September 24, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
PO Box 8013
Baltimore, MD 21244-1850

Via online submission at www.regulations.gov

Re: CMS-1678-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

We appreciate this opportunity to submit comments on behalf of four leading ophthalmology organizations with regard to CMS-1678-P, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems an Quality Reporting Programs*. Collectively, the members of our societies are responsible for performing the vast majority of all ophthalmic surgical procedures performed in the US, and most within the ophthalmic ASC setting.

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 and commitment to advancing the art and science of ophthalmic surgery.

The American Society of Retina Specialists (ASRS) is the largest retinal organization in the world, representing over 3,000 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 enhance the ability of its members to provide the highest quality of patient care.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical society that represents over 4,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective ASC environments. The programs and services of OOSS are designed to ensure top-quality and sustainable patient care and safety in surgical environments that support ever-changing technology and regulation. OOSS is 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 educating 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.

On behalf of ASCRS, ASRS, OOSS, and SEE, we are taking this opportunity to comment on this important regulation governing CY 2019 Medicare ASC payment rates and the Quality Reporting Program for ambulatory surgical centers. Particularly with respect to the latter, we are very pleased that a number of the recommendations of the ASC and ophthalmology communities have been adopted in the recent past and are proposed in this rulemaking and we appreciate the close collaboration among industry, medicine, and the agency that has characterized the development of the QR program. **Most importantly, we strongly support the agency's decision to change the ASC update factor from the Consumer Price Index – Urban (CPI-U) to the Hospital Market Basket (HMB), an amendment to the regulations that should ameliorate some of the distortions in relative payments to ASCs and HOPDs.**

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. 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. 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. Despite CMS' positive proposal to change the ASC update factor from the CPI-U to the HMB, 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.

Under the proposed rule, facility payment for cataract removal (CPT 66984) in 2019 would be $988, while reimbursement for the same procedure in the HOPD would be $1,926. The beneficiary's financial obligation in the form of copayments is $197.60 in the ASC and at least $385 in the HOPD; patient cost-sharing is always lower in the ASC. Therefore, for each cataract operation performed in an ASC instead of an HOPD, the program and beneficiary save over $938. With nearly three million cataract surgery cases performed per year, the impact of savings to the program and the beneficiary by performance of cataract surgery in the ASC, as confirmed now by a multitude of studies and reports, is well into the billions of dollars annually. While ASCs perform about 60 percent of cataract surgeries, there is still significant opportunity for volume migration as virtually every cataract operation can be safely and effectively performed in ASCs.

I. SUMMARY OF RECOMMENDATIONS

A. ASC Payment Recommendations

- **CMS should finalize its proposal to adopt for the period 2019 through 2023 the Hospital Market Basket in lieu Consumer Price Index-Urban as the annual update factor for ASCs.**

- **CMS should apply the OPPS relative weights to ASC services and discontinue the rescaling of ASC relative weights. Rescaling has had the effect of arbitrarily and inappropriately reducing ASC payment rates and causing a substantial divergence in payment rates between HOPDs and ASCs that is unrelated to the costs of delivering services in those settings.**

- **CMS should finalize its proposal to lower the device-intensive threshold to 30 percent.**

- **CMS should develop a policy that covers drugs that are administered at the time of cataract surgery, but are not integral or necessary to the cataract procedure, and have an FDA-approved indication to treat or prevent post-operative concerns, such as pain and inflammation, separately under Part B.**

- **CMS should eliminate its prohibition against ASCs billing for services that are reported using a CPT unlisted surgical code.**

- **CMS should modify its current payment policy for corneal tissue utilized in the HOPD to be based on invoice cost.**

B. Quality Reporting Recommendations

- **CMS should adopt in the final rule a quality measure for ASCs to report on Toxic Anterior Segment Syndrome (TASS) in cataract patients.**

- **CMS should remove ASC quality reporting measures ASC-8, ASC-10 and ASC-11.**

- **CMS should reconsider the proposed removal of ASC-1, ASC-2, ASC-3 and ASC-4.**

- **CMS should continue to delay implementation of the OAS CAHPS survey until the instrument is shortened and there is an electronic compliance option.**

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 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 comparable cost differences in the provision of care in the two settings, with respect to which technology and staffing costs are identical. We appreciate that CMS has responded to those concerns and is taking the important step of replacing the CPI-U with the HMB as the annual update factor for ASCs. This is a key step in encouraging additional procedures to be performed in the more cost-effective ASC. To ensure that this proposal has its full intended effect, however, we recommend CMS also eliminate the secondary rescaler.

