September 11, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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:

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 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 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 4,000 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 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.

Our members provide the vast majority of ophthalmic surgical procedures performed in ASCs in the United States. On behalf of ASCRS, ASRS, OOSS, and SEE, we are taking this opportunity to comment on this important regulation governing CY 2018 Medicare ASC payment rates and the Quality Reporting Program for ambulatory surgical centers. Particularly with respect to the latter, we are pleased that a number of the recommendations of the ASC and ophthalmology communities have been adopted in the recent past and appreciate the close collaboration among industry, medicine, and the agency that has characterized the development of the QR program. However, we do have serious concerns regarding some elements of the payment provisions of the proposal, which are discussed below.

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. 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.

Under the proposed rule, facility payment for cataract removal (CPT 66984) would be $1,000.12, while reimbursement for the same procedure in the HOPD would be $1,868.23. The beneficiary's financial obligation in the form of copayments is $200 in the ASC and at least $373 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 $868. 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 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 mirror in ASC payments any changes to the APCs adopted in the OPPS in a manner that preserves the alignment between the payment systems and ensures fair and accurate payment for services within the ASC. The agency should engage stakeholders in discussions regarding how to implement those changes given the proposed differences in how services are reported and paid.**

- **CMS should implement further policy changes in setting payments for device-intensive procedures to encourage migration of services into the less-expensive ASC setting. Specifically, the device threshold should be set at 40 percent of the unadjusted ASC payment rate.**

- **CMS should maintain standard cataract (CPT 66984) and complex cataract (CPT 66982) and related procedures in the same APC.**

- **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 collaborate with Congress and stakeholders to extend the drug and device pass-through period to five years.**

- **CMS should remove the "comprehensive" designation of APC 5494 or, in the alternative, divide the APC into procedures with and without J7311.**

- **CMS should study the impact of restructuring on ASCs as well as HOPDs and make appropriate adjustments to ensure that ASCs are appropriately reimbursed.**

- **CMS should not implement formal cost reporting for ASCs as a means of establishing an appropriate annual update factor.**

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

B. Quality Reporting Recommendations

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

- **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 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 comparable cost differences in the provision of care in the two settings.

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 2018 rates, the percentage would be further reduced to approximately 53.5 percent. This change in rates is the result of the application of different inflation updates and an irrational and punitive budget neutrality policy that 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, including standard screening colonoscopy.

In formulating ASC policy and establishing payment rates, it is imperative that the agency recognize that most ASCs are small businesses that must run efficiently to remain in operation. There are 5,561 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 that Medicare beneficiaries deserve.

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, have 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

ASCRS, OOSS 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 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 2016 (when HOPDs were 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 over 40 percent of its weight); only 8.5 percent of the index's inputs track anything having to do with health care. With respect to the HMB, about 55 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 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.

Application of different inflation factors unjustly expands the gap in payments to HOPDs and ASCs. With the exception of one 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 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. Under the proposed rule, the ratio of ASC to hospital payments will drop to 53.5 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 divergence in payment rates.

CMS should immediately adopt the Hospital Market Basket instead of the CPI-U as the 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. Indeed, the ASC is among the last CMS-regulated payment systems to be linked to a CPI-update (the others being ambulance, clinical lab fee schedules and DME). *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.*

There are other update factors that might be suitable for the ASC. We appreciate CMS' request for feedback on alternative update factors. As described in the comments of the Ambulatory Surgery Center Association, 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, OOSS and SEE believe that the HMB is more representative of the cost structure than the CPI-U for purposes of updating ASC rates. In the alternative, if CMS insists on using the Consumer Price Index as an update factor, it should consider adopting one of the CPI-U subsets such as Medical Care, Medical Care Services, or Outpatient Hospital Services,

the inputs of which are more consistent than the CPI-U with the services provided in the ASC setting; these are discussed further below.

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 note that there is strong bipartisan support in Congress for this change, as reflected in House and Senate cosponsorship of the *ASC Quality and Access Act of 2017* (H.R. 1838/S. 1001).

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 setting. 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 0.9030 in 2017– a three percent change in the scaler in one year. Under the proposed rule, the relative weight would be under 0.9000 for the first time. 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 rats. With respect to both suggestions – discontinuing the scaler 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 were reasonably satisfied last year that 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 recommend that the agency set the threshold at 40 percent of the unadjusted ASC payment rate*, thereby mirroring the current policy for establishing device-dependent services and pass-thru payments under the OPPS; this policy change is all the more important because ASCs are not included in the new C-APCs.

