Submitter : Dr. Norman J Dozier **Date:** 11/06/2006

Organization : Norman J Dozier MD PA

Category : Physician

Issue Areas/Comments

ASC Packaging

ASC Packaging

I would like for CMS to reconsider the packaging for implanted DME in an ASC. The codes I am specifically asking you to reconsider are 63685 and 63650 for Spinal Cord Stimulator trials and implantation. The leads and Stimulator (Battery) are very costly. For instance, a single channel battery with single electrode can cost around $6000-8000 wheras a dual octad rechargable battery system costs upward of $23,000. Either one of these technologies can be used with these codes depending upon the needs of the patient. Therefore, if you have the DME included with the procedure and the more costly Stimulator system is needed, the reimbursement needs to reflect the cost increase. Otherwise, it would be cost prohibitive to perform the procedure and use the more costly technology when the ASC cannot be reimbursed properly for the equipment. It seems more logical to include the procedure (which is pretty much the same no matter which DME you use) under one APC and reimburse the equipment separately under a different APC depending on the system implanted since the costs of the technology ranges from $6000 to $23,000. This could make a big difference in the reimbursement rate for this particular procedure. Thank you for your consideration in this matter.

Submitter : Mr. Eric Howard **Date:** 11/06/2006

Organization : Doctor's Outpatient Surgicenter/USPI

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

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

ASC Conversion Factor

ASC Conversion Factor

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

ASC Office-Based Procedures

ASC Office-Based Procedures

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

ASC Payable Procedures

ASC Payable Procedures

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

ASC Phase In

ASC Phase In

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

ASC Ratesetting

ASC Ratesetting

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

ASC Unlisted Procedures

ASC Unlisted Procedures

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

ASC Updates

ASC Updates

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

Submitter : Dr. C. Y. Joseph Chang **Date:** 11/06/2006

Organization : Dr. C. Y. Joseph Chang

Category : Physician

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

ASC List Reform

Submitter : **Ms. Laura Loeb** **Date: 11/06/2006**

Organization : **ACOS/AOAO**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachmcnt.

CMS-1506-P2-1053-Attach-1.DOC

#1053

November 6, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS – 1506 – P; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Norwalk:

The American College of Osteopathic Surgeons (ACOS) and the American Osteopathic Academy of Orthopedics (AOAO) appreciate the opportunity to comment on the Proposed Rule published in the August 23, 2006 *Federal Register* with respect to proposed revisions to the Ambulatory Surgical Center (ASC) payment system for services furnished on or after January 1, 2008.

Proposed ASC Ratesetting

The current ASC payment methodology of nine standard categories ranging in payments from $333 to $1,339 does not adequately reflect the costs incurred by the ASC and has effectively prevented the ASC from being a viable setting to treat Medicare beneficiaries for a number of procedures. This result is clearly not what CMS or the Bush Administration intended, nor is it conducive to optimal patient care. Therefore, it is imperative that the payment methodology be changed in a manner that would allow the ASC to be a viable option for all procedures that can safely and effectively be performed there.

Further, once a new payment methodology is in place, there must be an effective manner to increase these payments to keep pace with inflation. The overhead amounts for the ACS payment groupings are based on a 1986 survey of ASC costs.

Since 1990, Congress has frozen or reduced updates to ASC rates for varying periods of time. Currently the ASC payment rates are frozen at their FY 2003 level. Such failures to keep pace with inflation cannot continue under the new payment methodology without even more impact on access to care for Medicare beneficiaries.

We support the proposal by CMS to base the new ASC rates on the APC groupings and weights used in the hospital outpatient setting. We understand that these weights would be multiplied by an ASC conversion factor. We do, however, see a continuation of the current problem of underpayment for a variety of ASC services because CMS is bound by statutory language in the Medicare Modernization Act (MMA) to ensure that the aggregate payments under the new ASC payment methodology are no greater than what they would be under the current methodology. Given that significant and unreasonable constraint, we do not comprehend how a new methodology could achieve the goal of encouraging procedures to be provided in an ASC, which might very well be the most cost-effective setting if reimbursed fairly and therefore physicians used it to provide services.

If the Medicare payment rates for procedures performed in an ASC setting continue even under the new methodology to be reimbursed at such low amounts that an ASCs costs are not even captured, then physicians will continue to choose the hospital outpatient department as the preferred setting.

We understand that this budget neutrality requirement is being imposed on CMS by Congress. Nevertheless, we wanted to voice our extreme concern over this provision in these comments.

Proposed Packaging Policy

Currently, CMS packages drugs, biologicals, and diagnostic services into the ASC grouping rate. Under the hospital outpatient prospective payment system, Medicare pays separately for many of these same items in addition to the Ambulatory Patient Classifications (APCs) payment for the underlying procedure. Meanwhile ASCs currently receive separate payments for prosthetic implants and implantable durable medical equipment (DME), while under the hospital outpatient prospective payment system reimbursement for these items is bundled into the APC payments.

CMS is proposing to continue bundling all drugs, biologicals, contrast agents, anesthesia materials, and imaging services into the new ASC rates, and is also proposing to end separate payment for implantable prosthetic devices and implantable DME. The only separate payments under the new ASC payment methodology would be for physician services, laboratory services, x-rays or other

diagnostic procedures that are not directly related to performing the surgical procedure, nonimplantable prosthetic devices, ambulance services, leg, arm, back and neck braces, artificial limbs, and DME for use in the patient's home.

The appropriateness of any packaging proposal is directly related to the appropriateness of the payment for the underlying procedure. Since it appears that the payment for the underlying procedure will continue to be inadequately reimbursed under the new system, we would support separate payment for all items and services. Either the new system must appropriately reimburse for all the costs of performing a surgical procedure, including any implantable DME or drug that is necessary, or there must be another mechanism available to pay for these items. Without appropriate payment, access to care will again suffer for Medicare beneficiaries.

Proposed Payment for Office-Based Procedures

CMS is proposing to even allow procedures that are performed over 50% of the time in a physician's office to be paid for in an ASC, because there are some situations where, in the physician's judgment, due to the patient's condition, an ASC is a more appropriate venue. We agree that the physician should have the discretion to determine that a particular procedure should be performed in an ASC setting as opposed to an office setting.

However, CMS points out that if a high volume of services move from the less expensive office setting to the more costly ASC setting, then CMS will have to reduce the ASC conversion factor even more to maintain the statutorily mandated budget neutrality. Therefore, CMS is requesting comment on whether physicians really do want this option of performing these office-based procedures in an ASC setting.

We do not believe that physicians will unnecessarily perform procedures in an ASC setting if these procedures could safely be performed in the office. Physicians should be allowed the option of performing a procedure in an ASC when they believe it is medically necessary for the procedure to be performed there rather than the office. We do not foresee this shifting from the office setting to an ASC occurring to any extent that would require CMS to make an adjustment to the ASC conversion factor. If this venue shifting does occur in great volume, then CMS should revisit this issue.

Multiple Procedure Discounting

CMS is proposing to adopt for the ASC setting the hospital outpatient policy of reducing payment for multiple procedures performed on the same patient on the same day. Under the hospital outpatient prospective payment system, certain surgical procedures, such as those involved with the implantation of an expensive device, are exempt from the multiple procedure reduction. Under current ASC policy, multiple procedures are also reduced, with the most costly procedure paid in full and the other procedures reimbursed at 50 percent. There are no exceptions to this policy, particularly since implantable devices are currently reimbursed in an ASC separately.

We support the CMS proposal to exempt certain multiple procedures from this reduction under the new ASC payment methodology.

* * *

We appreciate this opportunity to comment on the proposed changes to the ASC payment methodology and look forward to working with CMS staff towards implementation of a more equitable payment system for January 1, 2008.

Respectfully submitted by,

Guy D. Beaumont, Jr.
ACOS Executive Director

Morton Morris, D.O, J.D.
AOAO Executive Director

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

Organization : American Academy of Ophthalmology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter that covers most of these areas

CMS-1506-P2-1054-Attach-1.PDF

#1054

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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1101 Vermont Avenue NW
Washington, DC 20005-3570

Tel. 202.737.6662
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http://www.aao.org

Federal Affairs Department

via Electronic Mail

November 6, 2006

Leslie V. Norwalk., Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; Proposed Ambulatory Surgical Center Payments System and CY2008 Payment Rates (Section XVIII)

Dear Ms Norwalk:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the 2008 proposed Ambulatory Surgical Center (ASC) Proposed Payment System rule. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the proposed rule.

Eye procedures are one of the most frequently and safely performed procedures in ASCs in this country. In 2003, the Office of the Inspector General reported that Medicare could save more than $1 billion if hospital outpatient (HOPD) and ASC payments were equalized. Nearly half of those savings would come from eye procedures (*http://oig.hhs.gov/oei/reports/oei-05-00-00340.pdf*) according to the OIG. This year, MedPAC reports little differences in patient outcomes and characteristics between ASC and HOPD settings when they examined three major procedures, including cataract. Such findings provide definitive evidence that there should be parity and alignment between these two settings and the Academy urges CMS to promulgate a true alignment that is transparent and provides beneficiary access through true comparisons in cost and quality.

General Comments: Alignment, List Expansion and Budget Neutrality

The Academy would like to commend CMS for taking into account the comments and recommendations from the ASC community as it moves forward in proposing a new payment system for this care setting. We are pleased that CMS recognizes that there should be alignment between the ASC and the Hospital Outpatient Settings as far as their payments are concerned.

