

September 2, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

Re: CMS-1613-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2015 Payment Rates

Dear Administrator Tavenner:

The American Academy of Ophthalmology (The Academy) is the largest association of eye physicians and surgeons – Eye M.D.s – in the world with more than 19,000 members in the United States. The mission of The Academy is to advance the lifelong learning and professional interests of ophthalmologists to ensure that the public can obtain the best possible eye care

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 2,400 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.

The Society for Excellence in Eyecare (SEE) is a professional organization of ophthalmologists dedicated to education its members about the most effective and advanced developments in ophthalmology, developing and implementing standards of practice for the effective and ethical provision of ophthalmologic services to patients, and serving as an advocate for patients in the promotion of high quality, cost-effective eye care services.

Our members provide the vast majority of ophthalmic surgical procedures performed in ASCs in the United States. On behalf of The Academy, ASCRS, ASRS, OOSS, and SEE, we are taking this opportunity to comment on this important regulation governing CY 2015 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 in the recent past and appreciate the close collaboration among industry, medicine, and the agency that has characterized the development of the QR program. However, as noted below, we continue to object to the agency's proposed adoption of one ophthalmic measure, ASC-11, even for purposes of voluntary reporting because it is inappropriate for application to ASCs.

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 migrating 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 (94 percent, with respect to cataract surgery) 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. {Koenig, Lane *et al*, KNG Health Consulting, "An Analysis of Recent Growth of Ambulatory Surgical Centers," June 2009}

- An analysis conducted by the University of California-Berkeley in 2013 determined that ASCs saved the Medicare program and its beneficiaries \$7.5 billion from 2008 to 2011 over what they otherwise would have expended had their care been provided in other settings. In 2011, cataract surgery alone accounted for \$829 million in savings to the program. Extrapolated to 2022, the projected savings for Medicare and its beneficiaries range from \$1.5 billion to \$2.95 billion per year. {University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, September 2013}.
- In 2014, the Office of the Inspector General, HHS issued a report in which it determined that surgery performed in ASCs from 2007 to 2011 saved the Medicare program almost \$7 billion and beneficiaries an additional \$2 billion, citing even greater potential savings in the future. Importantly, the OIG found that 68 percent of patients receiving outpatient surgery have no-risk or low-risk profiles, meaning that with respect to a significant majority of these cases, surgery can be performed safely and effectively in ASCs. With respect to cataract surgery, the highest volume surgical procedure furnished in both HOPDs and ASCs, only in the rarest of instances is the service not appropriate to be performed the ASC. {U.S. Department of Health and Human Services. Office of Inspector General. Washington: Government Printing Office, April 2014. (A-05-12-00020)}
- A study published this year in the journal *Health Affairs* concluded that not only did ASCs perform outpatient surgery as effectively and more efficiently than HOPDs, but they “provide high quality care, even for the most vulnerable patients.” {Munnich, Elizabeth L. and Stephen T. Parente. “Returns to Specialization: Evidence from the Outpatient Surgery Market.” *Health Affairs*, April 2014}

Under the proposed rule, facility payment for cataract removal (CPT 66984) would be \$957, while reimbursement for the same procedure in the HOPD would be \$1,767. The beneficiary’s financial obligation in the form of copayments is \$193 in the ASC and in the range of \$350 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 \$800. With nearly three million cataract surgery cases performed per year, the impact of savings to the program and the beneficiary by performing cataract surgery in the ASC, as confirmed now by a multitude of studies and reports, is well into the hundreds of millions of dollars annually. Yet, overall growth in Medicare spending on services provided in the lower-cost ASC has been at historic lows – approximately 3 percent per year. Our organizations caution CMS that there is a point at which rates can be reduced too much with negative ramifications for the program and for Medicare patients while ASCs strive to provide quality surgical care.

