September 4, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1589-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2013 Payment Rates

Dear Acting Administrator Tavenner:

The American Academy of Ophthalmology (The Academy) is the largest association of eye physicians and surgeons – Eye M.D.s – with more than 22,000 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 American Society of Retina Specialists (ASRS) is the largest retinal organization in the world, representing over 2400 members. Retina specialists are board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient 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. ASCQC developed the claims-based quality measures incorporated within the recent rulemakings governing ASC quality reporting.

Our members provide the vast majority of ophthalmic surgical procedures performed in ASCs in the United States. On behalf of The Academy, ASCRS, ASRS and OOSS, we are taking this opportunity to comment on this important regulation governing CY 2013 Medicare ASC payment rates and the Quality Reporting Program for ambulatory surgical centers. Particularly with respect to the latter, we are pleased that a number of the recommendations of the ASC and ophthalmology communities have been adopted and appreciate the close collaboration between industry, medicine, and the agency that has characterized the development of the QR program.

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.

Since 1982, ASCs have gradually expanded their role in meeting the surgical needs of the Medicare population and have done so saving billions of dollars annually. The KNG Consulting Group in 2009 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. This means that ASCs are not creating new volume, but rather, reducing the cost of services that would otherwise be furnished in the hospital environment.

Under the proposed rule, payment for cataract removal (CPT 66984) would be $978, while reimbursement for the same procedure in the HOPD would be $1,670. The beneficiary's financial obligation in the form of copayments is $193 in the ASC and in the range of $334 to $490 in the HOPD; it is always lower in the ASC. Therefore, for each cataract operation performed in an ASC instead of an HOPD, the program and beneficiary save more than seven hundred dollars. 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 well into the hundreds of millions of dollars annually. Yet, the number of cataracts performed in the ASC declined in 2011 and aggregate spending for CPT 66984 dropped to $31.2 million, or 3 percent, below 2010 levels. This trend is disturbing because it appears to be industry-wide; eight of the highest volume ASC procedures experienced decreased in aggregate spending. Our organizations caution CMS that there is a point at which the continued disparity between ASCs and their HOPD counterparts will have negative ramifications for the program and to the Medicare patients for whom it strives to provide quality surgical care.

I. SUMMARY OF ASC PAYMENT 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. Over the past five years, we have expressed grave concerns that the continued use of the Consumer Price Index – Urban (CPI-U) rather than the Hospital Market Basket (HMB) as the ASC update factor as well as maintenance of the rescaler to achieve budget neutrality will continue to 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. (As discussed below, while we appreciate the agency's consideration of establishing an ASC-specific update factor, we strongly believe that the HMB is the most appropriate measure of inflation in the ASC environment and that CMS should incorporate this policy in the final rule.)

Failure to increase payments to ASCs to reflect inflationary pressures cannot help but exacerbate disturbing trends in ASC payment, beneficiary access, program expenditures, and competition between the HOPD and ASC. Just eight years ago, aggregate ASC payments as a percent of HOPD rates were 84 percent; when the new system was established in 2008, the percentage had dropped to 65 percent; under the proposed 2013 rates, the percentage will be further reduced to approximately 57 percent. This change in rates is the result of the application of different inflation updates and an irrational and punitive budget neutrality policy and is entirely unrelated to the cost of providing services to Medicare patients within the respective outpatient surgical environments. We note that in comparing 2010 and 2011 Medicare service volume, there appears to be a slight reversal in the historic trend of cataract and other ophthalmic services being performed in the ASC setting, as allowed services declined by almost two percent. Similar declines in services were experienced by five of eleven specialties that practice in ASCs.

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. We noted in our comments a year ago that new center growth in 2009 marked an all-time low; even fewer ASCs opened in 2010 and 2011. Moreover, these historic lows in ASC growth are actually occurring at a time that the outpatient surgery market is expanding; however it appears that new volume is being added to the more costly HOPD facility.

Several members of Congress have expressed similar concerns to the agency about the payment system and resulting migration back to the hospital. We understand that both the agency and the Office of the Inspector General, HHS, are investigating these issues, particularly the increasingly prevalent practice of hospitals acquiring ASCs and converting them to HOPD status, thereby enabling the new entity to receive substantially higher payments for the same services delivered to the same beneficiaries. Our organizations strongly believe that immediate adoption of the payment recommendations of the ASC and ophthalmology communities to mitigate the continued divergence of ASC and HOPD rates would slow, if not reverse, this irrational and costly migration trend.

