



August 30, 2011

Donald Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-P
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1525-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2012 Payment Rates

Dear Administrator Berwick:

The American Academy of Ophthalmology, the Academy, is the largest association of eye physicians and surgeons – Eye M.D.s – with more than 19,000 members in the United States.

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 10,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1,100 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ASCs. OOSS is also a member of the ASC Quality Collaboration (ASCQC), a cooperative effort of organizations and companies interested in ensuring that ambulatory surgical center (ASC) quality data is appropriately developed and reported.

Our members provide the vast majority of ophthalmic surgical procedures performed in ASCs in the United States. On behalf of The Academy, ASCRS, and OOSS, we are taking this opportunity to comment on this important proposed regulation. On behalf of The Academy, ASCRS, and OOSS, we are taking this opportunity to comment on this important regulation governing CY 2012 Medicare ASC payment rates and the proposed Quality Reporting Program for ambulatory surgical centers.

The nation's ophthalmic 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. Simply stated, at a time when public policy-makers are searching for meaningful health care reform -- improving quality and access, while reducing costs -- ASCs embody the potential to be a significant part of the solution; yet, elements of the proposed regulation, particularly the payment provisions, continue to thwart, rather than enhance the ability of our facilities to continue to serve the nation's Medicare beneficiaries. Studies conducted by a number of federal agencies (including CMS, the Government Accountability Office; the Medicare Payment Advisory Commission, the Office of the Inspector General (OIG), 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.

Since 1982, ASCs have gradually expanded their role in meeting the surgical needs of the Medicare population and have done so saving hundreds of millions of dollars annually. The KNG Consulting Group recently cited the important role that ASCs play in moving patients into clinically appropriate but lower cost surgical environments. While finding substantial growth in the number of cases furnished in ASCs during the period 2000-2007, the investigators determined that 70 percent of this growth was attributable to the migration of cases from the more costly hospital outpatient department (HOPD) to the ASC. With respect to the ophthalmic services rendered in the types of facilities utilized by the members of our organizations, KNG determined that *94 percent of the growth in cataract surgery cases in ASCs was attributable to migration from more costly HOPDs into lower cost ASCs.*

As such, cataract surgery in the ASC is emblematic of the phenomenon of the ASC becoming the choice of physicians and patients for site of surgery. About 1.7 million cataract surgeries occur each year in the Medicare population; in consultation with their ophthalmic surgeons, more than 60 percent of beneficiaries 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.

Under the proposed rule, payment for the cataract operation (CPT 66984) would be \$953, while reimbursement for the same procedure in the HOPD would be \$1,667. *For each cataract operation performed in an ASC instead of an HOPD, the program saves more than seven hundred dollars. Moreover, out-of-pocket spending by the Medicare beneficiary is always lower when care is provided in the ASC.* With nearly two million cataract surgery cases performed per year, the impact of savings to the program and the beneficiary by performing cataract surgery in the ASC is approaches \$1 billion annually.

We note that in preliminary Medicare data for 2010, there appears to be a slight reversal in the trend of cataract surgery being performed in the ASC setting. Our groups caution CMS that there is a point at which rates can be reduced too significantly and have ramifications that would be negative to the program and to the Medicare patients it strives to provide quality patient care.

I. SUMMARY OF RECOMMENDATIONS

Problems with the Current ASC Payment System

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS implement by January 1, 2008 a new ASC payment system. Our organizations and the entire ambulatory surgery community reached consensus on the appropriate contours of an equitable and rational program. In the final ASC payment regulation that became effective in 2008, CMS adhered to the spirit, if not the letter, of many of these principles, most importantly, that the new payment system should be modeled on the methodology and payment rates applicable to surgical services furnished in HOPDs. In reviewing the proposed 2010 payment rule, we expressed grave concerns that the continued use of the Consumer Price Index – Urban rather than the Hospital Market Basket (HMB) as the annual ASC inflator as well as maintenance of the rescaler to achieve budget neutrality would significantly widen the gap between the ASC and HOPD payment rates in ways that were unrelated to actual cost differences in the provision of care in the two settings. Just seven years ago, aggregate ASC payments as a percent of HOPD rates were 84 percent; when the new system was established in 2008, the percent has dropped to 65 percent; under the proposed 2012 rates, the percentage will be reduced to below 57 percent.