I. SUMMARY OF RECOMMENDATIONS

The following represents a summary of our recommendations with respect to the proposed 2015 ASC payment rule:

A. Payment Recommendations

- **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 or consider adopting one of the CPI-U subsets such as Medical Care, Medical Care Services, or Outpatient Services.**
- **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 defer implementation of the restructuring all APCs for ophthalmology pending further review by the agency and the public regarding the criteria utilized to differentiate various levels of treatment or procedures encompassed by ophthalmic services.**
- **CMS should implement further policy changes for setting payments for device-intensive procedures to encourage migration of services into the less-expensive ASC setting.**

B. Quality Reporting Recommendations

- **CMS should withdraw ASC-11 as a voluntary reporting measure under the ASC Quality Reporting program.**
- **CMS should collaborate with the ophthalmology and ASC communities to develop and implement appropriate ophthalmic measures for the ASC community. These measures might include: incidence of toxic anterior segment syndrome (TASS), correct intraocular lens implantation (IOL), and unplanned anterior vitrectomy in cataract patients.**

CMS should modify the proposed ASC-8 data reporting timeframe to

mirror the August 15 reporting deadline for the other web-based reported measures.

II. ASC PAYMENT ISSUES

A. 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 seven 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 2015 rates, the percentage would be further reduced to approximately 55 percent. This change in rates is the result of the application of different inflation updates and an irrational and punitive budget neutrality policy and it is entirely unrelated to the cost of providing services to Medicare patients within the respective outpatient surgical environments.

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. During the twelve-month period March 2013 to March 2014, the number of operational ASCs has grown by only 51 facilities – the fifth consecutive year of growth less than 2 percent growth. Moreover, these historic lows in ASC growth are 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. Strikingly, ASC growth has been flat since the implementation of the new payment system in 2008. At a time when ASCs offer the very real potential of augmenting access to high quality services at substantially lower cost, policymakers and the public should be concerned about the growing and insidious risk of surgery migrating back to the higher-cost HOPD. Since the advent of the new payment system, hospital market share is growing for many high volume procedures, including standard screening colonoscopy. This trend is exacerbated by the insidious practice of hospitals acquiring surgery centers, converting them to HOPD status, and, while offering the same services to the same patients, enjoying the benefit of reimbursement at hospital rates that are almost twice that of ASCs.

The agency's continued utilization of the CPI-U as an update factor and rescaling to achieve budget neutrality in the 2015 proposal, as well as the reclassification of procedures into new APCs and packaging policies discussed below, will further exacerbate distortions in payment rates to ASCs and hospitals. In a very real sense, these policies 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.

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 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:

B. Annual Payment Update

The Academy, ASCRS, ASRS, OOSS, and SEE object to the application of any mechanism that widens the gap between ASC and HOPD payment rates unless it captures or is based upon 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; moreover, subsequent updates have been meager and always lower than those received by HOPDs. Under the 2014 payment rule, the CPI-U factor, reduced by the MFP, generated a Medicare update of 0.9 percent – almost a full point lower than the HOPD inflation update. For 2014, CMS has proposed an inflation update of 1.2 percent, compared with a hospital update of XXX percent. Every year, the HOPD receives a larger 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.

Unless these adjustments are made on the basis of the HMB, it is unlikely that ASCs will see reimbursement rates that reflect the true increases in costs of providing services to beneficiaries. Importantly, as CMS acknowledged as far back as the 2008 ASC payment rate rulemaking, 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.” The differential between the factors applied to HOPDs and ASCs 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. **In the final rule, CMS should adopt the Hospital Market Basket as the annual update factor for the ASC.**

- **The CPI-U does not reflect ASC cost growth; the HMB is a superior proxy for ASC cost increases.** 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 accurately 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. Pharmaceutical products and medical devices, including implants, have far outpaced all other categories of expenses, with many commonly used drugs experiencing price increases of 200 to 400 percent; these costs must be covered by facilities whose base rates and updates have remained flat.
- **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 arguably rewards its inefficiencies while penalizing the cost-conscious behaviors of the ASC. As discussed below, the higher inflation update certainly exacerbates the disturbing trend of providing an incentive for hospitals to acquire ASCs and immediately increase revenues – at Medicare’s and the beneficiary’s expense -- 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 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.
- CMS should forego development of an ASC-specific market basket and immediately adopt the Hospital Market Basket as an inflator for ASC payment rates or consider other equitable alternatives.** With respect to the 2013 ASC payment proposal, CMS requested comments regarding the establishment of an ASC-specific market basket to be utilized to determine the annual ASC inflation update. We embraced 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. First, 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. Second, efforts by the agency in the past to collect the type of data that would be required to develop an ASC-specific factor have been unproductive. Notably, 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. While the HMB might be an imperfect measure of ASC costs, it is more accurate than the CPI-U in that it reflects producer price inputs, measures health care delivery-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. In the alternative, if CMS insists on using the Consumer Price Index as an update factor, it should consider adopting one of the CPI-U subsets such as Medical Care, Medical Care Services, or Outpatient Services, the inputs of which are consistent with the services provided in the ASC setting.