- **While this rule takes initial steps at alignment, the Academy requests that the alignment be more directly tied to the HOPPS and be more transparent in its linkage.**

As we move to a final system the alignment should be directly correlated to the HOPPS. In particular, we strongly recommend that CMS provide the same annual update mechanism for both settings. Currently, CMS is proposing that ASC updates be based on CPI-U while the HOPD rate is tied to the hospital market basket. Such a disparity is contrary to alignment. Both delivery settings should receive the hospital market basket update.

Additionally, we understand that some commenters advocate that varying percentages of HOPD depending upon the type of facility, the specialty of the facility, or the financial impact of the rule on the facility. In the absence of a showing that the underlying relative weight of the APC in the HOPD does not reflect the resources consumed in providing the service in the ASC, the same conversion factor should apply to all services and facilities.

- **The Academy strongly recommends that CMS continue in its proposed single percentage rate for all procedures in the ASC setting and all types of facilities, regardless of specialty, in order to provide a fair and equitable payment system.**

We would also like to thank the agency for moving towards an expanded list of procedures that excludes only those procedures that have a patient safety concern or require an overnight stay. This follows the Academy supported recommendations from MedPAC and allows for many more ophthalmic procedures to be provided in the ASC setting then previously.

- **We encourage CMS to rely more specifically on its own "inpatient only" list (that is regularly updated) and the requirement that the patient will need to stay beyond 24 hours when considering exclusions. Additionally, we believe that the midnight designation is arbitrary and unnecessary if you utilize the 24 hour time limit.**

The Academy recognizes that the statutory language in DRA 2005 mandates that the initial calculation of the payment rate for ASC's be budget neutral. However, we strongly disagree with the manner in which such neutrality was applied. In looking at targeted outpatient aggregate expenditures, the Academy urges CMS to consider all Medicare expenditures for outpatient surgical services and not just those of ASCs. Again this would fit in with CMS's goal to better align these two systems and creates a more transparent methodology for calculating the budget neutrality adjustment.

- **The currently proposed conversion factor derived through a budget neutrality adjustment that pays ASC at a rate that is nearly 40% less then HOPPS is unfair and this differential is not an accurate reflection of the true cost differences of providing care in these two settings.**

In a recently released MedPAC study (October 2006), RAND could find little evidence to support any rationale for differing costs in the ASC and outpatient setting. This certainly does not lend support for such a significant reduction for the Medicare ASC payment system. Instead, their review of three procedures (including cataract) showed that while OPDs did see some patients with higher risks, those differences were not significant and were not able to be replicated in a consistent pattern.

- **At a minimum, ASCs should receive a percent of the HOPD fee schedule that is in the range of 73-75 percent for all covered procedures as called for in legislation introduced in 2005 and supported by the Academy.**

Data utilized by your agency when it proposed procedures for deletion in its 2005 rule demonstrated that the rate of performance of other office based procedures that had been included on the ASC list remained relatively stable over the previous ten-years. Considerations of patient safety and patient choice drive site-of-service selection for physicians.

- **The Academy firmly objects to CMS's assertion that there would be an overnight migration from the office-based setting to the ASC beginning on January 1, 2008 in its further calculation of budget neutrality. CMS has chosen a percentage that has no true relationship between HOPD and ASC costs. Furthermore, CMS does not take into account the migration that will occur from the HOPD to ASCs which generates substantial saving to Medicare. Any assumption must address the realities of savings that will occur and the Academy believes the 15% assumption currently proposed by CMS must be substantially reduced.**

As a final general comment, the Academy believes that if the draconian cuts being proposed by CMS are retained without adjustment, then CMS must extend the phase-in of this system beyond its current two years. Such an extension would help minimize disruptions that the ASC payment reductions will have on ophthalmologists and ASCs.

Our additional comments specific to proposals outlined in the rule focus on the following points in the Ambulatory Surgical Center Proposed 2008 Payment System:

1) **ASC Payable Procedures including:**
   a. Definition of Surgery
   b. Proposed Exclusions to the ASC List

2) **ASC Proposed Rate Setting Method including:**
   a. Proposed Packaging Policy
   b.Proposed Payment for Corneal Tissue
   c. Proposed Payment for Office-based Procedures

1) ASC Payable Procedures (Section XVIII.B.1)

Currently, CMS publishes a list of surgical procedures for which Medicare will pay if performed in an ASC. As stated above, the Academy supports the CMS decision to significantly revise this methodology. First, CMS proposes to allow payment for any surgical procedure performed on or after January 1, 2008, in an ASC, except those surgical procedures that the agency determines are not covered under the ASC benefit. Further, CMS is proposing to establish beneficiary safety and the need for an overnight stay as the principal clinical considerations in determining whether payment of an ASC facility fee would be allowed for a particular surgical procedure. This change will allow CMS to ensure that Medicare covers the full scope of procedures that are capable of being provided to beneficiaries in the ASC. This will allow patients to compare on the basis of both cost and quality in choosing the most appropriate clinical site for their surgery.

a Definition of surgery: CMS is requesting comment on whether or not their broad definition of surgery, which basically includes any codes in the surgery portion of the CPT book, capture all codes that should be viewed as surgical. The Academy appreciates the opportunity to comment on this suggestion and in fact would point to an area where CMS policy is not consistent with this definition. The Academy has repeatedly requested that add-on code 66990 be added to the ASC list. This newest proposed rule updating the ASC list for 2007 again mistakenly indicated that code 66990 is not a separate surgical procedure, and we do not believe it is an appropriate addition to the ASC list." **CPT code 66990 code, a procedure found in the surgical section of the CPT book, is an add-on code for a specific endoscopic surgical approach and therefore represents the distinct surgical work of the surgeon.** It is typically reported in conjunction with ophthalmic surgical services which are allowed in the ASC setting.

Exclusion of this code from the approved procedures list will prevent many ophthalmic surgical services from being performed in the ASC setting, necessitating their being performed in either the hospital outpatient department or inpatient setting at greater cost to the Medicare program. **The Academy strongly urges CMS to reconsider adding procedure code 66990 to the list of ASC approved procedures as it meets the definition of surgery proposed by CMS.** With that addition, we believe that the definition as outlined by CMS would be appropriate for the purposes of billing in an ASC as outlined by CPT in its guidance provision on this section.

b. Exclusions from the ASC List

80% Inpatient threshold--**The Academy sees no reason why CMS would set a threshold of 80 percent inpatient provision as a basis for excluding procedures from the ASC list.** This arbitrary figure is not based on clinical evidence and the data upon which this percentage is being drawn from are outdated and will be more so by the time this payment system is initiated. What rationale does CMS have that explains why the physician office or the HOPD are safe but an ASC is not for the other 20 percent of procedures? We see no logical reason for this distinction and suggest that the inpatient only designation is the most appropriate criteria.

Unlisted Procedures—For similar reason cited above, we do not see why there would be a safety issue in the ASC, but not in the HOPD, for unlisted procedures. At a minimum when all of the procedures that fall within the same section of CPT are covered services, then an associated unlisted code should also be eligible for payment at the carrier's discretion.

Again, if the agency truly wants to see alignment in these two settings, then it should apply uniform safety standards in the ASC and HOPD. The surgeon based on the patients needs should determine the best setting for safely performing the procedure(s) necessary. **These and other safety considerations should be studied more in depth and the AAO encourages CMS through MedPAC to expand its study of patient safety in these two settings. The input of the physicians who practice in the ASC setting who are most familiar with the expected risks, duration and complexity of procedures must be relied on for these determinations. The Academy urges creation of a patient safety panel comprised of ASC-based physicians to review the list of excluded procedures.**

2. ASC Proposed Rate Setting (Section XVIII.C.2)

Moving to expanded APC groups and relative payment rates that are based on the OPPS is the appropriate means for setting payments in the ASC. However, the use of a separate and reduced conversion factor for the ASC does not achieve the alignment that CMS suggests it is seeking. Differences in this rate setting also will not be transparent to beneficiaries and will hinder their ability to make direct comparisons based on price and quality.

a. ASC Proposed Packaging Policy

The Academy calls on CMS to ensure that alignment is truly achieved,
Because CMS has retained the same relative values as in the HOPD, it is only fair that any separately payable items that are provided in the ASC should be treated the same as those provided in the HOPD. To not do so completely undermines the payment system for ASC's since any separately payable items in the HOPD are able to be billed separately and NOT reflected in the relative value weights.

b. Proposed Payment for Corneal Tissue

On behalf of our members that provide such important services of corneal transplantation, the Academy very much appreciates the CMS decision to retain the existing policy to include in the Proposed Changes to the ASC Payment System the payment for corneal tissue on an acquisition cost basis, paid at reasonable cost. This action acknowledges that eye banking is no less variable in this present day as it was in 1998 when CMS acknowledged the role of community-based philanthropy and fund-raising utilized by most eye banks and the variable nature of the costs associated with obtaining this sight saving tissue. Of all the transplant surgery done today, corneal transplants are the most common and the most successful.

c. Proposed Payment for Office-based Procedures

The capping of payments at the non-facility payment rate will in fact push procedures that physicians could safely perform in the ASC into the HOPD unnecessarily increasing costs to Medicare and to beneficiaries through higher co-payments. We would ask the agency why is there not a similar cap on procedures that migrate from the office to the HOPD? This would suggest that it is not good payment policy. Such a policy will have the effect of limiting patient access to the safety and convenience of an ASC.

