Submitter : Mr. Robert Reinhardt **Date:** 11/06/2006

Organization : Olympus America Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1506-P2-1067-Attach-1.DOC

#1067

OLYMPUS

November 6, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4125-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via E-mail

Re: Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-4125-P): ASCs

Dear Ms. Norwalk:

Olympus America Inc. 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). Our review of the proposed rule identified several aspects of the proposed changes with which we are concerned.

The Medical Systems Group of Olympus America Inc. provides endoscopy knowledge and solutions that enable healthcare professionals in Gastroenterology (GI) hospital suites, ambulatory surgery centers (ASCs) and private practices to achieve excellent clinical outcomes across the continuum of care. Among other things, Olympus offers diagnostic and therapeutic endoscopy equipment and accessories; service and repair solutions; web-based endoscopy information products; GI lab integration services; and cleaning and disinfection products and services.

Gastroenterology represents the second largest ASC medical specialty in the United States. More than 20% of ASCs perform GI endoscopy procedures, such as colonoscopies for screening and detection of colorectal cancer and gastroscopies to identify gastroesophageal reflux disease and/or Barrett's esophagus. ASCs facilitate access to safe, cost-effective settings for performing endoscopy procedures.

The most recent data available established an average expense of $400 per case for performing GI endoscopy procedures in an ASC[1]. Typically, a cost per case analysis encompasses salaries for personnel (including the registered nurse required pre, intra and post procedure) and the costs associated with the endoscopy equipment, disposable supplies and accessories needed for the procedure, as well as the post procedure handling of the equipment necessary to properly reprocess the wide variety of required endoscopes.

[1] See *Foundation for Ambulatory Surgery in America (FASA), Financial Benchmarking Survey 2006.*

For the past six years, ASC payments have remained flat despite the increasing costs of the wages, supplies and equipment needed to provide high quality care. Under the Proposed Rule, instead of adjusting for these rising costs, Medicare would pay progressively less to ASCs, decreasing the reimbursement level by a low of 11% to a high of 30%, depending on the final scenario chosen. The proposed cuts are illustrated in the chart that follows and show that in 2008 the reimbursement level would not adequately cover the costs associated with providing these important procedures.

		CAGR (%) (2001-2007prop)		2006		2007 proposal		ASC 2008 proposal (w/ 50/50 transition)	ASC 2008 proposal (w/o 50/50 transition)
APC	Description	HOPD	ASC	HOPD AMT	ASC AMT, % of HOPD	HOPD AMT	ASC AMT, % of HOPD	AMT, % CHG from 07	AMT, % CHG from 07
0141	Level I Upper GI Procedures (I.e., 43239, 43251, 43250)	7.30%	0.60%	$480.03	$446.00 *92.9%*	$511.30	$446.00 *87.2%*	$387.84 *-13.0%*	$329.69 *-26.1%*
0143	Lower GI Endoscopy (I.e., 45378, 45380, 45385)	6.20%	0.60%	$509.34	$446.00 *87.6%*	$542.53	$446.00 *82.2%*	$397.91 *-10.8%*	$349.82 *-21.6%*
0158	CRC Screening Colonoscopy (G0105, G0121)	3.10%	0.50%	$449.56	$446.00 *99.2%*	$480.92	$446.00 *92.7%*	$378.05 *-15.2%*	$310.10 *-30.5%*

It is our concern that the proposed steep drop in Medicare ASC payment rates could possibly result in many ASCs discontinuing providing these commonly performed and important procedures, limiting patient access to screening colonoscopies and other preventive GI endoscopy services in the ASC setting, and ultimately compromising the health of Medicare beneficiaries. Moreover, discouraging the performance of procedures in the ASC setting could shift patient care to more expensive settings, paradoxically increasing costs to the Medicare program.

We also share the concerns expressed by the Medicare Payment Advisory Committee (MedPAC)[2] that CMS's charge data from 1986 are "probably no longer consistent with ASCs' actual costs." MedPAC points out: "[b]ecause CMS has not collected recent ASC cost data, we are not able to estimate ASCs' costs or determine which surgical setting has the lowest costs. Thus, the Commission is unable to judge whether an ASC conversion factor that equals 62 percent of the OPPS conversion factor is appropriate." We agree that it is inappropriate to establish an ASC conversion factor without a true picture of ASC costs. CMS should not establish a new payment system until it has reliable data that ensures ASCs are adequately compensated for providing quality care to Medicare beneficiaries.

In conclusion, the proposed Medicare ASC payment rates for 2008 do not cover the costs related to furnishing GI endoscopy procedures by efficient, high-quality providers. Such reductions in payments could force many ASCs to stop providing these services to Medicare beneficiaries. If procedures are not available in the ASC

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[2] See http://www.medpac.gov/publications/other_reports/101006_ASC_%20comment_AW.pdf?CFID=9299012&CFTOKEN=78096660.

setting, more Medicare patients would need to receive care in the hospital outpatient setting, forcing the Medicare program and Medicare beneficiaries to pay higher amounts for the same services. Likewise, beneficiaries may be discouraged from receiving important preventive services like colorectal screening colonoscopies due to limited facilities and longer waiting times.

To protect beneficiary access to quality care in the ASC setting, CMS should base payment rates on updated costs, and ensure that ASCs are compensated appropriately for providing high-quality care. CMS must reexamine its "one size fits all proposal" and establish ASC payment rates based on updated, actual cost data for these procedures.

We appreciate your attention to our comments. Please let me know if you have any questions.

Respectfully submitted,

Robert Reinhardt
Vice President & General Manager
Medical Products
Medical Systems Group
Olympus America Inc.
robert.reinhardt@olympus.com

Submitter : **Ms. Maureen Huddleston** **Date: 11/06/2006**

Organization : **DSA Surgery Center, Inc.**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P2-1068-Attach-1.PDF

#1068

November 6, 2006

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

To whom it may concern,

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

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

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

Sincerely yours,

Maureen Huddleston RN
Nurse Manager / Administrator
DSA Surgery Center
7515 Main Street Suite 240
Houston TX 77030

Submitter : Dr. Charles Coleman **Date:** 11/06/2006

Organization : Augusta Urology Surgery Center, LLC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1069-Attach-1.DOC

#1069

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:

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

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

ASC PAYABLE PROCEDURES

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

Procedures that could pose a significant safety risk

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

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

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

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

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

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

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

Question: Are there any urology codes in the "medicine" section of CPT to which this would also apply?

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 and I support this proposal, as such codes are eligible for payment under the OPPS, thus should also be eligible for payment under the new ASC payment system. Examples for urology include 0135 T, *Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy* and 0137T, *Biopsy, prostate, needle, saturation sampling for prostate mapping.*

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

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

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

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

For urology, these codes are:

CPT/ HCPCS	Description	SI
50394	Injection for kidney x-ray	N
50684	Injection for ureter x-ray	N
50690	Injection for ureter x-ray	N
51600	Injection for bladder x-ray	N
51605	Preparation for bladder xray	N
51610	Injection for bladder x-ray	N
54230	Prepare penis study	N
55300	Prepare, sperm duct x-ray	N

ASC RATESETTING

CMS proposes to base ASC relative payment weights on Ambulatory Payment Classification (APC) groups and relative payment weights established under the OPPS based on the belief that the relative payment weights established under the OPPS for procedures performed in the outpatient hospital setting reasonably reflect the relative resources required for such procedures and do so with sufficient coherence to be applicable to other ambulatory sites of service. The AUA and I agree 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. **Along with the AUA, I strongly disagree with CMS's proposal to package into the ASC facility fee payment the cost of implantable prosthetic devices and implantable DME inserted surgically at an ASC.** The proposed conversion factor and phase-in would only exacerbate this problem.