The Potentially Deleterious Impact of Current ASC Payment Policy on Beneficiary Access to ASC Services, Competition, and Program Savings

When the new ASC payment system was launched in 2008, CMS articulated a host of optimistic projections emanating from the new rules, ranging from diversification of the ASC industry to rapid volume growth as facilities enjoyed higher rates and eligibility to perform a broader list of procedures. At the time, the industry responded with concerns that the growth estimates were too aggressive and that the conversion factor the agency established was too low to promote significant migration of services into the lower-cost ASC environment. Today our concerns are being realized. New center growth in 2009 marked an all-time low and growth in new centers from March, 2010 to March, 2011 was just 2.1 percent. The volume of services provided by ASCs is unchanged since 2007 and 90 percent of the ASC services performed in 2009 were on the ASC procedures list before the list was expanded in 2008; when adjusted for changes in the Medicare fee-for-service (FFS) population, the volume per FFS beneficiary ophthalmology (and three other specialties) declined, notwithstanding the advances in technology that render ophthalmology so appropriate for the ASC.

The agency's utilization of the same rescaling mechanism and CPI-U update factor in the 2012 proposal will, we believe, further compromise the integrity of the ASC payment system, reduce realizable program savings, increase beneficiary out-of-pocket costs, and inhibit transparency regarding price and quality among Medicare providers, jeopardizing beneficiary access to affordable and high quality surgical care.

Summary of AAO/ASCRS/OOSS Recommendations

Since CMS decided almost a decade ago to overhaul the ASC payment system, our organizations have been engaged in discussions of ideas and data with the agency regarding the issues presented in this and recent rulemakings. We genuinely appreciate the agency's willingness to work with us and others within the ASC and ophthalmology communities and applaud CMS for the substantial work reflected in the development of the new payment system. With this same spirit of cooperation and commitment to formulating a rational and equitable ASC payment system, our organizations offer our specific comments, summarized below:

- ❖ CMS should adopt the Hospital Market Basket instead of the Consumer Price Index – Urban as the annual inflation index for ASCs, as the CPI-U is an unreliable indicator of ASC costs, with inputs unrelated to medical inflation or the delivery of surgical services. The market basket should be aligned with the HOPD productivity adjustment for purposes of adjusting ASC rates. **Finally, the agency should, in this year's update, correct for significant forecast errors in prior years.**
- ❖ CMS should cease the rescaling of ASC relative weights, which has had the effect of inappropriately reducing ASC payment rates and causing a substantial divergence in payment rates between HOPDs and ASCs that is **unrelated to the costs of delivering services in those settings.** The agency's assertions that scaling will not reduce ASC in perpetuity have not been borne out by experience.
- ❖ CMS should use the HOPD wage index for ASC payments to improve the coherency between the payment systems and to limit arbitrary variations in price at the local level.
- ❖ CMS should reverse its policy of designating certain procedures as “office-based” and **subjecting them to an arbitrary payment limitation.** These services should be subject to the same payment methodology as all other covered procedures.
- ❖ CMS should permit the billing for services under unlisted codes under similar

criteria for both hospitals and ASCS.

- ❖ With respect to several new drainage devices utilized to control intra-ocular pressure, we believe that these should be placed in APC 0673 rather than in APC 0234, as proposed by CMS.
- ❖ Our organizations also urge CMS not to finalize its proposal to conditionally package CPT code 65778 (placement of amniotic membrane on the ocular surface for wound healing; self-retaining) and instead adopt **the APC Panel's** recommendation to retain status indicator "T".
- ❖ With respect to the proposed ASC Quality Reporting Program, we recommend that: (a) the QRP should be open to *voluntary* reporting commencing January 1, 2012; (1) the performance period, against which payment decisions would be made, should not commence until January 1, 2014; (2) penalties should start at no higher than 0.4 percent, consistent with the inpatient hospital program; and, (3) the final regulation should clarify the specifics for data validation and completeness as well as the proposed process for reconsideration and appeals.

II. ASC INFLATION UPDATE AND THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT

The Academy, ASCRS, and OOSS object to the application of any mechanism that widens the gap between ASC and HOPD payment rates unless it captures actual differences in the costs of providing such care. During the past quarter-century, ASCs have been provided annual updates on only a sporadic basis and facilities received no adjustments for inflation for the period 2004-2009, notwithstanding the fact that our costs will have risen at levels that are commensurate with those of HOPDs. Under the proposed 2011 ASC payment rule, the inflation adjustment of 1.6 percent was essentially obliterated by the 1.4 percent productivity adjustment, which resulted in facilities having been without any meaningful update for seven of the past eight years. For 2012, the agency is proposing to provide less than a 1 percent increase. While we appreciate that, theoretically, CMS will be providing annual updates going forward, unless these adjustments are made on the basis of the HMB, it is unlikely that ASCs will see reimbursement rates that reflect the increases in the costs of providing services to beneficiaries.

