Description</u> ¹⁰
33206	Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial
33212	Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular
33213	Insertion or replacement of pacemaker pulse generator only; dual chamber
33214	Upgrade or implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33215	Repositioning of previously implanted transvenous pacemaker or pacing cardioverter-defibrillator (right atrial or right ventricular) electrode
33216	Insertion of transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
33217	Insertion of transvenous electrode; dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33218	Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter-defibrillator
33220	Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of generator)
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular

¹⁰ CPT 2006, CURRENT PROCEDURAL TERMINOLOGY (American Medical Association ed., Professional Edition).

- 33241 Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator
- 35473 Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk or branches, iliac
- 35474 Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk or branches, femoral-popliteal
- 35476 Transluminal balloon angioplasty, percutaneous; tibioperoneal trunk or branches, venous
- 35492 Transluminal peripheral atherectomy, iliac
- 35761 Reoperation, other vessels, more than one month after original operation
- 37205 Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel
- 37206 Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel
- 37250 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel
- 37251 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel
- 37650 Ligation of femoral vein

II. CMS should establish a fair and reasonable ASC conversion factor to ensure adequate payment to ASCs, enabling patients and Medicare to save money through the safe performance of procedures in the lower cost ASC setting and develop mechanisms to ensure patient access to all procedures. (ASC CONVERSION FACTOR)

MDMA is greatly concerned that the proposed conversion factor will result in insufficient payment to ASCs for their services across the board.¹¹ CMS proposes to revise the ASC payment system in 2008 using the OPSS's procedure groups (APCs) and relative weights. The conversion factor would be based on a budget neutrality adjustment designed to keep total payments under the new ACS payment system equal to total payments under the old system. To ensure that the new system is budget neutral relative to the old system, CMS proposes to multiply the OPSS conversion factor by a budget neutrality adjustment of 0.62. Quite simply, paying for procedures performed in ASCs at 62 percent of the hospital outpatient payment rate may be too low to ensure Medicare beneficiaries have access to surgical services in the

¹¹ 71 Fed. Reg. at 49656.

convenient, efficient and cost-effective ASC setting. MDMA is concerned that an ASC conversion factor that equals 62 percent of the OPPS conversion factor may reduce the viability of performing many of the newly added procedures, as well as established procedures, in the ASC setting.

While lack of ASC cost data makes it impossible to estimate the overall impact of the proposed ASC conversion factor, setting payment at 62 percent of the OPPS conversion factor may interfere with the ability to perform certain procedures in the ASC, some of which are well established in that setting. For example, insertion of a non-rechargeable neurostimulator pulse generator dual array (CPT 63685/APC 0222), commonly performed in the ASC setting, will be grossly underpaid if the proposed payment is enacted. The current ASC rate (including the DME payment for the pulse generator and patient programmer) – already below ASC costs – will drop from approximately \$10,200 to \$6,798, approximately \$4,800 less the acquisition cost of the non-rechargeable pulse generator only.¹²

The revised ASC payment system proposed by CMS will result in the redistribution of payments for many specialties. Rather than provide a full range of procedures, ASCs tend to provide a limited number of specialized services that use similar equipment and physician expertise. Accordingly, an individual ASC likely cannot readily adapt to payment changes resulting from the new system by changing the mix of procedures it performs. Instead it will respond by modifying its volume of Medicare patients. For ASCs with a small demand for services for non-Medicare patients, insufficient payment may cause the migration of services to hospital outpatient departments, causing an increase in costs incurred by the government and beneficiaries. For ASCs offering services with significant demand among non-Medicare patients, insufficient payment could cause ASCs to limit the amount of services offered to Medicare patients, reducing or delaying beneficiary access to important surgeries. In order to ensure the availability of the ASC setting to Medicare beneficiaries when clinically appropriate, we urge CMS to adopt a fair and reasonable conversion factor to adequately reimburse ASCs for their services. We think that a 75 percent conversion factor, as proposed by Senator Crapo and Representative Herger, is a more realistic amount to ensure beneficiary access to important surgical procedures in the economical and efficient ASC setting.¹³

Certain procedures provided in the ASC setting involve the use of medical devices and consumables. These products generally cost the same regardless of the setting in which they are provided. When these fixed costs exceed CMS' payment rate for the surgery, ASCs have strong financial disincentives to perform the procedure and typically will not offer it. If ASCs restrict or eliminate availability of these important procedures, beneficiaries may not have access to critical treatments in the most convenient and cost-effective settings. Instead Medicare beneficiaries will have to undergo surgical procedures in more expensive hospital settings even though such procedures could safely be performed in an ASC.