ASC PAYMENT FOR OFFICE-BASED PROCEDURES

Proposed payment for office-based procedures

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

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

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

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

Usually, office-based procedures do not require the extra capacity of an ASC. However, the option should be available to physicians if they find it necessary for clinical reasons. For example, sometimes patients refuse to have a procedure performed unless they can be

anesthetized. Also, urologists may choose to perform prostate biopsies on older patients or patients who require anesthesia in an ASC. Based on our analysis of Medicare data in the past for urology office-based codes that have been on the ASC list for quite some time, CMS's migration assumptions are not realistic. (52000, 52281 and 55700).

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

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

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

ASC INFLATION

Proposed adjustment for inflation
Although the MMA froze ASC inflation updates until 2010, the current updates are based on the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS

proposes to apply a CPI-U adjustment to update the ASC conversion factor for inflation on an annual basis. However, the OPPS is updated annually using the hospital inpatient market basket percentage increase. Because CMS states multiple times in the proposed rule that they desire for the revised ASC payment system to reflect the OPPS as closely as possible, and because MMA does not mandate that any particular update system be used for the ASC payment system, the AUA and I urge CMS to use the same update method for both payment systems, which would achieve parity and transparency in the market and assure that site-of-service determinations are made based on clinical indications rather than economic considerations.

ASC PHASE IN

Proposal to phase in implementation of payment rates

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

ASC CONVERSION FACTOR

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

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

Sincerely,

Charles H. Coleman, Jr., M.D.
Augusta Urology Associates, LLC
& member of The American Urological
Association

Submitter : Ms. Deborah McMillin **Date:** 11/06/2006

Organization : Baptist Ambulatory Surgery Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

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

ASC Conversion Factor

ASC Conversion Factor

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

ASC Inflation

ASC Inflation

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

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.

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

ASC Packaging

ASC Packaging

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

ASC 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 ASC's 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 Payment for Office-Based Procedures

ASC Payment for Office-Based Procedures

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and HOPDs will

improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extend permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Phase In

ASC Phase In

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

ASC Ratesetting

ASC Ratesetting

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

ASC Unlisted Procedures

ASC Unlisted Procedures

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

ASC Updates

ASC Updates

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

ASC Wage Index

ASC Wage Index

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

GENERAL

GENERAL

Please see comments in each area.

Submitter : **Ms. Erin McMahon** **Date: 11/06/2006**

Organization : **Wyatt, Tarrant**

Category : **Attorney/Law Firm**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

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

Interventional pain physicians treat patients with a myriad of problems. Often, these patients have had several back surgeries that have failed to alleviate their pain. They have mental health and economic issues, and need physical therapy. Interventional pain management physicians are their last real hope for relief. It would be tragic, indeed, if the proposed Medicare rule robbed these patients of access to treatment and, consequently, their ability to function at the highest possible level.

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

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

Sincerely,
Erin Brisbay McMahon

Submitter : Mrs. Jennie Fowler **Date:** 11/06/2006

Organization : Augusta Urology Surgicenter, LLC

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1072-Attach-1.DOC

#1012

Augusta Urology Surgicenter, L.L.C.

James J. Carswell, III, M.D.
Mark L. Cain, M.D.
Charles H. Coleman, Jr., M.D.
Richard B. Sasnett, Jr., M.D.
Henry N. Goodwin, Jr., M.D.
Michael F. Green, M.D.
J. Douglas Quarles, Jr., M.D.

November 1, 2006

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

Re: Ambulatory Surgicenter Reimbursement

Dear Administrator Norwalk:

I am currently employed by a urology practice in Augusta, Georgia as Nurse Director of their Surgicenter. They have a freestanding ambulatory surgery center as well as three offices in the surrounding area. We serve patients covered by private health insurance as well as an ever-growing Medicare/Medicaid and indigent population in the offices as well as the surgery center. I am writing because of the current legislation pending that will drastically reduce Medicare ASC reimbursement.

Augusta Urology Surgicenter provides high quality, cost effective care that offers an alternative to the hospital. We play an important role in holding down the costs of medical care in the Augusta area. I am disturbed to learn that Congress is considering proposals to cut our payments on the second most frequently performed Medicare ASC urologic procedure, prostate biopsy (CPT 55700). Payment for this procedure will be reduced in 2007 by 39% with even further reduction in 2008.

I understand elected officials want to limit our facility fees to the hospital outpatient department rate (HOPD). While on paper a few of our rates appear to be higher, this is very misleading. Our (ASC) fees cover the entire cost of procedures to include radiology, while hospitals bill separately for each service and itemize bills for supplies used. By any standard, the hospital almost always gets paid much more for procedures performed in this setting (outpatient). Ultimately the financial viability of free-standing outpatient surgery centers will be negatively impacted.

Instead of more competition within the healthcare arena this will result in a negative impact with still fewer choices for Medicare recipients. This philosophy for reimbursement greatly discourages the efficiency and excellence exhibited by a majority of surgery centers and does nothing to realistically reduce costs.

University Professional Center III
811 13th Street, Suite 17
Augusta, GA 30901
Phone: (706) 724-4111 Fax: (706) 823-0533

The proposal to reimburse surgery centers somewhere between 60-65% of hospital outpatient department rates is simply not adequate. Surgery centers must pay competitive wages to nurses and other staff the same as hospitals. The staff is highly skilled and credentialed and held to the highest standards. The care provided each patient is according to the State of Georgia Rules and Regulation for Ambulatory Surgical Treatment Centers and the Federal Guidelines for Ambulatory Surgery Centers. Additionally, many ASCs are accredited by AAAHC (Accreditation Association for Ambulatory Health Care) or JCAHO (Joint Commission on Accreditation of Healthcare Organizations).

Supplies as well as rent and taxes probably consume more of a surgery centers budget than those of hospitals. Most surgery centers are a small business and they do not have the political clout and resources of large hospitals. The increase in the cost of liability insurance along with the difficulty of obtaining coverage in some states has impacted surgery centers and hospitals in the same way. If all of this were not so this proposal would never have occurred.

The proposal to reimburse surgery centers between 60 65% of hospital outpatient reimbursement is simply inadequate. To allow HOPDs to perform any outpatient procedure but restrict many of the same procedures from being performed in an ASC frankly makes no sense. The same physicians performing these procedures in the hospital outpatient suites are also owners and practitioners in ASCs. There is no deterioration in their surgical skills between facilities and certainly on change in the standard of care provided to the patient population.

Since ASCs must compete for highly skilled staff as well as provide quality supplies and maintain all of the regulations mandated by CMS in addition to providing a safe, efficient and highly professional environment for Medicare patients, it is only equitable that CMS consider ASCs as equal partners in the medical services delivery system and not substandard enterprises.

Respectfully,

Jennie B. Fowler

Jennie B. Fowler, RN
Nurse Director
Augusta Urology Associates Surgicenter, LLC

Submitter : Dr. Alan Shikoh **Date:** 11/06/2006

Organization : Digestive Disease Consultants

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Ms. Heather Loy **Date:** 11/06/2006

Organization : Pain Treatment Cnter dba Stone Road Surgery Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Please see my attached letter regarding ASC Payable procedures

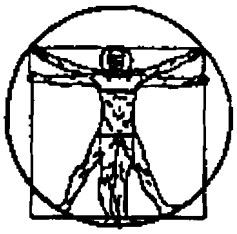
ASC Unlisted Procedures

ASC Unlisted Procedures

Please see my attached letter regarding ASC unlisted procedures

CMS-1506-P2-1074-Attach-1.DOC

#1074



THE PAIN TREATMENT CENTER, INC.
d/b/a
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(859) 278-1316
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"Specializing in advanced treatment for people in pain."

