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November 6, 2006

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**Via Overnight Mail**

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

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

Dear Ms. Norwalk:

MGI PHARMA appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") Proposed Rule on Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-4125-P) (the "Proposed Rule"), 71 Fed. Reg. 49,506 (August 23, 2006). MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi® (palonosetron hydrochloride) injection is one of MGI's products that is made available in the ambulatory surgical center ("ASC") setting. It is a 5-HT<sub>3</sub> anti-emetic used to treat chemotherapy-induced nausea and vomiting.

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

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

ASC Packaging Proposal: CMS Should Provide Separate Payment for Certain Drugs and Biologicals

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

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

Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs, biologicals, and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services.<sup>1</sup>

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

Moreover, bundling payment for all drugs and biologicals in the ASC setting while providing separate reimbursement in the outpatient hospital setting could create inappropriate incentives to base care decisions on payment considerations, contrary to CMS's oft-stated goal of decreasing such site-of-service differentials. We agree with concerns raised by the Medicare Payment Advisory Commission ("MedPAC") in its formal comments on the Proposed Rule submitted to CMS on October 10, 2006:

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<sup>1</sup> 71 Fed. Reg. 49582.

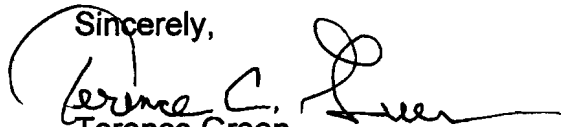
We support CMS's proposal to expand the ASC payment bundle but encourage the agency to make the payment bundles in the ASC and hospital outpatient settings even more comparable. . . . Different bundling policies may lead to different relative payment amounts in each setting, even if the base payment rates share the same relative values in both settings.<sup>2</sup>

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

To prevent an inappropriate site-of-service differential between hospital outpatient and ASC setting and ensure beneficiary access to medically-necessary drugs and biologicals in ASCs, CMS should carve out payments for certain drugs and biologicals in the ASC setting from the facility fee. Specifically, we propose that CMS provide separate payments to ASCs for (1) those drugs and biologicals that qualify for pass-through status under the OPSS system, and (2) those drugs and biologicals whose costs exceed the OPSS packaging threshold (\$50 in 2006). CMS could adopt these provisions as a temporary policy for two to three years as the agency collects ASC drug cost data and develops a mechanism to ensure that these costs are appropriately reflected in the ASC facility payment. This interim policy would help ensure adequate compensation for ASCs and safeguard Medicare beneficiary access to medically-necessary drugs and biologicals.

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MGI appreciates this opportunity to present these comments to CMS. Please do not hesitate to contact us if you have any questions.

Sincerely,  
  
Terence Green  
Vice President, Assistant General Counsel

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<sup>2</sup> See [http://www.medpac.gov/publications/other\\_reports/101106\\_PartB\\_comment\\_AW.pdf?CFID=9299012&CFTOKEN=78096660](http://www.medpac.gov/publications/other_reports/101106_PartB_comment_AW.pdf?CFID=9299012&CFTOKEN=78096660).

# ASC COALITION

November 6, 2006

## VIA HAND DELIVERY

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

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

Dear Administrator Norwalk:

On behalf of the undersigned members of the ambulatory surgical center (ASC) community, please accept the following comments regarding Section XVIII of the proposed rule published in 71 Fed. Reg. 49505 (August 23, 2006), which proposes revisions to the ASC payment system. These comments are submitted by a diverse coalition of national and state associations and companies representing all types of ASCs – single- and multi-specialty, physician owned, joint ventures between hospitals and physicians, and joint ventures between physicians and management companies. These operations range from the very small to the very large and are located in all parts of the nation. We appreciate the careful consideration and effort that has gone into developing the proposal for a new payment system for implementation in 2008.

The experience of ASCs is a rare example of a successful transformation in health care delivery. Thirty years ago, virtually all surgery was performed in hospitals. Waits of weeks or months for an appointment were not uncommon, and patients typically spent several days in the hospital and several weeks out of work in recovery. In many countries, surgery is still like this today, but not in the United States. Today, more than 80% of all surgery is performed in an outpatient basis.

Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way to serve their patients and found it through the development of ASCs. ASCs provide high quality care in a cost effective way.

Since the inception of the Medicare benefit in 1982, ASCs have steadily expanded the role they play in meeting the surgical needs of Medicare beneficiaries. From the 97 procedures provided in 1982 to the 2,547 different procedures provided to Medicare beneficiaries in 2006, ASCs have provided high quality, patient focused care at a savings to the Medicare program and its beneficiaries. This contribution has been recognized by the Department of Health and Human Services (HHS). For instance, according to the HHS's Office of Inspector General its regulatory treatment of ASCs "recognizes the Department's historical policy of promoting greater utilization of ASCs" and that "ASCs can significantly reduce costs for Federal health care programs, while simultaneously benefiting patients." Additionally, since Medicare expanded its benefits to include colorectal cancer screenings in 1998, ASCs have played a key role in providing life-saving screening health services. In 2005, about 37% of the screening colonoscopies performed on Medicare beneficiaries were performed in ASCs.

The major goal of any changes in Medicare ASC payment policy should be to expand Medicare beneficiaries' access to high quality, cost effective surgical care. In the comments that follow, we share our views on how existing access can be preserved and expanded.

## OVERVIEW

The broad statutory authority granted to the Secretary to design a new ASC payment system in the Medicare Modernization Act of 2003 (MMA) presents CMS with a unique opportunity to significantly improve Medicare beneficiaries' access to ASC services. The ASC community welcomes the opportunity to link the ASC and hospital outpatient department (HOPD) payment systems. Although the HOPD payment system is imperfect, it represents the best proxy for the relative cost of procedures performed in the ASC. By linking the ASC and HOPD payment systems, the Medicare program can achieve significant benefits. However, there are several provisions of this proposed rule that might reduce, rather than expand, access to surgical care because the proposal's links to the HOPD system are selective and incomplete.

To achieve the best access to surgical services for Medicare beneficiaries, CMS should focus on three basic principles as it implements a new payment system:

- ensuring meaningful beneficiary access to the wide range of surgical procedures that can be safely and efficiently performed in the ASC,
- establishing fair and reasonable payment rates to allow beneficiaries and the Medicare program to save money on procedures that can be safely performed at a lower cost in the ASC, rather than in the HOPD, and
- making the ASC and HOPD payment systems consistent to the maximum extent possible to provide Medicare beneficiaries with greater price transparency and eliminate distortions between the payment systems that could inappropriately influence site of service selection.

## **A. Ensuring Beneficiaries' Access to Services**

Improving access by Medicare beneficiaries to ASCs should be the primary goal of this rule making process.

We believe this goal will not be achieved by this rule for several reasons. First, the CMS proposal would limit a physician's ability to determine the appropriate site of service for a procedure because it does not allow payment for many surgical procedures that are clinically appropriate in an ASC. We support the proposal to expand access to a large number of new procedures in the ASC setting. This will offer convenience and access to Medicare beneficiaries. At the same time, we believe that this expansion can and should be carried further to include a number of other surgical procedures appropriate for the ASC setting.

Second, implementation of the proposed payment system would result in a significant redistribution of payments among many types of ASCs. Sudden changes in payments for services can have a significant effect on Medicare beneficiaries' access to services. In particular, the CMS proposal will result in a significant reduction in payment for gastroenterology and pain management procedures, which are often provided in ASCs that are exclusively or almost exclusively dedicated to providing these procedures. Because these ASCs have been clinically designed for the performance of one type of procedure, operators are not going to be able to make up these reductions in payment by performing other types of procedures that are receiving a payment increase. This is one significant way in which ASCs are different from hospital outpatient departments. While hospitals generally conduct a wide variety of types of surgery for inpatients and outpatients, ASCs frequently specialize in one medical specialty's procedures and the facilities are not configured so that they can perform the variety of procedures that the typical hospital can. The proposed 62% conversion factor will lower ASC payments for these two specialties by approximately 30% when fully implemented. This severe cut could force single-specialty ASCs to close, reducing access to life-saving detection and early treatment of colon cancer or critical pain management services for a significant number of Medicare beneficiaries. We do not believe that CMS intended to reduce access for important procedures that can reduce health care costs, such as screening colonoscopies.

Additionally, because many ASCs focus on services that require similar equipment and physician expertise, their response to changes in the payment system may be limited to adjusting their volume of Medicare patients. On the one hand, for procedures such as ophthalmology, there is a limited market for these services in the non-Medicare population. If the facility fee is insufficient to cover the cost of performing the procedure in an ASC, these procedures may be moved to the HOPD, where payments would be higher. This migration would increase expenditures for the government and the beneficiary. On the other hand, the demand for services such as colonoscopies is extremely high in the non-Medicare population. If ASCs determine that the payment rates for such services are below their cost, they may be able to decrease the proportion of Medicare patients they see without reducing their total patient volume. In that case, Medicare beneficiaries may experience significant delays accessing important screening or therapeutic services. Neither outcome is optimal for the beneficiary or the Medicare program.

Hospitals, like other businesses, are forced to make decisions based upon financial realities. In some geographic areas, hospitals may have inadequate capacity to absorb significant migration of services out of the ASC. Because some of the most significant shifts in payment affect some of the highest volume ASC services, the agency should ensure that the final regulation creates an environment in which ASCs can continue to serve Medicare beneficiaries at reasonable and appropriate payment rates. The table below highlights several states where the majority or large plurality of specific surgical services are provided in ASCs.

**TABLE 1**  
**ASC Market Penetration for Selected High-Volume Procedures, 2004**

State	CPT 43239 - Upper GI endoscopy, biopsy		CPT 45378 - Diagnostic colonoscopy		CPT 45385 - Lesion removal colonoscopy		CPT 66821 - After cataract laser surgery		CPT 66984 - Remove cataract/insert lens	
	Change in payment 2006-2008: -35%		Change in payment 2006-2008: -27%		Change in payment 2006-2008: -27%		Change in payment 2006-2008: -120%		Change in payment 2006-2008: -4%	
	Percent in ASCs	ASC Volume	Percent in ASCs	ASC Volume	Percent in ASCs	ASC Volume	Percent in ASCs	ASC Volume	Percent in ASCs	ASC Volume
<b>AZ</b>	52%	6,300	46%	6,440	49%	5,260	93%	10,820	86%	25,120
<b>DE</b>	68%	2,500	62%	3,060	76%	2,100	86%	1,220	80%	6,240
<b>FL</b>	63%	57,920	58%	47,160	64%	31,060	97%	53,820	87%	130,080
<b>ID</b>	50%	2,260	43%	1,580	52%	1,740	94%	2,560	84%	8,180
<b>MS</b>	49%	6,180	44%	5,960	63%	3,600	95%	6,960	79%	20,900
<b>MT</b>	13%	340	8%	300	14%	380	88%	1,820	64%	5,540
<b>NJ</b>	55%	18,900	57%	19,400	54%	10,140	85%	12,860	76%	40,180
<b>NM</b>	41%	2,280	41%	2,200	43%	1,360	88%	2,000	71%	6,520
<b>NV</b>	57%	2,500	66%	3,860	56%	1,300	97%	1,960	94%	10,260
<b>WY</b>	53%	1,420	38%	740	61%	900	87%	940	68%	2,500

Source: Cleverley & Associates analysis of 2004 Medicare claims data

In Appendix A, this data is presented by Metropolitan Statistical Area (MSA) to highlight some of the geographic markets where changes in the payment systems can have significant implications for beneficiaries' access.

## **B. Establishing Reasonable Reimbursement Rates**

We believe that the payment system for ASCs can and should use this opportunity to achieve the following policy goals, discussed in more detail in the sections to follow:

- Achieve savings to the Medicare program and its beneficiaries;
- Promote payment neutrality across sites of service delivery and competition among surgical service providers; and
- Encourage increased transparency of information on Medicare providers.

Medicare payment rates for ASC services have remained stagnant for nearly a decade while inflation has driven double-digit increases in the price of many services and supplies used by ASCs.

As HOPD payments have increased, ASC rates have been frozen since passage of the MMA. This has had the perverse effect of increasing the “cost” of the budget neutrality requirement for the new payment system imposed by the MMA. The Lewin Group estimates that the inflation updates applied to the HOPD rates since passage of the MMA account for 40% of the discount required to achieve budget neutrality under the agency’s proposed rule. This, combined with the agency’s narrow interpretation of budget neutrality, produce an unacceptably low conversion factor for ASC payments.

## **C. Alignment of ASC and HOPD Payment Policies**

Aligning the payment systems for ASCs and HOPDs will enhance the transparency of the cost of obtaining surgical care in different settings, thus allowing Medicare beneficiaries to make better choices regarding their surgical care. While we appreciate that the proposal moves towards consistency between the two systems, many policies would still be inconsistent. If these inconsistencies are not addressed in the final rule, these differences will lead to further distortions between the two payment systems. Moreover, failure to consistently apply the hospital outpatient policies to ASC services undermines the appropriateness of the APC relative weights, creates disparities in the relationship between the ASC and HOPD payment rates, and embeds incentives in the new payment system that will ultimately cost the taxpayer and the beneficiary substantially more.

There are several instances in which alignment of the ASC and HOPD payment systems is incomplete or inconsistent. The following inconsistencies between how the payment system is applied to HOPDs and is proposed for ASCs should be addressed in the final rule. The following eight paragraphs summarize our points on this issue. A more detailed examination of each point is provided in these comments.

***Procedures Covered.*** Although CMS proposes to significantly expand the ASC list, Medicare beneficiaries would continue to face unduly limited access to many services that are safely performed in ASCs. Rather than using only the inpatient only list to exclude services from coverage, as is done for HOPDs, and allowing physicians to determine the appropriate site of



service for procedures, the proposal would apply many additional criteria that would result in Medicare not paying for many surgical procedures clinically appropriate for the ASC setting.

**Unlisted Codes.** Procedures for which there is not an appropriate CPT code are reimbursed in the HOPD, but would not be in an ASC under the proposed rule. The final rule should make ASCs eligible for the payment of selected unlisted codes.