C. Area Wage Index

The Academy, ASCRS, ASRS, OOSS, and SEE 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 common wage index applicable to all outpatient surgical services.

D. Reclassification of Ophthalmic Procedures Within APCs

We have reviewed the CMS proposal that would restructure all APCs for ophthalmology. While we understand the agency's desire and recognize its authority to review and consider different options for categorizing procedures within payment classifications, we question the advisability of accomplishing the task on a piecemeal basis, one specialty at a time. We also disagree that creating broader categories with more procedures grouped together will ensure greater clinical and economic coherence within the groups. In fact, broader classifications embody the potential to aggregate procedures that are different both in terms of clinical comparability and resource consumption. In our view, the existing APCs did not appear to be out of step with the requirements for clinical coherence or resource use. Moreover, we are skeptical of the frequency use data that is now being used for rate setting as there appears to be a discrepancy in the new data for some consistently high volume procedures as compared to what the new 2015 data is showing.

Because this change in policy is substantial and the agency has provided no information regarding the criteria utilized to differentiate the various levels of treatments or procedures, our groups recommend that this proposal not be finalized for 2015. Instead, we would appreciate the opportunity to work with CMS to make appropriate adjustments to the groupings that would ameliorate payment swings among and ensure clinical coherence within APCs.

For instance, in moving from 24 APCs currently in place to the proposed 13 proposed APCs, cornea procedures no longer have their own APC as has previously been the case. All of the major cornea transplant codes are proposed to be in the new Level III Intraocular Procedure APC 0673 along with codes for procedures that treat glaucoma and

retina conditions. The equipment for these services performed in different areas and depths of the eye are vastly different as are the time and other resources necessary to perform the surgeries. We believe that additional APCs and or levels are needed in order to correctly align clinically and resource-similar procedures. Some procedures appear to be inappropriately categorized and we believe further review and discussion is needed before this proposal is implemented.

Since the creation of the OPSS, CMS has utilized an averaging mechanism that has consistently resulted in charge compression. CMS defines charge compression as the “practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services.” As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. Under the proposal for ophthalmic APCs, we believe that charge compression would become more of a concern, again suggesting that further study is required.

E. 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.

We are pleased that CMS has reevaluated its device-intensive policy by defining ASC device-intensive as those procedures that are assigned to any APC with a device offset percentage greater than 40 percent based on the standards OPSS APC rate-setting methodology. Unfortunately, many procedures with high fixed costs are not designated as device-intensive on the ASC list because while the cost of the device for many codes is greater than 50 percent of the *total ASC cost* for the service, it does not meet the 50 percent threshold in the HOPD setting and, therefore, the ASC would not be reimbursed for the service. We strongly recommend that the agency set the threshold at 50 percent of the *unadjusted ASC payment rate*, thereby mirroring the current policy for establishing device-dependent services and pass-thru payments under the OPSS; since surgery centers are not included in the new comprehensive APCs, this is the policy that should be referenced. In the alternative, if the agency insists on linking ASC device-dependent status to a threshold applied to HOPDs, CMS should consider further reducing the threshold to 30 percent.