The agency's continued utilization of the CPI-U as an update factor and rescaling to achieve budget neutrality in the 2013 proposal will, we believe, further exacerbate distortions in payment rates to ASCs and hospitals and 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, high quality surgical care.

Summary of AAO/ASCRS/ASRS/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 review of data with the agency regarding the issues presented in this and recent rulemakings. We genuinely appreciate the agency's willingness to work with the ASC industry, the ophthalmology community, and others. With this same spirit of cooperation and commitment to formulating a rational and equitable ASC payment system, we join the ASC industry and other surgical specialty organizations in offering 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. Further, the market basket should be aligned with the HOPD productivity adjustment for purposes of adjusting ASC rates. The agency should forego development of an ASC-specific inflation factor, but if it proceeds, should utilize the Hospital Market Basket on an interim basis.**

- **CMS should utilize the same wage index for the ASC and outpatient hospital environments to improve the correlation between the payment systems and to limit arbitrary variations in price at the local level.**

- **CMS should permit the billing for services under unlisted codes under similar criteria for both hospitals and ASCs. CMS should modify its policy for establishing payments for device-intensive procedures to encourage, rather than inhibit, the migration of services to the less intensive ASC setting.**

- **CMS should embrace several principles in implementing the ASC Quality Reporting Program, including: aligning measures across payment and reporting lines; ensuring that data submission requirements are administratively manageable and that measures adopted for the ASC assess aspects of patient care that are directly attributable to the surgery center; involving all relevant stakeholders, particularly clinicians, in the measure development process; and, updating quality measures on a timely basis.**

- **With respect to Measure ASC-5, CMS should adopt a "no volume" or "not applicable" exemption for facilities that never administer prophylactic intravenous antibiotics, or at a minimum, better clarify its position in the Specifications Manual. The agency should make specifically recommended changes to Measure ASC-6 (Safe Surgery Checklist) and Measure ASC-7 (ASC Facility Volume on Selected Surgical Procedures).**

- **CMS should narrow the time gap between quality reporting periods and payment adjustments. Moreover, CMS should permit ASCs to meet quality reporting data requirements by using CMS-approved registries.**

- **CMS should provide safeguards to providers that enable them to have access to data that will be made public, comment on its reliability and accuracy, and, make corrections thereto.**

- **CMS should limit to plus or minus five percent any changes in payment rates to ASCs that result from the recalibration of APC cost estimates from the median to the geometric mean.**

II. ASC INFLATION UPDATE AND THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT

The Academy, ASCRS, ASRS, 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; subsequent updates have been meager and always lower than those received by HOPDs. Under the 2012 payment rule, ASCs received a 1.6 percent increase to account for inflation. Under the proposed 2013 ASC payment rule, the CPI-U adjustment of 2.2 percent would be substantially reduced by the 0.9 percent multi-factor productivity adjustment (mandated by statute). Every year, the HOPD receives a higher increase than that afforded the ASC, notwithstanding the fact that surgery centers are treating the same patients for the same conditions and expending comparable resources to provide that care. 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 reflects 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. A comparison of the weights placed on goods in the CPI-U with those in the HMB demonstrates the fundamental differences in spending by consumers and hospitals. The CPI-U is dominated by inflation in the housing sector (accounting for about 40 percent of its weight); with respect to the HMB, about 60 percent is attributable to wages and benefits and virtually no weight is allocated to housing. As such, 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 hospital outpatient departments, should be utilized to update ASC rates since the inflationary pressures on HOPDs and ASCs, e.g., hiring personnel and purchasing equipment and supplies, are 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. Therefore, 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. As discussed below, the higher inflation update certainly provides an incentive for hospitals to acquire ASCs and immediately increase revenues by converting the surgery center to an HOPD.

Application of different inflation factors 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 and the productivity adjustment that applies to ASCs, the continued

utilization of different annual update measures totally compromises 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 conversation 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 2012 alone, several CPI sources' forecasts reflected significant variance: OMB CPI-U – 2.2%; CBO CPI-U – 1.7 %; and, Blue Chip CPI-U 2.3%. For 2013 projections, these same sources vary from 1.5 to 2.2 %, while CMS has selected a CPI-U estimate of 2.2 percent, which when offset by the productivity adjustment of 0.9 percent, yields another sub-inflationary adjustment to ASCs of 1.3 percent. Yet, the HMB for 2013 is projected to be 3.0 percent, which as in years past, is almost a point higher than the CPI-U utilized to calculate the ASC inflation update. 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.