**Payment Bundles.** The bundle of services for which Medicare is paying would continue to be different in the two surgical settings. Several of the proposed policies for packaging ancillary and other procedure costs into the ASC payment bundle result in discrepancies between service costs used to calculate the relative weights. Thus, the ASC payment rate would not be based upon appropriate costs as the relative weight would not include these costs. When HOPDs perform services that are not included in the bundle used to calculate the APC weight, they receive additional payments. ASCs should also be eligible for these payments.

**Device Related Services.** Under OPSS, payment for devices or implants is included as a portion of the APC. Historically, ASCs have not been consistently paid for these devices and have therefore provided few of these services to Medicare beneficiaries. Due to the steep discount that would be applied by this proposed rule, without a specific adjustment, these services will continue to be provided primarily in the more expensive hospital setting.

**Payment Limits.** CMS proposes to cap payments for certain ASC procedures commonly performed in physician offices at the physician practice expense payment rate, but does not propose to apply this limit to HOPDs. These policies should be reconciled.

**Inflation Update.** CMS updates the OPSS conversion factor for annual changes in inflation using the hospital market basket. The agency proposes to update ASC payments using the consumer price index for all urban consumers, a measure of consumer, not health care provider, inflation. As the hospital market basket was specifically designed to measure the costs of hospitals inflation, it is a better proxy for the inflationary pressures faced by ASCs.

**Secondary Rescaling of APC Relative Weights.** CMS applies a budget neutrality adjustment to the OPSS relative weight values after they are recalibrated with new cost data each year. A secondary rescaling of the relative weights is proposed when they are used by ASCs. This secondary rescaling will result in annual and potentially cumulative variation between ASC and HOPD payments without any evidence that the cost of providing services has further diverged between settings. Unlike the statute governing the HOPD payment system, the only provision relating to budget neutrality for ASC payments is the one that applies to the year of implementation. Use of this secondary rescaling will cause the two payment systems to diverge over time, as did the initial two tiered system for physician payment.

**Non-application of HOPD Policies to the ASC.** Over the years, CMS has used their statutory and administrative authority to implement numerous policies to support access to HOPD services, including additional payment for high-cost outliers, transitional corridor and hold-harmless payments to rural and sole-community hospitals, and payments for new technologies.

Although not all of these policies are appropriate for ASCs, CMS should start with the presumption that all policies should be applied consistently to both ASCs and HOPDs unless there are compelling reasons to differentiate between the two systems.

**Billing Systems.** CMS proposes to continue its policy of having the HOPD and ASC use the UB-92 and CMS-1500, respectively, to submit claims to the government for services. Use of different claims forms prevents ASCs from documenting all the services provided to a Medicare beneficiary, therefore undermining the documentation of case mix differences between sites of service. Most commercial payors require ASCs to submit claims using the UB-92. The final rule should require ASCs to use the UB-92.

### PROCEDURES TO BE PAID IN ASCS

ASCs have afforded significant savings to the Medicare program and its beneficiaries over the last several decades while delivering high quality services. Given the positive impact ASCs have had on health care delivery, CMS should develop a progressive policy and expand access to other interventional services in the ASC. In the process of implementing ASC payment system reform, CMS should avail itself of the opportunity to expand the scope of ASC services. Doing so would promote additional competition in the health care market for surgical services and further benefit the Medicare program and its beneficiaries.

When CMS (then HCFA) developed the regulations governing ASCs, it was very supportive of the idea that the ASC system be designed to encourage competition.<sup>1</sup> The preamble to the regulations noted:

*[P]reviously, Medicare coverage and reimbursement for facility services furnished in connection with surgical procedures were available only to hospitals. These regulations would remove a barrier to entry into the market for such services, and would thus encourage competition...*

*It appears that ASCs are able to provide services of at least equal quality and at less cost than either the hospital inpatient or hospital ambulatory surgical settings...the extension of coverage and reimbursement to ASCs will give beneficiaries and their physicians important additional options in their selection of sites for surgery. Those options in turn will enhance the competition between ASCs and hospitals.*

The benefits of market competition were also acknowledged more recently in a joint report issued by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) entitled *Improving Health Care: A Dose of Competition*. This report, based on a two-year study of the role of competition in the health care marketplace, concludes that "vigorous competition promotes the delivery of high quality, cost-effective health care" by lowering prices and promoting quality and innovation resulting in, among other things, "treatments offered in a

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<sup>1</sup> 47 Fed. Reg., 12574, 12583 (Mar. 23, 1982)

manner and location consumers desire." With respect to ASCs in particular, the FTC and DOJ concluded that ASCs "had a number of beneficial consequences for consumers," such as improved technology, a non-institutional, friendly environment and "more convenient locations, shorter wait times, and lower coinsurance than a hospital department." In commenting on the effect competition has on hospitals ability to provide certain services, the report stated:

*Competition has a number of effects on hospitals, including the potential to improve quality and lower costs. Competition will also undermine the ability of hospitals to engage in cross-subsidization, however. To address this issue, Congress and state legislatures should consider whether direct subsidies for desired conduct are advisable.*

We urge CMS to develop a forward-looking coverage policy that recognizes the ongoing, dynamic expansion of outpatient surgical and procedural services and expands the opportunities for the benefits that flow from a competitive market for facility services. We believe that the payments received by ASCs under the final ASC payment system adopted by CMS will continue to be appropriately characterized as composite rate payments such that ASC services remain excluded from the definition of "designated health services" for purposes of the federal physician self-referral law. We request that you confirm this interpretation.

#### **A. ASC Payable Procedures**

We are pleased CMS is proposing to adopt the recommendations of MedPAC presented in their March 2004 Report to the Congress. We fully support MedPAC's recommendation that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from payment of an ASC facility fee.

The use of an exclusionary, rather than inclusionary, list would allow Medicare beneficiaries access to the broader range of the ASC services that are currently safely offered to non-Medicare patients. Further, as new procedures are developed, Medicare beneficiaries are more likely to be assured timely access to these technological advances in ambulatory surgical care. In the discussion below, we offer several recommendations on how to improve the implementation of these criteria to ensure beneficiaries' access to the broad spectrum of services that can be safely and efficiently performed in an ASC.

#### **B. Proposed Definition of Surgical Procedure**

In this proposed rule, CMS solicits public comment regarding what constitutes a "surgical" procedure. Under the current ASC payment system, CMS defines surgical procedures as any procedure described within the Surgery section of CPT, which corresponds to Category I codes 10000-69999. The definition of surgical procedures should, at a minimum, continue to include all services within the Surgery section of CPT, including those that are primarily office-based.

## **1. Definition of surgical services**

To allow full access to surgical procedures that can be safely and appropriately performed in ASCs, we ask CMS to adopt a broader definition of "surgical" procedure. We agree that all services described in the Surgery section of CPT should continue to be defined as surgical procedures. However, this definition should be expanded to include additional service codes outside this range. As CMS notes in this proposed rule, there are other codes that describe surgical and procedural services outside of CPT Category I, namely CPT Category III and HCPCS Level II codes. In addition, both the "Radiology" and "Medicine" sections of CPT contain numerous codes that describe services appropriately offered in an ASC setting. Given the number of surgical and procedural services described outside CPT Category I codes 10000-69999, the current definition should be broadened in a manner that will allow coverage of all surgical and procedural services.

It is generally recognized that the traditional boundaries between surgery, radiology and certain medical specialties that perform invasive procedures are fading. Surgery is becoming less invasive, radiology has developed an interventional subspecialty, and certain internal medicine subspecialists routinely perform invasive procedures. Therefore, in lieu of the current definition limiting surgical procedures to those in the CPT 10000-69999 range, we propose that a surgical service be redefined as follows:

- (1) Any procedure described within the range of CPT Category I codes that the AMA defines as "surgery" (CPT codes 10000-69999);
- (2) Any procedure described within the range of CPT Category I codes that the AMA defines as "medicine" that are invasive, that are performed under general anesthesia or that are specifically designated as intraoperative services;
- (3) Any X-ray, fluoroscopy, or ultrasound procedures described within the range of CPT Category I codes that the AMA defines as "radiology" that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;
- (4) Any radiology procedure that is integral to the performance of a non-radiological procedure described in paragraphs (1) or (2) above and performed
  - (i) During the non-radiological procedure, or
  - (ii) Immediately following the non-radiological procedure when necessary to confirm placement of an item placed during the non-radiological procedure; and
- (5) Any procedure described by HCPCS Level II codes or by CPT Category III codes which are clinically similar to the procedures and services described in paragraphs (1)-(4) above.

This definition captures both the traditional forms of surgery as well as other invasive procedures appropriate to the outpatient surgical setting. Paragraphs (1) and (5) reflect elements that CMS has proposed to include in its definition of surgical services. The rationales for paragraphs (2) through (4) of the definition are discussed in further detail below.

Paragraph (2) Procedures described within the range of CPT Category I codes that the AMA defines as "medicine" that are invasive, that are performed under general anesthesia or that are specifically designated as intraoperative services: Due to the organizational structure of the CPT manual, invasive procedures performed by medical subspecialists such as gastroenterologists and pulmonologists have been classified as "Surgery," while the invasive procedures performed by medical subspecialists such as cardiologists have been classified as "Medicine." In the case of the invasive procedures performed by these subspecialists, the CPT distinction is an artificial one that disguises their similarities and commonalties. When considering whether services in the Medicine section of CPT are surgical in nature or not, it is more practical to focus on whether or not they are invasive procedures. Many procedures described in the Medicine section of CPT are invasive and, as such, require use of a dedicated procedure room, administration of anesthesia or sedation, patient monitoring, and/or use of a post-procedure recovery room. Therefore such services are just as appropriately considered surgical as the gastrointestinal endoscopies and bronchoscopies located in the Surgery section of CPT.

Additionally, there are services described in the Medicine section of CPT which are, by definition, performed under general anesthesia or are intraoperative services. Services which, by definition, require general anesthesia should be considered appropriate to the outpatient surgical setting. With respect to intraoperative services, these services are appropriately regarded as an extension of the surgical service during which they are provided. In recognition of the role these services play during selected procedures, we propose they be included in the definition of surgical service. This inclusion recognizes the increasingly multidisciplinary approach seen in modern operating and procedure rooms.

Paragraph (3) Procedures described within the range of CPT Category I codes that the AMA defines as "radiology" X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice: Regulations adopted pursuant to the federal physician self-referral law (commonly known as the "Stark law," Section 1877 of the Social Security Act) carve out interventional and intraoperative radiology services from the definition of "radiology" services subject to the Stark law's self-referral prohibition. See 42 C.F.R. § 411.351. Building on that precedent, paragraph (3) of the definition presented above would include invasive radiologic procedures that require the insertion of a needle, catheter, tube, probe, or similar device as surgical services. Accordingly, both interventional radiology services and intraoperative radiology services are appropriately considered surgical in nature.

Interventional radiology encompasses minimally invasive percutaneous treatments that use imaging guidance to direct the procedure. A few examples of procedures performed under the auspices of interventional radiology include angiography and balloon angioplasty, needle biopsy, biliary drainage and stenting, cancer treatments such as chemoembolization and radiofrequency ablation, vascular embolization, treatment of infertility in women, and treatment of compression

fractures of the spine. These procedures are surgical in nature in that they seek to diagnose by obtaining tissue or to treat by altering diseased or injured bodily structures.

As previously stated, many procedures involve services from more than one discipline. This is particularly relevant to procedures in which two components, a surgical injection and a diagnostic imaging procedure are integral. Both portions of the procedure are necessary to its successful completion. Excluding one or the other portion effectively excludes both. Therefore, this paragraph of our proposed definition includes those services in which surgical and radiological procedures are combined.

Paragraph (4) Radiology procedures that are integral to the performance of a non-radiological procedure described in paragraphs (1) or (2) above and performed (i) During the non-radiological procedure, or (ii) Immediately following the non-radiological procedure when necessary to confirm placement of an item placed during the non-radiological procedure: As noted above, the "Stark" regulations also carve out intraoperative radiology services from the definition of "radiology" services subject to the Stark law's self-referral prohibition. See 42 C.F.R. § 411.351. Paragraph (4) of the definition also builds on language found at 42 C.F.R. § 411.351 and would include radiology services performed in the intraoperative or immediate postoperative period.

This portion of the definition recognizes the role of concurrent radiological services in today's surgical practice. As a result of the ongoing trend toward less invasive surgery, the need for imaging guidance to direct certain procedures becoming increasingly prevalent. The use of imaging modalities such as fluoroscopy and ultrasound has become commonplace in operating and procedure rooms. This portion of our proposed definition recognizes that current surgical services may employ adjuncts traditionally viewed as radiologic in the past, but are now essential to certain advanced surgical techniques.

CMS acknowledged this point of convergence when it refined its definition of designated health services to exclude "radiology and ultrasound procedures that are integral to and performed during the time a nonradiology procedure is being performed, such as ultrasound used to provide guidance for biopsies and major surgical procedures or used to determine, during surgery, whether surgery is being conducted successfully."<sup>2</sup>

In summary, CMS should avail itself of this opportunity to expand and refine its definition of surgery so that it better reflects current practice patterns in outpatient surgical and procedural care. This approach will allow the policies developed around the definition to be reasonable and serviceable into the foreseeable future, rather than unduly constraining and in need of frequent and significant revision to retain relevance. The definition we have presented here fulfills these requirements.

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<sup>2</sup> 66 *Fed. Reg.* 856, 929 (Jan 4, 2001)

Based on the proposed definition presented above, there are several surgical services outside the Surgery section of CPT that are appropriately provided in a facility setting. These services are detailed below.

**a. Additional CPT Category I codes meeting the definition of surgical procedures**

Within the CPT Category I codes, the Surgery section is not the only one containing codes that describe procedural services. As referenced in the definition proposed above, the Radiology and Medicine sections of CPT also contain numerous codes describing invasive procedures, procedures requiring sedation and monitoring, as well as services that are provided under general anesthesia. Such services are appropriately performed in a facility setting. Those that are not currently packaged under OPPS are presented in Appendix B. In this appendix, the rationale for coverage is designated by a phrase, presented in the key provided, which corresponds to each subpart of the definition of surgical services proposed above.