Joint Commission
on Accreditation of Healthcare Organizations

November 6, 2006

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

Re: Comments to Proposed Rules regarding Ambulatory Surgery Centers

Dear Administrator Norwalk,

My name is Ms. Heather Loy and I am the administrator at The Pain Treatment Center, Inc. d/b/a Stone Road Surgery Center. The Center is a free-standing surgery center licensed by the state and JCAHO accredited; the Center is also part of the Kentucky Ambulatory Surgery Center Association. The Center is licensed to perform multi-specialty procedures and has two ORs and one procedure room where we perform pain management procedures.

I am writing to you to thank CMS for reviewing how ambulatory surgery centers ("ASCs") are reimbursed. However, it does give me concern that the procedures done in our centers are reimbursed at such a disparate rate compared to hospital outpatient departments ("HOPD"), even though ASCs provide a safe, effective and efficient service to the patients brought to our centers. Therefore, I would ask CMS to look at the reimbursement rates between ASCs and HOPDs and to align the payment systems in a more equitable way. Reimbursing ASCs at 62% is simply not adequate and it serves as an impediment to Medicare beneficiaries' access to safe and effective procedures at ASCs.

In addition to reimbursement equity, I would ask CMS to continue to review and expand the ASC list of procedures. Once again, I do appreciate CMS' addition of 21 procedures in 2007, but believe that that number should be higher. In fact, I feel strongly that based on the quality and efficient service we provide to the physicians who choose to perform their procedures at our facilities and to their patients, the ASC list of procedures should include any and all procedures that can be performed in an HOPD. Only those procedures that are on the in-patient only list should be excluded. Case in point for my facility, is procedure 64640 (radiofrequency of the SI joint). The HOPD and the physician's office is reimbursed for this procedure by Medicare, but an

ASC, which would provide a safer level of care than the physician's office and an equally safe, but more efficient level of care than an HOPD, is not.

Lastly, I would request that CMS update the reimbursement rates based upon the hospital market basket; the hospital market basket more appropriately reflects inflation in providing surgical services than does the consumer price index. Furthermore, the same relative weights should be used in ASCs and HOPDs; again, as compared to HOPDs, ASCs provide the same safe and quality environment in an efficient and patient-friendly environment.

Thank you again for your interest in providing quality care to Medicare beneficiaries. By expanding the ASC procedure list and providing fair and equitable reimbursement for ASCs, both the taxpayer and the Medicare consumer will benefit since such beneficiaries will be able to continue to undergo safe and effective procedures in our facilities.

Sincerely,

Heather W. Loy
CEO, The Pain Treatment Center, Inc.
d/b/a Stone Road Surgery Center

Submitter : Ms. Bonnie Handke **Date:** 11/06/2006

Organization : Medtronic, Inc

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P2-1075-Attach-1.DOC

#105

1

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
7500 Security Blvd.
Baltimore, MD 21244-1850

ELECTRONICALLY SUBMITTED

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

Dear Ms. Norwalk:

Medtronic, Inc. is one of the world's leading medical technology companies specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high quality products and to support innovative therapies that improve health outcomes. We appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505).

Medtronic appreciates the significant effort you and your staff have put into the Ambulatory Surgical Center rule. We also appreciate your willingness to work with us and other stakeholders to establish beneficiary access to appropriate treatment options in the Ambulatory Surgical Center setting, while mitigating the potential for significant safety risks to the Medicare population.

For procedures that do not pose a significant safety risk, we support CMS' goal to establish a new payment system based on aspects of the Hospital Outpatient Prospective Payment System (HOPPS). However, we have concerns about an approach that applies a percentage reduction to OPPS

payment rates without regard to ASC costs and believe that further study is required to determine if such a reduction results in more accurate payment rates relative to ASC costs, particularly for procedures that involve implantable devices. In addition, recommendations from the pending MMA-mandated GAO report, which was due 18 months ago, have not been released for consideration. If, after the release of this report, it is determined that a systematic reduction is appropriate for the ASC rate setting, we believe the reduction should only apply to the procedural component of the payment rates. Because the cost of the device is generally consistent across all sites of service, implementation of a payment system that applies a standard reduction in payment to device-dependent procedures creates significant disincentives for ASCs to provide device related procedures. The potential cost savings and efficiencies associated with a less acute site of service does not extend to the device component and therefore, any systematic reduction would result in limited beneficiary access to device-dependent services provided in the ASC setting.

We are also concerned with CMS' proposal to allow certain procedures to shift to an ASC setting if they are performed less than 80% of the time in the inpatient hospital setting. We believe this utilization threshold is set too high to ensure beneficiary safety. For this reason, we believe ASCs should only be allowed to perform services for which a significant risk is not evident. In addition, ASCs are currently not required to adhere to the same safety and quality standards that apply to hospitals. We are concerned that this has the potential to impact patient safety.

We will comment and provide recommendations on the following topics:

- **ASC Payable Procedures**
  - **Proposed Definition of Surgical Procedure**
  - **Procedures Proposed for Exclusion from Payment Under the Revised ASC System**
- **ASC Office Based Procedures**
- **Listing of Surgical Procedures Proposed for Exclusion from Payment of an ASC Facility Fee under the Revised Payment System**
- **ASC Ratesetting**
- **ASC Payment for Office Based Procedures**
- **ASC Phase In**
- **ASC Addenda**

ASC Payable Procedures

- **CMS' Proposed Definition of Surgical Procedure: Medtronic Recommendation**

  Medtronic agrees with CMS' proposed definition of surgical procedures as those included in the CPT range 10000-69999. However, we emphasize that only the surgical procedures proven not to pose a significant safety risk to Medicare beneficiaries should be allowed for payment in the ASC.

- **Procedures Proposed for Exclusion from Payment Under the Revised ASC System**

  Medtronic agrees that all procedures currently included on the current OPPS inpatient only list should also be excluded from the ASC setting. We encourage CMS to create an additional status indicator that more clearly identifies those procedures that are allowable in an outpatient setting but would not be allowable in the ASC setting due to safety concerns.

  Medtronic also encourages CMS to further define the criteria used to establish whether a procedure is inappropriate for performance in the ASC setting. This is especially important as CMS has proposed to shift from an inclusionary list of ASC covered procedures to an exclusionary one.

  Medtronic recommends that CMS further define the criteria used to determine procedures that may be safely performed in an ASC (major blood vessel, extensive blood loss, and major or prolonged invasion of body cavities).

  CMS has proposed to establish beneficiary safety and the need for an overnight stay as the principal clinical considerations and factors in determining whether payment of an ASC facility fee would be allowed for a particular surgical procedure. To support this proposal, CMS defines an overnight stay as 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. CMS indicates in the proposed rule that procedures requiring an overnight stay as defined above would be excluded from payment.

  CMS also proposes to exclude procedures that are performed 80 percent or more of the time in the hospital inpatient setting (according to the CY 2005 Part B Extract Summary System

(BESS). Medtronic believes that the 80 percent utilization threshold is too high to ensure beneficiary safety and doesn't appear to be supported by the definition of an overnight stay put forth by CMS in the proposed rule.