Given that the ASCs' non-device payment is only 53.5 percent of that paid to HOPDs – meaning that ASCs have about half the reimbursement of hospitals to purchase the same devices -- ASCRS, OOSS, and SEE strongly recommend that CMS reduce the device-intensive threshold to 30 percent. This will promote appropriate migration of services from the hospital to the ASC and generate savings for Medicare and the beneficiary.

E. Solicitation of Comments on Intraocular Procedure APCs

The agency is requesting comments regarding the advisability of creating a new Level 2 Intraocular Procedures C-APC that includes complex cataract surgeries identified by CPT 66982 (with other procedures that are similar in resources), thereby separating complex cataract services from those identified by CPT 66984. *ASCRS, OOSS, and SEE believe that, given the clinical coherence of these procedures and the wide variation in resource costs associated with 66982 and related services, this is neither necessary nor appropriate.*

In order to better understand the differences between a traditional and a complex cataract surgery, it is necessary to define each:

- A *traditional cataract procedure,* CPT 66984, is performed when the patient has a visually significant cataract and the cataract description is not advanced (e.g., brunescent). The cataract surgeon plans for the removal of the cataract with phacoemulsification and implantation of an intraocular lens for visual correction, if all goes according to the plan. The patient may choose to have upgraded procedures such as astigmatism correction and/or femtosecond laser; however, the cataract is still phacoemulsified for removal.

- A *complex cataract procedure,* CPT 66982, is performed when the patient has a visually significant cataract with an advanced cataract description. The procedures require excellent surgical skill and effort in order to maintain adequate pressure in the eye, protect the anatomy of the eye, and ensure safe and effective cataract treatment. The cataract surgeon comprehends prior to surgery that he will be required to implement different surgical techniques and utilize additional supplies and drugs.

There is no single one-size-fits-all definition of what constitutes a complex cataract or how it is surgically treated. A partial listing of relevant diagnostic codes associated with complex cataract surgery includes the following:

- *H21.221 Degeneration of ciliary body, right eye*
- *H21.222 Degeneration of ciliary body, left eye*
- *H21.261 Iris atrophy (essential) (progressive), right eye*
- *H21.262 Iris atrophy (essential) (progressive), left eye*
- *H21.271 Miotic pupillary cyst, right eye*
- *H21.272 Miotic pupillary cyst, left eye*
- *H21.273 Miotic pupillary cyst, bilateral*
- *H21.29 Other iris atrophy*
- *H21.531 Iridodialysis, right eye*
- *H21.532 Iridodialysis, left eye*
- *H21.561 Pupillary abnormality, right eye*
- *H21.562 Pupillary abnormality, left eye*
- *H21.81 Floppy iris syndrome*

- *H21.89 Other specified disorders of iris and ciliary body*
- *H21.9 Unspecified disorder of iris and ciliary body*
- *H22 Disorders of iris and ciliary body in diseases classified elsewhere*
- *H43.821 Vitreomacular adhesion, right eye*
- *H43.822 Vitreomacular adhesion, left eye*
- *H57.00 Unspecified anomaly of pupillary function*
- *H57.01 Argyll Robertson pupil, atypical*
- *H57.02 Anisocoria*
- *H57.03 Miosis*
- *H57.04 Mydriasis*
- *H57.051 Tonic pupil, right eye*
- *H57.052 Tonic pupil, left eye*
- *H57.09 Other anomalies of pupillary function*
- *H57.9 Unspecified disorder of eye and adnexa*
- *Q13.1 Absence of iris*
- *Q13.9 Congenital malformation of anterior segment of eye, unspecified*

Each of the above qualifying complex cataract diagnosis codes may necessitate a different surgical approach. *However, it is imperative to note that all of these procedures are, basically, cataract extraction and lens implementation procedures; all of these procedures are clinically homogenous and appropriate grouped together with CPT 66984 in the same C-APC.*

The facility costs associated with furnishing complex cataract surgery vary widely depending upon the diagnosis and surgical plan. Supplies can include any or all of the following, but are not limited to: Vision Blue for visibility, extra and/or thicker viscoelastics, mydriatics and/or dilating devices, iris expanders or hooks, capsular hooks, capsular tension rings, vitrectomy handpiece, additional medications, instruments, sutures and/or intraocular lenses. We truly appreciate CMS' effort to ensure that payment rates are adequate for complex cataract surgery. However, we believe that it is simply not practicable to identify one C-APC value that will accurately reflect the costs associated with the plethora of complex cataract diagnoses noted above. There is no one approach or technique to the surgery. There is no one device or combination of medications that is used uniformly to surgically treat complex cataract cases.