Conclusion

Despite the broadening of the list of covered services that will benefit many ophthalmic patients, the reductions in payment will in reality mean that those patients will be moved to or remain receiving care in more costly settings. Services that have tremendous benefits to beneficiaries such as cataract and after cataract surgery are facing reductions between 7 and 18 percent under this proposal. This is on top of reduced physician fees under the Medicare physician fee schedule. Such a trend is a perversion of the benefits of patient safety and convenience that Medicare sought to foster twenty years ago when it encouraged the provision of care in the ambulatory surgical setting.

Again, the Academy lauds the agency for taking this very important first step. We stand ready to work with the agency and its staff to help move to a point where there is true alignment between the ASC and HOPD settings. Such alignment can only be achieved more equitably in such factors as the updates for wage indexes and inflation (market basket and not CPI-U), the development of conversion factors and a transparent and fair budget neutrality adjustment at the onset of this system. Finally, we urge the adoption of a payment system that is founded on more current data then the 20-year old information on which it is currently based.

Yours truly,

Michael X. Repka, M.D.
Secretary, Federal Affairs

cc: Joan Sanow, CMS Ambulatory Payment Group
Cherie L. McNett, AAO Health Policy Director

Submitter : Ms. Laura Loeb **Date:** 11/06/2006

Organization : Dornier MedTech America

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1506-P2-1055-Attach-1.DOC

Dornier *MedTech*

November 6, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS – 1506 – P; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Norwalk:

Dornier MedTech America appreciates this opportunity to comment on the new Medicare payment methodology that the Centers for Medicare and Medicaid Services (CMS) is developing for ambulatory surgical centers (ASCs) to be implemented on January 1, 2008. In particular, we are concerned with the ASC reimbursement under any new methodology for extracorporeal shock wave therapy (ESWT) for the treatment of plantar fascia (CPT code 28890). Dornier is a manufacturer of medical equipment, including equipment for ESWT for plantar fascia.

We support the proposal by CMS to base new ASC payments on the weights of the same procedures under Medicare's hospital outpatient prospective payment system (HOPPS). While we believe that the new 2007 Medicare payment for CPT code 28890 performed in the hospital outpatient setting is appropriate, we do not believe that the Medicare payment for the same procedure in the physician office setting accurately reflects the resources required and the costs incurred by the physician. We would be opposed to any transfer of the physician office setting payment for this procedure to the ASC setting. The comparative standard should be the HOPPS weight.

We stand ready to assist CMS staff with respect to information on equipment costs for this procedure in order to ensure that CMS establishes an equitable payment amount for the ASC setting. If you have any questions with respect to these costs, please contact Tim Thomas of Dornier at 770-514-6163.

Sincerely,

Brian Walsh
President

Dornier MedTech America, Inc.

Submitter : Dr. Brett Coldiron **Date:** 11/06/2006

Organization : AADA, ACMMSCO, ASDS

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1506-P2-1056-Attach-1.DOC

#1056

American Academy of Dermatology Association
American College of Mohs Micrographic Surgery and Cutaneous Oncology
American Society of Dermatologic Surgery

November 6, 2006

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

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

Dear Administrator Norwalk:

On behalf of the dermatologic community, we appreciate the opportunity to submit written comments regarding proposed changes in the Ambulatory Surgical Center (ASC) Payment System. As advocates for dermatologists and their patients, the we believe that an adequate ASC payment schedule should ensure fairness and continued beneficiary access to safe, quality specialty health care services in the setting of their choice.

ASC Procedures
The Centers for Medicare and Medicaid Services (CMS) should be commended for expanding the procedures payable in ASCs to allow a much broader range of services for beneficiaries in this site of service. We agree with the Medicare Payment Advisory Commission's (MedPAC) recommendation that CMS should seek congressional authority to replace the current inclusionary list of ASC services with an exclusionary list. This is a similar concept to the list of procedures excluded from payment in hospital outpatient departments (HOPDs).

Physicians are best equipped to determine the safest place to perform a procedure. While an ASC may not always be the proper surgical setting, it may indeed be safe and appropriate for many patients undergoing procedures not typically performed in an ASC. And we believe that this determination should be made based on the expertise of the physician community. For this reason, we strongly encourage CMS to establish a process to consult with national medical specialty societies and the ambulatory surgical community to develop and adopt a means of fairly reimbursing ASCs for all safe and appropriate services, allowing for changes in technology and current-day practices.

ASC Payment for Office
CMS proposes to further expand the list of procedures by discontinuing the restriction on payment for procedures performed in an ASC that "are commonly performed, or that may be safely performed, in physicians' offices." However, CMS proposes to cap payments for these services at the lesser of the non-facility practice expense payment under Medicare's Physician Fee Schedule, or the ASC payment rate. This cap would result in reimbursement levels that make it economically infeasible for many ASCs to continue offering certain procedures.

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

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

This payment rate is wholly inadequate and does not reflect a realistic differential between the costs incurred by hospitals and ASCs in providing the same services. In fact, the proposed payment rate may result in the Medicare program paying more for outpatient surgery because beneficiaries' only choice for many procedures will be the more costly hospital setting.

We are pleased that CMS is moving forward with adoption of a new ASC payment system and we support CMS in this effort. Thank you for the opportunity to comment on this proposed notice. For further information, please contact Jayna Bonfini at jbonfini@aad.org or 202-842-3555 or Ted Thurn at tthurn@asds.net or 847-956-9126.

Sincerely,

American Academy of Dermatology Association
American College of Mohs Micrographic Surgery and Cutaneous Oncology
American Society of Dermatologic Surgery

Submitter : Mr. Mark Domyahn **Date:** 11/06/2006

Organization : Restore Medical, Inc.

Category : Device Industry

Issue Areas/Comments

ASC Addenda

ASC Addenda

See Attachment

ASC Packaging

ASC Packaging

See Attachment

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1057-Attach-1.DOC

#1057

Restore
MEDICAL

November 6, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8016
Baltimore, MD 21244-8018

Re: M edicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; [CMS-1506-P]

Dear Madam/Sir:

We appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule changes to the Ambulatory Surgical Center (ASC) Payment System for calendar year 2008. We understand that this proposed rule represents significant change to the ASC payment system, and commend CMS for developing the proposed rule. In this letter, we provide a brief background on Restore Medical, and comments on two proposals outlined in the rule.

Restore Medical, Inc.

Restore Medical is dedicated to improving patients' health and quality of life through practical, effective treatments for disruptive sleep and breathing disorders. We manufacture and sell palatal implants (The Pillar® Procedure) for the treatment obstructive sleep apnea (OSA). The Pillar Procedure received market clearance from the U.S. Food and Drug Administration in August 2004 for the treatment of mild-to-moderate OSA.

The Pillar Procedure involves implanting three small, braided, proprietary polyester inserts into the muscle of the soft palate using a specialized delivery tool for each palatal insert. The Pillar inserts stiffen and add structural support to the soft palate, thereby reducing the palatal tissue vibration that can cause snoring, and preventing or minimizing the soft palate tissue collapse and the resulting obstruction of the upper airway that can cause OSA. The Pillar Procedure is a safe, clinically-effective, long-lasting, low-risk procedure compared to other available treatment options that address the palate.

ASC Packaging

Consistent with its proposal to use the APC groups and relative payment amounts to determine ASC payments, CMS is proposing to cease making separate payment for implantable prosthetic

2800 Patton Road • St. Paul, MN 55113 • 651 634-3111 • 651 634-3025 Fax • www.restoremedical.com

devices and implantable DME inserted surgically at an ASC. Instead, the payment for implantable devices and DME would be packaged into the ASC facility fee.

We believe that following this methodology will cause significant payment issues at ASCs for those procedures that utilize implantable devices and DME such that these procedures will not be offered at ASCs for Medicare beneficiaries. The issue for these procedures in the ASC setting is that under the proposed methodology, ASCs receive a reduced conversion factor compared to that of hospitals. As stated in the proposed rule, the conversion factor for ASCs in 2008 is estimated to be 62% of the hospital conversion factor.

The OPPS determines its payment levels for device dependent APCs based on cost information as determined from claims data. Using this claims data, CMS is able to determine what percentage of these device-dependent APCs is related to the device versus what percentage applies to the facility costs associated with performing these procedures. By applying the reduced ASC conversion factor to these device-dependent procedures, CMS will, in essence, reimburse ASCs 62% of the calculated acquisition cost of the implantable devices and DME. This will most certainly render the ASC place of service meaningless for Medicare beneficiaries as ASCs will not be able to recover the difference between the actual acquisition cost of the implantable device and the payment rate.

To illustrate our concern, we refer to the Hospital OPPS final rule for calendar year 2007 (CMS-1506-FC). Table 20 of the final rule provides the device related portion of the total APC payment for device-dependent APCs. Using CPT 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver) that maps to APC 0039 (Level I Implantation of Neurostimulator) as an example, the listed CY 2007 total OPPS payment for APC 0039 is $11,518.00. Of this total payment, the device related percentage is 78.85%, which calculates the cost of the neurostimulator to be $9,081.84.

