August 31, 2015

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS–1633–P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2016 Payment Rates

Dear Mr. Slavitt:

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 active 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 2,700 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 2016 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.

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 policymakers 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 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.

- 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.

- 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.

- A study published last year in the journal *Health Affairs* concluded that not only did ASCs perform outpatient surgery as effectively and more efficiently than HOPDs, but that they “provide high quality care, even for the most vulnerable patients.” The authors admonish that “recent {Medicare} reimbursement changes have lowered payments to ASCs, which reduces the incentives to start or expand these facilities.

Under the proposed rule, facility payment for cataract removal (CPT 66984) would be $971, while reimbursement for the same procedure in the HOPD would be $1,753. The beneficiary’s financial obligation in the form of copayments is $194 in the ASC and at least $351 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 almost $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 and have negative ramifications for the program and to the Medicare patients for whom it strives to provide quality surgical care.

### I. SUMMARY OF RECOMMENDATIONS

#### 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 costs of delivery of surgical 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 implement further policy changes for setting payments for device-intensive procedures to encourage migration of services into the less-expensive ASC setting.

CMS should not adopt its proposal to rescind the extended pass-through to glaucoma shunt procedures that utilize cornea tissue grafts.

CMS should continue to pay for J7315 Mitosol, ophthalmic 0.2mg in 2016.

B. Quality Reporting Recommendations

CMS should adopt in the final rule its proposal to require ASCs to report on unplanned anterior vitrectomy in cataract patients.

CMS should continue to collaborate with the ophthalmology and ASC communities to develop and implement appropriate ophthalmic measures for the ASC community. The agency should seriously consider adopting an ASC measure regarding toxic anterior segment syndrome.

CMS should withdraw ASC-11 as a voluntary reporting measure under the ASC Quality Reporting program.

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.

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 2016 rates, the percentage would be further reduced to approximately 53 percent (actually, 52 percent, when excluding codes that represent comprehensive APCs in the OPPS system). 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. Our concerns are being realized. Strikingly, ASC growth has been flat since the implementation of the new payment system in 2008. Moreover, migration of Medicare services to the ASC setting has significantly diminished. Notwithstanding the appropriateness of cataract in the ASC, surgery centers realized only a three percent increase in market share over HOPDs from 2010 to 2013.

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 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, O OSS, and SEE object to the application of any payment update mechanism that widens the gap between ASC and HOPD payment rates unless it 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. As discussed in detail below, subsequent updates have been meager and, with the exception of 2016 (when HOPDs will be subject to the 2 percent MFP adjustment that was applied to our facilities several years ago), the hospital update is typically at least one percent higher than the ASC. This occurs notwithstanding the fact that surgery centers are treating the same patients for the same conditions and expending comparable resources to provide that care.

Unless the ASC is afforded an annual update comparable to the HMB, it is unlikely that ASCs will receive reimbursement rates that reflect the increases in the 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 better 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); only 7.5 percent of the index’s inputs track anything having to do with health care. 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. 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 never offered convincing 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 no 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 immediately adopt the Hospital Market Basket as an inflator for ASC payment rates or consider other equitable alternatives.** 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, as discussed above, 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 (currently, 6.7 percent), Medical Care Services (7.5 percent), or
Outpatient Hospital Services (18.2 percent), the inputs of which are more consistent than the CPI-U with the services provided in the ASC setting.

C. Area Wage Index

The proposed rule continues to promote payment disparity between the HOPD and ASC by using different wage index values. The Academy, ASCRS, ASRS, O OSS, 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. 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 reevaluated its device-intensive policy last year 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 OPPS 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 OPPS; 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.

E. Proposed CY 2016 Change to Corneal Tissue Payment Policy in the HOPD and the ASC

In the CY 2016 rule, CMS is seeking comments on its proposal to rescind a recently implemented policy that extended the pass-through payments for cornea tissue acquisition to glaucoma shunt surgeries in addition to cornea transplant procedures. Our organizations have actively supported both the original pass-through and this recently extended policy and the justifications for originally allowing this pass-through are as relevant today as they were when the original policy was implemented in 2000. We greatly appreciate CMS’ continued support of adequate payment for tissue that is implanted during transplants in all settings.