If a specific procedure warrants an inpatient admission even 50 percent of the time, prevailing medical practice has indeed dictated that the beneficiary *typically* requires active monitoring and care at midnight. Therefore, we urge CMS to adopt a 50 percent inpatient utilization threshold. If a procedure requires an inpatient stay at least 50 percent of to the time, there is valid clinical reason to require that the remaining procedures be performed in the hospital outpatient setting. There are many procedures that may be safely performed in a hospital outpatient department that may not be safely provided in an ASC, because only the hospital outpatient department has immediate access to the full spectrum of emergency and acute care facilities of the hospital. In addition, the 50 percent utilization threshold is consistent with the percentage threshold CMS uses to classify office based procedures, which obviously is a less acute site of service.

Medtronic recommends CMS change the inpatient utilization threshold to 50 percent going forward as the 80 percent threshold is too high to ensure beneficiary safety. This would not or should not impact procedures that are currently included on the ASC inclusion list.

ASC Office Based Procedures

Medtronic is supportive of CMS' proposal to allow payment of an ASC facility fee (equivalent to the non-facility portion of the Medicare physician fee schedule) for surgical procedures that are commonly and safely performed in the office setting. This is an appropriate approach given that many of these procedures are commonly an integral component of another procedure that is payable. An example of this would be CPT codes 62367 and 62368 (analysis and programming of infusion pump). This service is integral to the surgical procedure for implantation of an infusion pump which is used for treatment of severe spasticity and chronic pain. If procedures like these were excluded from payment in the ASC system, beneficiaries would likely have to visit a physician office following their surgery to have the programming performed and verification that the pump is functioning properly and administering the drug appropriately.

Listing of Surgical Procedures Proposed for Exclusion from Payment of an ASC Facility Fee under the Revised Payment System

CMS has already recognized that several of the procedures associated with the implantation of pacemakers and ICDs are not appropriate to be performed in an ASC. However, additional pacemaker and ICD procedures need to be added to the list of services specifically excluded from the ASC site of service.

Pursuant to 42 C.F.R. section 416.65(b)(3)(iii) of the ASC regulations, procedures that directly involve major blood vessels may not be performed in an ASC. The lead placement inherent in the implantation of pacemakers and ICDs requires the direct involvement of major blood vessels. When a pacemaker or ICD is implanted, the subclavian, cephalic or axillary veins are cannulated and the lead(s) are advanced transvenously through the superior vena cava to the right atrium and/or right and left ventricles of the heart. Given that the implantation, repositioning, and removal of pacemakers and ICDs involve leads that are passed through and ultimately remain in the subclavian, cephalic or axillary veins and the superior vena cava (major blood vessels), Medtronic strongly urges CMS to add the following procedures to the list of services specifically excluded from the ASC site of service:

33206: Implantation of a single chamber pacemaker system (generator and lead)
33214: Upgrade from a single chamber pacemaker to a dual chamber pacemaker (generator and lead)
33215: Repositioning of pacing/defibrillation lead(s)
33216: Insertion of single chamber pacing/defibrillation lead
33217: Insertion of dual chamber pacing/defibrillation leads
33218: Repair of single chamber pacing/defibrillation lead
33220: Repair of dual chamber pacing/defibrillation leads
33224: Left ventricular lead insertion (stand-alone procedure)
33225: Left ventricular lead insertion (add-on procedure)
33226: Repositioning of the left ventricular lead
33234: Removal of pacemaker lead(s)

On page 49637 of the proposed rule, CMS suggests that HCPCS code G0297 (Insertion of single chamber pacing cardioverter defibrillator pulse generator) represents a procedure that, "could be safely and appropriately performed in an ASC" setting, yet that procedure code is not listed in Addendum BB. We can only presume that the language on page 49637 was included in error, because, as indicated above, the implantation of an ICD system requires the lead placement in a major blood vessel. In addition, these procedures require electrophysiologic (EP) testing (including induction of arrhythmia), which may present significant safety

risks when performed in an ASC. Therefore, Medtronic also urges CMS to also add the following procedures to the list of services specifically excluded from the ASC site of service:

G0297: Insertion of single chamber cardioverter-defibrillator pulse generator
G0298: Insertion of dual chamber cardioverter-defibrillator pulse generator
G0299: Insertion of single chamber cardiovert-defibrillator system (generator and lead)
G0300: Insertion of dual chamber cardiovert-defibrillator system (generator and leads)

In addition, Medtronic requests that CPT codes 33212, 33213, (insertion/replacement of single/dual pacemaker) and 33233 (removal of pacemaker pulse generator) be added to the exclusion list. These codes were added as of 2006, but we feel that their inclusion is not appropriate. Although CPT codes 33212, 33213, and 33233 only involve the insertion or removal of the generator and not the cardiac leads, the procedures do require the connection to, and testing of, existing leads positioned in a major blood vessel. Therefore, Medtronic recommends that the CPT codes 33212, 33213, and 33233 be added to the list of services specifically excluded from the ASC site of service.

Medtronic recommends CMS exclude all pacemaker and ICD procedures from the ASC setting as these procedures have direct involvement with major blood vessels and therefore, pose a significant safety risk to beneficiaries when performed in the ASC.

ASC Ratesetting

- **CMS' Proposed CY 2008 Payment Policy: Medtronic Recommendation to Improve Payment Appropriateness**

Medtronic has been supportive of CMS' proposed approach to base the new ASC payment system on the HOPPS methodology. We are concerned, however, that CMS failed to take into account comments and suggestions/recommendations that were made prior to the proposed rule regarding device dependent APCs. Previously, Medtronic and other industry partners recommended that the device component of the ASC payment rates be held harmless. That is CMS should apply the ASC conversion factor only to the procedural component of the ASC payment, while paying the device portion of the ASC payment at 100% of the OPPS payment rate. Implantable devices are not an item for which ASCs can achieve costs savings over hospitals. Acquisition costs for devices generally do not vary by site of service. Therefore, if CMS were to

implement the revised payment system as proposed, devices such as neurostimulators and implantable infusion pumps would be significantly underpaid in this setting.

Medtronic recognizes that the MMA required budget neutrality in the conversion to a new ASC payment system. CMS has proposed an adjustment to achieve this. We believe that the proposed budget neutrality adjustment results in a conversion factor that is not reflective of the costs of services in ASCs as compared to hospital outpatient departments, particularly regarding procedures with device implants, and we believe further study is warranted.

To achieve budget neutrality while appropriately reflecting the resource utilization associated with implantable devices, Medtronic recommends that CMS modify its ASC rate-setting approach for device dependent procedures by incorporating 100% of the device component of the APC payment (as already determined during the OPPS rate setting process) into the ASC payment and then applying the budget neutrality adjustment to the procedural component only, while holding total payments under the new system equal to those projected for the old one. The impact to the budget neutrality factor is minimal based on analysis we have conducted. Medtronic also recommends that CMS conduct further studies to determine a conversion factor that is reflective of ASC costs.

There are issues that remain in the HOPPS setting (as outlined below) related to implantable devices that have not yet been fully addressed and remedied. CMS should address and correct these issues before carrying the OPPS rate setting methodology over to the new ASC payment system.

We are appreciative of the efforts CMS has made to improve the accuracy of the rate setting process for device-dependent APCs in the HOPPS, however the current OPPS rate setting methodology for device dependent APCs does not result in rates that accurately reflect the associated device costs. The use of only those claims with an appropriate device code and claims with nontoken charges for the device is a positive step towards payment accuracy in both the outpatient hospital and ASC settings. We note, however, that there are still several device-dependent APCs in HOPPS, especially those including high cost devices such as neurostimulators where the device acquisition costs continue to be underrepresented in the median cost data. These are also the APCs that have experienced continued and significant payment reductions since 2002.