Given the annual CPT code updates, Appendix B is not intended to be definitive, but rather to provide examples of additional services described by CPT Category I codes that fall within the bounds of our proposed definition.

We wish to emphasize that our comments are specifically directed at the issue of establishing an appropriate definition of a surgical service, and that we view this as a process that should be independent from determining which surgical services, once defined as such, are appropriately offered in the ASC setting. CMS should, as it does now for services described by codes within the CPT 10000-69999 range, apply safety criteria to exclude selected procedures as needed. This approach will allow CMS to identify all services that are surgical in nature, while still affording the benefit of future flexibility in a health care system where the continued shift of services to the outpatient surgical setting are reasonably expected to be ongoing as further technological advances are made.

**b. CPT Category III codes meeting the definition of surgical procedures**

CMS correctly proposes to include CPT Category III codes for consideration for payment of an ASC facility fee under the revised payment system. However, instead of the criteria proposed by CMS, namely that the Category III CPT "directly crosswalk to or are clinically similar to procedures in the CPT surgical range," the definition presented above should serve as the basis for determination of coverage.

Although CMS has proposed to consider appropriate Category III CPT codes for ASC payment, none of these codes has been included in Addendum BB as Medicare approved ASC procedures for 2008. The services presented in Appendix B currently described by CPT Category III codes are surgical services under the definitions presented above. Further, no services are excluded by safety concerns or the need for an overnight stay, and therefore should be approved for ASC coverage.

By convention, additional Category III codes are implemented by the AMA biannually and selected Category III codes become Category I codes. Therefore, we anticipate that the list of Category III codes appropriately viewed as surgical will be revised between now and the time the revised payment system is implemented in January 2008. Consequently, those services presented in Appendix B are merely current examples of Category III surgical services. CMS should allow ASC reimbursement for any newly established Category III codes meeting the definition of a surgical service presented above.

**c. Additional HCPCS Level II codes meeting the definition of a surgical service**

Although CMS has proposed to consider HCPCS Level II codes for ASC payment, very few of these codes have been included in Addendum BB as Medicare approved ASC procedures for 2008. Additional services which should be covered are also presented in Appendix B. These services meet our proposed definition of a surgical service, do not raise safety concerns or involve an overnight stay, and therefore should be approved for ASC coverage.

Again, annual coding changes may impact the list of services presented above, particularly those represented by the temporary C and G codes. Therefore, the codes presented in Appendix B are not intended to represent a definitive list of surgical services, but rather to illustrate the extensive number of surgical services beyond those that CMS has identified in this proposed rule.

In summary, while all the codes in the Surgery section of CPT are appropriately defined as surgical services, there are other services outside this range that are invasive and therefore appropriate to the ASC setting. We recommend CMS take a broader view of what constitutes a surgical service in order to remain in step with the continuing transformations occurring in the clinical realm of outpatient surgery that have been described above. The definition we have proposed reasonably identifies additional invasive procedures that are appropriately offered in the facility setting. If such services are not included in the definition of surgical services, beneficiary access to these procedures will be unnecessarily limited to hospitals and the Medicare program and its beneficiaries will incur higher expenditures, both of which are undesirable. These additional services should be eligible for payment of an ASC facility fee unless excluded by specific safety criteria or packaged under the OPSS payment guidelines.

**C. Procedures Proposed for Exclusion from Payment**

We are pleased CMS is planning to discontinue the use of operating and anesthesia times as standards for determining coverage under the revised ASC payment system. This is consistent not only with the longstanding position of stakeholders in the ASC industry, but also with MedPAC recommendations and with CMS's earlier proposal to eliminate these criteria.<sup>3</sup>

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<sup>3</sup> 63 Fed. Reg. 32298 (June 12, 1998)



We also agree that the existing standard at §416.65(a)(1), which requires covered ASC procedures to be commonly performed on an inpatient basis, is no longer appropriate and are pleased CMS will be eliminating this criterion. As MedPAC noted in its March 2004 congressional report, “it no longer makes sense to consider inpatient volume when updating the ASC list.”

### **1. Significant Safety Risk**

The ASC community has been, and remains, strongly committed to the safety of patients receiving services in ASCs. The excellent outcomes associated with ambulatory surgery reflect this commitment. One of the many reasons that ASCs have been and continue to be so successful with patients, physicians and insurers is their keen focus on ensuring the quality of the services provided.

#### **a. Significant Safety Risk**

The proposed regulations would cover surgical procedures that are “not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC.” We support this provision. In our view, this criterion makes the following criteria unnecessary.

#### **b. Exclusion based the current OPPS inpatient only list**

We agree with CMS’s proposal to exclude any procedure that is included on the then-current OPPS inpatient only list from payment of an ASC facility fee. As long as CMS remains committed to updating the inpatient only list on a regular basis, the possibility of excluding services that may become appropriate to the outpatient setting over time as a result of advances in technology can be avoided.

#### **c. Exclusion based on retention of specific ASC criteria for evaluating safety risks**

When CMS implemented the OPPS, it used three criteria to determine which procedures required inpatient care: 1) the invasive nature of the procedure, 2) the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or 3) the underlying physical condition of the patient. These standards remain in place today and are used to distinguish non-covered inpatient services from covered outpatient services.

The same criteria applied to determine which procedures are excluded from the outpatient setting in hospitals should be used to determine procedures excluded from payment in ASCs. CMS currently uses, and proposes to continue to use, the specific standards set forth at §416.65(b)(3) to determine covered services under the ASC benefit. These standards are proposed for incorporation under the new §416.166(c) as the following general exclusions:

- (1) Generally result in extensive blood loss;

- (2) Require major or prolonged invasion of body cavities;
- (3) Directly involve major blood vessels;
- (4) Are generally emergent or life-threatening in nature;

Analysis of the wording of these general exclusions reveals that their intent is strikingly similar to, and indeed closely parallels, the intent of the exclusionary language under OPPS. The exclusions that reference extensive blood loss, major or prolonged invasion of body cavities and involvement of major blood vessels are all indicators of what is described as “the invasive nature of the procedure” under OPPS. The exclusion of procedures that are generally emergent or life-threatening in nature is indication of “the underlying physical condition of the patient” as described under OPPS. Table 2 below displays these interrelationships.

<b>Table 2 Relationship Among Exclusionary Criteria</b>				
<b>MedPAC Exclusionary Criteria Recommendations</b>		<b>OPPS Inpatient Only Factors</b>		<b>Proposed ASC Exclusionary Standards</b>
Clinical safety standards	↔	Invasive nature of the procedure	↔	Expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC
				Generally result in extensive blood loss
				Require major or prolonged invasion of body cavities
		Directly involve major blood vessels		
		Underlying physical condition of the patient	↔	Emergent or life-threatening in nature
Need for an overnight stay	↔	Need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged	↔	Need for active medical monitoring and care at midnight following the procedure
-		-		Procedure performed 80% of more of the time in the hospital inpatient setting

As CMS stated in this proposed rule, “most of the procedures that our medical advisors identified as involving any of the characteristics listed currently in §416.65(b)(3), also require overnight or inpatients stays.” Given that this is the case, continuing to apply the current specific ASC standards is unnecessary. The proposed standards which would exclude both those procedures requiring an overnight stay and those that are currently on the inpatient only list are sufficient safeguards in and of themselves. In effect, these newly proposed protections have rendered the specific standards redundant.

Given that the wording and intent of the exclusionary guidelines under OPSS parallel those under the ASC payment system, it is not necessary to have different language determine the exclusions for outpatient surgery. Rather than maintaining two separate sets of criteria for defining appropriate outpatient surgery, CMS should apply one uniform set of standards. The OPSS standards have proven sufficient to safeguard patients in the hospital outpatient setting and therefore can be reasonably applied to the ASC setting.

**d. Exclusion based on being performed 80% or more of the time in the hospital inpatient setting**

CMS has proposed to establish a new site of service volume criterion under which any procedure performed 80% or more of the time in the hospital inpatient setting would be excluded from payment of an ASC facility fee. This criterion is not necessary or desirable, nor does it reflect the recommendations of MedPAC.

By their very nature, site of service volume criteria are arbitrary. Past site of service volume criteria have proven problematic, primarily because their static nature has clashed with the dynamic and constantly evolving landscape of outpatient surgical care. The results of applying these site of service criteria have been unsatisfactory. In the case of the current site of service criterion requiring ASC eligible procedures to be frequently performed on an inpatient basis, CMS has had to redefine its guidelines over time in order to prevent services such as cataract extraction from being excluded from ASC coverage. In the case of the site of service criterion excluding procedures commonly performed in the physician office from ASC coverage, the result has been unduly restricted access to patients for whom facility services are nonetheless medically necessary. We urge the agency not to repeat this approach.

Further, CMS has proposed to use Part B Extract Summary System (BESS) data to make the determination of whether a particular CPT code has been performed 80% or more of the time in the hospital inpatient setting. Relying on Part B claims data when determining the frequency with which procedures are performed in various settings is not a sound approach. It has been well established by the OIG that place of service reporting can be a highly unreliable indicator of the actual site of service; significant error rates (80% and higher in some cases) for selected services have been reported (OIG Report Numbers A-02-04-01010, A-05-04-00025, A-06-04-00046). Given the probability of significant flaws in the data CMS proposes to use to determine site of service, the criterion has questionable validity.

CMS has proposed this site of service restriction as a patient safety safeguard. Implementation of such a restriction is unnecessary because specific safety criteria have already been defined. If a procedure is to be excluded as inappropriate, let it be on the grounds that it is not consistent with a specific clinical safety criterion, rather than on the basis of the application of a standard which has no clinical basis.

The safety criteria under OPSS do not include any exclusionary standards based on site of service volume criteria. Clinical safety standards have been effectively employed as safeguards

in HOPDs. ASCs should not be treated differently in this regard; clinical standards should be used to determine excluded services in both settings.

Physicians should have the ability to determine the appropriate site of service for the individual beneficiary, irrespective of volume frequencies in the various sites of service. That discretion should only be overridden when there is a significant, specific, and clearly articulated safety concern.

In summary, we support the agency's proposal to use the inpatient only list to determine procedures which would be excluded from payment of an ASC facility fee. However, the proposed criterion excluding those procedures performed 80% or more of the time in the inpatient setting should not be implemented. The use of non-clinical measures is not a sound approach to protecting patient safety. Instead, the agency should apply clinical standards to exclude procedures that are not safely performed in the ASC setting.

## **2. Overnight Stay**

As part of its proposed overhaul of the criteria for determining which procedures are covered in an ASC, CMS would eliminate the four hour recovery time limit. We support the elimination of this provision. CMS would continue to exclude from the ASC list procedures that require an overnight stay.

The specific language of Section 416.166 provides that CMS would exclude from the ASC list procedures that "standard medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight." Although we are willing to concede to CMS excluding procedures from the ASC list because they generally require an overnight stay, we do not believe this definition is workable.

In the preamble to this proposed rule, CMS explained its selection of midnight was based on a generally accepted standard. As support for midnight being a generally accepted standard, CMS cites a patient's location at midnight as the determinant for his or her status as a hospital inpatient or skilled nursing facility patient. However, the use of midnight in these circumstances is designed to provide a basis for census counting for hospital cost reporting purposes or a specific reference point in time for situations involving interrupted stays and consolidated billing. While midnight may be useful for establishing clear billing guidelines or taking a patient census, there is little to recommend using an arbitrary *time* of day to define a clinically appropriate *length* of stay.

We have undertaken an extensive review of state regulations in an attempt to substantiate CMS's statement that the use of midnight is a generally accepted standard. Our research revealed that those states with guidelines regarding maximum length of stay almost universally use a specified length of stay, rather than a specific "cut-off" time. This approach to the definition of overnight stay is more appropriate, and affects all patients uniformly. It allows all patients, regardless of the time of day their procedure is scheduled, to have the same access to services. In other words,

the patient with a procedure scheduled in the afternoon is given the same opportunity for recovery as the patient whose procedure is scheduled in the morning.

Several states have expanded the concept of “ambulatory” over the years by permitting ASCs to perform procedures requiring stays of up to 24 hours. Of the 17 states that have either statutes or rules specifying the length of time a patient may remain in an ASC, 15 states allow for stays between 23 and 24 hours: Alabama, Arizona, Arkansas, California, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah. Several states permit stays of longer than 24 hours.

We also note that in determining which procedures are appropriate to the outpatient setting under OPPS, CMS only excludes those procedures for which there is the need for at least 24 hours of *postoperative* recovery time or monitoring before the patient can be safely discharged. This exclusionary standard does not take into account the time spent in the facility from the time of admission until recovery from the procedure begins. The effective result is that HOPDs are able to provide services requiring significantly more than 24 hours in total. Although an episode of care in an HOPD may exceed 24 hours, this length of stay is not considered inappropriate to outpatient surgery in that setting. As an alternative facility setting for outpatient surgery, ASCs should be able to offer beneficiaries a similar opportunity for recovery.

In the past, CMS has recognized that midnight is not necessarily the only definition of an overnight stay. In correspondence to the Federated Ambulatory Surgery Association dated May 18, 2005, CMS states that an overnight stay is a planned stay of over 24 hours and conversely that when the “length of stay is less than 24 hours, it is not considered an overnight stay.” The proposed use of midnight as the equivalent of overnight is counter to historic CMS statements on this matter. The previously articulated definition of an overnight stay as a stay of less than 24 hours in duration is long-standing and appropriate.

Given CMS’s historic statements on overnight stays in the ASC, state regulations that allow stays of up to 24 hours and the more extensive length of stay permitted in the HOPD, it is reasonable to allow ASCs to offer either an episode of care or a postoperative recovery period of less than 24 hours. CMS should abide by its previously stated position and continue to define an overnight stay in an ASC as a stay that is less than 24 hours in duration.

### **3. Proposed Treatment of Unlisted Procedure Codes**

Providers occasionally perform services or procedures for which the CPT book does not provide specific codes. To allow reporting of these services, each section of CPT includes an unlisted procedure code used to identify unlisted procedures in that specific section. HOPDs receive reimbursement for unlisted procedure codes under OPPS. However, under the current ASC reimbursement system, unlisted codes are not eligible for reimbursement.