To avoid this situation, we ask CMS to explore ways to ensure adequate reimbursement for all ASC eligible procedures. Any mechanism that would further reduce the proposed conversion

¹² Median acquisition cost of \$11,596 (mean cost \$11,585), based on IMS Health, Health Supply Index of non-federal, short-term acute care hospital purchases from January 1 through September 30, 2005.

¹³ See S. 1884 and H.R. 4042, 109th Cong. (2005).

factor is unacceptable, however, as the proposed factor already will impose a hardship on the performance of procedures in ASCs. MDMA would be happy to work with CMS to explore different alternatives.

One option would be for the agency to reallocate the savings that will be obtained for not allowing additional reimbursement under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule to specific procedures that use DMEPOS items rather than using the funds to update the conversion factor across the board. We understand that CMS did not include costs under the DMEPOS fee schedule when calculating the proposed conversion factor. These funds should be captured in the final rule, and allocating them to the procedures that use DMEPOS is fair and would result in more appropriate payment rates.

Specifically, reimbursement for procedures under the ASC payment system currently does not cover durable medical equipment (DME) and implantable prosthetic devices.¹⁴ For those supplies ASCs receive separate payment under the DMEPOS fee schedule.¹⁵ In contrast, reimbursement of prosthetic implants and implantable DME in the OPSS is included in the amount paid for the surgical procedure under the APC. CMS has proposed to similarly package implantable DME and prosthetic implants into the APC payment for procedures performed in ASCs. Because device costs remain about the same regardless of the setting in which a procedure is performed, we encourage CMS to develop a mechanism in the new payment system to allocate the DMEPOS funds that ASCs receive under the current system to those procedures using such implantable equipment or prosthetics. Providing these resources, to which ASCs currently are entitled to receive, to device-dependent procedures in the new payment system will help ensure the availability of such procedures to Medicare beneficiaries in a convenient and cost-effective setting. We also urge CMS to consider other mechanisms to ensure beneficiary access to device-dependent procedures in the ASC setting.

For these same reasons, we also strongly support the agency's proposal to mirror the hospital OPSS policy for discounting when a Medicare beneficiary has more than one surgical procedure performed on the same day at an ASC. The agency acknowledges that procedures involving costly implantable devices "are not discounted even when performed in association with other surgical procedures because the cost of the implantable device does not change, so resource savings due to efficiencies would be minimal."¹⁶ We agree that payments for these procedures should not be reduced when they are performed on the same day and that payment for the same set of multiple procedures in the OPSS and the ASC should be made using similar packaging and payment rules. CMS should finalize this proposal.

III. The rate-setting methodology for device-dependent procedures in the OPSS must require the use C-codes, ensure stable payment rates, and account for charge compression to ensure that ASC rates can be appropriately calculated. (ASC RATE-SETTING)

¹⁴ 42 C.F.R. § 416.60(b); 71 Fed. Reg. at 49648.

¹⁵ 71 Fed. Reg. at 49648; See also www.cms.hhs.gov/MLNMattersArticles/downloads/MM5026.pdf

¹⁶ 71 Fed. Reg. at 49651.

MDMA generally supports using the OPSS as a basis for the new ASC payment system; however, we continue to have some concerns about rate-setting within the OPSS for device-dependent procedures. Accordingly, we ask CMS to review the recent comments we submitted on the OPSS proposed rule for 2007¹⁷ and to ensure that the rate-setting methodology for device-dependent procedures requires the use of C-codes, ensures stable payment rates, and accounts for charge compression.