The proposed methodology of utilizing the ASC conversion factor would reimburse the ASC $7,141.16 ($11,518.00 x .62) for performing this same procedure. Based on this payment amount, the device related portion of the payment is $5,630.80 ($7,141.16 x 78.85%). Under the proposed methodology, an ASC would receive $3,451.4 less than a hospital to acquire the same neurostimulator to perform the implant procedure. The payment amounts for the hospital outpatient and ASC settings for performing this procedure are summarized in the table below:

	Hospital OPPS	Proposed ASC	Difference
CY 2007 Payment	$11,518.00	$7,141.16	($4.376.84)
Device Related %	78.85%	78.85%	
Device Related Cost	$9,081.94	$5,630.80	($3,451.14)
Non Device Related %	21.15%	21.15%	
Non Device Related Cost	$2,436.06	$1,510.36	($925.70)

It is not reasonable to assume that ASCs are able to acquire implantable devices at 38% less than can be acquired by hospitals. In fact, it is more reasonable to assume that hospitals have greater purchasing power due to volume purchasing than ASCs. This payment difference will create a substantial financial disincentive for ASCs to offer these procedures, and will prevent Medicare beneficiaries from this site of service for the procedures.

Instead, we offer two suggestions that CMS should consider in lieu of applying the ASC conversion factor to device-dependent procedures. The first suggestion is to apply the full OPPS conversion factor to device-dependent procedures when performed at the ASC. This would create equal payment in both the hospital outpatient and ASC sites of service, and eliminate any financial incentive for these procedures to be performed in one site of service over the other.

The second suggestion is to apply the ASC conversion factor to the facility related portion of the APC payment, and apply the OPPS conversion factor to the device related portion of the payment. The device related portion of the APC payment can be determined by using the information listed in the OPPS final rule concerning device dependent APCs. This would more closely follow CMS' assumption that costs to perform procedures are less in ASCs than it is for hospitals. This information could be used to calculate the device related and facility related portions of these procedures to apply the appropriate conversion factor.

	Hospital OPPS	Conversion Factor	Calculated ASC Payment
CY 2007 OPPS Payment	$11,518.00		
Device Related %	78.85%		
Device Related Cost	$9,081.94	100%	$9,081.94
Non Device Related %	21.15%		
Non Device Related Cost	$2,436.06	62%	$1,510.36
Total			$10,592.30

We believe that either of these two suggestions would avoid the financial disincentive that ASCs would experience for device dependent procedures that would occur under the proposed methodology, while still maintaining CMS' intent to use the OPPS as a basis for ASC payment.

One additional consideration in utilizing either of these suggestions is that device dependent procedures and APCs need to be identified. We suggest using the same list that is utilized in the Hospital OPPS final rule.

ASC Addenda

As CMS transitions the ASC payment system to more closely follow the hospital OPPS system, we believe it is important for ASCs to have the opportunity for payment for new technology that exists under OPPS, assuming the new technology meets the criteria to be performed in an ASC (i.e. surgical procedure that does not pose a significant risk or require a overnight hospital stay). Specifically, ASCs should receive payment for those procedures that have been granted either a New Technology APC Designation or APC Pass-Through Status under OPPS.

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MEDICAL

A New Technology APC Designation was granted for the insertion of palatal implants effective October 1, 2006. As a result, a HCPCS Level II code was created to identify the procedure (C9727 – Insert palate implants). We request this code be added to Addendum BB as it represents a surgical procedure that does not pose a significant risk or require an overnight hospital stay.

Again, we very much appreciate the opportunity to submit these comments on the ASC proposed rule for 2008. If you have additional questions, or require additional information, please do not hesitate to contact me at (763) 505-0201.

Sincerely,

Mark Domyahn
Director of Payer Relations
Restore Medical

Submitter : **Dr. Robert Sackheim** **Date: 11/06/2006**

Organization : **Pain Medicine of Northwest Florida**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

I can't understand why you don't appreciate the value of ASC's. Over and over again they have proven to be more cost efficient in treating ever patient and performing every procedure for ever type of specialty. I honestly prefer using an ASC because it is more expedient, less costly for the patient if they have a co-pay, and has easily accessibilty than a hospital out patient setting.

I think it is imperative that you reconsider a payment schedule that might all but eliminate ASC's. This, indeed, would be a travesty for the medical and patient community.

Thank you for your consideration.
Robert Sackheim, M.D.

Submitter : Mr. Michael Becker **Date:** 11/06/2006

Organization : GE Healthcare

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1506-P2-1059-Attach-1.DOC

#1059

GE Healthcare

Michael S. Becker
General Manager, Reimbursement

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November 6, 2006

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

ATTENTION: FILE CODE CMS-1506-P

Re: Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule (Section XVIII)

Dear Administrator Norwalk:

GE Healthcare (GEHC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding revisions to the 2008 Medicare ambulatory surgical center (ASC) payment system (*Federal Register*, Vol. 71, No. 163, August 23, 2006). Our comments address packaging of intra-operative imaging procedures, as well as contrast and optical imaging agents into ASC payments.

GE Healthcare is a $15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

In the rule, CMS proposes to package into the ASC payment all direct and indirect costs related to the facility's performance of the surgical procedure. This includes payment for all intra-operative imaging, as well as imaging agents. This approach to packaging differs from the treatment of these items and services under the hospital outpatient prospective payment system (HOPPS). Under HOPPS, hospitals are frequently reimbursed separate and additional amounts for intra-operative imaging services and related agents associated with surgical procedures.

In support of its proposed packaging method, CMS notes that it believes that ASCs generally treat a less complex and severely ill patient case mix. As a result, the agency believes 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.[1] Thus, CMS does not believe that there is a need to provide reimbursement for these items and services separately in ASCs.

GEHC is not aware of evidence supporting this CMS assertion. In fact, we believe that ASCs routinely use intra-operative imaging and agents during the course of surgery. Moreover, we do not believe that this rationale is appropriate justification for packaging these items and services into the ASC payment rates.

Advances in surgical techniques and related technologies have expanded the scope of services that ASCs are able to provide safely, effectively and efficiently to Medicare beneficiaries. Importantly, many surgical procedures performed today rely on intra-operative imaging to guide and improve surgical outcomes. This imaging can involve different modalities including fluoroscopy, ultrasound, CT or MR. In addition, intra-operative imaging may involve the use of contrast or optical imaging agents. Imaging may be integral to the performance of the surgical procedure itself, as in the case of image guidance. Alternatively, imaging may be used immediately following surgery to confirm placement of an implanted item or completion of the surgery plan.

GEHC believes that application of APC relative weights to ASC facility payment requires that CMS establish parity with respect to its packaging policies for the two payment systems. To the extent that ASCs provide intra-operative imaging under a payment system that is aligned with HOPPS, these facilities should be able to receive reimbursement for these services in the same manner as hospitals. Further, failure to allow for separate payment for intra-operative imaging and agents would result in systematic underpayment of procedures involving these items and services, compared to other reimbursable ASC procedures.

GEHC urges CMS to carefully align Medicare's ASC and hospital outpatient payment systems to ensure that ASCs are adequately and equitably compensated for all services provided. Specifically, **GEHC recommends that CMS adopt the same packaging policies for the ASC and HOPPS payment systems with respect to intra-operative imaging and imaging agents.**

*****

In summary, we urge CMS to carefully consider our recommendations which support more accurate and equitable payment for ASC services. Thank you for providing the opportunity to comment on these important issues. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,

Michael S. Becker
General Manager, Reimbursement

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[1] 71 *Federal Register* 49648

Submitter : Dr. Jim Garza **Date:** 11/06/2006

Organization : JIm Garza MD

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

ASC List Reform

Submitter : **Dr. Zaki Anwar** **Date: 11/06/2006**

Organization : **Pain Management Institute**

Category : **Physician**

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

Pain Management Institute
10181 Lincoln Highway
Frankfort, IL 60423

October 31, 2006

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

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

Dear Ms. Norwalk:

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

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

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

Sincerely,

Zaki Anwar, M.D.
Interventional Pain Management Specialist
Pain Management Institute

Submitter : **Dr. William Lahners** **Date: 11/06/2006**

Organization : **Center For Sight, LLC**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

Please find attached my comments regarding the proposed ASC payment reformand procedures list rulemaking.

Thank you,
William J. Lahners, MD
Medical Director of Laser and Surgical Services
Center For Sight, LLC
Sarasota, Florida

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

Organization : OOSS/ASCRS

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1063-Attach-1.PDF

1063

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

November 6, 2006

Leslie Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P, CMS-4125-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program—HCAHPS Survey, SCIP, and Mortality)

Dear Administrator Norwalk:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures furnished annually in ASCs and hospitals.

On behalf of OOSS and ASCRS, we are taking this opportunity to comment on Section XVIII of the proposed rule, which would substantially revise the ASC payment system, effective CY 2008.

I. OVERVIEW AND SUMMARY OF RECOMMENDATIONS

The nation's 4,200 ASCs are committed to providing Medicare beneficiaries with access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the

Medicare program in the containment of health expenditures. Studies conducted by a multitude of federal agencies (including CMS; the Government Accountability Office; the Medicare Payment Advisory Commission; the Office of the Inspector General, HHS; and the Federal Trade Commission) have lauded the work of ASCs, recognizing that surgery centers provide care at levels of quality equal to or surpassing hospital outpatient departments (HOPD), at lower cost to the program and to beneficiaries, and in a patient-friendly and convenient environment that leads to the highest levels of patient satisfaction.

