



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:

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- 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:

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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.

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- 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

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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.

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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)

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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

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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.

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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.

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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

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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

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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 operator 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

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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.

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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

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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,

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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

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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 egramham@ascrs.org or 703.591.2220.

Sincerely,



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