III. QUALITY REPORTING PROGRAM FOR AMBULATORY SURGICAL CENTERS

The Academy, ASCRS, ASRS, OOSS, and SEE very much appreciate the efforts undertaken by CMS to implement the ASC Quality Reporting Program (ASC QRP) over the past three years and the agency’s acceptance of many of the suggestions proffered by

our organizations. Accommodating the perspectives and concerns of the ASC and surgical communities is undoubtedly a major factor in the exceptional 98 percent reporting rate by facilities with respect to measures adopted to date. Since the publication of the 2014 ASC payment rule, we have strenuously objected to the application to ASCs of Measure ASC-11 (NQF 1536): *Cataracts – Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery*. We applaud the agency’s decision to withdraw the measure for purposes of mandatory reporting by facilities, but we must rigorously oppose its transition even to voluntary reporting status.

A. ASC-11 Should be Withdrawn as a Voluntary ASC Measure

ASC-11 should be withdrawn altogether. NQF 1536, from which it is derived, is a patient-reported outcome measure taken singularly from a measure group designed for registry-only reporting by physicians and was never intended to serve as a measure of facility-level quality and has never been tested for facility reporting. The most basic foundation of quality reporting in the ASC is that facility-level measures should relate to **an episode of care that occurs within the confines of the ASC, encompass data that is available within the ASC chart, be collectable by ASC staff, generate conclusions that are actionable by the facility, and have been tested in the ASC environment**. NQF 1536 meets none of these criteria.

For the reasons stated herein, we expect that few, if any, facilities will opt to report on ASC-11, and, therefore, sparsely reported results will not result in a sufficiently meaningful sampling in terms of measuring ASC quality, either on a facility-by-facility or industry-wide basis. Moreover, the existence of a single voluntary measure among a dozen (and growing) mandatory measures will be confusing to the ASC community, to those who review the data and for purposes of comparing the reporting results of centers.

- **The data required for reporting by facilities should be available within the records of the ambulatory surgical center; facilities should not be required to access and report data that is only available to other providers, such as the physician’s office.**

Even if NQF 1536 was to be tested and resubmitted for endorsement by NQF at the facility level, there are insurmountable barriers to collecting data for these measures within the ASC. *All of the currently implemented ASC quality measures utilize data that is housed within and collected by the ASC itself*. This new measure requires reporting on data that is located in the surgeon’s office and is wholly inaccessible by the ASC.

Data collection for ASC measures is complicated by the fact that ASCs are administratively and financially separate from physician offices. Under the Medicare program, an ASC operates exclusively for the purpose of furnishing ambulatory surgical services to patients requiring such a setting. Although the governing regulations permit the surgical facility to exist adjacent to a physician’s office under certain circumstances, Medicare ASC Conditions for Coverage state very clearly that the two entities must be physically, administratively, and financially separate from one another. *Importantly, medical record keeping must always be maintained separately and exclusively from other*

operations. While CMS has referred to NQF 1536 as a “chart-based” measure, none of the data necessary to appropriately comply with the measures is located in the ASC patient records. In other words, even though a physician in the clinic may perform surgery in the ASC next door, the medical records of one entity are *never* readily accessible by the other. As a practical matter, the ASC is staffed by registered nurses, operating room technicians, and clerical staff who are neither qualified to evaluate surgical outcomes nor located in the physician’s office where pre-operative and post-operative care might be efficiently and accurately evaluated.

- **It is not appropriate to migrate a measure across settings of care that was not considered in the design, testing, and implementation of the measure and with respect to which the measure is not actionable by the facility.**

NQF 1536 is inappropriate for reporting (mandatory or voluntary) by the ASC because facilities are not equipped to evaluate potential cataract outcomes. The facility is not involved in the baseline events preceding the surgery against which outcomes are measured in the post-surgical events that encompass the healing process. It is inconceivable that the ASC, which is neither licensed nor qualified to evaluate the cataract patient and make these assessments, would be involved in the professional decision-making contemplated by the measure. Any improvement in visual function would be attributable to the individual surgeon, not to the facility where the surgery occurred. Physician-level measures such as those incorporated within the Physician Quality Review System (PQRS) are formulated to assess quality within the physician’s office.

Importantly, NQF 1536 has not been tested nor endorsed as a facility-level measure for the ASC setting. Indeed, the Measures Application Partnership (MAP), in reviewing the measure, admonished that it should be tested and NQF-endorsed for the facility level of analysis; this has not occurred.