Cataract surgery in the ASC is emblematic of the phenomenon of the ASC becoming the choice of physicians and beneficiaries for site of surgery. More than 2.7 million patients receive cataract surgery each year; in consultation with their ophthalmic surgeons, more than 60 percent of them select the ASC over the HOPD as their site of surgery. A study commissioned by MedPAC and undertaken by RAND Health in October, 2006, *Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings*, concluded that with respect to all statistically significant measurements after risk adjustment, cataract patients had fewer adverse outcomes (endophthalmitis, iris prolapse, cataract fragments, and persistent corneal edema) following surgery furnished in the ASC, as compared with the HOPD. As for program savings, in 2006 alone, Medicare saves over $400 ($1,388 in the HOPD vs. $973 in the ASC) each time the cataract operation is performed in an ASC rather than a hospital, translating to hundreds of millions of dollars in expenditures annually. Simply stated, with respect to cataract surgery, the highest volume Medicare surgical procedure, the ASC is the predominant choice of the Medicare beneficiary because the quality of care provided is demonstrably high and the cost savings to the patient and the program are significant.

Notwithstanding these benefits attributable to Medicare's ASC program, the payment and regulatory mechanisms applicable to ASCs remain unchanged since the inception of the program in 1982. Payment rates have not been rebased since 1989 and are based on survey data collected in 1986. ASCs have received annual cost-of-living updates on only a sporadic basis and have been afforded no increases since 2003 (nor, until 2010, under current law.) Literally dozens of ophthalmic surgical services that can be safely and effectively performed on Medicare beneficiaries have been excluded from the ASC procedures list, depriving beneficiaries of access to high quality care and the government of considerable program budgetary savings. The Medicare ASC program is clearly in need of reform.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS implement by January 1, 2008 a new ASC payment system. OOSS, ASCRS, and the entire ambulatory surgery community have reached consensus on the appropriate contours of an equitable and rational program; these principles are embodied in *The Ambulatory Surgical Center Medicare Payment Modernization Act* (S. 1884; H.R. 4042), as introduced in Congress last year. We believe that it is imperative that the payment system the agency is charged with developing embody the following principles:

- ASCs should be permitted to perform and receive facility payment for *any* surgical service, except those services that require an overnight stay or pose a significant risk to beneficiary safety when furnished in an ASC.

- The new payment system should be modeled on the methodology and payment rates applicable to surgical services furnished in HOPDs.

- ASCs should be paid at least 75 percent of the HOPD fee schedule amount for each covered service. Whatever the percentage ultimately adopted by the agency, it should be applied *uniformly* to all services and all specialties, without exception.

- ASCs should receive the same annual updates and other relevant adjustments, such as pass-through payments for new and innovative drugs and devices, that are afforded to HOPDs.

- The beneficiary's copayment for services furnished in the ASC should remain at 20 percent of the Medicare payment amount.

- In order to ensure stability within the ASC industry and continuity in the delivery of care by ASCs to Medicare patients, the new payment system should be phased in over a four-year period.

We strongly believe that the new payment system should be tethered to each and every one of these principles. We are pleased that, at least with respect to the broad framework of the proposed payment system, CMS has incorporated many of these basic tenets, most notably the linkage of ASC and HOPD payment methodologies and rates. However, the agency, for a multitude of stated reasons – most notably, constraints it alleges are imposed by the MMA's budget neutrality requirement -- has deviated from these principles in many material respects, and in ways that embody the potential to compromise the integrity of the new system, reduce realizable program savings, thwart competition among providers of ambulatory surgical services, and inhibit transparency regarding price and quality among Medicare providers, and compromise beneficiary access to affordable and high quality surgical care.

Since CMS issued its last proposed ASC payment reform initiative in 1998, our organizations have been engaged in multiple discussions and exchanges of ideas and data with the agency regarding the issues presented in this rulemaking. We genuinely appreciate the agency's willingness to work with us and others within the ASC community and applaud CMS for the substantial work reflected in the development of this proposal. With this same spirit of cooperation and commitment to formulating a rational and equitable ASC payment system, OOSS and ASCRS offer our specific comments, summarized below:

With respect to the agency's proposal to modify the ASC procedures list:

- We support CMS' decision to include virtually all ophthalmic procedures on the list of services that can be performed and reimbursed in the ASC.

- CPT Code 66990 (use of ophthalmic endoscope) should be a covered procedure when furnished in the ASC.

- We support CMS' decision to eliminate operating and anesthesia times as ASC coverage criteria.

- We support CMS' proposal to exclude from coverage any procedure that is included on the "inpatient only" list.

- The proposed safety risk criteria (generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; and, are generally emergent of life-threatening in nature) should be modified to be identical to the standards utilized to evaluate the safety of procedures performed in the HOPD.

- CMS should maintain its current policy that defines an overnight stay as an episode involving a stay of less than 24 hours.

- ASCs should receive the same transitional pass-through payments for drugs, devices and biologics as HOPDs.

- CMS should provide coverage for "office-based procedures" performed in the ASC.

With respect to the agency's proposed ratesetting methodology:

- CMS should adopt a broader and more flexible interpretation of budget neutrality in calculating the ASC/HOPD conversion factor, as described below.

- CMS should utilize its alternative methodology and make appropriate modifications to account for procedure migration, yielding an ASC/HOPD conversion factor of 73.06 percent.

- Office-based procedures that are covered in the ASC should be paid on the basis of the ASC/HOPD conversion factor, not on the basis of the lower of the conversion factor or the MFS practice expense component.

- The ASC/HOPD conversion factor should be applied uniformly with respect to all services and all specialties.

- CMS should not carve out "device-dependent" services for special treatment.

- We support CMS' decision to continue to pay for the acquisition of corneal tissue on the basis of invoice in both the ASC and HOPD settings.

- ASCs, like HOPDs, should receive the Hospital Market Basket as the annual adjustment for inflation.

- The new payment system should be phased in over four years, not the two years recommended by CMS in the NPRM.

- We support CMS' proposal to continue the current policy that applies the 20% coinsurance for services in the ASC.

II. PROPOSED ASC PROCEDURES LIST ISSUES

OOSS and ASCRS are generally pleased with CMS' proposal to redesign the process through which procedures are designated as appropriate for performance in an ASC. Specifically, we support the adoption of MedPAC's recommendation, incorporated in its March 2004 Report to Congress, 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. For a quarter-century, CMS has permitted payment to ASCs only for services that have been specifically designated in advance by the agency as safe, effective, and less costly than care provided in the hospital. This concept of an inclusionary list is an artifact of another era, reflecting the concern of policy-makers more than two decades ago that ASCs, which numbered only a hundred or so at the time the enabling rules were promulgated, should not perform services that require the resource intensity of a hospital.

The proposed use of an exclusionary list will allow Medicare beneficiaries access to the broader range of the ASC services that are currently safely offered to non-Medicare patients. Indeed, we applaud the agency for accepting virtually all of our specific recommendations regarding coverage of ophthalmic surgical services.

As new procedures are developed, an exclusionary system should ideally promote timely access to technological advances in outpatient surgical care. Over the past fifteen years, OOSS and ASCRS have formally recommended in multiple rulemakings that CMS augment the ASC list with a number of ophthalmic procedures that, indisputably, can be safely and effectively performed in the ASC environment. Yet, until issuance of this NPRM, virtually none of our

recommendations have been adopted, nor, in most instances, has the agency provided any explanation, much less a credible justification, for its refusal to add these services to the ASC list. Adoption of a policy under which procedures are presumed to be appropriate for performance in the ASC represents a step in the right direction. However, as discussed below, we are concerned that the criteria CMS has proposed for excluding a procedure from the list are so restrictive, and the agency's discretion in making such determinations so intrusive, that, effective in 2008 when the new payment system becomes operational and well into the future as new surgical procedures are developed and adopted within the ASC environment, beneficiaries will be denied access to services that are entirely appropriate for conduct in the ASC.

The ability of ASCs to offer existing and new surgical services will, however, depend upon CMS' adoption of fair and reasonable payment rates for such procedures. As discussed in Sections III (D), (G), and (H) below, we have serious concerns about the adequacy of the proposed reimbursement rates, both with respect to the conversion factor that yields a specific percentage-of-APC payment rate and the agency's proposal that most office-type surgical services be paid at Medicare Fee Schedule practice expense amounts.

ASCs enjoy an unblemished record with respect to delivering the highest quality care to Medicare patients, exceptional surgical outcomes, and a patient-friendly operative experience. The nation's more than 4,200 surgery centers comply with patient health and safety, structural, governance, supervision, management, and utilization review and quality assurance standards which parallel those applicable to hospitals. Accordingly, all elements of the new ASC payment system, particularly Medicare coverage of surgical services, should be aligned with the payment and coverage policies applicable to HOPDs. In the discussion below, we present several recommendations that we believe will improve the implementation of ASC coverage criteria and enhance beneficiary access to the broad array of services that can be safely and effectively performed in the ASC environment.

A. Procedures Proposed for Medicare Payment in ASCs Effective for Services Furnished On or After January 1, 2008 {ASC Payable Procedures}

As noted above, OOSS and ASCRS are delighted that the Medicare program will now pay for virtually all ophthalmic surgical services, effective January 1, 2008. We support the agency's decisions not to exclude from coverage all such services.

B. Exclusion of CPT 66990 from Payment {ASC Payable Procedures}

For years, CMS has refused to permit payment for **CPT Code 66990 (use of ophthalmic endoscope)** claiming that the service is not a surgical procedure – rather, that the code is used to recognize the use of equipment that is integral to surgical procedures – and has refused to designate the service as appropriate for payment in the ASC. In our comments submitted to CMS with respect to the 2005 procedures list update, we objected to CMS' decision not to include CPT Code 66990 on the list of approved procedures. We reiterate our objection today with respect to the proposed rule.