The table below illustrates the repeated payment reductions that have been imposed on several device-related procedures since 2002.

APC/Description	2002	2003	2004	2005	2006	2007
0039, Level I Implantation of Neurostimulator	$15,489	$11,876	$12,832	$12,532	$11,602	$11,518
0222,Implantation of Neurological Device	$15,400	$11,877	$12,669	$12,372	$11,455	$11,164,
0315, Level II Implantation of Neurostimulator	N/A	N/A	N/A	$20,078	$18,590	$14,932

Over the past six years, Medtronic has presented multiple sources of third party, external data to demonstrate that the CMS median cost data for these device-dependent procedures has been thousands of dollars lower than the actual hospital acquisition costs.

APC	Proposed Payment 2007	Device Related %[1]	Device Related Portion	IMS Health Median cost[2]	Difference between CMS Device portion and IMS Data
0039	$10,828.84	78.51%	$8,502	$11,561	($3,059)
0222	$10,964.12	78.10%	$8,563	$11,995	($3,432)
0315	$14,500.02	83.52%	$12,110	$18,278	($6,168)

[1] Table 21 Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedure List [CMS-1506-P]

[2] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005 (includes all devices included in APC payment)

We have done extensive research to understand the reasons why the cost data do not accurately represent the actual costs of these implantable technologies. Our analyses have found that one of the most important shortcomings in the OPPS methodology is that it does not include any mechanism to address the known issue of charge compression.

Medtronic strongly believes that an adjustment can and should be used to address charge compression in OPPS before rates are carried over to the new ASC payment system.

ASC Payment for Office Based Procedures

Non-surgical Procedures Customarily Performed in Office Setting

In our review of the proposed rule, we did not see discussion on how non-surgical procedures, which may be occasionally performed in an ASC, would be paid. Since 2001, CMS has had a policy (see Program Memorandum B-01-43) under which physicians may bill for procedures not on the ASC list and be paid the non-facility value for these procedures. The ASC is not eligible for a separate facility payment. While the proposed rule is silent, we recommend that the existing policy continue to make payments to physicians for non-surgical procedures. Continuance of this policy is particularly important for non-surgical procedures that have clinical importance to accompany a surgical procedure. Examples of these types of procedures include analysis and programming of implanted neurostimulators (CPT 95971- 95975) and placement of a pH monitoring capsule (CPT 91035) following an upper gastrointestinal endoscopy procedure.

ASC Phase In

Given the magnitude of changes CMS has proposed, Medtronic urges CMS to transition the changes over three years rather than two. This approach is consistent with the transition period used for the Inpatient Prospective Payment System (three years) and the Practice Expense changes to the Physician Fee Schedule (four years).

ASC Addenda

Addendum BB of the proposed rule includes CMS' calculations of the CY08 payment rates with and without the transition. After careful review, it appears that CMS has inadvertently omitted payment for the implantable device component (from the DMEPOS fee schedule), when calculating the transitional payments.

For example, for CPT code 63685 (insertion of a non-recharageable neurostimulator pulse generator dual array) CMS has calculated the CY2008 payment without the transition at $7,069.67 (this is 62% of the proposed OPPS payment). The transitional payment should be 50% of this added to the sum of 50% of the group payment and 50% of the DMEPOS device payment, rather than as CMS has calculated using only 50% of the group payment.

CMS Calculations
CY 2008 Payment without transition - $7,069.67
CY 2008 Payment with transition ($7,069.67*.5)+(446*.5) = $3,757.83

Example of Correct Calculation
($7,069.67*.5)+(446*.5)+($8,795(avg pymt for L8688)*.5 = $8,155.33

It is critical that if CMS finalizes a transitional approach to the new payment system that they incorporate all of the payment components including the DMEPOS fee schedule payment for the implantable devices.

ASC Inflation

The revised ASC payment system rule proposes to adjust the ASC payment rates for inflation using the Consumer Price Index for urban areas (CPI-U) beginning in 2010. However, CMS updates the OPPS conversion factor using the hospital market basket. While the existing ASC payment system is required by statute to update rates using the CPI-U, the Medicare Modernization Act (MMA), which authorized the revision of the existing ASC payment system, does not require that CPI-U be used as the inflationary factor under the revised system. Therefore, in order to establish greater parity between the OPPS and ASC systems Medtronic recommends that the ASC rates be updated using the hospital market basket. Using the market basket instead of CPI-U will ensure that procedures which are performed in the outpatient and ASC settings receive similar inflationary updates while failure to align the methodology for updating the rate of inflation would undermine efforts to create parity between the two systems. Medtronic recommends that CMS update both the OPPS and ASC rates using the hospital market basket.

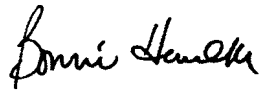
Additional Comment Period

The revised ASC payment system rule includes a number of proposed changes which may significantly impact the ability to provide procedures in the ASC setting. Among the most significant of these proposals is the plan to pay all ASC procedures that may be performed in a hospital outpatient department at 62 percent of the OPPS rate, including procedures which involve medical devices that may account for a significant share of the resources consumed under the respective payment group. Given the complexity of the changes, Medtronic recommends that CMS publish its response to the 2008 ASC revised payment system rule as either another proposed rule or as an interim final rule with comments in order to allow Medtronic and other stakeholders the opportunity to work with the agency to develop options

that would better protect access to ASC procedures that utilize devices to ensure that such procedures are not significantly underpaid.

In closing, Ambulatory Surgical Center services represent an important means for patient access to innovative and life-saving medical technology. It is critical that the new ASC payment system provide appropriate payment for these services to assure Medicare beneficiary access to services that can be safely performed in that setting. We appreciate the opportunity to submit these comments. Questions or requests for additional information on these comments should be directed to Bonnie Handke at (763) 505-2748.

Sincerely,



Bonnie J. Handke, RN
Sr. Manager, Health Policy and Payment
Medtronic, Inc

Submitter : Mr. Andrew Whitman **Date:** 11/06/2006

Organization : National Electrical Manufacturers Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1076-Attach-1.PDF

#1076

Setting Standards for Excellence

Andrew Whitman
Vice President, Medical Products

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November 6, 2006

Leslie 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; Comments Regarding Proposed Policies Affecting Ambulatory Surgical Centers (ASCs) for CY 2007

Dear Administrator Norwalk:

The National Electrical Manufacturers Association (NEMA) is pleased to submit comments on Proposed Policies Affecting Ambulatory Surgical Centers (ASCs) for Calendar Year (CY) 2007 in the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS).[1] As the leading trade association representing companies whose sales comprise over 90 percent of the global market for medical imaging, we appreciate the opportunity to provide our perspectives on the ASC provisions of the proposed rule.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, nuclear medical imaging including positron emission tomography (PET) and magnetic resonance imaging (MRI). Imaging is used both to diagnose and treat patients with disease and offers physicians the ability to view soft tissue and organs, often reducing the need for costly and invasive medical and surgical procedures. With advanced medical imaging, physicians are able to perform a range of less-invasive, highly targeted medical

[1] Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed rule with comment period, 71 Fed. Reg. 49506 (August 23, 2006).

therapies that translate into better and more comfortable care for patients.[2] [3] This leads to convenience and easier access for patients increasing the likelihood they will get the tests, treatments and follow-up they need.[4]

Imaging has become a standard of modern care for virtually all major medical conditions and diseases, including cancer, stroke, heart disease, trauma, and abdominal and neurological conditions. That role is reflected in the reliance of physicians upon imaging in everyday practice, including surgical procedures, and its prominence in physician-developed practice guidelines across a broad range of medical and surgical conditions.