The goal of the ASC QRP should be to reflect those aspects of patient care that are within the control of the facility (*e.g.*, patient safety, staffing, equipment) and for which it is reasonable to hold the ASC accountable. The surgeon’s decision to recommend cataract surgery is based upon factors other than the potential for functional benefit – visual acuity and visual impairment are also considered. *It is inconceivable that the ASC, which is neither licensed nor qualified to evaluate the cataract patient and make these assessments would be involved in the professional decision-making contemplated by the measure.* As discussed above, a measure should be applied to the ASC only where actions that might be undertaken to improve such quality are within the purview of the facility. *We do not believe that it is possible for ASCs to influence outcomes with respect to this measure; therefore it is not appropriate to include the measure in the ASC Quality Reporting Program.*

- **Implementation of this measure in the facility would be extremely burdensome and resource-intensive to the reporting ASC.**

The burden on ASCs to disseminate, collect, and report on this measure would be significant – even in a survey of 63-96 patients, as articulated in the Measure Specifications -- given that the facility’s exposure to the patient is essentially limited to the care provided at the ASC on the day of surgery. The measure requires that patients complete a visual function questionnaire both before and after their scheduled surgery. The results of the pre- and post-surgery questionnaires are then compared to assess patient-perceived improvement. The patient’s visual acuity is measured before and after surgery in the physician’s office, not the ASC. Single-specialty facilities like ophthalmic ASCs tend to be smaller, have fewer operating rooms and employees, and, typically, will have available diminished resources to meet the administrative burdens posed by regulatory initiatives like quality reporting.

In the case of ASC-11, facilities would be required to contract with an outside entity to administer pre- and post-surgical surveys and tabulate the results, a burdensome and expensive exercise considering the number of cataract surgeries performed in surgery centers, or somehow mandate that surgeons on the medical staff of the ASC conduct visual function surveys as a condition of maintaining ASC staff privileges. The process contemplated with respect to reporting on the measure, whether performed on a mandatory or voluntary basis, places the ASC in the arbitrary and unworkable role as “middleman” between the physician and the government and forces the ASC and/or the physician to report data that is already being collected under the Physician Quality Reporting System (PQRS). The numerous modifications to the manual specifications for ASC-11 -- which have continued to be confusing, ambiguous, and unrealistic – reflect the monumental challenge that even the agency has encountered in clarifying just what would be expected of facilities.

B. CMS Should Collaborate with the Ophthalmology and ASC Communities to Develop and Implement Appropriate Ophthalmic Measures for the ASC Setting

The Academy, ASCRS, ASRS, OOSS, and SEE understand that CMS has made inclusion of a cataract measure in the ASC Quality Reporting program a priority. To date, we have enjoyed a productive and collaborative relationship with the agency with respect to the development and adoption of quality reporting measures and implementation issues. We have communicated with agency officials over the past year regarding our efforts to identify meaningful ophthalmic measures that will improve the quality of care provided the patient *by the ASC*. In this spirit, we look forward to working with CMS, the ASC Quality Collaboration, the NQF, and others committed to designing appropriate ASC-level measures for cataract surgery.

Our thinking is guided by several unalterable principles. Any cataract outcome measure developed for the ASC setting should:

- Relate specifically to the episode of care in the ASC;
- Evaluate the practices and aspects of the quality of the care attributable to the facility;

- Involve reporting by the facility of data available in the ASC chart; and,
- Produce outcomes data that is actionable by the ASC.

The AAO, ASCRS, ASRS, OOSS, and SEE have identified three measureable outcomes that embody the potential to meet these criteria:

- **Incidence of toxic anterior segment syndrome (TASS) in cataract surgery patients**

TASS, an acute and serious inflammation of the anterior chamber, or segment, of the eye following cataract surgery, is directly related to extraocular substances that inadvertently enter the eye during surgery. Incidence of TASS is measurable, attributable, and prevention is actionable by the facility. There are published guidelines regarding cleaning and sterilizing of intraocular surgical instruments to help improve quality and prevent TASS. This measure would promote collaboration between the surgeon and the facility, as the surgeon would report back to the facility any incidence of TASS, as is already done by surgeons. Further, measuring the incidence may aid in better tracking and understanding the prevalence of TASS, as the Food and Drug Administration contends that TASS is significantly underreported and surveillance is underway. There are specific prevention guidelines that have been developed, and this measure would help ensure that they are being appropriately followed.