CMS has proposed to continue to exclude ASCs from payment for unlisted codes under the revised payment system, citing potential safety risks. This concern arises from the fact that unlisted codes do not include descriptor language specifying what service is being performed.

While we understand these concerns, we do not think it is necessary to exclude all unlisted codes from payment of an ASC facility fee in order to address potential safety risks. There are many subsections of the CPT manual for which CMS has determined that all the specific CPT codes within the clinical group are safely performed in the ASC setting. When this is the case, we submit that the unlisted codes for such sections would not pose a safety risk. For example, all the specific codes in the hysteroscopy subsection in CPT are currently on the ASC list. Given that CMS has concluded that all these procedures meet current safety criteria for the ASC setting, we believe that any unlisted hysteroscopy procedure performed would not pose a safety risk. Similarly, all the specific codes in the posterior segment subsection of CPT are currently classified as ASC list procedures or physician office procedures. Given this, we do not believe that an unlisted procedure on the posterior segment of the eye would pose a safety risk.

Therefore, when all the specific codes in a subsection of CPT are eligible for ASC payment under the revised payment system, the associated unlisted code should also be eligible for payment of an ASC facility fee.

#### **4. Procedures that are Not Paid Separately under the OPSS**

In principle, we agree that in a revised ASC payment system based on OPSS, services that are “packaged” under OPSS and therefore not separately payable to HOPDs should not be eligible for payment of a separate ASC facility fee. However, we have several concerns regarding the practical application of this policy.

##### **a. Packaging Policies Should be Applied to All Services Defined as Surgical**

We note that CMS states the proposed packaging policy would be limited to CPT codes in the surgical range. At a minimum, it should also be applied to covered procedures described by CPT Category III codes and Level II HCPCS codes since these are proposed by CMS for coverage under the revised ASC payment system.

##### **b. OPSS Policies that Package Surgical Service Codes into Radiologic Service Codes**

We are concerned about the impact of existing OPSS packaging policies on selected services that meet CMS’s current definition of ASC surgical services (CPTs 10000-69999). Services such as diskography have both an injection component and a radiographic component. In CPT, the injection portion of the service is described by a code in the surgical range (in this example, 62290 or 62291), while the radiographic portion of the service is described by a code in the radiology range (in this example, 72285 and 72295). Under OPSS, the injection portion of the procedure is packaged into the radiographic portion of the procedure. As a result, only CPT codes 72285 and 72295 are payable.

Appendix C presents those surgical service codes in the CPT Surgery section that would be adversely affected by current OPPS packaging policies. These services represent a subset of those we have proposed for addition in Appendix B as invasive radiologic procedures.

Given these established OPPS payment policies, it is crucial that the definition of surgical services we proposed earlier, which would include the radiologic portion of surgical procedures, be adopted. Otherwise, ASCs will remain hampered in their ability to offer these ASC appropriate services to Medicare beneficiaries.

### **c. Alignment of OPPS Packaging Policies with the Revised ASC Payment System**

We are also concerned about payment discrepancies that may arise between HOPDs and ASCs when concurrent services outside the CPT Surgery range (10000-69999) are rendered in conjunction with a covered surgical procedure. When HOPDs provide additional medically necessary services outside the surgical range that are not packaged in conjunction with a covered surgical procedure, they receive additional payments.

For example, CPT code 76000, describing the use of fluoroscopy, may be required in conjunction with a covered procedure. Because 76000 does not meet the packaging criteria required by the APC Panel, CMS will make separate payment for this service in the HOPD. The clinical pathways involving 76000 are similar in the ASC and HOPD. Other fluoroscopy codes are packaged with the primary procedure. As a result, ASCs would receive payment for some, but not all fluoroscopy dependent only on the packaging policy – not the clinical needs of the beneficiary.

Another illustrative example is HCPCS Level II code C9222, describing decellularized soft tissue scaffold. Services involving biologic tissues are routinely performed as outpatient surgical procedures. GRAFTJACKET® XPRESS Flowable Soft-Tissue Scaffold is used in the surgical treatment of chronic wounds. Under OPPS, separate payment is made. This payment should, since it is not packaged into the surgical service, also be available to ASCs under the revised payment system.

CMS should allow ASCs to receive separate payment for non-packaged brachytherapy sources placed during a collaborative procedure for the placement of brachytherapy needles or applicators and subsequent application of the radiation source. This will facilitate the treatment of cancer patients who have brachytherapy delivery devices implanted in the ASCs.

There are numerous other examples of services that are commonly performed for non-Medicare patients in conjunction with a surgical service that are not packaged under OPPS. The reimbursement rules should be applied consistently to both HOPDs and ASCs; therefore, ASCs should also be eligible for separate reimbursement when non-packaged services are performed in conjunction with a covered ASC procedure. Appendix B includes many examples of CPT codes for surgical services outside the surgical range that are not packaged. Table 3 presents examples

of HCPCS Level II codes for services that are not packaged, and are therefore separately payable under OPSS. In order to align the two payment systems, these services should be covered and separately payable to ASCs under the revised system.

<b>Table 3 CPT and HCPCS Level II Codes Describing Non-packaged Services that Should be Covered under the Revised ASC Payment System</b>		
<b>Code(s)</b>	<b>Descriptor or Type of Service</b>	<b>Rationale</b>
C1716	Brachytx source, Gold 198	Brachytherapy source
C1717	Brachytx source, HDR Ir-192	Brachytherapy source
C1718	Brachytx source, Iodine 125	Brachytherapy source
C1719	Brachytx source, Non-HDR Ir-192	Brachytherapy source
C1720	Brachytx source, Palladium 103	Brachytherapy source
C2616	Brachytx source, Yttrium-90	Brachytherapy source
C2633	Brachytx source, Cesium-131	Brachytherapy source
C2634	Brachytx source, HA, I-125	Brachytherapy source
C2635	Brachytx source, HA, P-103	Brachytherapy source
C2636	Brachytx source, P-103	Brachytherapy source
C2637	Brachytx source, Ytterbium-169	Brachytherapy source
C9220	Sodium hyaluronate	Drug not packaged
C9222	Graftjacket Sft Tis	Biologic not packaged
J series	Any non-packaged items payable under OPSS	Drugs not packaged
Q0166	Granisetron HCl 1 mg oral	Drug not packaged
Q0179	Ondansetron HCl 8 mg oral	Drug not packaged
Q1080	Dolasetron mesylate oral	Drug not packaged

In summary, while we agree in principle that the packaging rules applied for services under OPSS should be applied in the same manner to ASCs, CMS will need to alter its current definition of surgical services in order to avoid inconsistencies in its payment policies for the same procedures when provided in different sites of service.

**d. Coverage of OPSS Pass-Through Drugs, Biologicals and Devices under the Revised ASC Payment System**

CMS makes transitional pass-through payments to HOPDs for innovative medical devices, drugs and biologics. Coverage and payment of these items, when provided concurrently with a surgical service as defined above, should be extended to ASCs.

For example, CMS allows pass-through payment to HOPDs for C1820, which describes an implantable neurostimulator generator with a rechargeable battery and charging system. This device would typically be reported in conjunction with CPT code 64590. CMS has proposed to allow coverage of CPT code 64590 under the revised ASC payment system, but has not proposed to allow coverage of C1820. There are no clinical or policy reasons to allow separate payment toward the device in one setting, but not in the other. Medicare beneficiaries should be allowed equal access to such devices in both the HOPD and the ASC. Therefore, C1820 and any



comparable pass-through technologies paid for when a procedure is performed in an HOPD should be paid for when provided in an ASC.

CMS should adopt consistent coverage policies across sites of service. When drugs, biologicals or devices are integral to a covered surgical procedure, and have been afforded transitional pass-through status under OPPTS, that transitional pass-through payment should also be available to ASCs.

HCPCS Level II codes that currently describe items afforded pass-through status related to surgical services are listed in Table 4 below.

<b>TABLE 4</b>		
<b>Examples of HCPCS Level II Codes Describing Pass-Through Items that Should be Covered under the Revised ASC Payment System</b>		
<b>Code(s)</b>	<b>Descriptor or Type of Service</b>	<b>Rationale</b>
C1820	Generator neuro rechg bat sys	Integral to covered procedure
C9225	Fluocinolone acetonide intravitreal implant	Integral to covered procedure
J2278	Ziconotide injection	Integral to covered procedure
J2503	Pegaptanib sodium injection	Integral to covered procedure

Given that pass-through status is transitional, not all these items may be eligible for separate payment at the time the revised ASC payment system is implemented. These current examples are presented to illustrate the appropriateness of extending coverage for pass-through items to ASCs when they are provided in conjunction with a covered surgical procedure. CMS should ensure consistent coverage policies, regardless of the type of facility setting, for innovative drugs, biologicals and devices.

#### **D. ASC Office-Based Procedures**

We wholeheartedly support CMS's proposal to discontinue the current provision which excludes procedures commonly performed in the physician office from payment of an ASC facility fee. Though a procedure may be commonly performed in physician offices, certain beneficiaries may require the additional resources available in a facility setting. We are pleased physicians will now be allowed to exercise their clinical judgment and select the site of service based on individual beneficiary needs without having to consider whether the procedure is eligible for reimbursement in the site of service they deem most appropriate.

While physicians routinely perform these procedures on Medicare beneficiaries in the office setting, certain beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. A brief summary of these factors, which affect a minority of cases, follows. Unless ASCs are an eligible alternative site of service in such cases, these procedures will have to be performed in a more costly hospital-based setting.

**Patient Characteristics.** Patient characteristics affect the selection of the appropriate site of service. Factors such as size, comorbid conditions, and the patient's ability to maintain position for long periods of time may affect whether a procedure can or should be performed in a physician office.

**Procedure Differences.** Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12 to 20 biopsies. Due to the more invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

In another example, the excision of a soft tissue lesion from the external auditory canal (CPT code 69145) may often be appropriately performed in the physician's office under local anesthesia. However, if the lesion is in the medial canal near the tympanic membrane, careful dissection using microscopy will be required and local anesthesia may not be adequate. Under these circumstances, the physician may opt to perform the procedure in an ASC or HOPD.

**Office Differences.** Physician offices vary greatly in terms of equipment and personnel. To a large extent, this varies based upon the volume in the office. A small office simply may not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

**Medical Liability Policy Differences.** In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

**State Laws and Regulations.** State laws and regulations impose limitations on what can be done in physicians' offices. These state provisions may require specific equipment, staff or even accreditation for certain procedures. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

In developing an exclusionary ASC list, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and exclude from coverage only those services deemed inappropriate "based on clinical safety standards and whether the service requires an overnight stay."

In this proposed rule, CMS states that it has concerns that allowing ASC payment for office-based procedures will lead to overutilization of ASCs or lead physicians to convert their offices to ASCs. However, there is no evidence that coverage of office-based procedures in the ASC setting leads to such behaviors. There are many services that have been on the ASC list since its inception although they technically qualify as office procedures based on the criteria currently employed by CMS. CMS itself has acknowledged that inclusion of certain services on the ASC list – although commonly performed in the physician office – has not resulted in excessive utilization of ASCs.<sup>4</sup> CMS stated, “Consistently, the physician office is the predominant service setting even though the procedures were included on the ASC list.” CMS subsequently concluded “that the relative stability of the utilization and site of service is evidence that the inclusion of the codes on the ASC list has not influenced the physician’s selection of setting for performance of the procedures and provides strong evidence that there is a small but consistent population of beneficiaries for whom the ASC setting is the most appropriate for these procedures.”<sup>5</sup>

Therefore, we do not believe concerns regarding ASC overutilization have any empirical basis, and are not supported by historical claims data.

We further note that MedPAC, in its comments to CMS on this proposed rule dated October 10, 2006, also supports CMS’s proposal to add procedures that are primarily performed in physician offices to the ASC list. The Commission states, “Even though physicians can safely perform many surgical services on healthy beneficiaries in their offices, sicker patients may require the additional infrastructure and safeguards of an ASC or outpatient department. Physicians and patients should have the discretion to decide which setting is most clinically appropriate.” We are in full agreement with MedPAC on this point; these services should be eligible for payment of an ASC facility fee. Though certain procedures in the range of surgical codes in CPT are commonly performed in the office, the physician should be able to select either an ASC or a HOPD if a facility setting is required.

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

Tables 44 and 45 of this proposed rule set forth the procedures proposed for exclusion from payment of an ASC facility fee on the basis of their being performed 80% or more of the time in the inpatient setting and the procedures proposed for exclusion on the basis of requiring an overnight stay, respectively.

As noted above, we disagree with the proposed use of site of service volume criteria that would exclude those procedures that are performed 80% or more of the time in 2005 from payment of an ASC facility fee. Therefore, we do not agree with excluding any of the services presented in Table 44 from payment of an ASC facility fee on this basis. For example, based on this criterion

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<sup>4</sup> 70 Fed. Reg., 23696 (May 4, 2005)

<sup>5</sup> 70 Fed. Reg. 23689, 23696 (May 4, 2005)

CPT code 64447, describing a femoral nerve block, would be excluded. Nerve blocks are appropriate to the ASC setting; this procedure would not be excluded on the basis of any of the clinical criteria.

As stated above, we are opposed to the use of midnight as the basis for the definition of an overnight stay. All of the procedures listed in Table 45 can be performed safely with recovery times of less than 24 hours. If this were not the case, CMS would have included them on the OPSS inpatient only list.

In this proposed rule, CMS requests that commenters who disagree with a proposed exclusion from payment of an ASC facility fee submit "data to support that the preponderance of Medicare beneficiaries upon whom the procedure is performed do not require overnight care or monitoring following the surgery." Medicare does not currently cover these procedures in the ASC setting, so there is little to no ASC data that is specific to Medicare beneficiaries. Further, we do not believe that it would be meaningful to use HOPD length of stay data as a proxy given the inherent inefficiencies of that setting, where cases may be affected by delays resulting from urgencies and emergencies that would not be experienced in the ASC setting. Therefore, we propose to share data derived from our care of non-Medicare beneficiaries.