Without extending the pass-through for the cost of the corneal tissue, the APC payment for these procedures is inadequate to cover the cost of the expensive shunt and the graft material, making it untenable for these procedures to continue to be performed in the ASC setting. This will result in these procedures shifting to the more expensive hospital setting, with greater program costs to Medicare and out-of-pocket costs to the beneficiary than were the procedures furnished in the more cost-effective ASC setting.

In withdrawing the extension, CMS states that the acquisition of cornea tissue used for glaucoma shunt surgery has a lower acquisition cost than the tissue used for cornea transplant. We do not dispute this; the fact that it is less costly is related to the back end of processing. However, processing is only a part of the cost of the eye bank supplying corneal tissue to the ASC or hospital. There are significant attendant costs in determining donor eligibility and recovering the tissue, then evaluating it to determine its potential utilization (e.g., type of corneal transplant, glaucoma shunt, other patch graft, research), all of which must be accomplished prior to processing. These costs apply to all corneal tissues, not just those used for corneal transplantation. In addition, the cost of donor blood testing and compliance with regulatory requirements are the same for tissue used in glaucoma shunt and corneal transplant surgery. It is true that processing costs are lower when the cornea tissue is utilized for multiple patch grafts; however, the patch grafts likely remain prohibitively expensive to be acquired by the ASC under APC 5492, thereby creating the unfortunate scenario of the glaucoma shunt procedure migrating to the hospital setting where Medicare payments are almost twice as high as in the ASC. We also do not disagree that there are other types of tissue available. What sets them apart from donor cornea is that they are sourced primarily from discarded non-organ tissues and not considered donor material. Our organizations strongly disagree with the proposal
to rescind the extended pass-through to glaucoma shunt procedures that utilize cornea tissue grafts. We request that CMS continue the cornea tissue pass-through for glaucoma shunt procedures in the ASC setting.

Should the agency decide to retain its proposed policy, we strongly suggest that CMS establish a new higher-level APC for glaucoma shunt services and other procedures whose costs are well above the current APC 5492 payment rate. Presently, there is a $6200 gap between the payment rate for APC 5492 ($3,438.26) and APC 5493 ($9,626.59). We realize that, given this disparity, it is not practicable to move any procedures in APC 5492 to the 5493 level. Establishment of a new higher-level APC that reflects the costs associated with these procedures would allow ASCs to continue to perform shunt surgery.

Our organizations would look forward to working with CMS and all stakeholders, including patients, providers, and the tissue community, to identify and implement a solution that enables patients to continue to have their surgical care in accessible, high quality, and cost-effective facilities and the government to realize significant savings compared to care in the hospital.

F. Unconditional Packaging of J7315 Mitomycin, ophthalmic, 0.2mg

CMS is proposing to package Mitomycin ophthalmic (HCPCS code J7315 “Mitomycin, ophthalmic, 0.2mg”) for use in glaucoma surgery. We oppose the unconditional packaging of Mitosol because we do not believe it meets the criteria for a packaged supply. CMS will package drugs and biologicals when they are integral to, dependent on, or supportive of a surgical procedure. Mitosol does not function in this manner. Instead, Mitosol is a drug that is indicated only a subgroup of patients undergoing glaucoma surgery, and when it is indicated, is administered through the same surgical incision. Although furnished coincident with some glaucoma surgeries, Mitosol is incident-to a physician’s service—it is not a typical supply furnished as part of the surgical procedure. In fact, Mitosol is used in only a minority of glaucoma procedures.