Among ophthalmic surgery centers, margins vary widely from procedure to procedure based on internal cost structures, surgical skill and technique, and available products. Fortunately, complex cataract surgery rarely accounts for more than 5-7 percent of a facility's aggregate cataract volume. Every business has loss leaders and, with respect to ASCs, margins vary considerably from procedure to procedure and from center to center. However, on balance and with years of operational experience, facilities have learned to manage and contain their costs in performing cataract, complex cataract, and other procedures consistent with the presenting needs of the patient and the advanced skills of the surgeon. We believe that variations in payment for complex cataract surgery should be appropriately reflected in the surgeon's professional fee, as it is presently, rather than in the ASC facility fee.

We appreciate the agency's effort to "ensure our clinical groupings appropriately group items and services while maintaining the integrity of a prospective payment system under which bundled encounters-based payments are essential." All the procedures incorporated within the current APC are clinically homogenous and, as such, ASCRS, ASRS, OOSS, and SEE believe that these codes should remain in this one C-APC.

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

CMS is soliciting 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. Specifically, ASCRS, OOSS, and SEE are concerned with the potential 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, 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.*

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 during 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 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, 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 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. We are fortunate as clinicians and ASCs to have multiple options to treat our patients' post-operative challenges -- excellent self-administered drugs and effective 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, separately under Medicare Part B.

G. Continued Access to Drugs that Function as Supplies in Cataract Surgery – When Pass-Through Payments End and Are Bundled into the Facility Fee

Over the last few years, several ophthalmic drugs that are considered supplies during cataract surgery have been granted pass-through reimbursement status and, since then, either have either been bundled into the facility fee or are so scheduled by the end of this year. Our members have expressed serious concerns regarding the adequacy of the bundled payment to cover these drugs once pass-through status has expired and thus their ability to continue to utilize these drugs during surgery. The original intent of the pass-through statute was to promote the advancement of innovative drugs, biologics, and medical devices. Under current law, the pass-through status is transitional and can last for a minimum of two years, but not more than three. However, in an attempt to provide for a uniform policy, CMS recently granted three years for all drugs in this category.

During this time period, because the pass-through drug is reimbursed in addition to the facility fee, physicians have an opportunity to become familiar with the drug and determine whether it is beneficial to their patients' surgical care. The agency then tracks the utilization of the drug so that CMS can appropriately incorporate this into the APC rates when the drug comes off pass-through status. ASCRS, ASRS, OOSS, and SEE strongly believe that two to three years is not adequate time for the incorporation of the new drug into routine use during cataract surgery. *An extension of the pass-through period from three to five years would enable CMS to assess realistic marketplace accommodation and ensure that OPPS (and, ultimately ASC) rates reflect the costs of using these drugs. This change in policy would assist our member physician and facilities continue to afford Medicare patients continued access to these new and innovative drugs.*

H. Removal of the "Comprehensive" Designation for APC 5494

Over the past three years, we have expressed our serious concerns regarding the impact of CMS's decision to package drugs into procedures through the "Comprehensive APC," specifically its effect on APC 5494 (Level IV Intraocular Procedures). APC 5494

is a "single procedure" APC, which only includes services for which the HOPD or ASC has billed HCPCS 67027. Since the procedure is designated as "comprehensive," all related items and services on the hospital or ASC bill are "packaged" into the APC as well. The 2016 CMS dataset indicates that the majority of procedures billing HCPCS code 67027 were one of three types: procedures used for the implant of a drug (J7311), procedures used for the injection of a different drug (J7312), and procedures for which no drug was billed on the claim at all. The 2016 claims data reveals procedures using J7311 have a geometric mean cost of $18,433, procedures using J7312 have a geometric mean cost of $3,757, and procedures without a drug on the claim have a geometric mean cost of $1,1512. Yet, regardless of which procedure is performed, CMS in 2017 has been providing reimbursement at a level of $12,042 and, in 2018, the agency is proposing to reduce this payment to $8,762.

In our view, this violates the "two times rule," enacted by Congress to prevent procedures with widely divergent geometric mean costs from being packaged together. Moreover, the impact of the under-reimbursement for J7311 is even more severe at the ASC level than the HOPD due to the payment differential discussed above. It is simply not practicable for an ASC to furnish these services in the ASC, depriving beneficiaries of access to this care in the surgery center and depriving the program of thousands of dollars in savings for each case.

Given that the highest geometric mean item (and service) for J7311 is more than four times the cost of J7312 procedures and six times the cost of the procedures without drugs, we urge CMS to remove the "comprehensive" designation of APC 5494 or at the very least split the APC into procedures with and without J7311.

