September 8, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Revisions to Part B for CY 2016 Proposed Rule**

Dear Mr. Slavitt:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing nearly 10,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care.

We appreciate the opportunity to comment on the 2016 Medicare Physician Fee Schedule Proposed Rule. We have provided comments below on nonfacility cataract surgery, valuation and coding of the global package, the Value-Based Payment Modifier, Physician Compare, and the Medicare Access and CHIP Reauthorization Act of 2015.

**Request for Information on Nonfacility Cataract Surgery**

ASCRS appreciates the opportunity to provide information regarding in-office surgical suite cataract surgery. In the proposed rule, CMS states that "advancements in technology have significantly reduced operating time and improved the safety of the procedure and patient outcomes." While it is true there have been significant advances in technology over the years, cataract surgery is still surgery—and is a complicated procedure with a high surgical intensity. In addition, the patient population is usually very elderly with co-morbidities and significant medical issues. **Therefore, patient safety is an important factor, and ASCRS would caution CMS to think through all possible complications and issues associated with performing this procedure when considering nonfacility cataract surgery.**

Below, we provide comment on specific questions raised by CMS, as well as identify issues for CMS to consider that are not addressed in the proposed rule. We believe there could be some potential benefits, but at the same time, there are additional factors CMS needs to take into consideration that would affect nonfacility cataract surgery. In addition, ASCRS is willing to work with CMS in more detail to develop direct practice expense inputs in the future, if CMS decides to move forward with a specific nonfacility cataract surgery proposal.

***Additional Factors to Consider***

When contemplating office-based cataract surgery, there are several issues to consider, which CMS did not identify or address in the proposed rule. First and foremost, patient safety is paramount, along with the real possibility of complications. The use of anesthesia, including intravenous sedation, and the certification requirements for in-office surgical suites are also important factors.

***Patient Safety and Possible Complications***

In the proposed rule, CMS states "routine cases in patients with no comorbidities could be performed in the nonfacility surgical suite, while more complicated cases could be scheduled in the ASC or HOPD." However, many complications do not arise until the cataract surgery is already taking place. **Often, surgeons are unaware whether a particular cataract surgery will be complicated until they have begun the procedure. Since what may be considered routine initially, may not turn out to be routine, all locations where cataract surgeries are performed would need to be equipped to deal with both complicated and non-complicated cataract surgeries, including in-office surgical suites.** Adequate personnel and equipment need to be available to take care of medical problems that could arise during cataract surgery. Elderly patients have a higher likelihood for complications related to pulmonary, cardiac or hypertension issues, which can complicate a "routine" cataract surgery if not properly monitored and treated quickly. In addition, complications can arise from sedation or the surgery itself.

***Anesthesia***

In the proposed rule, CMS states that "except in unusual circumstances, anesthesia for cataract surgery is either local or topical/intracameral." **That statement is inaccurate as most of our members use intravenous anesthesia or sedation for cataract surgery as an addition to local or topical anesthesia.** Some patients require more than topical and or IV sedation in order to provide them with the optimal environment in terms of procedural safety and best outcomes, as well as optimizing safety as it relates to the general health and well-being of the patient. This should be monitored by a CRNA or an anesthesiologist as our patients are often elderly, have multiple medical problems, and need to have their vitals monitored and the ability to do deeper anesthesia when needed. Therefore, the use of CRNA's and anesthesiologists during cataract surgery is essential, as well as having ready access to skilled nursing. Patients must also be monitored while on intravenous anesthesia, and possible side effects of cataract surgery in an in-office surgical suite anticipated. In addition, providers typically employ drugs such as epinephrine or phenylephrine in most cases, which have cardiac effects, including arrhythmias. There is also an oculo-cardiac reflex that causes a slowing of the heart rate, which can lead to serious cardiac events. **These issues illustrate that intraocular surgery with anesthesia remains an intensive surgery that has significant risks.**

***Certification Requirements***

CMS also states in the proposed rule that "cataract surgery patients require a sterile surgical suite with certain equipment and supplies that we believe could be a part of a non-facility based setting that is properly constructed and maintained for appropriate infection prevention and control." We agree and believe it is imperative there are safety standards, infection control, and quality assurance/benchmarking requirements. There needs to be an assurance of the standard of care in sterility, equipment, staffing and anesthesia. Therefore, infection control, sterility, and proper staffing would all need to be similar to ASC standards and in compliance with state law. **In order to guarantee appropriate infection prevention and control, regulation of in-office surgical suites at both federal and state levels, and development of certification requirements for these nonfacility surgical suites by CMS will need to be addressed.**