66990 is an add-on code for a specific endoscopic surgical approach and does constitute surgery. It is reported in conjunction with many ophthalmic surgical services that are permitted and reimbursed in the ASC environment. (For example, endoscopic glaucoma surgery has a 60-70% rate of success, decreasing the drugs needed for glaucoma management and mitigating the need for more costly glaucoma surgery.) Failure to cover the code for payment purposes will result in these services being performed in the hospital inpatient or outpatient environments, at greater cost to the Medicare program and inconvenience to the beneficiary.

CMS has included on the ASC list other similarly situated add-on codes. In the final HOPPS rule, the agency added CPT Code 61795 (stereotactic guidance) to the ASC list. This code is similar to 66990 in that it is an add-on code representing a device used during a surgical procedure and cannot be reported alone.

We recommend that 66990 not be excluded from the ASC list of covered services.

C. Criteria Proposed for Excluding Procedures from Payment {ASC Payable Procedures}

OOSS and ASCRS offer the following comments regarding the criteria CMS proposes to apply in determining whether a procedure can be performed and reimbursed within an ASC:

- **Operating and Anesthesia Times.** We strongly support CMS' proposal to revise the current ASC coverage criteria by discontinuing the use of operating and anesthesia times as criteria for determining the appropriateness of a service for performance within an ASC. We have long advocated such a policy and are delighted that MedPAC concurs with the views of the ASC community.

- **Commonly Performed on an Inpatient Basis.** We agree with CMS' proposal that the existing criterion (Sec 416.65(a)(1), which requires that covered ASC services be ones that are commonly performed on an inpatient basis, is antiquated and should be eliminated.

- **Significant Safety Risk.**

  - **Exclusion Based On Inpatient Only List.** We concur with CMS' proposal to exclude from coverage any procedure that is included on the "inpatient only" list. We are comfortable with this policy so long as CMS updates the inpatient only list on a regular basis.

  - **Exclusion Based on Evaluating Safety Risks.** As suggested above, the same criteria should apply to both the ASC and HOPD in determining the appropriateness of performing a surgical procedure in the outpatient settings. CMS proposes to apply to ASCs the following criteria for purposes of excluding services from the ASC: (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. These general exclusions actually parallel the exclusionary language under the HOPD coverage and payment system. We believe that the standards applied in the HOPD environment, coupled with the requirement that ASCs not perform surgical services requiring an overnight stay, provide ample safeguards for patient safety. The safety risk criteria should be modified to comport with the standards utilized to evaluate the safety of procedures performed in the HOPD.

- **Overnight Stay.** CMS is proposing to define, for purposes of excluding a procedure from coverage within an ASC, a procedure requiring an "overnight stay" as one that contemplates the patient will be present in the facility at midnight. We believe that CMS should maintain its current policy that defines an overnight stay as an episode involving a stay of less than 24 hours in duration.

D. Payment for Pass-Throughs {ASC Payable Procedures}

The Medicare program makes transitional pass-through payments to HOPDs for innovative devices, drugs and biologics. ASCs that provide these products as an integral part of a covered service should also receive these same payments. In its effort to appropriately align the ASC and HOPD payment systems, the agency should ensure consistent coverage policies for devices, drugs, and biologics, regardless of the type of surgical setting.

E. Coverage of "Office-Based Procedures" in the ASC {ASC Office-Based Procedures}

CMS is soliciting comments 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 include all services within the Surgery section of CPT, including those that are predominantly office-based. While some of these services are office-based or require relatively inexpensive resources to perform, they should be eligible for payment in the ASC, and, as discussed below in Sec III (D) and (G), paid for at the uniform percentage of HOPD applicable to procedures that are not office-based.

OOSS and ASCRS believe that the physician, in consultation with his patient, should determine the appropriate site of surgery. CMS' current policy of denying coverage for office-based services pre-supposes that procedures which are performed more than a majority of the time in the "physician's office" are inappropriate for conduct in the ASC setting. We understand that the intent of this criterion is to prevent the migration of procedures from the less intensive and less costly office setting to the more intensive and more expensive ASC environment. However, although a procedure may be more commonly performed in a physician's office, it is rare that it is furnished exclusively in the office – and for many good reasons which are below elucidated. The decision as to the appropriate site of surgery should not be made based upon reimbursement incentives, but rather, because the surgeon comprehends and considers the unique

needs and circumstances of the individual patient and uses his expertise to determine which surgical environment will optimize the potential for ensuring patient health and safety and securing the best clinical outcome, while minimizing the risk of complications.

- First, a combination of factors unique to a particular patient's clinical condition – including his age, size, comorbidities, prior operative experience, or simply his personal preference for the more convenient and less costly ASC – may lead the physician to conclude that, with respect to a particular procedure, an ASC is the appropriate site for a case which, for a different patient, might be safely and effectively performed in an office setting. A simple chalazion incision in a patient with high anxiety and a history of fainting may require pre-operative sedation and the conduct of the procedure while the patient is in a reclined position. The operating room would be the appropriate site of service under these circumstances.

- Second, CPT codes, which are designed to define physician (not facility) services, are often sufficiently broad as to encompass surgical services which might be appropriate for the office setting under some circumstances but not in others where the patient's underlying condition, anticipated length of operation or recovery time, type of anesthesia, extent of tissue involvement, or geometrics of the required incision, warrant the use of the ASC.

- Third, there is significant variation in the ways in which physicians' offices are equipped and staffed. For example, radio-frequency surgical instrumentation, which is most often used in the ASC, would not likely be available in the physician's office.

- Fourth, the training, skills, and experience of the surgeon may vary – as may be the scope of his professional and facility malpractice insurance coverage – all legitimate considerations in his and the patient's decision as to the appropriate site for surgery.

- Fifth, state regulation may, without regard to the physical structure, equipment, or staffing of a facility, define whether a facility is a physician's office or an ASC. In jurisdictions governed by rigorous certificate-of-need laws, a surgical facility which is constructed, equipped and staffed to meet Medicare ASC conditions of coverage may be precluded from being certified as an ASC; this facility's claims would be submitted with a physician's office site of service. 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 receive their surgical care in offices, but some require the more regulated ASC or HOPD environments.

For all of these reasons, it makes little sense for CMS to conclude that a procedure is inappropriate for reimbursement in an ASC simply because, according to site of service data, it is performed more frequently in a physician's office. The data may be misleading in that the facility is truly functioning as an ASC. The patient's individual clinical condition may warrant the performance of the surgery in a fully equipped surgical environment with a sterile operating room, the ability to render conscious sedation or provide appropriate emergency treatment in the event of an intra-operative problem.

There are two conceivable justifications for this coverage policy: (1) that permitting payment for these services will lead to overutilization of ASCs or induce physicians to convert their offices to ASCs; and, (2) that relegation of these services to the physician's office conserves Medicare expenditures, since these services will not be eligible for ASC facility reimbursement. With respect to the former argument, CMS has presented no evidence that coverage of office-based services in the ASC leads to overutilization. Indeed, there exist today a number of procedures on the ASC list that would technically qualify as office procedures based on the criteria currently utilized by CMS. The agency admits 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."

The justification that Medicare can appropriately reduce expenditures by essentially requiring that certain services be performed in the office setting is specious. If the procedure is performed in the physician's office, the program will pay a higher professional surgical fee; and, if the physician feels compelled to provide the service in the hospital outpatient department, Medicare will pay a substantially higher facility fee than would have been afforded the ASC and the patient will be responsible for a higher copayment. In point of fact, assuming that CMS were to pay for these procedures with the uniform ASC/HOPD percentage of HOPD conversion factor applicable to procedures that are not 'office-based,' we believe it is more likely that cases would migrate from the much more costly HOPD site to the less costly ASC than from the less costly office-based site to the more costly ASC facility, saving Medicare considerable outlays.

MedPAC, which recommended that the list of ASC services be significantly expanded in its March 2004 Report to Congress, also stated in its October 10, 2006 comments to CMS regarding the NPRM that CMS should add to the ASC list those services that are primarily performed in physician offices. 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 concur with MedPAC's reasoning and recommendation. Medicare should not provide reimbursement incentives which might impact upon the decision as to the appropriate site of service. CMS should adopt in the final rule its proposal to not exclude from coverage those surgical services that are frequently performed in the physician's office. Moreover, as discussed below, these services should be paid for in the ASC setting at the uniform percentage of HOPD applicable to procedures that are not office-based.

III. PROPOSED ASC RATESETTING METHODOLOGY

Congress' mandate that CMS establish a new payment system, as provided in the MMA, provides an historic opportunity for CMS to enhance beneficiary access to the highest quality of care in outpatient surgical settings and also reduce Medicare program costs. As discussed above, OOSS and ASCRS have met on multiple occasions with CMS officials over the past decade in an effort to garner consensus on the contours of a rational, equitable, and coherent ASC payment system. Although the HOPD system embodies certain flaws, it is an appropriate proxy for the relative cost of services furnished in the ASC. Designed appropriately, such an approach will generate improvements in both the ASC and HOPD systems, provided the agency is vigilant in adhering to several critical principles:

- Ensuring comprehensive and meaningful access to the wide range of surgical procedures that can be safely and effectively furnished in ASCs, as provided in our comments above;

- Establishing equitable and reasonable payment rates that compensate facilities for their costs, yet also reduce expenditures by the Medicare program and beneficiaries;

- Aligning the ASC and HOPD systems to provide beneficiaries with greater price transparency and eliminate distortions between the systems that might inappropriately influence the selection of the site for surgery;

- Promoting competition among providers of ambulatory surgical services.