Failure to increase payments to ASCs to reflect inflationary pressures cannot help but continue to exacerbate disturbing trends in ASC payment, beneficiary access, program expenditures, and competition between the HOPD and ASC. In 2003, aggregate ASC payments as a percent of HOPD rates were 85 percent. When the new system was established in 2008, the percentage had dropped to 65 percent; under the proposed 2019 rates, the percentage would be further reduced to about 53 percent. This change in rates is the result of the application of the rescaler and 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 essentially flat since the implementation of the new payment system in 2008. Moreover, migration of Medicare services to the ASC setting has significantly diminished.

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 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.

In formulating ASC policy and establishing payment rates, it is imperative that the agency recognizes that most ASCs are small businesses that must run efficiently to remain in operation. There are about 5,600 Medicare-certified ASCs – about 1,100 of which specialize in ophthalmology – and over half have only one or two operating rooms. Our facilities purchase the same equipment, devices, implants, and supplies as HOPDs and must compete with hospitals for the same nurses and other personnel, while complying with the same federal and state patient health and safety requirements and the ever-growing demands of the Medicare ASC quality reporting program. Our centers operate efficiently; however, receiving reimbursement that is about half that of competing hospitals can compromise the ability of our facilities to continue to provide the care and technology that Medicare beneficiaries deserve.

The agency's continued utilization of rescaling to achieve budget neutrality in the 2019 proposal, as well as the reclassification of procedures into new APCs and packaging policies, has exacerbated 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 have appreciated the agency's willingness to work with the ASC industry, the ophthalmology community, and others and believe that there are many positive components to the proposed rule. 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

Our organizations strongly support the agency's proposal to change the ASC update factor from the CPI-U to the Hospital Market Basket. ASCRS, ASRS, OOSS and SEE have objected for years to the application of any payment update mechanism that widens the gap between ASC and HOPD payment rates unless it is based upon true 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 only a couple of years (now that HOPDs are subject to the 2 percent MFP adjustment to which our facilities have been subject since 2015), 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. We applaud the agency for finally proposing identical cost-of-living updates for hospitals and ASCs.

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 over 40 percent of its weight); only 8.6 percent of the index's inputs track anything having to do with health care. With respect to the HMB, about 55.8 percent of the factor 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 cannot adequately be covered by facilities surgical 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.

Application of different inflation factors unjustly expands the gap in payments to HOPDs and ASCs. With the exception of two years over the past decade, the HMB has exceeded the CPI-U, typically by about 1 percent. In combination with the application of the rescaler and the recent efforts to restructure APCs, the 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 cost of

performing surgical procedures. Even under the proposed rule, which contemplates application of the Hospital Market Basket update to the ASC, the ratio of ASC to hospital payments will drop below 53 percent, compared to 65 percent at the advent of the ASC payment system in 2008. 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 guarantees further distortion in payment rates for comparable services. Application of the HMB to both the HOPD and ASC settings would ameliorate some of the irrational and counterproductive divergence in payment rates.

There are other update factors that might be suitable for the ASC. We appreciate CMS' request for feedback on alternative update factors. If the CPI-Medical Care index had been applied to our rates during the timeframe 2010-2017 instead of the CPI-U, the ASC conversion factor would be 10.6 percent higher. If the CPI-Medical Care Services index had been used, the ASC conversion factor would be 11.4 percent higher; the CPI-Outpatient Hospital Services index, 26.4 percent higher; the CPI-Medicare Care Commodities index, 8.3 percent higher. For the reasons stated above, ASCRS, ASRS, OOSS and SEE believe that the HMB is more representative of the cost structure than the CPI-U for purposes of updating ASC rates.

Changing the ASC update from the CPI-U to the Hospital Market Basket embodies the potential to save Medicare dollars. The Ambulatory Surgery Center Association examined the volume of procedures performed in the ASC and HOPD. It modeled the total cost with the proposed update factor versus the CPI-U. Based on this analysis, the cost of switching update indices would be approximately $33.2 million. A volume shift of merely 0.37 percent -- 0.86 percent of ASC volume – from the hospital setting to the surgery center would make the proposed change to the HMB budget neutral.