NEMA asks that CMS consider its comments under this proposed rule in the following areas:

I. Proposal to Base ASC Relative Payment Weights on APC Groups and Relative Payment Weights Established Under the OPPS

CMS proposes to utilize Ambulatory Payment Classification (APC) groups and the relative payment weights for surgical procedures established under the outpatient prospective payment system (OPPS) as the basis of the payment groups and the relative payment weights for surgical procedures performed at ASCs.[5] According to CMS, these payment weights would be multiplied by an ASC conversion factor (which CMS estimates is approximately 62 percent of the OPPS conversion factor) in order to calculate ASC payment rates.[6]

NEMA appreciates the factors that persuaded CMS to advance this payment proposal, however, we have serious concerns regarding applying OPPS relative payment weights to ASC relative payment weights to determine ASC payment. Namely, APC weights and ASC weights are not inherently "equal" and, therefore, could ultimately institute a skewed ASC payment system under the proposed method. OPPS relative weights are derived from historical cost and charge data patterns of *hospitals*. Hospital outpatient departments' relative costs and charges do not necessarily parallel those of ASCs. A deeper analysis of ASC cost and charge data, relative to that of hospital outpatient departments, is necessary to fully understand the differences and similarities between the two settings. Such an analysis would ensure that whatever ASC APCs are adopted accurately reflect the resources required to perform procedures in the ASC setting. CMS's failure to conduct such an analysis and incorporate the findings into the proposed ASC APCs could lead to excessive payments for some APCs and significant underpayments for

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[2] "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., *New England Journal of Medicine*, Vol. 352, No. 17; pp 1760-1768, April 28, 2005.

[3] "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." Jelinek, JS, et. al., *Radiology,* 223 (2002): 731-737.

[4] "Travel Distance to Radiation Therapy and Receipt of Radiotherapy Following Breast-Conserving Surgery." Athas WF, et. al. *Journal of the National Cancer Institute*, Vol. 92, No. 3, February 2, 2000; pp. 269-271.

[5] 71 Fed. Reg. at 49647

[6] 71 Fed. Reg. at 49656

others, leading to unintended consequences for patient care and beneficiary coinsurance liabilities.

Furthermore, the revised ASC payment system mandated by section 626(d) of Pub. L. 108-174, requires CMS to take into account General Accounting Office (GAO) recommendations, as reflected in a GAO report to Congress which was to have been submitted by January 1, 2005. The GAO recommendations are to be based on a comparison of the comparative relative costs of procedures furnished in ASC and hospital outpatient department settings, and the extent to which the APCs reflect procedures performed in ASCs. Although the statutory due date for the GAO's report is January 1, 2005, GAO has yet to publicly release its report. Consequently, CMS is proposing an entirely new ASC payment methodology without the benefit of research and analysis provided by the GAO's independent body of researchers who have the potential to present data and address aspects of reform policies that CMS might not have otherwise considered. In addition, the affected industry is hampered from fully responding to CMS's proposals because it also has not had the benefit of GAO's study results and recommendations.

II. ASC Packaging - Proposed Packaging Policy

As stated in the proposed rule, Medicare currently applies different rules under the ASC payment system and the OPPS system for determining whether payment for items and services directly related to a surgical procedure is packaged into the facility payment for the associated surgical procedure or paid for separately.[7] In the proposed rule, CMS states:

> *We are 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 as listed in § 416.164(a).* (Emphasis added.)

In fact, however, the packaging of imaging guidance into the ASC facility rate would reflect a change in current policy - a change that is not acknowledged in the proposed rule and that is inconsistent with the provision of high quality, minimally invasive services in ASC settings.

Imaging guidance for procedures is not packaged under OPPS because many surgical procedures can be performed with or without imaging guidance depending upon the clinical situation. Additionally, if imaging guidance is utilized, sometimes the patient's condition requires that different modalities be used to guide the procedure. For example, a liver biopsy could be guided using ultrasound, fluoroscopy, CT or MRI. So, having a single payment accurately reflect the costs of providing the procedure when there is variation in how the procedure is performed is not possible. Thus, imaging guidance is correctly billed separately under OPPS.

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[7] 71 Fed. Reg. at 49647

Because imaging is paid separately under OPPS, the relative payment weights for the procedures for which guidance is utilized do not reflect the costs of providing the imaging guidance. Therefore, the APC payment, because it will be derived from the OPPS relative payment weight, will not cover the costs of providing *any* imaging guidance. This could drastically impact accessibility of imaging services to Medicare beneficiaries who receive care in the ASC setting.

Furthermore, current instructions authorize separate payment for imaging guidance when an ASC enrolls in the Medicare program as an Independence Diagnostic Testing Facility (IDTF).[8] We believe that this policy is appropriate, since it ensures that ASCs do not experience a financial disincentive when they provide imaging guidance in conjunction with minimally invasive procedures. Failing to provide a mechanism for ASCs to obtain separate payment for these services will provide a significant incentive not to provide imaging guidance even if it improves the safety and efficacy of the procedure.

More generally, we encourage CMS to examine more closely the differences in "packaging" policy between ASC and hospital outpatient department settings. NEMA encourages CMS to allow for separate payment for imaging guidance and other imaging-related items and services across *all* settings if separate payment is provided in one or more settings.

III. ASC Payment for Office-Based Procedures

Physicians' office-based surgical procedures will comprise two-thirds of the additional 750 new codes that CMS proposes adding to the revised ASC list for 2008. We applaud CMS for expanding the ASC list to ensure that ASCs, like hospital outpatient departments, are able to receive payment for services that also can be performed in hospital outpatient departments.

In principle, NEMA agrees that payment parity across surgical settings is a logical means of preventing the migration of surgical services to other sites of care for the sole purpose of higher reimbursement. We understand that it is to prevent migration of surgical services based on payment differentials that CMS is proposing to cap payments for office-based surgical procedures at the lesser of the Medicare Physician Fee Schedule (MPFS) non-facility practice expense (PE) payment or the revised ASC rate.

As a practical matter, however, we have a number of concerns about this proposal. First, we are concerned that CMS may be overstepping its statutory bounds in implementing a cap on Medicare payment under the MPFS without explicit authority from Congress. Second, we note that, since office-based surgical procedures are only now being proposed for inclusion on the ASC list, ASCs historically have not performed these procedures; therefore, the practical impact of the cap will not be to discourage the migration of office-based procedures from the ASC to the physician's office setting, but rather to simply reduce the amount paid for surgery conducted in physicians' offices. Third, like the cap on diagnostic procedures performed in non-hospital settings, the cap on payment for surgical services in physicians' offices does not actually reflect payment parity. Payment will be limited for office-based procedures if the applicable PE-RVUs

[8] CMS Guidance Memorandum. Ref: S&C-03-22, June 12, 2003.

yield payment that is higher than the comparable ASC facility fee, yet payment for office-based procedures with payment at rates lower than the comparable ASC facility rate will not be raised. Finally, it is our understanding that CMS plans to institute a new methodology in CY 2007 to ensure that PE-RVUs for all services are truly resource-based. We respectfully suggest that, to the extent that ASC facility rates are lower than the amounts resulting from the new methodology, it may be worthwhile examining whether or not the ASC facility rates are sufficient. We urge CMS to consult with medical specialties to ensure that beneficiaries will retain access to high quality office-based surgical procedures if this cap is implemented.