The CPI-U does not reflect ASC cost growth; the HMB is a better proxy for ASC costs. The CPI-U measures the average change in prices over time of all goods and services purchased by households, primarily those related to food, transportation, and housing. The HMB 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. In the HMB, spending on wages and benefits represent nearly 60 percent of the index; on the other

hand, the CPI-U is dominated by inflation in the housing sector (about 42 percent of its weight). Over the past several years, we have seen great volatility in energy and housing prices drive huge swings in the CPI, factors that adversely affect our assigned annual update but are entirely unrelated to the costs of providing surgical services.

In its March, 2010 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) added its voice to the criticism of the CPI-U as the ASC update:

“Although the CPI–U is a widely used measure of price inflation that is updated on a regular basis by the Bureau of Labor Statistics (BLS), the mix of goods and services in this price index probably does not reflect ASC inputs. The CPI–U is based on a sample of prices for a broad mix of goods and services, including food, housing, apparel, transportation, medical care, recreation, personal care, education, and energy (IHS Global Insight 2009). The weight of each item is based on spending for that item by a sample of urban consumers during the survey period. Although some of these items are probably used by ASCs, their share of spending on each item is likely very different from the CPI–U weight. For example, housing accounts for 43.4 percent of the entire CPI–U (Bureau of Labor Statistics 2009).”

The very construction of the CPI-U limits its ability to predict ASC cost growth. The HMB, to the extent that it is applied to the hospital outpatient department, should be utilized to update ASC rates since the resources consumed by each in treating surgical patients should be virtually identical.

ASCs and HOPDs consume commensurate resources. CMS has not offered realistic evidence for the proposition that ASCs consume fewer or different types of resources than HOPDs. Indeed, the surgical services performed by ASCs are identical to those furnished by hospitals and the costs incurred by the freestanding facility 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.

Application of different inflators unjustly exacerbates the gap in payments to HOPDs and ASCs. Each year over the past decade, the HMB has exceeded the CPI-U by an average of about one percent. In combination with the application of the rescaler (discussed below) and the productivity adjustment that applies to ASCs, the continued utilization of different annual update measures is also inconsistent with the goal of aligning the HOPD and ASC payment systems. Applying the CPI-U to ASC payment rates for inflation drives a difference in the conversion factor between the HOPD and the ASC that is wholly unrelated to the actual cost of performing surgical procedures. In a regulatory system under which CMS should be 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. Application of the HMB to both the HOPD and ASC settings would ameliorate some of the divergence in payment rates.

Wide fluctuations in CPI-U forecasts demonstrate its inappropriateness as an ASC inflator. Theoretically, the index selected to update a provider's payment rates should reflect the projected increase in costs for the bundle of costs and services it will consume in the year ahead. With respect to 2011 alone, several CPI sources' forecasts reflected significant variance: OMB CPI-U – 1.5%; CBO CPI-U – 1.3 %; and, Blue Chip CPI-U – 3.1%. For 2012, these same sources vary from 1.3 to 2.2 %, while CMS has selected a CPI-U estimate of 2.3 percent, when offset by the productivity adjustment of 1.4 percent, yields another sub-inflationary adjustment of .9 percent. Importantly, during times of great uncertainty, CPI-U forecasts have varied even more significantly, reflecting substantial volatility. The very fact that these projections are so divergent suggests that it makes no sense for the agency to tie ASC inflation updates to the CPI-U when the HMB is based on the same bundle of supplies and services that should be applicable to both HOPDs and ASCs.

In establishing the 2012 update, CMS should adjust for forecasting errors in prior years. The Bureau of Labor Statistics recently reported that inflation for the 12-month period ending June, 2011 was measured at 3.6 percent, 2.1 percent higher than was afforded ASCs under the 2011 payment update. Had facilities been paid an update at this rate, ASCs would have realized an increase in spending of approximately \$68 million based on estimated 2010 spending under the 2011 rule. So that the agency is not penalized for forecasting errors, the agency should use its discretion under Sec. 1833(i)(2)(C) of the Social Security Act to provide an update other than the CPI-U to ASCs.