The ASC and ophthalmology and other surgical communities have long believed that the playing field between hospital and ASC cost of living adjustments must be leveled and that the application of HMB to ASCs would accomplish this objective. We strongly support the agency's proposal to make this change and we look forward to working with the agency over the next five years as it considers alternative updates that might be appropriate for the ASC.

C. Rescaling Adjustment Applied to ASC Relative Weights

ASCRS, OOSS, and SEE strongly believe that CMS should eliminate the rescaling of the ASC relative weights, as this practice has increasingly exacerbated the gap between ASC and HOPD payments and inappropriately reduced payments to ASCs without evidence of growing differences in capital and operating costs in the two settings. As we have noted in our comments to past ASC payment rulemakings, our organizations support the utilization of the same APCs and relative weights in creating a rational and coherent payment system encompassing the services offered by both HOPDs and ASCs:

". . . the rescaling of ASC relative weights . . . will result in further divergences in

weights and payments, exacerbating exactly the types of distortions that the new system was presumably intended to correct. The only legitimate basis for change in relative payments to HOPDs and ASCs should be changes in the relative costs of providing specific outpatient services. There is little basis for believing that these variations will occur, and to the extent that they do, they should be accounted for directly through adjustments to the conversion factor."

It is important to note that APC relative weights are already adjusted once for budget neutrality. Contrary to CMS' assertion in 2007 that rescaling would protect ASCs from decreases in payments for procedures due to changes in OPPS relative weights, recent experience reflects otherwise. *The rescaling adjustment has had the opposite effect, decreasing the relative weights on ASC surgical procedures each year. Since 2010, our relative weights have decreased by an average of 7 percent each year*. In 2016, the rescaler was 0.9332 and, in 2017, 0.9030; in 2018, the rescaler fell to .8995 for a 10.1 percent reduction to ASC weights. Under the proposed rule, the relative weight would be 0.8854, which, if implemented, would result in an 11.5 percent reduction. This historical trend suggests that the application of the rescaler in the ASC environment will continue to erode the relationship between ASC and HOPD payments.

We strongly recommend that the agency discontinue the use of the rescaler. *If CMS is unwilling to do so, we believe that the agency should create a minimum ratio of ASC payment to OPPS payment for any service whose payment rate is based on OPPS rates. We would suggest that the floor should be implemented in such manner that no ASC service is paid less than 55 percent of the comparable HOPD rate.* This represents the payment ratio between the sites before the comprehensive APCs were developed and exacerbated the more substantial disparity between the payment systems. We recommend that for OPPS codes that fall within C-APCs, the floor should be implemented relative to the alternative payment rate (i.e., without C-APC status) for these codes that CMS already calculates in the process of establishing ASC rates. With respect to both suggestions – discontinuing the rescaler and establishing a minimum relationship ratio – these must be implemented without applying a budget neutrality adjustment within ASC payments. To do otherwise would further undermine and dilute the important policy objective of encouraging appropriate migration of surgical procedures to a lower-cost setting.

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

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 typically not able to

extract greater discounts on devices and supplies than hospitals. We applaud the agency for proposing changes for device-intensive codes in 2019 and urge CMS to implement these policies to serve beneficiaries who require procedures with significant device costs.

In 2017, CMS reevaluated its device-intensive policy by defining ASC device-intensive as those procedures that were assigned to any APC with a device offset percentage greater than 40 percent based on the standard 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 40 percent of the total ASC cost for the service, it does not meet the 40 percent threshold in the HOPD setting and, therefore, the ASC is not reimbursed for the service. **We strongly support the agency's proposal to lower the device-intensive threshold to 30 percent.**

E. Solicitation of Comments Regarding Packaging of Items and Services Under OPPS – Drugs that Function as Supplies in Cataract Surgery