***Possible Benefits of Office-Based Surgical Suite Cataract Surgery***

In the proposed rule, CMS states one potential advantage to in-office surgical suite cataract surgery is "it might provide surgeons with greater flexibility in scheduling patients at an appropriate site of service depending on the individual patient's needs." CMS also notes "cataract surgery in the office setting might provide [patients] the additional convenience of receiving preoperative, operative and postoperative care in one location." ASCRS agrees that one possible benefit of office-based surgical suite cataract surgery might be additional flexibility and convenience for both patients and providers.

Many ASCRS members live in states that have strict Certificate of Need (CON) laws, making it difficult for providers to build their own Ambulatory Surgical Centers (ASCs). In these states, our members must either perform cataract surgeries in Hospital Outpatient Departments (HOPDS) or multispecialty ASCs. Typically, in these cases, our members may have difficulty scheduling their cataract surgeries in a timely manner. **We agree that particularly in states with CON laws, the ability for providers to offer in-office surgical suite cataract surgery would make scheduling procedures more convenient for both patients and providers. It may also be more convenient for patients, especially the older Medicare patient population our members tend to treat, to visit one office for the surgery, pre- and post-operative care. Office-based surgical suite cataract surgery might offer a more flexible option for both patients and providers.**

***Direct Practices Expenses***

Creating an exhaustive list of direct practice inputs and valuing these inputs for office-based cataract surgery would be a difficult and time-intensive process. As referenced in our comments, there will be significant costs associated with providing cataract surgery in an in-office surgical suite that would need to be accounted for in determining an accurate non-facility payment rate. It would be imperative that CMS recognize costs for equipment, technology, anesthesia and nursing staff, certification requirements, labor and other supplies. Other indirect expenses, such as the cost of construction and maintenance of an office-based surgical suite and increased overhead would also need to be addressed. ASCRS is willing to work with the AMA, the RUC, and other ophthalmology specialty societies to identify the list if CMS chooses to move forward with a nonfacility cataract surgery option.

***Conclusion***

Cataract surgery remains a major surgery with a high level of intensity. ASCRS laid out additional factors for CMS to consider surrounding in-office surgical suite cataract surgery. These factors, discussed above—patient safety, the possibility of complications, the use of anesthesia and the need for certification requirements from the proper accrediting body for in-office surgical suites—should be addressed by CMS as they consider whether to create a nonfacility cataract surgery option.

ASCRS also highlighted some of the potential benefits of nonfacility cataract surgery, including flexibility of location for patients and convenience of scheduling cataract surgery for providers who are not able to perform the surgery in an ophthalmic ASC. As we stated above, ASCRS is also willing to work with CMS and the RUC if this proposal moves forward to develop specific direct practice inputs. **To reiterate, our patients are often elderly and have multiple medical problems, therefore, cataract surgery should not be trivialized.**

**Valuation and Coding of the Global Package**

CMS noted in this proposed rule there is still an unmet need to address some of the fundamental issues with the 10- and 90-day post-operative global packages, however, we disagree, and believe the RUC fairly and accurately values the global surgical packages. The RUC reviews each code every five years, and the number of post-operative visits are assessed through surveys, which results in accurate valuation of the components of the surgical package. For example, in 2013 the Extracapsular Cataract Removal (66984) and Complex Cataract Surgery (66982) codes were revalued by the RUC. Ophthalmologists were surveyed, the medical societies presented their results, and both codes were significantly reduced, based in large part on the decrease in surgical time and number of postoperative visits required following surgery. This RUC process occurs for all codes and one main point of the assessment is looking at postoperative visits and revising any inaccuracies. If CMS decides additional information is needed on other independent surgical components, the RUC is in the best position to evaluate individual components of the global surgical package, and ASCRS encourages CMS to work with the RUC to gather any additional information needed.