Based on our experience, and using the definition of overnight stay CMS has proposed, several procedures presented in Table 45 would not require recovery beyond midnight. For example, ASCs have extensive experience performing sacroiliac joint injections, CPT code 27096. These procedures typically require less than an hour of recovery time. We note that the HCPCS Level II code equivalent, G0260, has not been included on the list of procedures requiring an overnight stay. We believe the inclusion of this code in Table 45 was likely in error, particularly since this code is not included in Appendix B for OPSS payment.

The data presented in Table 5 is based upon a review of the clinical logs of the undersigned corporations. When possible and reasonable to do so, data is presented specifically for patients age 65 and older.

<b>TABLE 5</b>					
<b>Procedure Times for Selected CPT Codes Excluded by CMS as Requiring an Overnight Stay</b>					
<b>CPT</b>	<b>Average Age</b>	<b>Age Range</b>	<b>Average OR + Recovery Time (minutes)</b>	<b>Range OR + Recovery Time (minutes)</b>	
19240	52	18-65	227	142-368	
19260	55	49-75	139	93-176	
21470	34	17-45	294	215-395	
27412	28	13-50	242	155-293	
27415	26	17-40	215	121-402	
27524	73*	65-85	200	135-346	
29866	36	14-51	200	130-232	

29867	42	24-65	170	121-310
43280	52	48-58	202	171-226
44180	36	18-68	137	70-224
44970	36	23-50	216	105-426
47562	71*	65-86	153	84-214
49200	48	25-63	96	59-145
53500	56	36-75	100	68-125
57106	45	23-69	120	58-232
57295	60	44-77	144	67-400
58553	43	39-46	284	208-441
60210	49	36-70	250	131-437
63030	43	19-71	209	101-512
63075	45	28-64	246	155-515
* Data subset for patients age 65 and older only				

Based on the data presented above, there are a number of procedures that should not be excluded from the ASC setting. They do not require an overnight stay and would not be excluded based on other clinical safety standards.

In summary, we believe that physicians should, in consultation with their patients, retain the ability to determine the site of service for a given procedure. Site of service volume characteristics are arbitrary and without clinical basis and should not be used to determine ASC eligibility. Regardless of which standard CMS uses to define overnight stay, the agency should use ASC data to determine length of stay requirements. We continue to encourage CMS to consult with the ASC community and national specialty societies when determining whether to exclude procedures from ASC coverage.

### **PROPOSED ASC RATESETTING METHOD**

Using a common payment system for both ASCs and HOPDs is the appropriate approach. The infrastructure developed by CMS to establish the APC relative weights is the best single proxy for the relative costliness of services in the ASC provided that the ASC conversion factor is set high enough to cover the facilities' costs. Within the spectrum of ASC services, however, there appear to be some classes of services for which the APC relative weights are imperfect, including GI and pain management. Using the same system for ASCs and HOPDs has tremendous potential to improve the transparency of price information for beneficiaries, ensuring that they can be savvy consumers.

CMS should take advantage of this opportunity to enhance Medicare beneficiaries' access to surgical services and enhance savings to the Medicare program. However, significant changes to the proposed rule are necessary to achieve these important objectives. Absent substantive changes, the new system will under-compensate providers for many services, such as gastroenterology surgical services, and cause procedures to migrate to the higher-cost HOPD setting. The current proposal would align only portions of the payment systems and thus greatly limit the potential of the payment systems to contribute to efficiency, transparency and savings

for the government and beneficiaries. Without truly parallel payment systems, these goals simply will not be achieved.

In the sections below, we discuss our view of the major elements of CMS's proposal for a new payment system. We articulate how several adjustments to the proposed system could better align ASC and HOPD payment and improve the proposal.

#### **A. Linking ASC & HOPD Relative Weights & APCs**

Using the same APCs and the same relative weights in 2008 for both ASC and HOPDs is a major step towards creating a consistent payment system for surgery regardless of whether it is provided in an ASC or an HOPD. We are troubled that the same weights will only be used in 2008, however. In 2009 and beyond, the proposed policy of re-scaling ASC relative weights the second time will result in a divergence of the relative weights between settings over time. The relative costliness of procedures in the ASC and HOPD setting will not change over time, and differences in the payments between ASCs and HOPDs should be addressed transparently, based on findings that the relative costliness has changed and implemented directly through adjustments to the conversion factor.

#### **B. Proposed ASC Packaging Policy**

Under the current ASC payment system, the use of only nine payment groups requires that the bundle of services be extraordinarily large to cover the range of services provided in association with 2,547 surgical procedures eligible for ASC payment. Moving to the HOPD payment system, with more than 200 new payment bundles, means that CMS can more closely capture the costs associated with a particular set of clinically similar services. In order for the HOPD relative weights to be appropriate across settings, the bundles in both settings must be comparable. This proposed rule, however, contains an amalgamation of the HOPD and ASC policies that would result in underpayment when procedures with fixed device costs are performed in ASCs. CMS considered several options for packaging of services and devices directly related to a surgical procedure. We urge you to reconsider these options and implement a policy that uses the same packages of services for both settings. This policy is most appropriate in our view for two reasons. It contributes to the overall goal of unifying the payment systems for outpatient surgery and contributes to transparency, fairness and efficiency. In addition, since the HOPD relative weights are based upon the costs of providing a particular bundle of services, the integrity of the system is undermined if items and services that are separately payable in the HOPD, and thus not included in the underlying cost of the APC payment, are not paid separately in the ASC. This distorts the purpose of using the HOPD payment rates as a proxy for ASCs' relative costs.

##### **1. Implantable prosthetic devices and implantable DME**

The current Medicare ASC procedure list includes services requiring the use of medical devices or implants, which represent an additional variable cost to the delivery of these services. While ASCs frequently provide these services to commercially insured patients, due to difficulties in

consistently securing separate reimbursement from Medicare carriers for the necessary implants, these services are not commonly performed for Medicare beneficiaries.

Allocated device costs, as derived from the CMS file displaying device related percentages of APC costs for 2005, frequently exceed the ASC facility payment under the current payment system. Table 6 provides a comparison of the top 10 HOPD device-related services, HOPD device costs, and current ASC facility reimbursement rates. Because ASCs rarely receive separate reimbursement for implanted prosthetic devices, the assigned group payment rate for the associated procedure is often the only reimbursement that ASCs currently receive.

<b>TABLE 6</b>				
<b>Top 10 HOPD Device Services, 2006 Q1 HOPD and ASC Rates, 2005 CMS Device Cost %</b>				
<b>CPT4</b>	<b>Description</b>	<b>ASC Rate</b>	<b>HOPD Device Cost</b>	<b>Variance</b>
33213	Insertion of pulse generator	\$510.00	\$5,404.85	-\$4,894.85
36870	Percut thrombect av fistula	1,339.00	297.68	1,041.32
57288	Repair bladder defect	717.00	804.34	-87.34
33212	Insertion of pulse generator	510.00	4,258.96	-3,748.96
63685	Insrt/redo spine n generator	446.00	9,873.56	-9,427.56
69930	Implant cochlear device	995.00	19,973.00	-18,978.00
54405	Insert multi-comp penis pros	510.00	4,684.79	-4,174.79
62362	Implant spine infusion pump	446.00	7,577.02	-7,131.02
63650	Implant neuroelectrodes	446.00	1,734.28	-1,288.28
64590	Insrt/redo perph n generator	446.00	9,873.56	-9,427.56

Due to these disparities in reimbursement and inability to cover the costs of delivering these services to Medicare beneficiaries, ASCs performed less than 3% of these services in 2004 with the majority of these treatments being at a loss.

**a. Inadequacy of Proposed Payment Policy**

Moving to a new ASC payment system offers CMS the opportunity to address the problem of inadequate payment for device dependent services and expand beneficiaries' access. Because the cost of the implantable item is bundled under the proposal, the previous inconsistent implementation of ASC coverage policies discussed above will be significantly ameliorated.

CMS proposes to cease making separate payments for implantable prosthetic devices and implantable DME, consistent with the treatment of these items in the HOPD. However, unless changes are made to the proposal, expanded access will not be realized because at the currently proposed 62% conversion factor, there are many procedures that will remain economically unfeasible for ASCs. The proposed ASC payment for services that are comparable to those for APCs with high device costs will result in under-payment for the non-device portion of the procedure, especially where the device represents a large proportion of the total procedure costs.

Table 7 provides a list of procedures for which the 2005 device cost exceeds the proposed ASC total rate.

<b>TABLE 7 Examples of Device Services Performed in ASCs With CMS Device Cost % Greater Than 62% Conversion Factor</b>		
<b>CPT4</b>	<b>Description</b>	<b>2005 Reported Device %</b>
63685	Insrt/redo spine n generator	86%
64590	Insrt/redo perph n generator	86%
69930	Implant cochlear device	85%
62360	Insert spine infusion device	85%
62361	Implant spine infusion pump	82%
62362	Implant spine infusion pump	82%
33214	Upgrade of pacemaker system	82%
33213	Insertion of pulse generator	81%
61885	Insrt/redo neurostim 1 array	80%
64553	Implant neuroelectrodes	79%
64573	Implant neuroelectrodes	79%
33282	Implant pat-active ht record	79%
33212	Insertion of pulse generator	79%
33206	Insertion of heart pacemaker	78%

In 2005, CMS reported that 40 APCs, encompassing 76 procedures had device costs included in the bundled payment rate. If ASC payment is based on 62% of the APC rate, the device cost of 36 of these procedures (47%) would exceed 65% of the ASCs' payment. This means that ASCs would have to cover the cost of the facilities' services with the remaining 35% of the payment rate, including nursing and other clinical and non-clinical labor, rent, utilities, and other supplies.

ASCs are usually more efficient than hospitals. However, these efficiencies are not factors in the cost of acquisition for medical devices. Acquisition costs are inversely related to the volume of supplies purchased and directly related to the ability to consolidate the volume order through a single ordering source. With the proposed conversion factor of 62%, ASCs would need to be able to purchase devices at a rate lower than hospitals in order to provide services in APCs with large device costs. This is simply not realistic.

Upon reviewing overall volume of CMS ASC services in 2004 versus the HOPD for the proposed surgery procedure range of 10000 to 69999, ASCs performed less than 26% of all



services. This means that hospitals, due to their higher service volume, are in a much stronger position when it comes to the ability to leverage their buying power to lower their acquisition cost. Besides the surgical volume advantage, hospitals also have the ability to consolidate orders from all of their ancillary departments to further lower their purchasing price. Most ASCs are small businesses and not affiliated with a larger organization. Only 10 to 15% are part of an organization with 75 or more locations.

Table 8 provides some examples of the CMS 2005 device related percentages versus current ASC acquisition costs for a large ASC corporation for medical devices. The variance in ASC costs and HOPD device related payments highlights the differences in purchasing power between the two settings.

<b>TABLE 8 Comparison of HOPD Device Portion to ASC Acquisition Cost</b>						
<b>CPT4</b>	<b>Description</b>	<b>2006 Q1 HOPD Payment</b>	<b>2005 Device %</b>	<b>2006 HOPD Device Payment Amount</b>	<b>ASC Sample Acquisition Cost</b>	<b>Supply Cost Variance (ASC vs. HOPD)</b>
						-
63685	Insrt/redo spine n generator	\$11,455.57	86%	\$9,873.56	\$14,995.00	\$5,121.44
63650	Implant neuroelectrodes	3,025.08	57%	1,734.28	2,250.00	-515.72
19357	Breast reconstruction	3,185.67	40%	1,277.45	1,175.00	102.45
26536	Revise/implant finger joint	2,582.51	28%	732.40	1,128.00	-395.60
57288	Repair bladder defect	2,453.75	33%	804.34	945.25	-140.91
19325	Enlarge breast with implant	3,185.67	40%	1,277.45	1,175.00	102.45
62360	Insert spine infusion device	4,319.33	85%	3,675.32	10,752.00	-7,076.68
26531	Revise knuckle with implant	2,582.51	28%	732.40	650.00	82.40
62362	Implant spine infusion pump	9,226.77	82%	7,577.02	10,752.00	-3,174.98
19342	Delayed breast prosthesis	3,185.67	40%	1,277.45	1,175.00	102.45
50398	Change kidney tube	411.69	27%	109.63	181.30	-71.67

Source: ASC Coalition corporate member acquisition price.

**b. Device Policy Recommended**

To address the problem of inadequate reimbursement to cover medical devices so that Medicare beneficiaries will have access to services requiring their use in ASCs, we recommend that a specific adjustment be made so that ASCs are paid 100% of the device-related percentage of the OPPS APC payment and the conversion factor be applied only to the non-device related portion of the payment. This is essentially the same policy used in setting HOPD payments. The payment for each APC would be determined using the following formula: APC Device Portion + (the budget neutral factor \*(APC Total Rate – Device APC Portion)). This policy recognizes the efficiencies ASCs can achieve in their operations while acknowledging their limited buying power.

This approach would improve the probability that ASCs would be able to cover their costs and provide these services to Medicare beneficiaries. It would also increase the likelihood that these services would migrate to the ASC and provide additional savings to the government and the beneficiary. Table 9 provides a comparison of rates using this revised payment approach based upon 2006 rates.