CMS has the authority to update ASC rates with the HMB. After an eight-year (except 2010) period during which ASCs received no inflation updates, expansion of the ASC industry has essentially been halted largely due to the constraints on Medicare payment discussed above. Given the potential for savings afforded by the migration of services from the HOPD to the ASC, it is imperative that CMS, at this juncture, make the right decisions as to payment issues such as the inflation adjustor. CMS acknowledged in its response to comments to the proposed 2008 ASC payment rule that it possesses “considerable discretion in determining an appropriate update mechanism” and that the CPI-U is mandated for update purposes only as “the default update mechanism in the absence of any other update.” We strongly believe that the HMB should be utilized to update the rates of both HOPDs and ASCs. Not doing so will exacerbate the differential in the conversion factors for the ASC and HOPD payments, far exceeding the original relationship established by the 2008 rule that established the new payment system. Such a differential cannot be justified by real differences in the increase in costs of the goods and services of ASCs and HOPDs and should not be perpetuated by CMS when it possesses the authority to make an administrative correction.

Multifactor Productivity Adjustment. Section 3401 of the Patient Protection and Affordable Care Act (ACA) revised the ASC payment methodology to require that rates be reduced by an additional “productivity adjustment” equaling the ten-year rolling average of the economy-wide, private, non-farm multifactor productivity rate (MFP). This provision was intended to encourage efficiency by reducing Medicare payments to reflect economy-wide productivity enhancements. We believe that the ASC Association, in its comments to this rulemaking, articulates important concerns regarding the appropriateness of using the MFP as a measure of ASC efficiency.

First, applying the MFP *and* the CPI-U essentially reduces ASC payment rates *twice* for productivity gains, hence requiring such providers to achieve twice the rate of productivity increases in order to break even. Second, because CMS uses different timeframes for application of ASC (calendar year) vs. HOPD (fiscal year) adjustments, there is a 0.4 percent discrepancy in updates between the providers; the agency should apply a single productivity factor to providers. Finally, economic factors that influence the hospital and ASC industries are not analogous to those of the overall economy and it is likely unrealistic to expect that health industries will be able to supplant labor with capital-intensive technology to the extent of manufacturing industries. The ASC community has, for years, demonstrated its ability to achieve efficiency in a manner directly relative to hospitals by providing care in ASCs with 43 percent less than HOPDs. While it is reasonable to expect that hospitals can generate further efficiency gains with the substantial “bonus” they receive over ASCs, it is unrealistic to assume that surgery centers can continue to do so, particular when their inflation updates are tethered to a CPI-U factor that is unrelated to its costs; we are fearful that this phenomenon will jeopardize beneficiary access to ASCs as facilities exit the market or convert to HOPDs. We urge CMS and Congress to consider appropriate reforms to the MFP process.

III. THE CONVERSION FACTOR AND RESCALING OF APC RELATIVE WEIGHTS

The Academy, ASCRS, and OOSS believe that CMS should, in the final regulation, reject the rescaling of the ASC relative weights, as this practice further exacerbates the gap between ASC and HOPD payments and inappropriately reduces payments to ASCs. As we have noted in our comments to past ASC payment rulemakings, our organizations strongly support the utilization of the same APCs and relative weights in creating a rational and coherent payment system encompassing the services offered by both HOPDs and ASCs:

“ . . . the rescaling of ASC relative weights . . . 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.*”

It is important to note that APC relative weights are already adjusted once for budget neutrality under the HOPD rules, resulting in rates that are less than 60 percent of HOPD rates. *When rescaling is added to the equation, the results are even more punitive: since 2008, when ASC rates were 65% of HOPD payments, the percentage has dropped to 61% in 2009 to 59% in 2010 to a projected 2011 percentage below 57% -- all reductions unrelated to the relative costs of providing such services.*

CMS is not required to maintain rescaling. Congress imposed a budget neutrality requirement on the new ASC payment system *only* during the inaugural implementation year of 2008; CMS is under no legal obligation to continue to apply rescaling and should not do so when it creates significant disparities in relative payments to ASCs and hospitals that are not related to the costs incurred in providing such services.

CMS was granted broad authority to establish the new payment system for ASCs based on the recommendations of the Medicare Payment Advisory Commission and the Government Accountability Office; both entities embraced the principle of revising the ASC payment system so that its relative weights and procedure classification groups are aligned with those of the HOPD system. CMS explains again this year that rather than using the HOPD relative weights in the ASC system, it is proposing to use a secondary rescaling to achieve year-to-year budget neutrality for ASCs. This reasoning is specious. Rescaling has been used in other payment systems where cost and volume data are derived directly from the providers affected by the rescaler; however, because CMS bases the ASC payment system off the HOPD relative weights, the weights should be equal in both settings.