Specifically, CMS proposes to base the CY 2007 OPSS device-dependent APC medians on CY 2005 claims and the median costs calculated from those claims with appropriate device codes that do not have token charges on the claim.¹⁸ We agree that CMS should use only correctly coded claims containing C-codes to set median rates for these APCs in order to better reflect hospital costs for device-dependent procedures that then will be multiplied by the ASC conversion factor to establish ASC payment. Use of correctly coded claims is preferable for rate-setting for both hospitals and ASCs.

We also strongly encourage CMS to ensure it has an adequate amount of such claims to set rates appropriately. Because hospitals often require several months to correctly code a device and establish appropriate charges for a new procedure, Medicare data in the first year or two following issuance of a new C-code for a device may not accurately reflect its use. We are very concerned that decreases and fluctuations in any device-dependent APC payment rates resulting from use of inaccurate data could lead to limited patient access to these cutting-edge devices and procedures in both hospital outpatient and ASC settings. Therefore, CMS only should use mature, device-specific data that accurately encompasses the device portion of an APC that, by ensuring appropriate payment, will help enable both hospitals and ASCs to provide important device-dependent procedures to Medicare beneficiaries.

Finally, we encourage CMS to adjust the OPSS payment rates to compensate for charge compression. We are encouraged that the agency has hired a contractor to study this phenomenon in the hospital inpatient setting and ask that CMS consider the issue of charge-compression as it applies to the ASC setting as well. As you know, OPSS payment rates are based on a methodology using Medicare claims and hospital cost reports. CMS applies the same cost-to-charge ratio to the different items and services provided in a hospital department that assumes that hospitals mark up items by a uniform percentage.¹⁹ Hospitals assign different mark-ups to different items, however. Generally, high cost items are marked up to a lesser extent than lower cost items. Use of a single cost-to-charge ratio thus underestimates the costs of low mark-up items and overestimates the costs for the high mark-up items. Charge compression results in payment inequities, disfavors high cost items, such as devices, and consequently adversely affects reimbursement for device-dependent procedures.

¹⁷ Letter to Mark McClellan, Administrator, CMS, from Mark Leahy, Executive Director, MDMA, regarding proposed changes to OPSS and calendar year 2007 payment rates (Oct. 6, 2006), available at <http://www.medicaldevices.org/public/documents/MDMA07OPSScomments.FINAL.pdf>.

¹⁸ 71 Fed. Reg. at 49570.

¹⁹ Government Accountability Office (GAO), Medicare Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, Report to Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, September 2004.

In order to ensure continued beneficiary access to important procedures in both hospitals and ASCs, we encourage CMS to adjust its payment rates to account for this distortion. We request that the agency at least establish a payment minimum so device-related rates are not below their 2006 level. CMS also use the best available data in setting rates, whether such data are generated internally by CMS or accepted from outside sources. We agree with the APC Panel's recommendation that CMS should use readily available external data to validate costs determined by CMS' claims data.²⁰ In particular, external data can be used to identify and adjust payment for technologies that have been under-funded in the past under the OPPS, as well as for those products and procedures that received significant cuts in recent years. External data also can be used to rectify the effects of charge compression on reimbursement rates and to allow manufacturers to demonstrate how their products are disadvantaged by the fact that differential mark-ups are considered into cost-to-charge ratio calculations. Appropriate payment for procedures provided in ASCs that use a device is essential to maintaining the availability of such procedures to Medicare patients.

IV. ASC Packaging

CMS proposes changes to some of the packaging rules under the new ASC payment system effective January 1, 2008. MDMA supports applying the current HOPPS packaging rules to the new ASC system. Comparable packaging rules advance the CMS goal of parallel payment systems.

Under HOPPS, diagnostic and therapeutic imaging services are paid separately and in addition to the surgical procedure. The CMS proposal to package the costs of these otherwise separately payable items into the ASC facility fee would lead to significantly reduced payment for these procedures when performed in the ASC and reduce the ability to provide these procedures in that setting. We support the HOPPS policy and recommend that it be applied to the ASC system.

Further, brachytherapy sources are paid separately and in addition to the brachytherapy procedures in both hospital outpatient departments and ASCs. Under the new ASC payment system, we support continued separate payment for brachytherapy sources payable under the Medicare Part B Physician Fee Schedule.