<b>TABLE 9 Revised Payment Methodology</b>						
<b>CPT4</b>	<b>Description</b>	<b>2006 Q1 HOPD Payment</b>	<b>2005 Device Pct</b>	<b>2006 HOPD Device Payment Amount</b>	<b>ASC Device Service Payment</b>	<b>Overall Cost Reduction</b>
63685	Insrt/redo spine n generator	\$11,455.57	86%	\$9,873.56	\$10,854.40	5%
63650	Implant neuroelectrodes	3,025.08	57%	1,734.28	2,534.58	16%
19357	Breast reconstruction	3,185.67	40%	1,277.45	2,460.55	23%
26536	Revise/implant finger joint	2,582.51	28%	732.40	1,879.47	27%
57288	Repair bladder defect	2,453.75	33%	804.34	1,826.97	26%
19325	Enlarge breast with implant	3,185.67	40%	1,277.45	2,460.55	23%
62360	Insert spine infusion device	4,319.33	85%	3,675.32	4,074.61	6%
26531	Revise knuckle with implant	2,582.51	28%	732.40	1,879.47	27%
62362	Implant spine infusion pump	9,226.77	82%	7,577.02	8,599.87	7%
19342	Delayed breast prosthesis	3,185.67	40%	1,277.45	2,460.55	23%
50398	Change kidney tube	411.69	27%	109.63	296.91	28%

Potential savings to the program on a per service basis would be, at a minimum, from 5% to 28%. Without reimbursement that covers the costs of devices, these procedures will not move to the ASC and thus no savings will occur. Previous experience with these services in the ASC setting support this contention.

Beneficiaries would also save by being able to access these services in the ASC. The beneficiary will always save from the lower price of the procedure, and the reduced coinsurance, as the HOPD coinsurance on the overwhelming majority of these procedures is above 20%.

Table 10 compares the minimum HOPD coinsurance to the ASC coinsurance for the same service.

<b>TABLE 10 Beneficiary Savings</b>				
<b>CPT4</b>	<b>Description</b>	<b>HOPD Minimum Beneficiary Coinsurance</b>	<b>ASC Coinsurance</b>	<b>Beneficiary Savings</b>
63685	Insrt/redo spine n generator	\$2,291.11	\$2,170.88	\$120.23
63650	Implant neuroelectrodes	605.02	506.92	98.10
19357	Breast reconstruction	637.13	492.11	145.02
26536	Revise/implant finger joint	516.50	375.89	140.61
57288	Repair bladder defect	490.75	365.39	125.36
19325	Enlarge breast with implant	637.13	492.11	145.02
62360	Insert spine infusion device	863.87	814.92	48.95
26531	Revise knuckle with implant	516.50	375.89	140.61
62362	Implant spine infusion pump	1,845.35	1,719.97	125.38
19342	Delayed breast prosthesis	637.13	492.11	145.02
50398	Change kidney tube	82.34	59.38	22.96

If implemented, this policy will impact the budget neutrality calculation. The cost of separately payable devices is not contemplated in either of the agency's budget neutrality calculations. The Lewin Group estimates that CMS paid an additional \$12 million for implantable prosthetic devices and DME. That number would increase significantly if devices that were implanted, but not reimbursed by the carriers were reflected in the calculation. We include this device service adjustment in our recommendations related to budget neutrality later in this document.

Without adequate reimbursement, ASCs simply will not be able to perform such procedures for Medicare beneficiaries. This results in a substantial missed opportunity for the government and the beneficiary.

### **c. New Technology**

In addition to the adjustment for device-related services described in this section, it is critical that CMS reconsider its position on pass-through payments to ASCs. Without allowance for these additional payments, new technology services will be limited to the higher cost hospital environment. CMS has an opportunity to save additional program costs by allowing pass-through payments to ASCs for new technology. Without this adjustment, these services will not be economically feasible in the ASC. As a result, Medicare program costs for new technology will be higher than necessary.

While the current threshold requirements for approval of a new technology under the OPSS are very high and few services qualify, innovations that could quickly be implemented in the ASC may be delayed until CMS updates the APC relative weights. Beneficiaries should not be limited to the HOPD for access to a service that can be safely performed in ASCs. If the new technology

is not yet available in a hospital in the community, Medicare beneficiaries will be denied the service entirely.

**B. Bundling of Other Separately Payable Items in the HOPD**

The proposal to treat services and supplies paid separately in the HOPD as part of the ASC facility fee bundle undermines the appropriateness of the HOPD relative weights for ASC services. The table below shows the ancillary services associated with a commonly performed ASC procedure. The representation of the costs of those separately payable items is not captured in the median cost of the primary procedure. As a result, the weights for procedures in the ASC that have significant ancillary costs will result in under-payment for ASCs.

<b>TABLE 11</b>								
<b>Procedure profile of CPT 43248 in the ASC and HOPD, Including Services Excluded from Separate ASC Payment</b>								
2° Codes	2° Procedure Definition	2° Procedure HOPD Payment Terms	ASC Utilization Rate	HOPD Utilization Rate	HOPD Charge per Occurrence	HOPD Actual Payment per Occurrence	2006 APC Status	2006 ASC Group
<b>Primary Procedure: CPT 43248 - Upper GI endoscopy/guide wire</b>								
43248	Uppr gi endoscopy/guide wire	APC Payment	100.3%	100.3%	\$1,269.46	\$ 382.92	T	2
76000	Fluoroscope examination	APC Payment		8.0%	\$ 317.26	\$ 69.30	X	
	No CPT Code	No Additional Payment		253.6%	\$ 173.56	\$ -	N	
J2250	Inj midazolam hydrochloride	No Additional Payment		23.1%	\$ 41.34	\$ -	N	
J3010	Fentanyl citrate injeciton, .1	No Additional Payment		18.4%	\$ 24.20	\$ -	N	
99141	Sedation, iv/im or inhalant	No Additional Payment		13.1%	\$ 204.80	\$ -		
J2175	Meperidine hydrochl /100 MG	No Additional Payment		11.4%	\$ 19.32	\$ -	N	

Source: Cleverley & Associates analysis of Medicare claims data.

Note: percent exceeds 100 if more than one procedure was reported on the claim.

CMS posited in the preamble:

[W]e believe that ASCs generally treat a less complex and severely ill patient case mix, as a result, we believe that ASCs are less likely to provide on a regular

basis many of the separately paid items and services that patients might receive more consistently in a hospital outpatient setting. Thus, we do not believe there is a need to pay for these services separately in ASCs, because that would unbundled some items and services that are currently packaged into the ASC facility fee, reduce incentives for cost-efficient delivery of services at ASCs, and increase the complexity of the revised ASC payment system.

We are unaware of any evidence to support the allegation that ASCs less frequently provide many of the separately paid items and services. Moreover, we are not aware of a clinical basis for this assertion. Furthermore, CMS does not state that claims data shows such a difference. If one exists, we would assert that it results from differences in the billing and payment systems. When HOPDs are paid for services that ASCs are not paid for providing and thus do not report to CMS, claims data is not an adequate indicator for services actually delivered

When CMS calculates the median cost for an APC, the agency excludes claims for services that have separately payable items on the claim. This isolates the cost of services provided as part of the APC payment bundle and excludes the cost of services for which the hospital will receive separate reimbursement. In the table above, the cost of services for which the hospital receives no additional payment are included in the calculation of the APC relative weight for the primary procedure; however, the cost of procedures and services with a status X, T, or A are not included in the median cost calculation for the primary procedure. If CMS includes these procedures in the payment bundle for ASCs without an adjustment to the relative weight, the APC median cost will under-compensate ASCs any time they perform a procedure that is separately reimbursed under the OPSS. Because the current ASC payment system does not provide separate reimbursement for these services, and ASCs are using the CMS-1500 for billing, there is no claims history to identify if, and how frequently, these other services are performed in the ASC under the current payment system. There are no reasons to exclude ASCs when they are medically necessary.

Even assuming CMS is correct and HOPDs provide ancillary services more frequently, our recommended policy would still be appropriate. If ASCs do not provide the services, Medicare will not incur expenses for them. However, barring payment to all ASCs for all patients will result in under-payment or denied access despite medical necessity.

If the payment for a procedure is determined based upon the inclusion of certain elements in the package, additional payment would be made for components not included in this calculation. This logic is followed in the HOPD system. If a larger bundle of services is more appropriate policy for surgical procedures, the median cost for the expanded bundle should be determined for the APC relative weights and applied to both the OPSS and revised ASC payment system. There is no justification for implementing separate bundling policies for the same services while using the same relative weights.

We strongly urge CMS to reconsider its policy on ancillary services and adopt a uniform approach for ASCs and HOPDs.

### **C. Payment for Corneal Tissue under the Revised ASC Payment System**

CMS pays separately for the acquisition cost of corneal tissue in both the ASC and the HOPD. The agency proposes to continue to pay ASCs separately, based on their invoiced costs, for the procurement of corneal tissue. This policy has effectively reimbursed providers for these costs in both settings, and we agree that continuing this policy is desirable.

### **D. ASC Payment for Office-Based Procedures**

Although we applaud CMS's expansion of the ASC procedure list, we oppose CMS's payment cap on office-based procedures. We are concerned that the proposed payment limit will force patients who are not appropriately treated in the physician office to go to an HOPD, bypassing the ASC where the service could safely and cost-effectively be performed. Physician offices generally treat a less complex and severely ill patient case mix. As such, the office is less likely to have the staff and equipment resources to provide on a regular basis many of the services that a more medically complex patient might require. Capping payment at the physician office rate undermines the stepped reimbursement policies that underlie the level of resources available to the physician and beneficiary at the three sites for outpatient surgical services: the HOPD, ASC, and physician office.

CMS asserts that such a policy is intended to mitigate inappropriate movement of procedures from the office to the ASC; however the historical claims experience belies suggestions that such migration is a likely threat to the integrity of the payment system. In cases where CMS has made exceptions to allow ASC payment for procedures primarily performed in the office, there has not been significant shifts in the site of service for those procedures.

The CMS experience is consistent with what ASC managers have observed – physicians are unwilling to bring procedures to the ASC when the procedure can be appropriately performed in their offices. Physicians seek to provide services in the most convenient setting that is appropriate. Physicians who have acquired the equipment and personnel to perform these procedures will want to continue to provide such services in their office.

CMS has expressed repeated concerns that incentives in the payment system inappropriately drive site of service determinations. We are concerned that establishment of a cap for payment of the agency's office based procedures is problematic at best, and detrimental to the agency's desire to create a setting-neutral payment system. As such, we recommend the agency exclude this provision from the final rule and pay all procedures using a single conversion factor.

Should CMS find significant movement, this policy could always be reinstated at a later date. We discuss our suggestions for implementing this improvement to the proposed policies in more detail in our comments on calculation of the budget neutrality adjustment below.

We support CMS's proposal to exempt procedures already on the ASC list from this policy. As discussed above, no problem has occurred with these procedures and therefore extending application of this policy is unnecessary.

**E. Multiple Procedures Discounting Policy**

CMS proposes to apply the multiple procedures discounting policy used in the OPPS to services provided under the ASC payment system. This policy ensures that services with high fixed costs are not discounted when provided in conjunction with another procedure. We applaud the agency for creating a truly parallel process to pay for multiple procedures.

**F. ASC Wage Index**

Following the MMA's freeze on ASC payments, CMS has not updated the wage index values used to adjust payments for geographic price differences. In the intervening years, CMS has implemented, for its other prospective payment systems, the Office of Management and Budget's updated criteria for defining metropolitan statistical areas (MSAs). For counties whose designation as urban or rural changes as a result of the new MSAs, the change in the Medicare wage index and resulting impact on payments can be dramatic. Because the agency proposes to revise both the payment system and the geographic localities at the same time, we are concerned that providers in certain areas will experience dramatic shifts in payment as a result of the cumulative effect of the wage index and other policy changes in this rule.

The relatively small labor-related share of the ASC payment blunts the impact of wage index changes on total payments. However, we note that the agency provided at least a 2-year transition of the wage index impact changes for most other payment systems, and held harmless for three years (in the inpatient hospital PPS), providers whose wage index would fall as a result of the loss of their urban status. While CMS did not propose any transitional policies related to the implementation of the most recent wage index values, we encourage the agency to consider the cumulative effect of the wage index and other policy changes on payments to provider and develop a transitional approach that protects providers from significant reductions in payment.

<b>TABLE 12</b>				
<b>Selected County Wage Index Changes, FY 2004-2007</b>				
County	MSA (or state)	FY04 Wage Index	FY07 Wage Index	Percent Change
Mahoning Co, OH	Youngstown-Warren-Boardman MSA (OH-PA)	0.9214	0.8799	-5%
Madison Co., KY	Lexington-Fayette MSA (2004), Rural KY (2007)	0.8685	0.7805	-10%
Buncombe Co., NC	Asheville MSA	0.9720	0.9264	-5%
Houston Co., GA	Macon, GA (2004), Rural GA (2007)	0.8975	0.7825	-13%

**G. ASC Inflation**

Congress, in the MMA, gave the agency wide latitude in designing a new payment system, including determining how to update the payment system once implemented. We commend the

agency for including policies to provide annual updates to payments for changes in inflation, but urge CMS to use the hospital market basket to update the ASC rates annually for inflation. The hospital market basket is a better proxy for the inflationary pressures facing ASCs. Hospitals and ASCs must purchase similar inputs to provide surgical services and thus inflation will affect each provider similarly. The alternative proposed by CMS is a measure of inflation in goods purchased by the typical individual consumer. This in no way reflects the increases an ASC incurs. In fact, Medicare ties no other provider's inflation update on the basis of consumer inflation. Thus, the hospital market basket would most appropriately reflect the increases in costs that ASCs experience from year to year.

In addition to being an inappropriate measure for this purpose, the use of two different factors to update payments for ASCs and HOPDs will further increase the discrepancies between payments. The table below depicts the comparison between market basket and consumer price index for all urban consumers (CPI-U) for the last several years. Both CBO and OMB project that the differences between the update factors will persist for the foreseeable future.

Embedding these differences in the payment system produces two arguably undesirable policy outcomes. First, one could argue that the higher update applied to the HOPD may reward persistent inefficiencies, allowing the gap between the ASC and HOPD payment rate to grow over time. Second, the use of differing update methodologies suggests that the inflationary pressures for the same set of services are different in the ASC than in the HOPD. However, the relative resources used by each setting to provide a service are influenced by the same economic pressures in any given market. For example, the typical wage of a nurse has risen by more than 5% between 2004 and 2005 – fast outpacing the growth in the CPI-U.<sup>6</sup> In the hospital market basket, civilian hospital labor comprises more than 16% of the inputs of the hospital market basket (total labor is more than 50% of the weight of the index).<sup>7</sup> Conversely, housing, transportation, and food and beverage input price measures dominate more than 75% of the CPI input price weights.<sup>8</sup> The CPI-U inputs have little relationship to the inflationary pressures faced by ASCs and we strongly recommend that CMS use the hospital market basket to update ASC payments.