We concur generally with CMS' decision to utilize one payment system for both ASCs and HOPDs. However, in a myriad of material respects, the proposed rule falls short in truly incorporating these principles, thereby squandering an opportunity to optimize the potential to dramatically improve beneficiary access to the high quality and lower cost care that ASCs have been providing Medicare patients since 1982.

We discuss below our views on the principle components of the proposed regulation and offer our recommendations for more rationally aligning the ASC and HOPD payment systems. Please note that, with respect to several payment-related issues, we are incorporating the recommendations of the ASC Coalition, which is comprised of several national and state ASC associations and several ASC management and development companies representing single- and multi-specialty ASCs, all types of ownership, in all parts of the country.

A. Linking ASC and HOPD Relative Weights and APCs {ASC Ratesetting; ASC Conversion Factor}

OOSS and ASCRS strongly support the utilization of the same APCs and relative

weights in creating a rational and coherent encompassing the services offered by both HOPDs and ASCs. However, as proposed in the rulemaking, the same weights will likely be used only in 2008, after which time the rescaling of ASC relative weights the second time will result in further divergences in weights and payments, exacerbating exactly the types of distortions that the new system was presumably intended to correct. The only legitimate basis for change in relative payments to HOPDs and ASCs should be changes in the relative costs of providing specific outpatient services. There is little basis for believing that these variations will occur, and to the extent that they do, they should be accounted for directly through adjustments to the conversion factor.

B. New Technology Pass-Throughs and Innovative Ophthalmic Technology (NTIOL) {ASC Packaging}

The new technology APC program and the pass-through program administered with respect to the HOPD system have promoted the development, adoption, and dissemination of new innovative drugs and devices. As discussed above in Sec. _____, we believe that it is imperative that ASCs be afforded the benefit of pass-through payments for all drugs, devices, and biologics that are made available to HOPDs. In the absence of such adjustments, ASCs will be unable to offer many services that are appropriate for conduct in the surgery center environment and beneficiaries will be provided access to only the HOPD for such services, augmenting their out-of-pocket payments and Medicare expenditures. In its effort to appropriately align the ASC and HOPD payment systems, the agency should ensure consistent coverage policies for devices, drugs, and biologics, regardless of the type of surgical setting.

We take this opportunity to applaud the agency for its efforts to faithfully implement the program under which Medicare beneficiaries are provided access to the most advanced intraocular lenses implanted during cataract surgery. We provided detailed comments on the new technology IOL (NTIOL) program in our submission to the agency regarding Section VII of the NPRM.

C. ASC Payment for Corneal Tissue

Under current policy, the agency pays for the acquisition cost of corneal tissue in both the ASC and HOPD environments. We concur with CMS' proposal to continue to pay ASCs separately, above and beyond the base facility fee and on the basis of invoice, for the procurement of corneal tissue. Indeed, this same policy should apply with respect to all other items and services provided by both hospitals and surgery centers.

D. ASC Payment for Office-Based Procedures

We applaud CMS significantly expanding the ASC procedures list to include many ophthalmic surgical services that, although more frequently performed in the physician office setting, are often appropriate for conduct in the ASC setting. However, we strenuously object to the agency's proposal to cap payments for these services at the lesser of the amount allowable

under the conversion factor (62% under the NPRM) or the amount the physician would receive under the practice expense component of the Medicare Professional Fee Schedule. Simply stated, CMS has given with one hand and taken away with the other. This policy makes little sense and embodies the potential to force Medicare patients into the more costly HOPD, as well as compromise patient safety by providing financial incentives for the patient to be treated in the less regulated office setting.

As discussed in detail in Sec II (E) above, there are many reasons why the physician might select the ASC, rather than the office operatory or treatment room, for the conduct of a particular service. First, the patient's clinical condition, including his age, size, comorbidities, prior operative experience might dictate that the ASC is the appropriate environment for surgery. Second, there are considerable variations in the ways in which physician offices are equipped and staffed. Third, the training, skills, and experience of the surgeon may warrant the choice of one setting over the other. Fourth, state certificate of need, ASC licensure, or professional scope of practice regulations, as well as the physician's professional or facility malpractice coverage, might impact upon the choice for site of surgery. All of these considerations might legitimately impact upon the selection of the ASC for performance of the surgical procedure.

For example, many ophthalmic surgeons locate their laser equipment in the ASC, rather than in the office, in order to ensure that the patient always receives optimal available medical and nursing care when undergoing laser surgery. For example, Pan Retinal Photocoagulation (PRP) for proliferative diabetic retinopathy is typically a very painful procedure and the level of pain increases with each successive treatment. The Focal Retinal Laser (FRL) procedure, indicated for background diabetic retinopathy, is typically less painful; however, because the surgeon is working near the macula and any sudden eye movement can cause macular damage, the patient is more at risk for visual loss. With respect to both procedures, the patient treated in the ASC receives a retrobulbar anesthesia injection to numb the eyes which involves inserting a needle beneath the eye, through the lower lid, advancing it into the orbital space behind the eye, and delivering 6-8 ml of lidocaine anesthetic solution. These services require the services a registered nurse and sometimes an anesthesiologist or nurse anesthetist. A medical exam is performed and vital signs are monitored prior to and following the injection and laser treatment. Each laser surgery treatment requires an operative note and is subject to the same basic protocol as scalpel surgery in a regulated environment. Many other non-laser surgical procedures, such as exploration and repair of subconjunctival/scleral nonperforating lacerations and foreign bodies, may be categorized as office services; however, depending upon the patient's clinical condition, may be more safely and effectively treated under the controlled sterile conditions of the ASC.

As discussed above, CMS has presented no evidence that coverage of office-based services in the ASC would lead to overutilization. It is true that paying for these services at the new ASC rates might lead to higher Medicare costs, but only if more procedure-costs move from office to ASC than from HOPD to ASC; this phenomenon is difficult to predict. Nevertheless, Medicare expenditures will definitely increase by orders of magnitude if these office-type services migrate, by virtue of the caps on ASC payments, to the HOPD setting, where reimbursement rates exceed ASC rates by at least 38% under the new payment system. The

physician, in consultation with his patient, is professionally, legally, and ethically obligated to make the clinical decision as to whether the hospital, ASC, or office is the appropriate operative environment. The Medicare program should not provide reimbursement incentives which might impact upon these decisions.

E. Proposed ASC Adjustment for Inflation {ASC Inflation; Proposed Annual Updates}

During the past quarter-century, ASCs have been provided annual updates on only a sporadic basis and facilities have received no adjustments for inflation for the period 2004-2009, notwithstanding the fact that our costs rise at rates that are identical to those of HOPDs. We appreciate that CMS recognizes that ASCs' costs rise and have included in the NPRM provision for annual updates. However, the proposed adoption of the Consumer Price Update – Urban (CPI-U) makes little public policy sense. ASCs should receive the same update factor as HOPDs, i.e., the hospital market basket (HMB).

The HMB percentage increase represents the increase in the cost of the mix of goods and services (based on hospital inpatient operating costs) for the period at issue over the cost of such mix of goods and services for the prior 12-month cost reporting period. The HMB much more accurately reflects the types of health-related goods and services that are typically consumed in the ASC than the CPI-U, which is a more general index reflecting increases in the costs of consumer goods. Indeed, over the past decade, year after year, the HMB has exceeded the CPI-U by an average of about one percent.

CMS provides no foundation for the proposition that ASCs consume fewer or different types of resources than HOPDs. Indeed, the surgical services performed by ASC are identical to those furnished by hospitals and the costs incurred by the freestanding facility to account for staffing, equipment, supplies, overhead, and administration are commensurate with those incurred by hospitals which treat the same patients. Hence, the inflationary pressures for the same services are no different and the services are influenced by the same economic pressures in a given market. As such, the higher update proposed to be awarded to the HOPD could be argued to reward its inefficiencies while penalizing the cost-conscious behaviors of the ASC.

The adoption of different annual update measures is also inconsistent with the agency's stated goal of aligning the HOPD and ASC payment systems. In a regulatory system under which CMS is attempting to parallel-track payments to HOPDs and ASCs (albeit subject to a conversion factor), it makes little sense to literally build into the equation an update factor that promises to further distort payment rates for comparable services. We strongly believe that the HMB should be utilized to update the rates of both HOPDs and ASCs; if CMS is concerned that it lacks the statutory authority to adopt the HMB as the update factor for ASCs, the agency should aggressively urge Congress to amend current statutory law to accomplish this objective.

F. Proposed Beneficiary Coinsurance

We applaud CMS for its many recent endeavors to promote transparency in the Medicare program that enables beneficiaries to become informed consumers in evaluating the cost and quality of health care services. As such, OOSS and ASCRS strongly support CMS' decision to maintain the current policy that applies the 20% coinsurance for services in the ASC. Because copayments for HOPD services are determined based on hospitals' charges and range from 20% to over 35% of facility fees that, effective in 2008, will always be higher than the payments made to ASCs, the beneficiary will realize cost-sharing savings each and every time he or she selects the ASC as the operative environment.