Last year, CMS solicited public comment regarding a number of packaging and bundling policies under the OPPS, among them whether they might adversely impact patient access and or provide inadequate payment. However, CMS did not respond to the significant comments we made, and is only proposing to pay for non-opioid pain management separately in the ASC. Specifically, ASCRS, ASRS, OOSS, and SEE are concerned with the bundling of FDA-approved drugs that are administered at the time of cataract surgery—either during or at the end of the procedure—but have an indication for the treatment of post-operative pain and inflammation and/or other sequela of the surgery. *ASCRS, OOSS, ASRS and SEE maintain that these medications are not integral or necessary to the cataract procedure and should not be bundled into the facility payment, but instead be covered under Medicare Part B. Furthermore, ASCs face the same challenges in affording to provide these drugs as they do to provide the non-opioid pain management CMS proposes to remove from the facility fee for that reason.*

In early 2015, CMS issued a sub-regulatory guidance that directs Medicare contractors not to pay separately for compounded drugs administered at the time of the cataract procedure but are intended to treat post-operative pain and inflammation. These medications are intended to replace some or all of the eye drops patients must administer post-procedure and that are covered and reimbursed separately under Medicare Part D. Specifically, CMS determined that compounded medications given at the time of the procedure are covered facility services that are encompassed within the facility rate already paid to the hospital outpatient department or ambulatory surgery center. Therefore, a facility currently providing these medications is not reimbursed for the additional cost of the compounded drug product.

We are concerned that branded products on the market or in the pipeline for FDA approval will be treated similarly, which would render it virtually impossible for Medicare beneficiaries to access these important intracameral treatment options. Several companies are

pursuing costly research and development of products that can deliver the medications necessary during the extended post-procedure period, including intercameral antibiotics, yet be administered at the time of the cataract surgery. Current policy will impede the development of these important pharmaceutical products. Cataract patients are typically aged and many have memory limitations, significant physical conditions, and comorbidities. Intracameral medications, administered by the surgeon at the time of surgery, are a valuable treatment alternative to post-op drops.

If CMS considers payment for FDA-approved products indicated to treat or prevent issues in the post-operative period to be packaged/bundled into the existing payment for cataract surgery—as it has for compounded medications—without a commensurate increase in the facility payment for cataract surgery, then facilities will not be in a financial position to offer patients the option to receive these products. As noted in our comments above, ASCs are already fiscally challenged because we receive only about half of the payment available to hospitals, yet our drug costs are the same. CMS recognizes this challenge and is proposing to pay separately for non-opioid pain main management in the ASC because the cost of available non-opioid options may prevent ASCs from using the drug. We believe, though, that the exclusion, which cites only Exparel, is too narrow**.**
While we appreciate and support the efforts CMS is taking to combat the nation's opioid epidemic, we believe, as indicated above, that ASCs may also be unable to provide patients access to all FDA-approved medications with post-operative indications because they are too costly to provide as part of the current bundled facility fee.

We are fortunate as clinicians and ASCs to have multiple options to treat our patients' post-operative challenges – which are excellent self-administered drugs and effective surgeon-administered intracameral injectables. Our members and facilities believe that patients should be afforded the option of using self-administered eye drop medications post-procedure or to have FDA-approved drug products administered via injection at the time of the cataract surgery.

Therefore, our organizations urge CMS to develop a policy that covers drugs that are administered at the time of cataract surgery, but are not integral or necessary to the cataract procedure, and have an FDA-approved indication to treat/prevent post-operative issues, such as pain and inflammation, and in the future, infection, separately under Medicare Part B.

F. 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 stated 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 narrowly-defined anatomic region of the service that could provide the basis for a determination about the safety of the procedure in the ASC. There is no clear safety rationale for this policy and commercial insurers typically afford ASCs the flexibility to use unlisted CPT codes to make claims for payment. We note that the agency does permit HOPDs and even physician offices to use unlisted codes; allowing this practice for ASCs will enable CMS to derive savings for both the program and beneficiaries. If physicians are permitted to choose to perform a procedure with an unlisted code in HOPDs, facilities that are managed, staffed and equipped like Medicare-certified ASCs, surgeons should be allowed to utilize unlisted codes in the ASC. We urge CMS to revise the Federal Code of Regulations to eliminate this restriction.

G. HOPD Reimbursement for Corneal Tissue

We recommend that CMS modify its current payment policy for corneal tissue in the HOPD to be based on invoice cost to align with the current reimbursement model in ASCs. This model would protect patients from unexpected and unreasonable out-of-pocket costs due to factors that are beyond their control.