IV. CPI-U Update

Beginning with the CY 2008 revised payment system for ASCs, CMS is proposing to update the ASC conversion factor annually using the CPI-U.[9] We understand that CMS is required by statute to increase ASC payment rates by the percentage increase in the CPI-U in years when CMS does not update the ASC payment amounts.[10] However, updating the ASC *conversion factor* annually using the CPI-U is a decision CMS is making without Congressional authority. NEMA acknowledges the importance of ensuring that ASC payments reflect cost increases attributable to inflation. Nevertheless, we are again struck by the inconsistency in seemingly small yet important aspects of the new payment methodology as it compares with hospital outpatient department payments. Under the recently released 2007 OPPS proposed rule[11] CMS proposes to include a 3.4 percent market basket update to hospital outpatient departments; whereas, ASCs receive an update based on the CPI-U. The CPI-U reflects spending patterns for all urban consumers and does not necessarily correspond precisely with other national indexes, such as the hospital market basket index. Despite the fact that the CPI-U includes medical care among expenditure categories, it also includes goods and services purchased for consumption in over 200 categories, which include recreation, housing, apparel, education, and communication, among others.[12] The hospital market basket index, on the other hand, is a statistical construct designed to measure the pure price increase component of rising hospital expenditures.[13] This index uses hospital industry versus economy-wide measures in establishing payment updates, and therefore, better reflects actual changes in costs that are unique to the health care environment. As you know, the health care environment experiences rates of cost increases that are not necessarily reflective of overall nationwide cost increases for all categories of goods and services. Correspondingly, NEMA believes that to remain consistent with other prospective health care payment methodologies, the hospital market basket index update, while not ideal, is still a better measure by which to base ASC conversion factor updates.

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[9] 71 Fed. Reg. at 49657

[10] § 1833 (i)(2)(C) of the Act.

[11] 71 Fed. Reg. at 49506

[12] U.S. Department of Labor, Bureau of Labor Statistics. www.bls.gov/cpi.cpifaq.htm.

[13] Freeland, Mark S., et. al., *Health Care Financing Review*, Spring 1991.

V. Proposed Addition of CPT Code 61795 to ASC Payment List

Lastly, we appreciate the addition of CPT code 61795 (brain surgery using computer) to the 2008 proposed ASC payment list. NEMA agrees that the payment rate for this procedure under the proposed revised system makes it an attractive addition to the existing surgical choices that ASCs currently offer Medicare beneficiaries. Improving access to this crucial surgical procedure will improve the lives of beneficiaries who warrant this valuable medical technology.

* * *

Ensuring that Medicare beneficiaries have access to clinically appropriate imaging services during surgical procedures performed in ASCs is critical to advancing health outcomes and improving quality of care. NEMA hopes that these comments will be useful to CMS regarding proposed policies affecting ASCs for CYs 2007 and 2008. We look forward to further dialogue on the issues we put forth in this letter and encourage CMS to contact us promptly with any questions, comments, or requests for additional information.

Sincerely,

Andrew Whitman
Vice President, Medical Products

Submitter : Mr. TERRILL DICK **Date:** 11/06/2006

Organization : ST GEORGE SURGICAL CENTER

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

November 6, 2006

CMS-1506-P
Department of Health and Human Services,
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I wish to comment on the proposed ASC payment proposals presented by your organization. The comments listed below will be included in one or more of the following categories of concerns:
1 The seemingly inconsistent application of logic associated with the proposals.
2 The grossly disproportionate reimbursement in the proposals as it relates to ASCs vs HOPDs
3 The Inconsistent update policy between HOPDs and ASC as is proposed
4 The difficulty / impossibility of the Medicare Beneficiary (or any other entity) to compare outpatient surgical services between provider types as it relates to Quality and cost; ASC vs HOPD
5 The narrow interpretation of the Budget Neutral stipulation mandated by congress. The great potential for not only being Neutral but also actually saving money exists in shifting HOPD reimbursement to the ASC and more closely paying the ASC rate to both HOPD and ASCs.

I A If the ASC should be paid a reduced % of the HOPD because the
overhead of the HOPD is much higher than the ASC, then the ASC should be paid a much higher % than the physician office because the ASC certainly has a much higher overhead than the office.
B If CMS is willing to pay for implants and expensive disposable components of a surgical procedure to the HOPD then the same payment should be available to the ASC.
C If a procedure is so common and such low risk that 80% of the time it is performed in a physician office and therefore should either not be reimbursable to an ASC should not be paid more than the office rate, then the same procedure surely does not meet any criteria to be paid at an HOPD and certainly should not be paid more than the office rate either.
2 A Equipment, salaries, supplies liability all cost the ASC the same or likely even greater than the HOPD for any particular procedure. ASCs are not likely to get as good of rates on purchase contracts or insurance reimbursement contracts as the larger hospital entity. The proposed 62% although perhaps logic based, simply is not enough money to meet even the direct operating expenses of many procedures and is not enough to make a modest return on investment for most procedures. This becomes absolutely true when implants, durable medical equipment, expensive probes and other components that are essential to the

2
procedure are either reimbursed directly to the HOPD and NOT to the ASC or the overall reimbursement rate is sufficient for the HOPD to cover the component but the ASC reimbursement is NOT sufficient to cover the component.
(i.e. CPT codes 50590,58353,58563,47563,63685,L8687, L8689,L8681, 49650, 57288 etc, etc, etc, etc.)

3 Reimbursement updates for the ASC and HOPD should both be calculated on the same standard. The market basket is a much better criterion than the price index. However, whatever standard is applied, it should also be applied to the other entity.
4 With payment systems different for the ASC than the HOPD the
transparency spoken of by our public officials is almost impossible. Apples to apples seems to be the goal yet dissimilarities between the two entities continue to be proposed. I am absolutely convinced that the taxpayer and the Medicare consumer would BOTH benefit from aligning the payment policies to the maximum extent permitted by law.
5 The great savings to the tax payer is evident in the two different fee schedules
for the ASC and the HOPD (both current and proposed). Even to the casual observer there is a GROSS and inconsistent disproportion between the schedules. True, there are a few cases (200+) where the ASC is paid more than the HOPD but the difference in both # of CPT codes and $ difference is outrageous in favor of the HOPD. There is no consistent % difference. It seems arbitrary at best.

Submitter : **Dr. Frederick Cahn** **Date: 11/06/2006**

Organization : **BioMedical Strategies LLC**

Category : **Device Industry**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

See attachment.

CMS-1506-P2-1078-Attach-1.PDF

#1018

November 6, 2006

Leslie V. Norwalk, Esq.
Administrator (Acting)
Centers for Medicare and Medicaid Services
C5-11-24
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244

Via: CMS e-rulemaking web site

Re: CMS-1506-P,
Section XVIII.B.4

Dear Ms. Norwalk:

We wish to comment on Section XVIII of CMS-1506-P concerning the "Proposed Revised Ambulatory Surgical Center (ASC) Payment System for Implementation January 1, 2008." We believe that the CPT codes 15170, 15171, 15175, and 15176 for acellular dermal replacement have been mistakenly excluded from the ASC payment system.