CMS should forego development of an ASC-specific market basket. CMS has requested comments regarding the establishment of an ASC-specific market basket to be utilized to determine the annual ASC inflation update. We embrace the views of the ASC Association and others within the ASC and surgical communities in expressing our skepticism regarding the viability of establishing an index that will better reflect ASC cost growth than the Hospital Market Basket:

- **Given the heterogeneity of the centers comprising the ASC industry, an ASC-specific market basket would move us no closer to the full alignment of parallel payment systems than any other index, except the application of the update that is applied to HOPDs.** As demonstrated by past endeavors of CMS, the GAO, and the OIG to ascertain ASC costs, we do know that there is significant variation in the cost weights among ASCs representing different specialties. Indeed, most facilities are specialized and have cost structures that are aligned with the cluster of the highest volume procedures they provide. There would, for example, be very little similarity between the relative weight of the cost components of an ophthalmic ASC and a GI center or an ASC that serves multiple specialties. While an ASC-specific index would use different weights and price proxies from the CPI-U, the cost weights would likely be no more accurate for any particular center.

- **Efforts by the agency in the past to collect the type of cost data that would be required to develop an ASC-specific factor have been unproductive.** The last comprehensive survey of ASC costs in 1994-6 resulted in the submission of data that was unreliable and inequitable rates that were based on a flawed payment methodology. For these reasons, the agency abandoned the use of a survey methodology to establish ASC rates and, working with industry, developed a system that was intended to align the payments systems of the ASC and HOPD. That was and should remain our goal. Just three years ago, as part of the 2010 ASC payment rulemaking, CMS solicited industry comment on the feasibility of requiring facilities to submit cost reports to the agency. Our views remain the same: since ASCs are not experienced in collecting and providing reliable cost data, the agency has not demonstrated the capability to effectively analyze such data, and the HMB is an adequate proxy for cost growth, it is unnecessary and burdensome to devote provider and governmental resources to developing an

alternative index to the HMB.

- **CMS should immediately adopt the Hospital Market Basket as the update factor pending any efforts to develop an alternative ASC-specific index.** CMS and MedPAC have both acknowledged that the CPI-U is not an accurate proxy for inflation in the ASC. In the past, CMS has selected the best available proxy when no direct means of measuring the cost weights and price proxies is available. Indeed, the agency has admitted that the hospital market basket is an imperfect measure of HOPD costs, particularly in light of expansion and diversification of hospital services. Yet, according to the Office of the Actuary, separate market baskets for the inpatient and outpatient sectors have not been developed in part because CMS is unable to separate the cost categories developed from the Medicare cost reports into inpatient and outpatient services. Hence, there is precedent for adoption of a best available index. While the HMB might be an imperfect measure of ASC costs, it is certainly more accurate than the CPI-U in that it reflects producer price inputs, measures health care deliver-related costs, and is utilized by the HOPD setting that provides a similar mix of services. The agency should, at the very least, adopt the HMB as the inflation update factor for ASCs until such time that a more accurate one is developed.

Modifications should be made to the Multifactor Productivity Adjustments for ASCs. 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 will always be a discrepancy in updates between the providers; the agency should apply a single productivity factor to all 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 relative to the hospital; yet, 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 HOPD status. **We urge CMS and Congress to consider appropriate reforms to the MFP process.**

III. AREA WAGE INDEX

The Academy, ASCRS, ASRS, 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 or the development of a comment wage index applicable to all outpatient surgical services.

IV. UNLISTED CODES

An important 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 extra ocular 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 listing, 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 group 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 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 can and should be developed; our organizations and other surgical specialty groups would be delighted to work with the agency in effectuating such a policy.

V. PAYMENTS FOR DEVICE-INTENSIVE PROCEDURES

Like hospitals, ASCs have occasion to use expensive devices and operative supplies during certain surgical procedures. Although surgery centers are adept at achieving greater operational efficiencies than HOPDs, they are not able to extract greater discounts on devices and supplies than hospitals. Unfortunately, many procedures with high fixed costs are not designated as device-intensive on the ASC list. Moreover, CMS has proposed changes in its policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit that will further result in arbitrary and irrational reductions in payments to ASCs for certain services.