The agency has also stated repeatedly that rescaling will *protect* ASCs from changes in the HOPD relative weights that could significantly reduce payments for certain procedures; there is little evidence to suggest that rescaling will have anything but a negative impact on ASC relative weights going forward. Because ASC volume is highly concentrated in a limited number of services, changes to the Outpatient Prospective Payment System (OPPS) rates for those procedures have a significant impact on the ASC scaler. Hypothetically, if the relative weights for the most common ASC services decreased in the HOPD, the ASC scaler would be positive to offset that difference. Yet, due to a variety of factors, in 2011, the scaler caused the weights and rates for the ASC services to often move in the opposite than expected direction – a change that reflects again how the annual recalibration process generates arbitrarily distorted results for the ASC vis-à-vis the HOPD that treats the same patient.

As such, we strongly recommend that CMS abandon the application of rescaling to the calculation of 2012 ASC payment rates. The budget neutrality calculation used to develop the conversion factor was designed to take into account the mix of services that surgical centers provide and establish a relationship between payments for procedures in the two settings. *Since the 2012 relative weights reflect actual growth in the relative cost of providing services in the HOPD, from this point forward, the relative difference in*

payments between the ASC and HOPD at the aggregate and procedure level should be driven only by changes in the conversion factor.

IV. AREA WAGE INDEX

The Academy, ASCRS, and OOSS strongly recommend that CMS utilize the same wage indices for both ASCs and HOPDs. As emphasized above, we believe that any differences in payments to ASCs and HOPDs should be attributable to actual differences in costs in providing services to Medicare patients. ASCs provide the same services to the same patients in their communities, and thereby directly compete for the same employees, particularly nurses and other health professionals. As such, the relationship between payments to ASCs and HOPDs should be consistent not just in the national rates, but also in each market.

For the inpatient and outpatient hospital systems, CMS applies a number of adjustments to the wage index that address market-specific or provider-specific competition for labor. The application of different wage index values between ASCs and neighboring hospital outpatient departments can result in payment differentials in excess of 45 percent, variations that are unrelated to the differences in treating a patient in the ASC compared to the hospital. These anomalies would be ameliorated by the use of the hospital wage index with relevant adjustments for both ASCs and HOPDs.

V. UNLISTED CODES

Another anomaly in CMS' effort to align the ASC and HOPD payment systems is the treatment of procedures for which there is not an appropriate CPT code. In some ASCs, surgeons utilize innovative techniques or new technologies to perform a procedure; this can mean that the service is not described by a specific CPT code. These services are reimbursed in the HOPD, but are not eligible for payment in the ASC. In the proposed 2008 ASC payment rule, CMS states that, without knowledge of the procedure's code, it cannot determine whether the procedure performed would have been excluded from the ASC payment under the rule's safety criteria. Although an unlisted code doesn't allow the reporting of specific procedures, the code does include the anatomic region of the service that could provide the basis for a determination about the safety of the procedure in the ASC.

With knowledge of the anatomic location, CMS should apply the safety criteria to the entire spectrum of services reportable by the unlisted code. Under such an analysis, the agency would determine that no procedure on the extraocular muscles would compromise patient safety, and that, therefore, any service encompassed by 67399, Unlisted procedure, ocular muscle, meets the safety criteria utilized to evaluate services furnished in the HOPD and should be reimbursed in the ASC. The same analysis would result in the conclusion that services encompassed by 67299, Unlisted procedure, posterior segment of the eye, should be covered in the ASC.

In addition to the CPT manual, CMS' construction of the APCs provides a means for identifying unlisted procedures that can be safely performed in an ASC. For example, with respect to APC 032, Level I Anterior Segment Eye Procedures, the grouper was constructed by bringing together services that were homogeneous in terms of clinical characteristics and resource consumption. Most of the dozen procedures in APC 032 are on the ASC procedures list, while the two that aren't have been designated as office-based, meaning that they are typically performed in a physician office; an unlisted code in this APC would be appropriate to report a procedure for which an appropriate CPT is not available. There are numerous other codes for Unlisted Procedures (66999, 67299, 67399, 67999, 68399, and 68899) that encompass services that meet any rational safety criteria (i.e., do not involve major blood vessels, major or prolonged invasion of body cavities, or extensive blood loss, or are emergent or life-threatening in nature) and should be eligible for reimbursement in the ASC. In our view, only one ophthalmic Unlisted Procedure, 67599, Orbit, might be subject to such safety limits.