Currently, the HOPD's reimbursement model requires hospitals to mark up the cost of corneal tissue for the sole purpose of having it discounted by its cost-to-charge ratio – a practice that is in opposition to the public's understanding of eye/organ/tissue donation, and leads to confusion when these charges are revealed. The cost-to-charge ratio ensures CMS does not reimburse for inflated tissue costs, but patients, whose co-insurance is calculated on the billed charge and not the allowed charge, are not protected. In some cases, patients may even pay more than the cost of the tissue itself, if the hospital has a high mark-up. However, in ASCs, the reimbursement of the tissue is based on the invoice price, and patients pay a lower and predictable copayment.

Patients rarely have the choice in which type of facility they receive treatment. And in fact, patients with certain comorbidities may be required to receive their transplant in the HOPD. We are concerned that the reimbursement policy creates a situation where the sickest patients are forced to pay excessive out-of-pocket costs due to factors outside of their control.

CMS should modify its model in the HOPD, so that corneal tissue reimbursement is based on the invoice price, as it is in the ASC.

III. QUALITY REPORTING PROGRAM FOR AMBULATORY SURGICAL CENTERS

ASCRS, ASRS, OOSS and SEE very much appreciate the efforts undertaken by

CMS to implement the ASC Quality Reporting Program over the past several 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-plus 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. Toxic Anterior Segment Syndrome Measure (TASS) in Cataract Surgery Patients Treated in the ASC

In 2018, CMS invited public comment regarding the adoption of a measure, developed by the ASC Quality Collaboration to assess the number of patients diagnosed with TASS within two days of undergoing anterior segment surgery in the ASC. The measure was reviewed by the Measures Applications Partnership (MAP) three years ago and received conditional support pending endorsement by the National Quality Forum (NQF). CMS did not finalize adoption of this measure in the 2018 rulemaking.

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 is actionable by the facility. There are published guidelines regarding cleaning and sterilization 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, under current practice, would report back to the facility any incidence of TASS. 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. Specific prevention guidelines have been developed and this measure would help ensure that they are being appropriately followed.

ASCRS, ASRS, OOSS, and SEE strongly support inclusion of the TASS measure in the ASCQR program.

B. Proposed Removal of Measures

Our organizations support the removal of *ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel*. We agree with the agency that the costs associated with compliance with this measure outweigh the benefit of its continued application in the

program.

We also support removal of ASC-8, ASC-10, and ASC-11. We commend the agency for proposing to remove these measures. We note that when the National Quality Forum endorsed these measures several years ago, they did so as physician, not facility, measures. With respect to *ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery,* we strenuously objected to its adoption because it failed to meet *all* of the prerequisites to adoption of an ASC measure.

CMS should reconsider the proposed removal of ASC-1, ASC-2, ASC-3, and ASC-4. CMS has proposed removing these measures because they represent rare events. However, we believe that they encompass information that is important for patients and ASCs. These measures are currently reported using quality data codes on ASC Medicare claims. All stakeholders would benefit if this data were submitted via Quality Net and reporting expanded to all patients treated by the ASC, not just Medicare beneficiaries. Continued adoption of these measures would enhance provider accountability and the transparency of public reporting. We strongly urge the agency to continue aligning measures across all sites of service; if feasible, data collected by HOPDs should be collected by ASCs and vice versa.

C. Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measure for CY 2020 Payment Determination Year

We appreciate the agency's efforts to assess patient outcomes and satisfaction with providers. Our organizations have submitted comments with respect to prior iterations of this measure. We have repeatedly emphasized several concerns: the need to minimize the administrative and financial burdens of participation; efficient and effective survey administration; the imperative of limiting survey questions/topics provided by the facility; and, the challenges of patient self-reporting on outcomes. We were disappointed that in great measure, the survey under discussion two years ago did not address these concerns. CMS cited, last year, its desire to "appropriately account for the burden associated with administering the survey in the outpatient setting of care" as one reason for delaying mandatory implementation of the Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS). **ASCRS, ASRS, OOSS, and SEE, support delaying such implementation until the survey is shortened and there is an electronic compliance option, both of which would reduce the cost burden to our facilities, facilitate patient completion of the survey, and generate meaningful information for consumers.**

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Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2019 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: Nancey McCann, Director of Government Relations, ASCRS,

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Thank you for your consideration of our views.

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