CMS should modify its policy for reimbursement of device-intensive services to encourage, rather than inhibit, the migration of services to the less intensive ASC setting. As long as an ASC-approved procedure has fixed costs that can be captured in the OPPS median cost data, we believe that the procedure should be protected from the full application of the conversion factor, enabling the facility to be fully paid for the fixed cost of the device. Second, CMS should establish the device intensive threshold as a percentage of the ASC rate, rather than the OPPS relative weight.

VI. RECALIBRATING APC COST ESTIMATES FROM THE MEDIAN TO THE GEOMETRIC MEAN

In the proposed rule, CMS is proposing to recalibrate the relative payment weights for APCs by changing how it calculates costs from the previous mean of estimated costs to the geometric mean of cost estimates. Our groups recognize the Secretary's authority to make this adjustment; however, we are concerned about the dramatic changes that occur with respect to some ophthalmic and other surgical services, i.e., decreases in payment of more than 30 percent for some codes. In order to ameliorate the destabilizing impact of significant and immediate changes in payment rates, we would recommend that CMS consider applying a limit on any changes in payment of plus or minus 5 percent.

VII. QUALITY REPORTING PROGRAM FOR AMBULATORY SURGICAL CENTERS

Our organizations appreciate the agency's diligent endeavors to solicit input from the ASC industry and surgical community over the past couple of years and are pleased to comment on the agency's proposal for the ASC Quality Reporting Program (ASC QRP) and appreciate its diligent efforts to solicit input from the ASC industry and surgical community over the past couple of years. We applaud the extensive effort CMS has undertaken to prepare for implementation of the new program and for the agency's acceptance of many of the recommendations of the ASC and surgical communities, including those of our organizations. The Academy, ASCRS, ASRS, and OOSS share CMS' 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 continued collaboration with the agency to meet these goals; the ASC QRP represents a positive first step – albeit with some deficiencies that we hope will be corrected in this and future rulemakings.

Quality Reporting Criteria

We appreciate the agency's flexibility with respect to compliance with quality reporting criteria during the early years of the program. The penalty for failure to meet quality reporting criteria is onerous -- a two percent reduction in the facility's annual payment update. While we are disappointed that CMS did not as we

recommended phase in penalties over a one- or two-year transition, we applaud the decision to recognize centers as having met their quality reporting obligations by successfully reporting the measures on 50 percent of their claims for 2014 and 2015 updates. We are also grateful that the agency will provide additional time for ASCs to submit reconsideration requests to avoid these penalties, as well as grant waivers and extensions to facilities that have suffered "extraordinary circumstances" that impede impeding their ability to participate. This demonstration of flexibility and fairness will promote participation in the program and ensure that accurate information is submitted by facilities to the agency.

Principles for the ASC QRP

The agency has outlined general principles it has applied in the selection of measures included in its other quality reporting programs. We offer our thoughts with respect to these principles that should apply to the ASC QRP:

- **Data should be reported across payment systems.** In addition to promoting quality in the ASC, one ultimate goal of a quality reporting program is to ensure that beneficiaries have access to meaningful data from which they can make informed selections regarding which specific provider will furnish their care. Therefore, we join the ASCQC in urging CMS to make every effort to align measures across reporting and payment systems, enabling the patient to determine which type of provider (e.g., HOPD vs. ASC) might be desirable for surgical services, as well as the appropriate specific facility. As such, the five claims-based measures adopted for the ASC QRP could be applied to HOPDs, generating expanded comparative data available to Medicare.

- **The quality data submission requirements of the ASC QRP must be administratively manageable.** CMS has indicated that it will continue to seek adoption of electronic-specified measures so that data can be calculated and efficiently submitted via certified electronic health records (EHR) technology. While the objective is laudable, the agency should recognize that the approach is not practical for most ASCs at the current time. As the lowest reimbursed of providers of surgical services, ASCs operate "lean and mean." 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, typically, will have available lesser resources to meet the administrative burdens posed by regulatory initiatives like quality reporting. Moreover, ASCs have not been provided access to electronic health records (EHR) federal funding support. As such, EHR use has not yet broadly penetrated the ASC industry.

- **Physician-level quality measures should not be adopted for non-physician providers such as ambulatory surgical centers.** ASC quality measures must reflect those aspects of patient care that are directly attributable to the facility itself (i.e., its staff, equipment, and role in the delivery of care) and for which it is reasonable to hold the ASC accountable. 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. The data collection and reporting tasks that would have been assigned to the facility – including the collection and evaluation of records only available in the surgeon's clinical practice -- would have been impossible for the hospital or ASC to successfully accomplish. While this cataract measure was ultimately withdrawn, the experience provides an excellent reminder of the importance of devising and implementing measures that directly reflect responsibilities attributable to the ASC.