We understand CMS' concern about providing a singular exemption for unlisted codes. *However, we believe that a uniform system to identify unlisted codes that are appropriate to bill the program and applicable to any specialty could be developed; our organizations and other surgical specialty groups would be delighted to work with the agency in effectuating such a policy.*

VI. APC CLASSIFICATION ISSUES

APC 0673 -- Level V Anterior Segment Eye Procedures

There are a number of newer glaucoma surgeries that involve the placement of drainage devices to control intra-ocular pressure (IOP). The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments (OTA) to evaluate new and existing procedures, drugs, and diagnostic and screening tests. In a recently approved OTA (a copy of which is attached), the newer devices show promise as alternative treatments to lower intraocular pressure in the treatment of open angle glaucoma and for such patients who require cataract surgery. In 2010, our organizations requested to the APC Advisory Panel that these devices be placed in similar APC's and we reiterate that request to CMS for 0253T (*Insertion of anterior segment aqueous drainage device, internal approach, into the suprachoroidal space*). By doing so, CMS will minimize any financial incentive or disincentive for performing these clinically similar procedures and provide better alignment and equity within the classification. In the 2012 proposed rule, CMS has proposed that 0253T, a similar device that is inserted into the suprachoroidal space rather than the trabecular meshwork as 0191T is defined, be classified in APC 0234.

These devices all perform clinically similar functions and are also priced similarly. We believe that these devices should all be in APC 0673. All of the codes in this category describe the insertion of a device to relieve ocular pressure associated with

primary open angle glaucoma. These include 66180 (*Aqueous shunt to extraocular reservoir (eg, Molteno, Schocket, Denver-Krupin)*), 0192T (*Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach*), 0191T (*Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach*) and 0177T (*Transluminal dilation of aqueous outflow canal; with retention of device or stent*). Conversely, none of the procedures described in APC 0234 describe a procedure that utilizes a stent or shunt that is retained within the structures of the eye. They are instead procedures that deal with direct repair or filtering which would have little if any device cost associated with it. For these reasons, we believe that 0253T should also be in APC 0673 rather than APC 0234.

CPT 65778 -- Placement of Amniotic Membrane on the Ocular Surface for Wound Healing; Self-Retaining

At its August meeting, the APC Advisory Panel recommended that CMS continue to assign status indicator “T” to CPT code 65778. CMS’ proposed rule decision to conditionally package CPT code 65778, changing its status indicator from “T” to “Q2” for CY 2012 is now inconsistent with that recommendation. Our organizations urge CMS not to finalize its proposal to conditionally package CPT code 65778 and **instead adopt the APC Panel’s recommendation to retain status indicator “T”**.

Retaining the proposed ruling will result in no payment for the procedure in most cases because CMS lacks that data necessary to ensure that the costs of the procedure are reflected in the costs of the independent services with which it is packaged. We are concerned that this payment indicator creates a financial disincentive for continuing utilization of these important procedures that have clearly been documented to promote healing for a variety of ocular surface diseases and conditions. Even though CMS has agreed to move this procedure into a higher APC, this is basically negated by the additional decision to bundle the device into that APC. The price difference between the two APC is not enough to cover the cost of the device with the decision to bundle. This will impede beneficiary access to this unique ocular reconstructive procedure in the less expensive, safe and convenient ASC setting. We had already received numerous complaints from members who have had to send patients to the hospital setting and now one of major eye trauma centers is reporting that their facility is contemplating discontinuing these services.

VII. PROPOSED QUALITY REPORTING PROGRAM FOR AMBULATORY SURGICAL CENTERS

PROPOSED QUALITY REPORTING PROGRAM FOR AMBULATORY SURGICAL CENTERS

Our organizations are pleased to comment on the agency’s proposal for the ASC Quality Reporting Program (QRP) and appreciate its diligent efforts to solicit input from the ASC industry and surgical community over the past couple of years. The Academy,

ASCRS, and OOSS share your goals of promoting maximum participation of facilities in the Program, generating meaningful information to consumers and other purchasers of surgical care, and achieving our mutual priorities of enhancing outcomes, quality, patient health and safety, and patient satisfaction. The ophthalmology community is committed to collaborating with the agency to meet these goals; the proposed QRP represents a first step – albeit with some deficiencies that we hope will be corrected in the final regulation.

Timeline and Implementation of the Quality Reporting Program

With the exception of about 1,200 ASCs that have participated in a voluntary quality reporting program administered by the ASCQC, our industry is new to quality reporting. The vast majority of facilities have neither collected nor reported data and it is only reasonable to provide ample time for ASCs to ramp up before fully undertaking these important responsibilities. As the lowest reimbursed of providers of surgical services, ASCs operate “lean and mean.” CMS estimates that almost three-quarters of ASCs meet SBA standards as “small businesses, *i.e.*, employing fewer than 20 persons; three years’ survey data of Outpatient Ophthalmic Surgery Society members reflect that over 80 percent of ophthalmic ASCs meet this threshold. Single-specialty facilities like ophthalmic ASCs (and those specializing in gastroenterology, orthopedic, and pain management) tend to be smaller, have fewer operating rooms and employees, and are more acutely sensitive to administrative burdens posed by regulatory burdens like quality reporting. Finally, it is important to note that, with ASCs having been afforded only very limited access to electronic health records (EHR) federal funding support, EHR use has not yet broadly penetrated the ASC industry. As such, it is imperative that both the quality measure and data submission requirements be administratively manageable, particularly during the embryonic period of the QRP initiative.