I. Ambulatory Payment Classifications Restructuring

As stated above, it is imperative that CMS mirror in ASC payments any changes to the APCs adopted for OPPS in a manner that preserves the alignment between the payment systems and ensures fair and accurate payment for services within the ASC. We understand that APC restructuring is intended to promote clarity and simplicity in the OPPS system. However, restructuring has had the unintended effect of reducing payments to ASCs and further distorting the relative reimbursement of HOPDs and ASCs.

In developing its C-APC policy, the agency conducted a comprehensive review of OPPS claims data, but it appears that no consideration was afforded the impact on surgery centers. It is notable that over half of all ASC approved procedures were encompassed within the C-APCs constructed in 2016 and, as of 2017, CMS had designated all but two APCs for ophthalmic procedures as comprehensive. *We strongly recommend that, going forward, CMS study the impact of restructuring on ASCs as well as HOPDs and make appropriate adjustments to ensure that ASCs are appropriately reimbursed.*

J. Solicitation of Comments Regarding Payment Reform for ASCs – Collection of Cost Data

We are pleased that the agency is soliciting feedback on payment reform for ASCs, including the collection of data that may support a rate update other than the CPI-U. This represents an excellent opportunity for CMS, industry, and medicine to collaborate to ensure that facilities are fairly and appropriately paid.

As noted in detail above, our organizations strongly believe that ample rationale exist to adopt the Hospital Market Basket as the update factor for ASCs. CMS has continued to express reservations about the use of this index and suggests that cost data could be utilized to verify cost structures used so that the agency cold apply its actuarial model to the ASC cost structure. ASCs incur the same costs as hospitals but we do not know if weighting is commensurate between the two settings. We are amenable to working with CMS to potentially develop a simple survey, perhaps voluntary in nature, that calculates expense categories as a percentage of total expenses, thereby enabling us to help determine appropriate weights and price proxies for the ASC setting.

ASCs already incur significant administrative burdens to meet current certification and other requirements and we would strongly oppose the implementation of a program that would require formal cost reporting. Again, we look forward to working with you to ensure that an appropriate update factor be applied to ASC rates.

K. 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 procedure 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.

II. 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

CMS has 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) two years ago and received conditional support pending endorsement by the National Quality Forum (NQF).

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 can 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. 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 a year ago did not address these concerns. CMS has cited, in the proposed rule, 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 through which providers and improve the quality of care and experience of our patients.*

Our main concerns include the following:

The survey instrument is too long. Simply stated, in our experience, patients will not participate in surveys that require an inordinate amount of time to complete. Most of our member facilities request that their patients participate in patient experience surveys. Our members report that these instruments are short and concise, typically including from 5 to 10 questions/topics; even with the simplicity of these forms, the response rates are only in the 15-30 percent range. Participation in the OAS CAHPS measure would be a substantially more intense undertaking by the patient. Despite the reduction of the number of items from the original 49 to the current 37, the instrument remains much too long. This problem is exacerbated if the facility opts to add questions that it believes will generate useful information about the patient's experience at the ASC. It is notable that the Hospital CAHPS survey includes only 32 items and, given the potential complexity of patient stays, it is incomprehensible that a longer survey would be appropriate for the ASC. The comments of the ASC Quality Collaboration address specific survey items that should be omitted or revised.

Information technology should be used to minimize the burden on facilities and patients. In addition to the proposed survey modes, facilities should be permitted to send surveys by email as well as text message (SMS) and use a web-based survey administration modality. The agency states, incorrectly we believe, that "any additional forms of information technology, such as web surveys, would be less feasible with OAS CAHPS patients, as patient information is not readily available through HOPDs and

ASCs." To the contrary, email addresses are as routinely collected by facilities as the patients' home addresses and phone numbers. CMS also suggests that Medicare beneficiaries are not likely to respond to surveys administered online; the reality is that government studies have concluded that internet use among the elderly is well above 50 percent and is growing. Besides the convenience that online distribution of surveys and web-based survey administration offers patients, ASCs have found that significant savings can be accrued compared with traditional survey approaches. If CMS intends to make this survey mandatory for both ASCs and hospitals commencing in 2018, it is imperative that email and web-based survey modes be permitted and, indeed, encouraged.

There are significant costs to facilities in administering the survey. Presently, there are three approved methods for administration of the survey: mail only, telephone only, and mail with a telephone follow-up. Based on our members' experience in identifying a third-party vendor, we would estimate that our facilities would incur an average cost per center of about $500 per month, which includes vendor fees, maintenance and staff time, an amount that could be higher depending upon the mode of administration selected by the facility. To reiterate, these costs can be reduced if electronic survey options are available to facilities and vendors.

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Thank you for providing our organizations with the opportunity to present our views on the proposed regulation regarding 2018 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