- **All relevant stakeholders should be afforded the opportunity to participate in the measure**

development process. When myriad interested and informed parties are integrally involved in the process, accurate and meaningful clinical information will be reported and made available to the government, providers, and patients. Conversely, when clinicians and others familiar with the surgical care that is the subject of reporting are not included in the process, the opportunity to develop of a useful measure is substantially compromised. The Academy, ASCRS, ASRS, and OOSS are generally pleased with the measures that will be implemented on October 1, in great part because they emanated for the very rigorous consensus approval process of the National Quality Forum (NQF). Referring again to the agency's proposed cataract measure in 2009, we are skeptical of the agency's position that consensus among interested parties can be thoroughly and effectively garnered through other means, such as alternative measure development processes, broad acceptance and use of a measure, and through public comment. Ophthalmologists were not directly involved in the development of the aforementioned cataract measure. The studies purporting to demonstrate that significant percentages of cataract patients do not benefit from surgery were fundamentally flawed or their results misconstrued. Finally, the proposal ignored the voluminous data demonstrating the high success rate of cataract surgery and the significantly improved quality of life of patients undergoing the procedure.

- **CMS should make timely updates to measures with input from stakeholders.** When a national consensus building entity (such as NQF) updates measure specifications, the agency should update its specifications as well. CMS should also consider the changes made by the developers and stewards of measures, as these can occur at any time based on a change in evidence, consensus standards or other factors. With respect to measures that are not endorsed by a national entity, the agency should consult with ASC clinical and operational experts. Technical Expert Panels charged with the maintenance of these measures should include substantial representation from the ASC industry and relevant surgical specialty societies.

Comments Regarding Specific Quality Measures

Prophylactic Intravenous (IV) Antibiotic Timing (ASC-5). In our respective organizations' comments regarding the Hospital Inpatient Prospective Payment System regulation (CMS-1588-P), we strongly objected to the requirement that all facilities, including those that never provide services requiring prophylactic IV antibiotics, file claims using QDC G8918 denoting that IV therapy was not utilized. Virtually without exception, ophthalmic ASCs administer topical, rather than IV, antibiotics for SSI prevention. The collection of this data will not generate any information that can be used in performance improvement or to inform consumer-decision making; as such, the policy imposes an unnecessary regulatory burden on for ASCs that do not administer prophylactic IV antibiotics.

CMS has determined that it will not provide for an exemption from reporting on this measure. The Academy, ASCRS, ASRS, and OOSS urge the agency to reconsider its position and adopt a "no volume" or "not applicable" exemption for facilities that certify that they never administer prophylactic IV antibiotics. The agency could develop a G-code that would be submitted on a one-time (or annual) basis that reflects the facility's confirmation that it does not administers IV antibiotic prophylaxis for SSI. Alternatively, such an exemption could be claimed through the facility's Quality Net account. This would ameliorate the burden of many ASCs that never use prophylactic IV antibiotics from having to repeatedly include code G8918 on all of their Medicare claims. If CMS adheres to its current policy, it should revisit the need for compliance with Measure ASC-5 if a year or two of experience in the ASC QRP confirms that, as we know to be the case, ophthalmic (and perhaps other specialty ASCs) do not use prophylactic IV drugs.

We do appreciate that CMS has at least taken steps to better clarify its position that all ASCs must report on

Measure ASC-5. However, we are concerned that facilities may remain confused by the Manual's internally inconsistent instructions regarding the use of G8918. In one sentence the manual states, "CMS requires all facilities to report on the ASC-5 measure for all Medicare fee-for-service patients, even if there is no indication for or order for perioperative antibiotics (G8918)" (emphasis added). In the very next sentence the manual states, "IMPORTANT: For surgical patients with an order for prophylactic antibiotics, information on the fifth measure, Prophylactic IV Antibiotic Timing, will be reported separately." We also note that due to the late release of the updated manual, many ASCs may not be aware of the revised reporting instructions.