We fear unintended negative consequences that could result from this policy. It is important for CMS to understand and appreciate that Mitosol is the only mitomycin product approved by FDA for use in the eye and that it is a substantial cost relative to the payment for the procedure. In the absence of adequate payment, many ASCs may not find it financially feasible to furnish glaucoma procedures; in fact, those procedures could migrate to the more costly (i.e., more costly to both the Medicare program and beneficiary) hospital setting.

For these reasons, we urge CMS to continue to separately pay for Mitosol in CY 2016.
III. QUALITY REPORTING PROGRAM FOR AMBULATORY SURGICAL CENTERS

The Academy, ASCRS, ASRS, O OSS, and SEE very much appreciate the efforts undertaken by CMS to implement the ASC Quality Reporting Program 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 implemented to date. We believe that the following are prerequisites to the adoption of a quality measure for the ASC. A measure should:

- Relate specifically to the episode of care in the ASC;
- Evaluate the practices and quality of the care facility;
- Involve reporting by the facility of data available in the ASC chart;
- Produce outcomes data that is actionable by the ASC, embodying the potential to improve the quality of care provided in the facility; and,
- Have been tested in the ASC environment.

A. CMS Should Adopt the Unplanned Anterior Vitrectomy Measure in the 2016 Final Rule

The proposed rule would require ASCs to 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.) Measuring this outcome embodies the potential to reduce the rate of unplanned vitrectomies. Moreover, there is little burden associated with reporting on the measure because the patient is still in the ASC when the complication occurs and the patient’s ASC record will include the relevant information that will be reported.

We believe that measuring this event in the ASC setting 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).

This measure is fully developed and has been specifically tested in the ASC setting. It was reviewed last year by the MAP and received conditional support pending endorsement by the National Quality Forum. Reliability testing was completed in 2014 with very strong results which have been shared with CMS at that time. The measure is already in use in the ASCQC’s quarterly public reporting program.
B. CMS Should Consider Future Adoption of a Toxic Anterior Segment Syndrome Measure (TASS) in Cataract Surgery Patients Treated in the ASC

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 to the ASC, 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.

The ASC Quality Collaboration has conducted reliability testing on a TASS measure and it is expected to be in use by facilities by the end of 2015. It has been submitted to the Measures Application Partnership for inclusion on the Measures Under Consideration List (MUC) for July, 2016.

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

In light of the aforementioned parameters, our organizations strongly believe that ASC-11 should be withdrawn altogether as a voluntary measure. 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 not been tested for facility reporting. Any improvement in visual function would be attributable to the individual surgeon, not to the facility within which the procedure is furnished. It is inconceivable that the ASC, which is neither licensed nor qualified to evaluate the cataract patient and make assessments as to visual function, would be involved in the professional decision-making contemplated by the measure. Moreover, with respect to design and testing, it is notable that the measure has been neither tested in ASCs nor endorsed as a facility-level measure by the Measures Application Partnership (MAP).

Implementation of this measure in the facility would be extremely burdensome and resource-intensive to the reporting ASC. There are insurmountable barriers to collecting data for this measure within the ASC, as it requires reporting on data that is located in the surgeon’s office and is wholly inaccessible by the ASC. In fact, 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. For these reasons, we suspect that very few ASCs have reported or will in the future report on this measure. Indeed, the inclusion of this measure in the ASC
QRP is inconsistent with CMS’ goals of improved health care outcomes, quality, safety, efficiency or satisfaction for patients. Because of the low sample size, any performance data related to this measure from the ASCQR program would be neither reliable nor valid, and will not be meaningful for driving improvements in ASC quality. As we stated a year ago, while we are pleased that CMS is proposing not to penalize ASCs for failing to report this measure by continuing to make it a voluntary measure, we strongly urge CMS to completely remove the measure altogether from the program.

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Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2016 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@aaoadc.org, 202.737.6662; Nancey McCann, Director of Government Relations, ASCRS, nmccann@ASCRS.org, 703.591.2220; Robert Gerson, Director of Practice Management, robbie.gerson@asrs.org, 312.578.8760; 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