BioMedical Strategies LLC provides consulting services in medical economics, statistics, coding and other issues regarding the coverage, coding, and payment for new medical technologies. We have extensive experience with "skin substitutes," and one of our clients is Integra LifeSciences Corporation, which manufactures and markets the "acellular dermal replacement" products described by CPT codes 15170 to 15176. In addition, I am chairman of ASTM International subcommittee F04.41, Terminology and Classification of Tissue Engineered Medical Products. This subcommittee developed and published ASTM International standard F2311, "Standard Guide for Classification of Therapeutic Skin Substitutes," which defines terminology and classifies skin substitutes according to their clinical utility. I am also a member of the Skin Substitute Workgroup of the CPT Editorial Panel. This workgroup is responsible for creating and revising the procedure coding and explanatory information for skin replacement surgery and skin substitutes, which include CPT codes 15000 through 15431. (ASTM standard F2311 was one of the resources used by the American Medical Association for the revisions of the 2006 and 2007 CPT codes.)

In section XVIII.B.4 of the proposed rule ("Listing of Surgical Procedures Proposed for Exclusion from Payment of an ASC Facility Fee under the Revised Payment System"), Table 45 lists the "CPT SURGICAL PROCEDURE CODES PROPOSED FOR EXCLUSION FROM ASC FACILITY FEE PAYMENT BECAUSE THEY REQUIRE AN OVERNIGHT STAY." Included in this list are CPT codes 15170, 15171, 15175, and 15176, which identify procedures for "acellular dermal replacement." However, ADDENDUM AA.--PROPOSED LIST OF MEDICARE APPROVED ASC PROCEDURES FOR CY 2007

WITH ADDITIONS AND PAYMENT RATES includes *all* of the other CPT codes in the Skin Replacement Surgery section of the 2006 CPT codes:

HCPCS	Short Descriptor	ASC Payment Group	OPPS Payment Rate	ASC Payment Rate	DRA Cap	ASC Copayment Amount
15000	Wound prep, 1st 100 sq cm	2	$313.49	$313.49	Y	$62.70
15001	Wound prep, addl 100 sq cm	1	$313.49	$313.49	Y	$62.70
15040	Harvest cultured skin graft	2	$91.86	$91.86	Y	$18.37
15050	Skin pinch graft	2	$313.49	$313.49	Y	$62.70
15100	Skin splt grft, trnk/arm/leg	2	$1,308.85	$446.00		$89.20
15101	Skin splt grft t/a/l, add-on	3	$1,308.85	$510.00		$102.00
15110	Epidrm autogrft trnk/arm/leg	2	$1,308.85	$446.00		$89.20
15111	Epidrm autogrft t/a/l add-on	1	$1,308.85	$333.00		$66.60
15115	Epidrm a-grft face/nck/hf/g	2	$1,308.85	$446.00		$89.20
15116	Epidrm a-grft f/n/hf/g addl	1	$1,308.85	$333.00		$66.60
15120	Skn splt a-grft fac/nck/hf/g	2	$1,308.85	$446.00		$89.20
15121	Skn splt a-grft f/n/hf/g add	3	$1,308.85	$510.00		$102.00
15130	Derm autograft, trnk/arm/leg	2	$1,308.85	$446.00		$89.20
15131	Derm autograft t/a/l add-on	1	$1,308.85	$333.00		$66.60
15135	Derm autograft face/nck/hf/g	2	$1,308.85	$446.00		$89.20
15136	Derm autograft, f/n/hf/g add	1	$1,308.85	$333.00		$66.60
15150	Cult epiderm grft t/arm/leg	2	$1,308.85	$446.00		$89.20
15151	Cult epiderm grft t/a/l addl	1	$1,308.85	$333.00		$66.60
15152	Cult epiderm graft t/a/l +%	1	$1,308.85	$333.00		$66.60
15155	Cult epiderm graft, f/n/hf/g	2	$1,308.85	$446.00		$89.20
15156	Cult epidrm grft f/n/hfg add	1	$1,308.85	$333.00		$66.60
15157	Cult epiderm grft f/n/hfg +%	1	$1,308.85	$333.00		$66.60
15200	Skin full graft, trunk	3	$821.29	$510.00		$102.00
15201	Skin full graft trunk add-on	2	$313.49	$313.49	Y	$62.70
15220	Skin full graft sclp/arm/leg	2	$821.29	$446.00		$89.20
15221	Skin full graft add-on	2	$313.49	$313.49	Y	$62.70
15240	Skin full grft face/genit/hf	3	$821.29	$510.00		$102.00
15241	Skin full graft add-on	3	$313.49	$313.49	Y	$62.70
15260	Skin full graft een & lips	2	$821.29	$446.00		$89.20
15261	Skin full graft add-on	2	$313.49	$313.49	Y	$62.70
15300	Apply skinallogrft, t/arm/lg	2	$313.49	$313.49	Y	$62.70
15301	Apply sknallogrft t/a/l addl	1	$313.49	$313.49	Y	$62.70
15320	Apply skin allogrft f/n/hf/g	2	$313.49	$313.49	Y	$62.70
15321	Aply sknallogrft f/n/hfg add	1	$313.49	$313.49	Y	$62.70

According to ASTM standard F2311-06, skin replacement therapy is:

> 2.1.6.3 *skin replacement surgery, n*—surgery that permanently replaces lost skin with healthy skin.

Skin replacement therapy is described in the standard:

> 4.2.3 Skin replacement surgery is a two-step procedure:

4.2.3.1 The first step of skin replacement surgery is surgical excision of the lesion and any necrotic tissue or microbial contamination, resulting in a clean surgical skin wound.
4.2.3.2 The second step in skin replacement surgery is the application of skin autograft to the clean surgical skin wound.

Thus, common to all of the skin replacement therapy procedures is excision, which is coded as CPT 15000 – 15001 (CPT 2006). It is the excision step of skin replacement surgery that has the greatest risk to the patient since it is subject to blood loss, whereas the application of the graft is mostly suturing and bandaging.

Furthermore, most of the other skin replacement procedures included in Addendum AA are skin autografts (CPT 15100, 15101, 15120, 15121, 15200, 15201, 15220, 15221, 15240, 15241, 15260, 14261). Skin autograft requires the harvest of donor skin tissue, which has additional and similar safety risks to the patient as excision, such as blood loss.

The exceptions in Addendum AA are procedures that do not require harvest of autograft: tissue cultured epidermal autograft (15150, 15151, 15152, 15155, 15166, and 15157) and allograft (15300, 15301, 15320, and 15321). The procedure for acellular dermal replacement is essentially the same as for allograft. For example, the September, 2006 edition of the CPT Assistant, published by the American Medical Association describes an example of an allograft procedure:

"Description of Procedure (15300)

"After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. Human allograft skin is obtained from the skin bank. A total of 100 sq cm is applied to the leg and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear."

From the same reference, an example of an acellular dermal replacement procedure is:

"Description of Procedure (15170)

"After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The acellular dermal replacement is removed from the rinsing solution and a total of 100 sq cm is applied to the trunk and secured to the excised wound with interrupted sutures or surgical staples. A net dressing is applied and expanded over the graft site and secured with staples to prevent mechanical shear. The wound is covered with gauze dressings and secured with a bulky dressing to further prevent mechanical shear."

It is apparent that the procedures are essentially the same, and have essentially the same safety risk and recovery and observation time. Both are actually *safer* then autograft procedures, since they do not require the harvest of autograft tissue.

Thus, under the criteria of the proposed new §416.166 of the regulations, acellular dermal replacement should not be excluded from ASC payment when, under the same criteria,

other skin replacement therapy procedures of equal or greater safety risk and recovery time are included. These considerations would apply to Medicare beneficiaries as well as other patient populations.

We recommend that the codes 15170, 15171, 15175, and 15176 be removed from table 45, and included in Addendum AA.

Sincerely yours,

Frederick Cahn, Ph.D.
CEO