MDMA supports continuation of the current ASC policy of separate payment for items and services paid under the Medicare Part B Physician Fee Schedule, including brachytherapy sources and diagnostic and therapeutic imaging not directly related to performance of the surgical procedure. These medical devices and service would not be packaged in the ASC facility fee.

Further MDMA supports applying the current HOPPS packaging rules to the new ASC system as it relates to items and services directly related to performing the surgical procedure.

²⁰ Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.

V. CMS should allow payment for new technologies in the new ASC payment system through new technology APCs and new technology pass-throughs established in the OPPS. (ASC RATE-SETTING)

MDMA is pleased that CMS proposes to update annually the list of procedures for which Medicare would not make payment of an ASC facility fee.²¹ We also appreciate that the agency intends to include Category III CPT codes in this annual update.²² These issues are particularly important in light of the fact that the agency intends to exclude the unlisted surgical codes from payment in an ASC.²³

We agree with CMS' characterization of the dynamic nature of ambulatory surgery, resulting in a "dramatic shift of services from inpatient to outpatient settings over the past two decades."²⁴ In large part, this shift has been fostered by new technologies such as those developed by our many member companies. It is imperative that Medicare beneficiaries have the same access to cutting-edge care as their private sector counterparts.

Toward this end, we urge CMS to extend the use of the new technology APCs and device pass-through payments from the OPPS to the ASC setting whenever appropriate for beneficiary care. This will further CMS' goal of having the new ASC payment system parallel the OPPS wherever possible and will help ensure Medicare beneficiary access to new technologies in ASCs. Specifically, CMS should permit payment to ASCs for new technologies using the same methodology and application process as for the OPPS. In fact, for ease and simplicity, we recommend that CMS allow applicants for new technology APCs and pass-throughs to request payment in ASCs as well when they submit their application. In conjunction with the information already required, applicants who request that the new technology APC or pass-through be applicable in the ASC setting would need to submit additional information in the same application to show that the new technology satisfies the criteria necessary for a procedure to receive payment in an ASC (i.e., does not require an overnight stay, does not involve major blood vessels, etc.). We believe that extending the new technology APCs and device pass-throughs to ASCs is the best way to ensure Medicare beneficiaries have access to new technologies and procedures in the most appropriate, efficient, and cost-effective clinical setting. We urge CMS to make this change in the final rule.

VI. CMS should use the market basket to update the ASC conversion factor for annual changes in inflation rather than the CPI-U. (ASC INFLATION)

CMS has proposed to update the ASC conversion factor for annual changes in inflation using the CPI-U.²⁵ In contrast to the proposal for updating the ASC conversion factor, CMS modifies the OPPS conversion factor for inflationary changes by using the hospital market basket. We are pleased that CMS has proposed a method to update ASC payments for changes in inflation; however, we encourage CMS to align outpatient hospital and ASC payment systems wherever

²¹ 71 Fed. Reg. at 49659.

²² Id. at 49636-37.

²³ Id. at 49638.

²⁴ Id. at 49637.

²⁵ Id. at 49655.

possible. Such alignment would be undermined by the use of two different mechanisms to adjust payments to each setting for inflation.

MDMA believes the discretion provided by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to CMS in creating the ASC payment system includes discretion regarding updating the ASC conversion factor for inflationary changes. Because it better captures the affects of inflation, we strongly encourage CMS to use the market basket to revise payments to ASCs as well. ASCs perform many of the same services as hospital outpatient departments and are subject to the same inflationary pressures borne by the health industry. Use of the CPI-U may result in inaccurate payment to ASCs and consequently may limit patient access the efficient and cost-effective ASC setting. Therefore, we ask CMS to adopt the same method for updating the ASC conversion factor for inflation as it has for the OPPS conversion factor – the hospital market basket.

VII. Conclusion

We look forward to working with CMS on these and other issues of concern regarding the new ASC payment system. If you have any questions or would like to discuss our comments further, please contact me at 202-349-7174 or mleahey@medicaldevices.org.

Sincerely,



Mark B. Leahey
Executive Director
Medical Device Manufacturers Association