



Excellence

September 27, 2019

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-1717-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc.

Dear Administrator Verma:

We appreciate this opportunity to submit comments on behalf of four leading ophthalmology organizations with regard to CMS-1717-P, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and 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 2020 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 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 last year to change the ASC update factor from the Consumer Price Index – Urban (CPI-U) to the Hospital Market Basket (HMB). We will discuss below other payment policy changes 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 use of the rescaler to achieve budget neutrality, will 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 2020 would be \$1,012, while reimbursement for the same procedure in the HOPD would be \$1,995. The beneficiary's financial obligation in the form of copayments is \$202 in the ASC and at least \$400 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 70 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

- CMS should maintain use of the hospital market basket as the annual update mechanism for ASC payments.
- 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 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.
- As CMS has claims data on the constituent codes for each of 66X01 and 66X02, it should use the combined information for the claims data (for 66711 and 66982 for 66X01 and for 66711 and 66984 for 66X02) and establish hospital outpatient and ASC payment rates accordingly.
- 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 reconsider the removal of ASC quality measures ASC-1, ASC-2, ASC-3, and ASC-4. CMS should maximize efforts to align quality measures across all sites of service.
- If feasible, data collected by HOPDs should be collected by ASCs and vice versa and reported so that patients can compare cost data and quality results from competing hospitals and ASCs.

## **II. ASC PAYMENT ISSUES**

#### 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 some of our concerns, particularly taking the important step of replacing the CPI-U with the HMB as the annual update factor for ASCs, a key step in encouraging additional procedures to be performed in the more cost-effective ASC. To ensure that this proposal has its intended effect, however, we recommend CMS also eliminate the secondary rescaler.

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 2020 rates, the percentage would be further reduced to 48.15 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. 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 1,200 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 evergrowing demands of the Medicare ASC quality reporting program. Our centers operate efficiently; however, receiving reimbursement that is about half that of competing hospitals compromises 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 2020 proposal, as well as the recent 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:

#### A. Annual Payment Update and Request for Cost Data

As we emphasized in our comments a year ago, our organizations strongly support the agency's decision to change the ASC update factor from the CPI-U to the Hospital Market Basket (HMB). The CPI-U does not reflect ASC cost growth; the HMB is a better proxy for ASC cost increases. ASCs and HOPDs treat the same patients for the same conditions and consume commensurate resources and incur similar costs. Application of different inflation factors has unjustly expanded the gap in payments to HOPDs and ASCs. We believe that applying the same update factor to both types of facilities can potentially promote appropriate migration of services from the HOPD to ASC, generating significant cost savings to the Medicare Program. ASC growth has been compromised by lack of parity in payment to HOPDs and ASCs. Aligning conversation factors – in addition to eliminating the rescaler, as discussed below – will equitably level the playing field between hospital and freestanding surgical facilities.

CMS has, in the proposal, again expressed a desire to "assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner." For the reasons stated above, we believe that the HMB is an appropriate update factor for ASCs. If, however, CMS elects to collect data to establish a new market basket, the agency should expand its analysis to create an index that will be applied to both the HOPD and ASC to ensure that payments using the same relative weights are aligned over time. In developing a data collection modality, CMS should keep in mind that ASCs already incur excessive administrative burdens in complying with current regulations; requiring formal cost reports would diminish the agency's commitment to promulgate rules and policies that allow facilities to maintain efficiency in the delivery of services to our patients. We look forward to collaborating with CMS on this endeavor.

## B. Rescaling Adjustment Applied to ASC Relative Weights

ASCRS, ASRS, 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 0.8452, which, if implemented, would result in a 15.5 percent reduction in ASC weights. 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. The agency is needlessly increasing Medicare program costs by making it financially impracticable to furnish these services that are clinically appropriate, and hence encouraging physicians to provide these procedures in the most expensive HOPD setting. We strongly recommend that the agency discontinue the use of the rescaler.

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. Therefore, we implore the agency to encourage savings and greater access to ASCs for Medicare beneficiaries by eliminating the ASC weight scaler.

### C. Packaging of Items and Services Under OPPS – Cataract Surgery

Two years ago, 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. We are extremely disturbed that CMS has not responded to the significant comments we submitted or the letters sent by bipartisan members of Congress on this issue, and is only proposing to continue to pay for a specific non-opioid pain management drug 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 procedurebut 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 since these medications have a post-operative indication, they should not be considered surgical supplies bundled into the facility payment, but instead be covered and paid for under Medicare Part B. ASCs face the same challenges in affording to provide these drugs as they do to provide the specific non-opioid pain management drug CMS removed from the facility fee for that reason. In addition, CMS' policy will have the unintended consequence of stifling innovation because manufacturers do not have the assurance there will be a payment pathway when these new and innovative drugs come off pass-through.