We have profound concerns regarding the agency’s aggressive timetable for implementation of the regulation as well as some significant lapses in clarity of the proposed regulation. The CMS has proposed that facilities commence reporting quality data on selected measures on January 1, 2012; *it would appear that these data would be used for the CY 2014 payment determination*. If, as in years past, the final ASC/OPPS payment regulation is published in late October or early November, ASCs will have less than 60 days to become educated with respect to the final requirements, develop and implement myriad processes and operational systems to implement the new program, and to launch data reporting. To put the arbitrariness of the timetable assigned to the implementation of the ASC quality reporting program in context, CMS provides inpatient and outpatient hospital departments *at least three months* advance notice to accommodate *changes* in ICD-9, CPT, NUBC, and HCPCS codes and *at least six months* notice for substantive changes to data elements that would require significant systems changes.

In order to promote optimum participation in the QRP and ensure **consistency with other providers’ reporting programs, we recommend that the following schedule be utilized before penalties are administered for failure to report in CY 2014.**

- The QRP should be open to *voluntary* reporting commencing January 1, 2012.
- The *performance period*, against which payment decisions would be made, should not commence until January 1, 2014.
- Penalties should start at no higher than 0.4 percent, consistent with the inpatient hospital program.
- The final regulation should clarify the specifics for data validation and completeness as well as the proposed process for reconsideration and appeals.

With regard to this final recommendation, CMS has demonstrated flexibility in the past in meeting the needs of smaller providers, such as hospice, first encountering quality reporting responsibilities; we would urge the agency to begin with more modest requirements imposed on ASCs as well. Alternatively, since CMS has proposed to publish standards for data validation and completeness in the 2013 regulation, we would suggest that the agency adopt a lower threshold for data completeness in 2012, given that providers will not know until late next year the rules by which they will be judged.

Measure Development -- Importance of Stakeholder Involvement

We applaud the work of the ASC Quality Collaborative and believe that its efforts are reflective of the importance of developing outcome and process measures through a collaborative process involving all interested stakeholders, including clinicians, medical associations, accreditation entities, and facilities. *As such, we are generally supportive of CMS' adoption of the four outcome measures endorsed by the National Quality Forum (NQF) for the CY 2014 payment determination, as well as the two ASCQC and NQF-endorsed facility-level process measures included in the QRP.*

However, we offer the following comments and concerns with respect to the development of measures going forward. As noted above, the AAO, ASCRS and OOSS are pleased with the breadth of stakeholder participation in the development of the measures ultimately included in the proposed regulation. When myriad interested parties are integrally involved in the process, accurate and meaningful clinical information will be reported and be made available to the government, providers, and patients. To the contrary, when clinicians familiar with the surgical care that is the subject of reporting are excluded from the process, the likelihood of developing a useful measure is nil. For example, in July, 2009, CMS issued a proposed cataract outcome measure that, if implemented, would have required hospital outpatient departments and, ultimately, ambulatory surgery centers, to determine whether a patient scheduled for cataract surgery would achieve a 20 percent improvement in vision, and, if not, disallow the procedure. *No ophthalmologist was directly involved in the development of the measure.* The studies purporting to demonstrate that significant percentages of cataract patients do not benefit from surgery were fundamentally flawed or their results misconstrued. The proposal ignored the voluminous data demonstrating the high success rate of cataract surgery and the improved quality of life of patients undergoing the procedure. Moreover, the data collection and reporting tasks that would have been assigned to the facility would have

been impossible for the hospital or ASC to successfully undertake. While the aforementioned cataract measure was ultimately withdrawn, the experience provides an excellent reminder of the importance of involving a broad array of interested parties.