G. Adherence to a Uniform Percentage of HOPD: Medical Device Hold Harmless, Specialty Carve-Outs, and Transitions to the New Payment System {ASC Ratesetting; Phase In; ASC Conversion Factor}

We discuss below in detail our recommendations regarding the application of budget neutrality restrictions to the new payment system and the adoption of a conversion factor that establishes ASC rates as a percentage of the amounts paid for services rendered in the HOPD. In the view of OOSS and ASCRS, one indelible and unalterable principle of the new payment system – and one which is reflected in *The Ambulatory Surgical Center Medicare Payment and Modernization Act,* which is supported by virtually the entire ASC community -- is that the ASC/HOPD conversion factor should be applied evenly and uniformly to all services provided by ASCs, without regard to the type of service, the historic rates paid for such services, or the specialty or discipline of the ASC.

Alignment of the ASC and HOPD payment systems ensures fairness and administrative simplicity with respect to the rates paid to hospitals and ASCs, as well as among subsets of surgery centers. Importantly, in a system already hamstrung by payment limits attributable to budget neutrality requirements, special relief for a subset of facilities or services has the effect of inappropriately and inequitably diluting payment rates to the vast majority of ASCs. Establishment of a multiple rate structure would have the perverse impact of further distorting the alignment of the ASC and HOPD payment system, compromising the benefits of adopting the linkage between these outpatient surgical providers.

Device-Dependent Procedures. We understand that some parties within the ASC community are recommending that the discount (i.e., 38% under the NPRM) attributable to application of the ASC/HOPD conversion factor to ASC rates not be applied to the device portion of the ASC payment under the new system. We do not believe that this recommendation should be adopted in the final rule. Theoretically, ASCs may lack the purchasing power to secure costly devices at deeply discounted rates. However, under the current payment system with rates substantially below those of hospitals, ophthalmic ASCs, as efficient providers and prudent purchasers, have adopted new technologies and have offered new services encompassing

the use innovative and costly equipment and implants, making them available to literally millions of Medicare beneficiaries seeking vision-restoring surgery. Adoption by CMS of a medical device "hold harmless" provision would suggest that certain high-cost implantable medical devices are fundamentally different than all of the other items and services utilized in delivering surgical care. OOSS and ASCRS believe that special relief for device-dependent procedures will unfairly dilute the payment rates for all other services and should not be incorporated within the final regulation.

Dual or Multiple Conversion Factors Applied by Type of Service or Specialty of ASC. We understand that some within the ASC community are recommending that a higher percentage conversion rate apply to ASCs that offer services that would be subject to greater than average reductions under the new payment systems. In the alternative, some have suggested that a disproportionate share of any increase in the conversion factor incorporated within the final rule and attributable to the use of a more flexible and generous budget neutrality formula be applied to these facilities and services.

The ophthalmology community fully comprehends the concerns of those whose facility fees would decline under a new payment system. Yet, under every conceivable calculation of the impact by specialty of the proposed payment system on ASCs, centers that provide ophthalmic services bear by far the greatest aggregate reductions in ASC facility payments. Nonetheless, the ophthalmology, gastroenterology and pain management communities must recognize that these payment reductions are attributable in great measure to the fact that with respect to many of these services, e.g., CPT 66821 (after cataract laser surgery), facility payments formerly exceeded payments made to HOPDs. Under any system in which payment rates will be established as a percentage of HOPD, reductions in payment for services which were heretofore paid at HOPD rates will occur. Despite this hardship, we believe that the simple application of a uniform percentage conversion factor is fair and equitable, easy to administer, an appropriately aligns the ASC and HOPD payment systems.

Four-Year Transition. We agree that precipitous declines in reimbursement may, over the short term, threaten the viability of single-specialty ASCs that are not able to spread such shortfalls over a broader pool of surgical service offerings that are paid at higher rates. To address this problem, reimbursement increases and decreases imposed by the new payment system should be phased in over four years, rather than the two years proposed by the agency.

H. ASC Conversion Factor and Budget Neutrality {ASC Conversion Factor}

Our comments are premised on the concept that, ultimately, the benefits of reform of the ASC coverage and payment system to the beneficiary (greater access to high quality care at reduced out-of-pocket cost in a convenient and patient-friendly environment) and to the government (reduced program expenditures and more efficient program administration) will be realized only if payment is adequate to encompass the costs of the services provided. CMS' proposed rule falls short in this material area. While some specialties would realize increases in procedure payments, no increases are provided for the services in ophthalmology,

gastroenterology, and pain management that account for over 80 percent of the Medicare services furnished in ASCs. Indeed, CMS is reducing payment rates for CPT 66984 and 66821, both ophthalmic services which account for more than 86% of total ophthalmic ASC volume. In devising a payment system, CMS must recognize that almost two-thirds of ASCs are small businesses employing fewer than 20 employees and that half of the nation's surgery centers are single-specialty and have limited ability to compensate for losses in some procedures by augmenting volume in others.

Implementing a longer transition to the new system – as discussed above, we recommend four years – should enable facilities to adapt to the new system. However, payment rates must be established at reasonable and equitable rates if Medicare is to realize the benefits of payment reform and, importantly, ameliorate disruption in the provision of the services millions of beneficiaries have come to expect from ASCs. Simply stated, the 62% ASC conversion factor proposed by CMS is inadequate and unacceptable. In the industry's legislation, we have recommended that ASCs be paid at 75% of the rates paid to HOPDs. Based on extensive review of Medicare data files and analysis by the Lewin Group, we join our colleagues in the ASC industry in recommending that the conversion factor be set at 73.06%. This recommendation is reasonable, particularly in light of the fact that when Congress enacted the MMA requirement in 2003 – prior to the implementation of the freeze of ASC cost-of-living adjustments -- the budget neutrality calculation utilized in the NPRM would have yielded a conversion factor of 86%.

OOSS and ASCRS offer a number of recommendations regarding the calculation of the ASC conversion factor. As a basic principle, CMS should utilize the "alternative" budget neutrality proposal to calculate the conversion factor, with several adjustments that account for positive migration of procedures from the HOPD to the ASC attributable to payment increases, as well as negative migration from the ASC to the HOPD for services that will encumber reimbursement decreases.

We support the analysis provided by the ASC Coalition and the Lewin Group, which proposes to modify CMS' calculation of a 62% conversion factor by adding several methodological steps:

- **Use of 2007 ASC Rates for 2008.** CMS' calculation of costs for procedures subject to payment reductions in payment mandated by *The Deficit Reduction Act of 2005* failed to include the 2008 update that would be applied to HOPD rates in the absence of a payment system, **increasing the conversion factor to 63.01%.**

- **Inclusion of Costs for Separately Payable Devices.** Under the current ASC payment system, Medicare makes a separate payment to account for the costs of implantable prosthetics and durable medical equipment rather than incorporating these costs within the facility fee. The proposed system would bundle these services within the facility payment and the formula includes the cost within the denominator. Because these device costs have always been paid in the ASC and

presumably at comparable rates as in the past, the cost of the device must also be added to the numerator, **increasing the conversion factor to 64.42%.**

- **Migration of Services from Physician Offices to ASCs.** As discussed in detail above, hundreds of services the agency has proposed to add to the ASC list in 2008 are appropriately performed in physician offices. CMS has assumed that 15% of these services would migrate to the ASC; were this assumption valid, office-to-ASC migration alone would exceed the total volume of ASC services in 2005. In reality, once physicians equip their offices to perform these services, it is unlikely that a significant percentage will be performed in the ASC. We believe that it is more reasonable to assume that 2% of office services will migrate to the ASC, (and many of these same services will migrate from HOPD to ASC, saving Medicare outlays), **increasing the conversion factor to 66.53**

- **Treatment of Office Beneficiary Coinsurance.** In the calculation, CMS failed to incorporate savings incurred under budget neutrality for the rates that apply to procedures that are capped at the physician office practice expense rate. CMS should apply the 20% coinsurance to all services in the denominator, **increasing the conversion factor to 66.96%.**

- **Treatment of Variable Coinsurance Rates.** The conversion factor should be adjusted to account for the fact that while ASCs receive a copayment of 20%, HOPDs receive up to 35-40%. CMS should use total payments, **increasing the conversion factor to 68.00%.**

- **Migration of Current ASC Procedures Due to Price Changes.** The proposed rule assumes that, with respect to *new services added to the ASC list* in 2008, 25% of services will migrate from the HOPD to the ASC, generating program savings. Positive migration will also occur with respect to existing procedures on the ASC list if they are afforded significant increases. To model positive migration, CMS should assume, with respect to given procedures, that 1.5% of volume currently performed in HOPDs will move to ASCs for each 10% increase in payment, **increasing the conversion factor to 73.57%.** There would also be a cost to the Medicare program with respect to procedures that, by virtue of significant decreases in payment, migrate from the ASC to the more costly HOPD environment. CMS should assume for every 10% decrease in payment for a procedure, 1.5% of ASC volume will move to HOPDs, **decreasing the conversion factor to 73.06%.**

OOSS and ASCRS believe that establishing an ASC conversion factor of 73.06 would yield fair and reasonable payment rates, yet fully comport with the budget neutrality limitations imposed by the MMA.

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Thank you for providing our organizations with the opportunity to present our comments on the new ASC payment system. Should you have any questions, please do not hesitate to contact our Washington representatives: Michael Romansky, Washington Counsel, OOSS at mromansky@ooss.org or at 301.332.6474; or Emily Graham, RHIT, CCS-P, CPC, ASCRS Manager of Regulatory Affairs at egraham@ascrs.org or 703.591.2220.

Sincerely,

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