Our organizations oppose CMS' policy that restricts separate payment for drugs administered at the time of the cataract procedure but are intended to treat post-operative pain and inflammation because it prevents patient access to these medications in the ASC setting. 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 Cataract patients are typically aged, and many have memory limitations, significant physical conditions, and comorbidities. Medications, administered by the surgeon at the time of surgery, are a valuable treatment alternative to post-op drops and have the potential to improve patient outcomes by reducing or eliminating the need for patient-administered post-operative medication. Because they have an FDA-approved postoperative indication, these drugs are unique and have benefits well beyond traditional surgical supplies.

Yet, once these drugs come off pass-through status and are bundled into the APC payment, ASCs struggle to afford them. ASCs, who typically operate on tight margins, are paid at a lower rate than HOPDs, but must purchase the drugs at the same price. Drugs that have recently come off pass-through have experienced a precipitous decline in use once their cost is bundled into the APC payment because the payment is not high enough for ASCs to afford the drug. CMS recognized this challenge and began paying separately for one 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 also concerned that CMS' policy is having the unintended consequence of stifling innovation as branded products on the market or in the pipeline for FDA approval will be virtually impossible for Medicare beneficiaries to access once they come off pass-through. Several companies are pursuing costly research and development of products that can deliver the medications necessary during the extended post-procedure period, including intracameral antibiotics, yet be administered at the time of the cataract surgery. Current policy will impede the development of these important pharmaceutical products. Without the assurance that ASCs will be able to afford to provide these treatments to patients, manufacturers will discontinue their innovation in this area.

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 at the time of the cataract surgery.

Therefore, our organizations urge CMS to develop a policy that covers and pays for drugs that are administered at the time of cataract surgery, and have an FDAapproved indication to treat/prevent post- operative issues, such as pain and inflammation, and in the future, infection, separately under Medicare Part B.

#### **D. 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.

#### **E.** Cataract Surgery and ECP

New CPT code 66X01 is a combination of 66982 and 66711 (complex cataract and endoscopic cyclophotocoagulation (ECP)) and new CPT code 66X02 is a combination of 66984 and 66711 (routine cataract and ECP). Our organizations are concerned that the proposed payment rates for these new codes do not adequately capture the resources hospitals and ambulatory surgical centers (ASCs) will expend for each combined procedure.

ECP (66711- Ciliary body destruction, cyclophotocoagulation, endoscopic) is a surgical glaucoma procedure that can be performed alone or with cataract surgery, depending on the type and severity of disease being treated. The ciliary processes are treated with laser energy to reduce the production of aqueous, thereby lowering the intraocular pressure. The processes are accessed through a corneal or pars plana incision. When ECP is combined with cataract surgery, access to the ciliary processes is gained through the cataract incision. About 1 in 5 patients undergoing cataract surgery also suffer from glaucoma of varying severity. For that reason, over 75% of reported ECP procedures were combined with cataract surgery in 2017. This high frequency lead to the American Medical Association (AMA) creating the two new codes 66X01 and 66X02 for the combined procedures.

ECP is performed using a laser microendoscope connected to an Endo Optiks system that houses a laser, light source and video camera. This allows the surgeon to simultaneously view on a monitor and treat the intraocular tissue. There is a high capital cost associated with this system and the reusable endoscopes must be maintained, including periodic repairs at the expense of the ASC. The average cost of an endoscope including maintenance and careful sterilization between cases is greater than the proposed rate of reimbursement. Additionally, the mircoendoscope is an essential imagining tool for retinal and pediatric surgeons performing complex surgeries, without ECP.

The capital equipment used for ECP is entirely different than that used for cataract surgery. It must be purchased and maintained individually. When cataract and ECP are performed together, there is a very limited overlap in resources – just some consumables and knives and some procedure time savings.

CMS proposes to pay ASCs for each new combined CPT code at \$1330.72, representing more than a 10% reduction in payment than had the codes not been created. This significant reduction makes ECP a money-losing proposition for ASCs and, despite the important clinical benefits, will likely lead to a steep drop-off in utilization. We believe that the hospital and ASC payment levels should be determined in a way that recognizes that the new codes largely reflect the combined resources of the two constituent codes. Since CMS has claims data on the constituent codes for each of 66X01 and 66X02, it should use the combined information from the claims data (for 66711 and 66982 for 66X01, and for 66711 and 66984 for 66X02) and establish hospital outpatient and ASC payment rates accordingly.

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

## **B.** Proposed Removal of Measures

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

## C. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

Thousands of services can be performed safely and effectively at more that one site of service, i.e., HOPD and ASC. Congress has instructed the Department of Health and Human Services to develop a cost-companion website for Medicare beneficiaries. 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 and reported so that patients can compare cost data and quality results not just of one ASC, but also from competing ASCs and hospitals.

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Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2020 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, nmccann@ASCRS.org, 703.591.2220; Jill Blim, ASRS, jill.blim@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 Society of Cataract and Refractive Surgery American Society of Retina Specialists Outpatient Ophthalmic Surgery Society Society for Excellence in Eyecare