<b>TABLE 13 Comparison of CPI-U and the OPSS Market Basket, 2001-2007 (proposed)</b>					
CPI-U			OPSS Market Basket		
Measured	% Change		Used for payment	% Change	
for CY	CPI-U	CPI	in CY	Change	Difference
2001	2.8	2.7	2001	3.4	

<sup>6</sup> AORN salary survey available at [http://www.findarticles.com/p/articles/mi\\_m0FSL/is\\_6\\_82/ai\\_n16100877](http://www.findarticles.com/p/articles/mi_m0FSL/is_6_82/ai_n16100877)

<sup>7</sup> Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, March 2002, Appendix A.

<sup>8</sup> Relative importance of components in the Consumer Price Indexes: U.S. city average, December 2005. Available at [http://www.bls.gov/cpi/cpiri\\_2005.pdf](http://www.bls.gov/cpi/cpiri_2005.pdf)



2002	1.6	1.4	2002	3.3	
2003	2.3	2.2	2003	3.5	
2004	2.7	2.6	2004	3.4	
2005	3.4	3.5	2005	3.7	
2006	NA	2.9	2006	3.3	
2007	NA	2.3	2007	3.4	
Average	NA	2.5	Average	3.4	0.9

Source: Lewin Group, 2006

In other areas of Medicare payment where a relationship exists between two different provider categories, Medicare's policies have established a fixed relationship between the two points. For example, the Medicare statute provides that a nurse practitioner receive only 85% of what Medicare pays a physician providing the same service. Presumably, this reflects a congressional judgment that recognizes the higher costs of the educational preparation of the physician. However, the Medicare program does not reassess, through differential updates, the relationship between the points once it has been established. Similarly, the agency should ensure that the difference between ASC and HOPD payments does not change over time due to the use of an inappropriate measure of inflation.

#### **H. ASC Coinsurance**

We support CMS's proposal to continue to apply the 20% coinsurance for services in the ASC. Price transparency is absolutely critical to helping beneficiaries be informed consumers of outpatient surgical services. The discounted rate paid to ASCs allows beneficiaries not only to save money relative to the expense of the same service in the HOPD, but the fixed 20% coinsurance allows ease in determining their financial liability for an ASC service.

#### **I. ASC Phase In**

CMS propose to provide a two-year transition to the new ASC payment system, using a 50-50 blend of the payment rates in the transition year (2008), and the fully-implemented rates in the second year (2009). The agency does not propose policies to minimize disruptions in payments to providers whose rates would be significantly cut under the new payment system. As proposed, the transitional payment policy described by the agency does not address payment for devices that are reimbursed separately under the current payment system, but will be bundled in the APC for a procedure. We urge the agency to devise a strategy to either accelerate full implementation of the APC payment for device-dependent procedures or develop a transitional payment policy that does not exclude the cost of the device paid under the DMEPOS fee schedule. This brief transition period provides a very short timeframe for providers to adjust to significant changes in the payment rates.

In legislation supported by the ASC community and introduced by Senator Crapo (S. 1884) and Representative Herger (H.R. 4042), a 4-year transition from 2008 to 2012 is proposed for procedures whose payment rate would decrease under the new system. The legislation proposes to establish ASC payments at 75% of the HOPD rate.

In other payment systems, CMS has proposed a variety of approaches to soften the impact of significant payment system changes. When implementing the PPS for long-term acute care hospitals, for example, CMS allowed providers to choose a multi-year transition or to opt for full implementation of the new payment system for their facilities. When the agency implemented new Metropolitan Statistical Area definitions for the inpatient PPS wage index, the agency held harmless for three years providers who would lose their urban designation and see a reduction in payment as a result of moving from an MSA wage index to the statewide rural floor index value. Other policies to hold providers harmless from payment system changes or blunt the negative impact of changes have been devised under the agency's broad administrative authority. We urge the agency to implement policies to decrease the sudden drop in payments for procedures whose rate will fall significantly during a transition to the new payment system

#### J. ASC Conversion Factor

Appropriate payment policies are driven by many factors, but ultimately only one question matters to Medicare beneficiaries – is payment adequate to provide access to services? At the proposed payment rate of 62% of the HOPD rate, access to certain ASC services may be compromised. Some ASC payments would increase over current rates and thus, should expand access. Some large increases, particularly for orthopedic procedures, are driven by the inclusion of the device payment in the base rate. These increases are overstated when compared to current rates that do not include payment for the device. Moreover, at the specialty level there will be no increases for the three specialties – GI, ophthalmology and pain management – that constitute the majority of Medicare ASC services today (83%). Payment for GI services, which currently constitute the largest volume of Medicare ASC services (34%), and pain management would decrease significantly in aggregate when fully implemented. Many ASCs will be unable to absorb these cuts and would discontinue providing these ASC services.

<b>CPT®/ HCPCS Code</b>	<b>Specialty</b>	<b>ASC Volume from 2004 PSPS File</b>	<b>2007 ASC Payment</b>	<b>Fully- implemented 2008 rate at 62%</b>	<b>Percent Change</b>
66984	Ophthalmology	1,094,801	\$ 973.00	\$ 935.31	-4%
43239	Gastrointestinal	348,735	\$ 446.00	\$ 329.69	-26%
45378	Gastrointestinal	333,676	\$ 446.00	\$ 349.82	-22%
66821	Ophthalmology	314,059	\$ 315.55	\$ 203.46	-36%
45385	Gastrointestinal	232,553	\$ 446.00	\$ 349.82	-22%
62311	Pain management/neurology	231,665	\$ 333.00	\$ 253.16	-24%
45380	Gastrointestinal	212,475	\$ 446.00	\$ 349.82	-22%
64476	Pain management/neurology	113,196	\$ 333.00	\$ 220.03	-34%
64483	Pain management/neurology	110,573	\$ 333.00	\$ 253.16	-24%
45384	Gastrointestinal	106,771	\$ 446.00	\$ 349.82	-22%

In assessing the capability of ASCs to absorb such cuts, two financial factors warrant consideration. First, most ASCs are small businesses. According to 2005 ASC Employee Salary & Benefit Survey, 64.2% have 20 or fewer.<sup>9</sup> Small businesses generally have less capability to absorb sudden decreases in payment. Second, a significant percentage of ASCs are single-specialty. Increases in payment rates on some procedures may allow some ASCs to make up for losses on other procedures. Single-specialty ASCs will have a limited ability to do so. In gastroenterology for example, only two of the 30 highest volume procedures have an increase and most will have double digit decreases. In pain management, nine of the ten highest volume procedures will decrease by more than 20%. In ophthalmology, prices are reduced for the two highest volume procedures, which constitute more than 86% of total ophthalmic ASC volume.

Setting the payment the ASC rate too low has the potential to limit Medicare beneficiaries' choices and to increase their out-of-pocket costs and the overall expenditures of the Medicare program. CMS should set the payment rate at a reasonable and fair level to promote access to ASCs. We do not believe that 62% is either reasonable or fair to providers or Medicare beneficiaries. We had previously proposed legislation that would have set payment rates at 75% of HOPD payments. Under this legislation, Medicare would save at least 25 cents on every dollar spent relative to HOPD prices. We believe that this is a reasonable level of savings and that CMS should seek to use this rate. Even using a 75% conversion factor would result in ASC payments that are a lower percentage of HOPD rates than ASCs received just a few years ago. When Congress enacted the new payment system requirement in 2003, the budget neutrality method that today results in 62% would have resulted in an ASC conversion factor of 86% of the HOPDs. To maintain beneficiary access, CMS should seek ways of providing a higher conversion factor.

#### **K. Proposed Annual ASC Updates**

CMS proposes to revise its historical update schedule for the ASC payment system to link it to the update process and schedule for the annual revision of the outpatient prospective payment system. This alignment is appropriate and allows the industry to review and contemplate the changes in both systems simultaneously.

#### **L. UB-92 for ASC claims**

CMS proposes to continue its policy of having the HOPD and ASC use the UB-92 and CMS-1500, respectively, to submit claims to the government for services. Use of different claims forms prevents ASCs from documenting all the services provided to a Medicare beneficiary, therefore undermining the documentation of case mix differences between sites of service. Most commercial payors require ASCs to submit claims using the UB-92. The final rule should require ASCs to use the UB-92.

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<sup>9</sup> Published by the Federated Ambulatory Surgery Association, Alexandria, VA 2005.

## BUDGET NEUTRALITY

CMS is constrained by the MMA in how it may design a new payment system. Specifically, Congress directed the Secretary to develop a system that is designed not to cost any more than if no change in payment to ASCs had been made. Specifically, the MMA provided that:

*“(ii) In the year the system described in clause (i) is implemented [i.e., the revised ASC payment system], such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary.” (Emphasis added.)*

The term “same aggregate amount of expenditures” is assumed to contemplate that the new payment system would be budget neutral or otherwise result in the same amount of aggregate spending for such services had this provision not been enacted in the year the new system is implemented.

When proposing significant changes to other Medicare payment systems, CMS has recognized and discussed the implications of changes in efficiency, site utilization, and behavioral modifications providers would make in adapting to the new payment system. For example, in proposing to implement the inpatient rehabilitation facility prospective payment system, the agency discussed how behavioral offsets of physicians played an important role in the discussion of budget neutrality:

*This provision requires the Secretary, in establishing budget neutral rates, to consider the effects of the new payment system on utilization and other factors reflected in the composition of Medicare payments...The purpose of the budget neutrality provision is to pay the same amount under the prospective payment system as would have been paid under the excluded hospital cost-based payment system for a given set of services, but not to pay that same amount for fewer services furnished as a result of the inherent incentives of the new prospective payment system. Thus, our methodology must account for the change in practice patterns due to new incentives in order to maintain a budget neutral payment system. Efficient providers are adept at modifying and adjusting practice patterns to maximize revenues while still maintaining optimum quality of care for the patient. We take this behavior into account in the behavioral offset.<sup>10</sup> (Emphasis added.)*

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<sup>10</sup> 66 Fed. Reg. 41, 366 (August 7, 2001).

The ASC coalition commissioned The Lewin Group to conduct numerous studies to assist us in understanding the proposed rule and drafting comments. The Lewin Group constructed a series of impact models as did the coalition which produced comparable results. The Lewin Group has reviewed the budget neutrality calculations presented in these comments and have replicated them with their own models.

**A. Expanded Alternative Budget Neutrality Calculation Should Be Used**

To establish fair and reasonable payment rates within the congressionally imposed budget neutrality constraints, CMS should expand its alternative proposal to calculate a budget neutral conversion factor by considering positive and negative migration. This broader view of budget neutrality includes spending for all services that will be performed in the ASC in 2008. This broader view accounts for the likely "positive" migration of procedures into the ASC setting from other sites of service for all procedures that face higher prices and for those that will be newly reimbursed in the ASC in 2008. As such, it captures savings to the Medicare program from all procedures that move from the HOPD into the less costly ASC setting. Similarly, CMS should consider "negative" migration out of the ASC for procedures receiving lower payments.

In adopting this expanded alternative budget neutrality calculation, CMS would need to make some changes in its model and assumptions to better capture the appropriate expenditures under existing law and the changes that would occur if the proposed rule is adopted.

The table below shows each adjustment that we propose and the impact of that adjustment. Appendix D illustrates the volume and expenditure impact of these changes by specialty. Following the table, a discussion of each recommended change, why the change is appropriate and the projected result of the change are discussed.

<b>TABLE 15</b>		
<b>Proposed Adjustments to CMS Alternative Budget Neutrality Calculation</b>		
Starting Point	62.90	CMS's Calculation (This includes migration of HOPD at 25% for new procedures and migration from physician offices at 15% for new procedures.)
Change 1	+0.11	To accurately reflect ASC payment rates for procedures capped at HOPD rate if no new payment system in 2008
Subtotal	=63.01	
Change 2	+ 0.41	To include in the 2007 device costs that were paid to ASCs in addition to facility fees.
Subtotal	=63.42	
Change 3	+ 3.11	Net savings of reducing movement from physician offices; CMS assumed 15%; Coalition reduced to 2%
Subtotal	=66.53	
Change 4	+ 0.43	Correction to exclude beneficiary copayments for procedures

subject to the physician office limit		
Subtotal	=66.96	
Change 5	+1.04	Adjust for variable co-insurance in hospital by using total payment rates or by applying 20% co-insurance discount to all 2007 services in formula.
Subtotal	=68.00	
Change 6	+ 5.57	Net savings of positive migration from HOPDs for procedure on the ASC list. Assume that for every 10% increase in reimbursement rate, 1.5% of HOPD volume moves subject to maximum of 25% of HOPD volume or 25% increase in ASC volume if more than 4,600 procedures are performed in ASCs annually.
Subtotal	=73.57	
Change 7	-0.51	Net cost for negative migration from ASC to HOPD. Assume that for every 10% decrease in ASC reimbursement, 1.5% of ASC volume moves from ASC to HOPD.
Total	=73.06	Final conversion percentage after seven changes made to original CMS alternative model

Beginning with the CMS alternative model, which assumes migration of procedures that will first be on the ASC list in 2008, the conversion factor is 62.90%. ASCs will be eligible for payment for more than 750 procedures that ASCs were not previously reimbursed for providing. Physicians have demonstrated a preference for performing surgical procedures in an ASC over an HOPD when the ASC is an appropriate setting. To the extent that ASCs have sufficient capacity to absorb the influx of procedures, new services will inevitably migrate into the ASC. CMS's model assumes that 25% of new procedures on the list currently provided in the HOPD and 15% of the new procedures on the list currently performed in the physician office would move to the ASC. (We believe the later assumption significantly overstates the likely movement from the physician office to the ASC and will discuss our recommendations on this below.)

From this base, the following adjustments are recommended.