- **Incorrect intraocular lens implantation (IOL) in cataract surgery patients**

This measure would account for mistakes that may occur while implanting an IOL during cataract surgery, including wrong eye, wrong type of IOL, and wrong power of IOL. Because these errors, on rare occasion, do occur, many ASCs have adopted and implemented internal protocols to reduce these errors. This measure would be meaningful to patients, improve quality and promote collaboration among the surgeon, other clinicians and the facility. The current wrong site, wrong implant, wrong patient measure that applies to all procedures on the ASC list is not sufficiently granular to help ophthalmic surgical facilities readily identify and correct problems that might be occurring with respect to IOL implantation. Given the significant number of IOLs being implanted each year in the US, having a separate measure to evaluate correct IOL implantation would be warranted. We are hopeful that the NQF will adopt this as a sub-measure to ASC-3 when the measure undergoes maintenance in 2015.

- **Unplanned anterior vitrectomy in cataract surgery patients**

This proposal would measure the number of cataract surgery patients who had an unplanned anterior vitrectomy. The procedure is performed while the patient is in the facility for cataract procedure. While the complication is generally not the fault of the facility – it is typically dependent upon the complexity of the patient’s condition or the surgeon’s expertise – collection and reporting of data will enable facilities to better identify surgeons who have higher rates of complication than the norm. For example, academic centers with residents may have higher unplanned vitrectomy rates. This

measure has been submitted by the ASCQC to the MAP for consideration, possibly for inclusion by CMS in the 2016 ASC rulemaking cycle.

These measures reflect three prevalent factors related to cataract complications that are within the purview of the facility and its staff. The measure topics are well-supported by the clinical literature. We believe that measuring these events in the ASC and HOPD settings presents an opportunity to improve the quality of cataract surgery for Medicare patients by the ASC. Moreover, these measures would serve as an important complement to the outcomes measures already being reported through the Physician Quality Reporting System (PQRS). We are committed to working with CMS and other interested stakeholders to fully develop measures that address these measure concepts over the course of the next calendar year so that they may be considered in the near future.

C. The Proposed ASC-8 Data Reporting Timeframe Should Be Modified to Mirror Other Web-Based Reporting Deadlines.

We believe CMS should minimize reporting burdens associated with the ASC Quality Reporting Program. We believe that multiple submission requirements for the program (claims, QualityNet portal, the Centers for Disease Control and Prevention's National Healthcare Safety Network System) result in significant confusion among practices. Under CMS' proposal, ASCs would be required to submit their October 1, 2014-March 31, 2015 influenza vaccination data by May 15, 2015. CMS notes that moving the date from the previously considered August 15 deadline would allow reporting alignment between the ASC Quality Reporting Program and the hospital reporting programs. CMS also states the earlier deadline would enable ASCs to use data summarizing the results for their previous influenza vaccination campaign to set targets and make plans for their campaigns prior to the next influenza season. We do not believe these reasons provide a compelling argument for creating a different reporting deadline for ASC-8. **We believe the reporting deadline for ASC-8 should mirror the August 15 reporting deadline for the other Web-based reported measures.**

Our organizations 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. None of these objectives will be enhanced by reporting by ASCs on ASC-11; we urge that it be withdrawn as a voluntary measure in the final regulation.

Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2014 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; Michael Romansky, JD, Washington Counsel, OOSS, mromansky@OOSS.org, 301.332.6474; and, Allison Shuren, JD, Washington Counsel, SEE, allison.shuren@aporter.com, 202.942.6525.

Thank you for your consideration of our views.

American Academy of Ophthalmology
American Society of Cataract and Refractive Surgery
American Society of Retina Specialists
Outpatient Ophthalmic Surgery Society
Society for Excellence in Eyecare