Quality Data Reporting Mechanisms

The AAO, ASCRS and OOSS support the agency's proposal to collect data through the submission of quality data codes (QDC) on administrative claims. This approach is preferable to other options, such as retrospective chart abstraction, which would have a truly burdensome impact on day-to-day operations. *Finally, while there is currently no registry available as an option for the reporting of ASC services, we believe that registries may offer cost-effective alternatives to claims-based reporting in the future and should be considered, as appropriate.*

Data Collection and Submission Requirements for Claims-Based Reporting

The agency has deferred proposing the administrative requirements for the ASC Quality Reporting Program until the CY 2013 ASC payment rulemaking. We believe that the proposed rule is extremely vague as to what constitutes "successful" reporting, i.e., a complete submission. Moreover, it is unclear regarding how a facility should report with respect to a measure that may not be applicable to the services furnished by that type of ASC. For example, a center dedicated to the provision of ophthalmic services definitely should not be subject to process measures for Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264) or Appropriate Surgical Site Hair Removal (NQF#0515). Moreover, because the "cold" lasers utilized in ophthalmic surgery operate at a low intensity, we do not believe that Patient Burn (NQF#0263) would apply to an ophthalmic ASC. Given the significant variability in ASC case-mix, one can expect that from the outset of the QRP and into the future, there will be instances in which measures implemented will not apply to all ASCs. There are not codes that our members would report on in the measure specifications. We seek clarification that they would not need to be reported on by all ASCs, and that only those measures that apply need be reported.

We believe that during the initial phase of the QRP, CMS should be mindful of the ambulatory surgical facilities' lack of familiarity with reporting and permit centers to successfully report on a limited number of claims, e.g. 50 percent. This particularly makes sense during CY2012 and 2013, which we have recommended be designated as a voluntary reporting period, during which ASCs can be educated regarding their reporting responsibilities, receive meaningful feedback. Similar to the PQRS, CMS should consider whether 50 percent should remain the applicable threshold for the duration of QRP.

ASC Volume Data for Selected Procedures

The agency has proposed that in, CY 2015, ASCs report all-patient volume data for six broad categories of procedures. This measure is poorly conceived and drafted and would impose a considerable burden on facilities without generating meaningful information to consumers or the government. The ASC Quality Collaboration has outlined a series of questions that illustrate just how confusing and misleading the information emanating from this initiative be to the consumer. We concur with the ASCQC's recommendation that, instead, CMS consider the development of a system for outpatient surgery that is similar to its Hospital Compare website that offers the consumer an opportunity to choose from among many common inpatient operations, and then displays the volume of Medicare patients treated by each facility and across different facilities, assuring consistency and comparability. CMS should abandon this measure and develop a comparable approach to ASC volume that allows for consistent data development and publication of meaningful consumer information.

ASC Measure Topics for Future Consideration

The Academy, ASCRS, and OOSS look forward to working with the ASCQC, the NQF, other surgical organizations and CMS in the development of other outcome and process measures that will generate meaningful data on the quality of care provided by ASCs and enable patients to make informed decisions in choosing their providers of surgical services. With two-thirds of cases now performed in the ASC, our organizations are exploring appropriate topics for a quality outcome measure that is specific to the ASC facility and not the surgeon. We are pleased that the agency recognizes that the development of an effective measure, involving stakeholders and eliciting broad clinical and industry acceptance, is a process encompassing more than a year or two.

Publication of QRP Data

As we have stated elsewhere, our organizations welcome transparency and a fair presentation of ASC quality and cost information, particularly that which can be compared to other providers such as hospital outpatient departments that treat similar patients for the same conditions. At this point, the proposal specifies only that QRP-generated data will be displayed on a CMS website and presented at the level of the CMS Certification Number (CCN) and that facilities will be afforded an opportunity to preview any data made public. As additional safeguards for the ASC, CMS should provide contact information for program content area experts that facilities can contact to ask questions or raise concerns *prior to publication*. There should also be a provider narrative section for each provider-specific section presented to the consumer that would enable the facility to comment on the reliability or accuracy of the information presented and the ability to ensure corrections are made in a timely manner. We are aware of the considerable problems and issues facing the Physician Compare website and CMS should ensure that similar issues do not occur with ASC data. We also believe that the government should provide other useful information to the public, including facility

accreditation status. We look forward to reviewing and commenting upon more detailed elements of the QRP as they are issued in later rulemakings

Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2011 Medicare ASC payment rates. Should you have any questions or require further information please feel free to contact us at: Cherie McNett, Director of Health Policy, AAO, cmcnett@aaodc.org, 202.737.6662; Nancey McCann, Director of Government Relations, ASCRS, nmccann@ASCRS.org, 703.591.2220; or, Michael Romansky, JD, Washington Counsel, OOSS, mromansky@OOSS.org, 301.332.6474.

Thank you for your consideration of our views.

Sincerely,

American Academy of Ophthalmology
American Society of Cataract and Refractive Surgery
Outpatient Ophthalmic Surgery Society