**Change 1-Use of 2007 ASC Rates for 2008.** The Deficit Reduction Act (DRA) requires that ASCs be paid no more than the HOPD rate for a given service. This cap will be applied to ASC payments beginning in 2007 until a new payment system is implemented. Absent implementation of a revised payment system in 2008, the payments for services capped under the DRA would increase in 2008 consistent with increases in HOPD rates for these services. Based on our review of CMS methodology, discussions with CMS staff and our attempts to replicate this model, we conclude CMS's calculation of the costs for procedures affected by the cap did not include the 2008 update that would apply in the absence of a new payment system (e.g. the CMS model assumes the same rate for DRA-capped procedures in 2007 and 2008). Since HOPD rates are projected to increase 4% in 2008, the rates for these procedures should be projected to increase 4%, up to the appropriate ASC grouper rate. Our calculations show that this produces an increase of 0.11 percentage points in the conversion factor, bringing it to

63.01%. Of course, changes in the market basket would affect this number slightly. If the market basket were only 3%, the conversion factor would rise slightly less. (This adjustment is also needed if CMS uses the budget neutrality calculation in the proposed rule.)

***Change 2-Inclusion of Costs for Separately Payable Devices.*** Under the current ASC payment system, Medicare makes a separate payment to cover the costs of implantable prosthetics and DME rather than reimbursing for the costs of these devices as part of the facility fee. For services with device costs, using only the ASC facility payment in the numerator understates the cost of the service to the government under the current payment system. The proposed system would bundle these devices with the facility payment and thus the formula includes the costs for these items in the denominator. This can be corrected by adding the cost of the device into the numerator of the agency's calculation. Our analysis shows that inclusion of these costs would increase the conversion factor by .41 percentage points, bringing it to 63.42%. (This adjustment is also needed if CMS uses the budget neutrality calculation in the proposed rule.)

Unfortunately, inconsistent implementation of coverage policies for implantable devices by Medicare's administrative contractors results in an under-representation of device costs in the claims data. Providers often do not receive payment for a device implanted during a surgical procedure. In their formula, CMS could simply impute the device cost with HCPCS codes associated with the insertion of prosthetic devices or DME. Because these costs are bundled in the HOPD payment, the representation of the device cost in the numerator and denominator is essential for comparison of expected government expenditures. Because CMS cannot estimate that the carriers will inappropriately deny claims for these procedures in 2007, an imputation of the expected device payments in the base year is the most appropriate way to represent the government's expected liabilities in the numerator.

***Change 3-Migration of Procedures from Physician Offices to ASCs.*** Many of the procedures proposed to be added to the list in 2008 are frequently, and appropriately, performed in physician offices. A significant volume of these procedures are unlikely to migrate to the ASC, as physicians can safely and efficiently perform these procedures without moving patients to ASCs. ASCs find that once physicians have the equipment and resources to perform a procedure in their offices, they prefer to perform this procedure there. In this situation, they perform procedures in ASCs or HOPDs only when they believe a particular patient needs a facility setting. In this situation, movement from the physician office to the ASC would occur in lieu of movement of the procedure to the HOPD (at a savings to the government and beneficiary). Over time, many procedures currently on the procedure list have migrated to physician offices even though ASCs can be paid. In the final rule on 2005 ASC list, CMS noted that being on the ASC list did not appear to encourage physicians to perform the procedure in the ASC.

In the proposed rule, CMS assumes that 15% of the physician office volume of procedures added to the ASC list in 2008 will migrate to the ASC. We believe this assumption is far too high, as the volume of office migration under a 15% assumption exceeds the current case volume of the entire ASC industry in 2005. The opportunity cost to the industry numerous low reimbursement minor procedures that are appropriately provided in physician offices would be great considering the alternate use of the ASC capacity in the provision of more complex procedures, which can be

more efficiently provided in the ASC setting. Accordingly, we recommend that CMS assume only a 2% movement from the physician office to the ASC. When we model this migration, we find that it increases the conversion factor by 3.11 percentage points, to a total of 66.53%.

***Change 4-Treatment of Physician Office Beneficiary Coinsurance.*** In calculating costs of the proposed payment system, CMS discounts all payments by 20% to reflect coinsurance except the payment rates that are capped at the physician office practice expense rate. Correctly applying 20% coinsurance to all services in the denominator increases the conversion factor by 0.43%, for a total of 66.96%.

***Change 5-Treatment of Variable Coinsurance Rates.*** A second coinsurance adjustment is appropriate to account for the fact that coinsurance payments in hospitals can range from 20 to 40%. ASCs and beneficiaries should not be penalized because for historical reasons hospitals charge higher coinsurance. If total payments are used, the conversion factor rises by an additional 1.04 percentage point to a total of 68.00%.

***Change 6 & 7-Recognizing Price Changes Will Impact Migration of Current ASC Procedures.*** The final two adjustments that we recommend would account for movement of procedures now performed in the ASCs resulting from reimbursement rate changes. The current model does not fully capture the migration that will occur when payments within the ASC sector are redistributed among currently covered services.

ASC payment rates for some services have been grossly inadequate and are thus infrequently performed in the ASC even though the clinical characteristics of these procedures make them appropriate for this setting. Orthopedics is a good example of a specialty that could move many procedures from the HOPD to the ASC if the payment rates were appropriate. An industry quarterly outcomes monitoring study reports that in the second quarter of 2006, only 22.5% of ASCs were operating above 60% operating room capacity, demonstrating the ability of ASCs to increase volume.<sup>11</sup>

To model positive migration we assumed that for each 10% increase in the reimbursement rate, 1.5% of the volume currently performed in HOPDs would move to ASCs. Recognizing that there is a limit on how many procedures will move even with extremely large price increases, we assumed a maximum movement of 25% of the HOPD volume, the same assumption that CMS used for the new procedures added. In other words, the maximum movement we calculated for existing codes with price increases is identical to the percentage CMS assumed for new codes. In addition, we believe ASC capacity will limit movement and accordingly we limited the movement to the ASC to 25% of existing ASC volume. This last limit was not applied to procedures with ASC volumes of less than one per ASC as we assume that this level of volume increase can be accommodated no matter the percentage increase. This assumption increases the conversion factor by 5.57 percentage points to a total of 73.57%. The assumptions used vary the calculation greatly. We believe this assumption results in a reasonable limit on movement from hospitals and a reasonable increase in total ASC volume.

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<sup>11</sup> Outcomes Monitoring Project Report, Second Quarter 2006 (Sep. 15, 2006). FASA



Finally, we believe that there will be a cost to Medicare (negative migration) for procedures that move to the HOPD as a result of price reductions. Some high volume Medicare procedures may move. For these we assumed that for every 10% decrease in ASC reimbursement, 1.5% of ASC volume will move to HOPDs. By paying a higher to ASCs, fewer procedures are likely to leave the ASC for the higher cost hospital. Although we do believe that hospital capacity for procedures is limited we did not limit the maximum movement. This assumption reduces the conversion factor by 0.51 percentage points, bringing a total to 73.06%.

Taken together, the changes we propose to the calculation correct basic calculation errors in the proposed alternative budget neutrality model developed by CMS and account for how we believe the industry will respond to the changes in the payment system. Establishing a budget neutrality factor of 73% maximizes the volume of procedures likely to migrate from the more expensive HOPD setting and minimizes the reductions in payment that would induce "negative" migration from the ASC to a more expensive setting. The discount produces significant savings for the government and the Medicare beneficiary.

MMA requires that CMS implement a system that is designed to be budget neutral in the year in which the new payment system is implemented. The proposal provides for implementation in 2008 with the payment of a blended rate between the 2007 rate and the 2008 rate. Accordingly, in its estimate of budget neutrality, CMS uses this blended rate to calculate budget neutrality. We believe this is an appropriate interpretation of the legislation and produces the most reasonable result. As discussed elsewhere in these comments, to achieve the best result for Medicare beneficiaries reasonable payment must be provided. To accomplish this goal, CMS needs to use the discretion given to it by Congress. Using the blended rates for 2008 provides one such opportunity and complies with the mandate given to it by Congress. We recognize that because the 2008 rates are blended, the system will have increased expenditures in 2009 unless migration follows a different pattern.

Given that the ASC payment system has not undergone a major recalibration of rates in almost two decades during which time major changes in the volume, type and intensiveness of procedures performed in the ASC have changed greatly achieving the correct balance without driving cases back to the hospital supports this interpretation.

Moreover, due to the effects of the six-year freeze compounded by the DRA cuts, the budget neutral conversion factor has decreased significantly. Had the ASC system been tied to the HOPD system in 2003 when Congress directed CMS to implement a new payment system, the budget neutral rate under the most conservative assumption would have been in the 84 to 86% range. Congress gave CMS the authority to do this between 2006 and 2008. Had CMS implemented a new system in 2006, the first year that CMS was authorized to do so, it would have been at least 8% higher.

## **B. Methodology in Proposed Rule**

For the reasons stated above, we believe the above methodology is more appropriate than either of the methodologies recommended in the proposed rule. The proposed rule's methodologies reflect an extremely narrow view of budget neutrality that does not evaluate the volume of procedures currently being provided in the ASC. We believe this is an inappropriate approach to calculating budget neutrality because it ignores the effect of price changes on existing ASC services provided in the new payment system, physician's preference to perform procedures in the ASC, and the expansion of the ASC procedure list that will allow thousands of procedures done in the HOPD to migrate to the ASC at a savings to the government and beneficiary. We strongly recommend that in the final rule CMS reject this methodology in favor of the alternative methodology described above.<sup>12</sup>

\* \* \* \* \*

We appreciate the agency's consideration of our comments on behalf of the ASC community. While our modeling of the new payment system suggests that budget neutrality can be achieved when ASCs are paid 73% of the HOPD rates, we believe that 75% is an appropriate percentage of the HOPD payment, as proposed in legislation supported by the ASC community. A 62% conversion factor is inadequate for many procedures that are frequently performed in ASCs. Inadequate payment will force providers to respond in a variety of ways – the end result of which may limit patients' ability to have their surgical service performed in a low cost environment. The implementation of the revised ASC payment system will result in significant redistribution of dollars within the ASC payment system. As such, we strongly urge CMS to use its broad discretionary authority to ensure a smooth transition to the new payment system. As leaders in the ASC industry, we want to ensure that patient access is not jeopardized by abrupt changes in the payment system.

Although these comments address a number of discrete issues, there is one message the Coalition wants to emphasize. We believe that Medicare beneficiaries and their families as well as prudent taxpayers will be significantly advantaged if CMS implements a new payment system for ASCs. We believe that the proposed rule is certainly a positive first step in that direction. We urge the agency to recognize that a successful payment system:

***Must be transparent.*** As proposed, it will be very difficult for Medicare beneficiary to determine the differences in what they will pay in an ASC versus an HOPD. If ASC payment is linked to HOPD payment, the link should be straightforward and consistent.

***Must recognize the clinical capabilities of ASCs.*** As proposed, physicians will continue to have to treat Medicare beneficiaries at sites of care that are clinically redundant and consequently

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<sup>12</sup> If used, this formula needs to have the two corrections discussed under the alternative method of budget calculation on page 43-44.

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more costly to both the beneficiary and the Medicare program. The list of procedures that can be performed at an ASC should be virtually identical to the list applicable to HOPDs.

***Must provide an economically viable alternative.*** As proposed, the conversion factor is too low to make the provision of many procedures in ASCs viable, particularly for single-specialty ASCs that are not able to diversify the mix of their services. The conversion factor should be high enough so that physicians can make decisions about where to treat Medicare beneficiaries exclusively on the basis of clinical appropriateness.

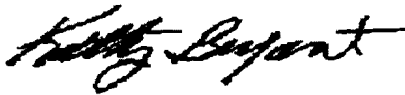
Finally, we urge CMS to use the discretion given to HHS by Congress in the MMA to develop a revised ASC payment system that is "designed to" be budget-neutral. Congress understood that it is difficult to predict the migration of services from HOPD to ASC due to the revised payment system and CMS' expansion of the list of covered procedures. Therefore, CMS should implement a revised payment system that appropriately pays for services provided in an ASC. We believe Medicare costs will be held in check by the competition that will result from a fair Medicare reimbursement environment for all outpatient surgical settings.

Thank you for considering our comments. If you have any questions or need additional information, we would be happy to assist you.

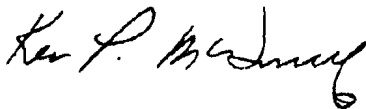
Sincerely,



John Duggan, M.D.  
President  
American Association of Ambulatory Surgery Centers

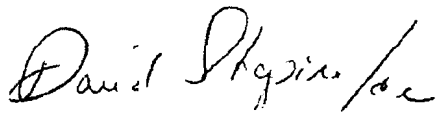


Kathy Bryant  
President  
FASA



Ken P. McDonald  
President and Chief Executive Officer  
AmSurg

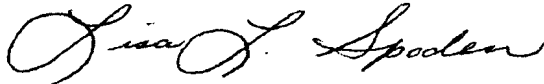
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David Shapiro, M.D.  
Florida Society of Ambulatory Surgery Centers



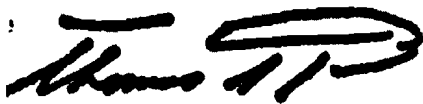
Joe Clark  
President, Surgery Division  
HealthSouth



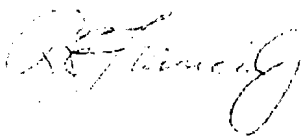
Lisa Spoden  
Executive Director  
Ohio Association of Ambulatory Surgery Centers



Richard D. Pence  
Chief Operating Officer  
National Surgical Care

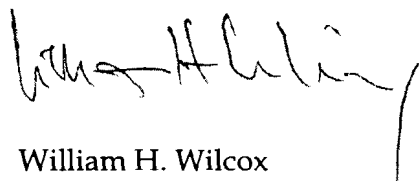


Thomas Hall  
President and Chief Executive Officer  
NovaMed, Inc.



Richard Francis  
Chairman and Chief Executive Officer  
Symbion, Inc.

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A handwritten signature in cursive script, appearing to read "William H. Wilcox". The signature is written in black ink and is positioned above the printed name and title.

William H. Wilcox  
President & CEO  
United Surgical Partners International