Safe Surgery Checklist (ASC-6). Our organizations support the use of safe surgery checklists and have, indeed, developed a guideline checklist for use by ophthalmic ambulatory surgical centers. We are very pleased that on the Quality Net website, the agency has clarified that, with respect to 2012, the first year of implementation of this measure; a facility will be deemed to be in compliance upon affirmation that a checklist was utilized at any time during the year. The Specifications Manual, however, indicates that a facility is to report whether the checklist was used "during the designated period" (emphasis added), suggesting potentially more extensive application of the measure; we urge CMS to update the Specifications Manual to include the information provided on the Quality Net website.

ASC Facility Volume on Selected Surgical Procedures (ASC-7). The agency has finalized Measure ASC-7, which specifies that, in 2013, ASCs must report all-patient volume data for six broad categories of procedures performed between January 1, 2012 and December 31, 2012. As we stated a year ago, 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. Moreover, the measure specifications are not sufficiently detailed to ensure consistent data preparation and reporting. We believe that CMS must more effectively clarify this measure or abandon it altogether.

Reporting Periods

CMS proposes to base the 2015 payment adjustment on data reported during 2013. The Academy, ASCRS, ASRS, and OOSS continue to have concerns with CMS' policy of basing payment adjustments on participation in quality reporting programs a full two years before the payment adjustment is scheduled to occur. We believe this policy of backdating the payment adjustment is confusing to facilities and goes against what Congress intended when it authorized CMS to create a quality reporting program for ASCs. We urge CMS to look for ways to shorten the gap between the reporting period and the payment adjustment for the ASC Quality Reporting Program.

Quality Data Reporting Mechanisms; Electronic Health Records

The Academy, ASCRS, ASRS, and OOSS support the agency's proposal to collect data through the submission of quality data codes on administrative claims at the outset of the ASC QRP. However, we believe that CMS should also permit ASCs to meet the quality data reporting requirements under the program by using CMS-approved registry-based reporting. The agency has provided physicians (and other providers) with multiple data reporting options under the Physician Quality Reporting System (PQRS) – the Ophthalmic Patient Outcomes Database is one such example – and ASCs should be afforded the same flexibility.

The ASC Quality Collaboration is considering the development of an ASC-specific registry that would collect data from participating facilities on a broad variety of quality measures, including those adopted by CMS under the

ASC QRP. For planning and development purposes, it is important that the agency clarify whether registry-based reporting will be an option available to ASCs. Our organizations are excited about the prospect of an ASC registry as a cost-effective alternative to claims-based reporting in the future.

CMS should also permit the submission of quality data through an EHR-based reporting mechanism to accommodate those facilities that have adopted the technology. This will be particularly helpful if an ASC registry is developed by the ASC Quality Collaboration.

Publication of QRP Data; Feedback to Providers

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 by consumers to other providers such as hospital outpatient departments that treat similar patients for the same conditions.

As safeguards for the ASC, CMS should provide contact information for program content area experts so that facilities can reach appropriate agency personnel 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 make timely corrections. 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 proposals governing the publication of ASC quality data.

We note that CMS finalized plans in the final 2013 Inpatient Prospective Payment System rule to issue a confidential feedback report to ASCs that participate in the QRP on an annual basis. In addition to providing confidential feedback to ASCs, CMS may also consider making the data collected through the program available to participating ASCs for benchmarking purposes, thereby enabling facilities to measure their performance relative to their peers and to effectuate actions that might improve performance going forward.

ASC Measure Topics for Future Consideration

The Academy, ASCRS, ASRS, and OOSS note CMS' continued interest in developing procedure-specific measures for ASC quality reporting. We 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 would be appropriate for and specific to the ophthalmic ASC.

The ASC industry believes that several principles should guide the process through which new measures are adopted for the ASC QRP. First, the measures must reflect aspects of patient care that are within the sphere of influence of the ASC and necessarily congruent with the responsibilities and capabilities of the surgery center. Second, CMS should focus on measures that have been developed by the ASCQC or other relevant organizations and endorsed by the NQF, thereby ensuring that the measures have been vetted by interested stakeholders and will likely be broadly accepted by the ASC and surgical communities. Third, new measures should be meaningful decision-making tools, generating information that is relevant to the consumer's health care decisions. If the agency is mindful of these principles, we will avoid the promulgation of measures such as the cataract outcome

proposal published in 2009 and then withdrawn.

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Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2013 Medicare ASC payment rates and the ASC Quality Reporting Program. 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; Pravin Dugel, MD, Chairman of the ASRS Government Relations Committee at pdugel@gmail.com, 602.222.2221; 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
American Society of Retinal Specialists
Outpatient Ophthalmic Surgery Society