If CMS moves forward with valuing physician work and practice expense portions of the global surgical package, ASCRS reminds CMS, as we have stated previously, that simply using a reverse building block method to back out the post-operative services would be inappropriate and methodologically unsound. As we have explained, there is a difference between post-operative direct practice expense inputs for global E/M codes and separately reported E/M codes. The E/M services performed in a global surgical period often include additional practice expenses (PE), such as supplies and equipment including specialized dressings and bandages, specialized examination tables, and surgical lights that are often more expensive. Therefore, if CMS removed the direct PE from the 10 and 90-day surgical codes, they would need to account for these additional direct PE inputs. In addition, the codes with higher practice, as well as malpractice expenses, such as ophthalmology, would be negatively impacted by a reverse building block methodology because these higher expenses would not be accounted for if E/M codes were backed out of bundled codes using the reverse building block method. Specialties with high practice or malpractice expenses, such as ophthalmology, would be at a disadvantage. To reiterate, the reverse building block method to back out post-operative services is not an accurate method to

value physician work and practice expense, and ASCRS urges CMS to refrain from using this methodology when valuing physician work and practice expense.

CMS states they are "soliciting comments regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished by the practitioner reporting the procedure code during the current post-operative periods) needed to increase the accuracy of the values for surgical services." Office visit codes physicians provide on claims can provide information regarding the number of post-operative visits provided within each bundled global surgical package. However, CMS should be aware this data has limitations, as many surgeons do not include the post-operative office visit codes since they know the codes are bundled within the 90-day global surgical period. While some practices do use the post-operative follow-up visit code to keep track internally of how many times they see the patient during the global fee period, many practices do not use the code at all since they do not bill it to Medicare. CMS should be aware of the significant issues with using office visit codes to track post-operative visits, if they move forward with that methodology.

Finally, CMS is seeking comments regarding stakeholder interest in the potential for an open door forum, town hall meetings with the public and other avenues for direct communication regarding these provisions. ASCRS strongly encourages CMS to host open door forums and town hall meetings to gather information regarding the global surgical packages, and would gladly participate in any public meetings or direct communication requests from CMS regarding these issues.

**Value Based Payment Modifier (VBPM)**

ASCRS continues to have major concerns with the VBPM program, and its application to specialty providers. The cost measures do not apply to our specialty, and we are concerned that these same cost measures will be used as the Resource Use Measures in the Merit-Based Incentive Payment System (MIPS) program.

***Cost Measure Issues***

As we have stated previously, the cost measures used in the VBPM program do not apply to our specialty. It is impossible for CMS to evaluate specialists based on their cost data using these measures since none of the measures apply to specialty providers, such as cataract surgeons. Chronic obstructive pulmonary disease, coronary artery disease, heart failure and diabetes are not medical conditions that our providers typically have any impact on or control over, and therefore, should not have patients attributed to them based on these cost measures. ASCRS believes the VBPM should not apply to specialists until more meaningful cost measures are developed and tested. We encourage CMS to work with specialty societies to develop more meaningful cost measures.

***Inaccurate Data***

ACSRS cautions CMS to refrain from holding providers responsible for possible inaccurate data. As illustrated by the recently released announcement from CMS, there are errors in the 2014 VBPM data, therefore, we believe all providers should be held harmless from penalties until the measures for the VBPM program can be further evaluated and modified.

***Program Changes***

Finally, ASCRS generally supports that CMS did not increase the quality reporting requirements for the PQRS and VBPM programs. We agree that with the upcoming MIPS program starting with 2017 reporting, there should be no additional changes to these programs.

ASCRS also agrees with the change to the Medicare Spending Per Beneficiary measure, which increases the number of attributed episodes before CMS can include the measure in the cost composite from 20 to 100. ASCRS would support an even larger number of episodes, such as 200, as the minimum requirement.

**Physician Compare**

ASCRS believes there are significant problems with CMS' proposal to publish additional data on the Physician Compare website. First, the minimum sample size of cases required for a measure to be reported on the website is too small. **The sample size should be at least 30 patients if not higher.**

In addition, CMS currently includes a notation on the Physician Compare website for individual practitioners and group practices who receive an upward adjustment for the VBPM. This is misleading as in 2013, practices had the ability to opt into the quality tiering portion of the VBPM. The optional nature of participating in quality tiering needs to be adequately explained, or the notations should be removed. In this proposed rule, CMS proposes to go one step further and add downward or neutral VBPM adjustments to the Physician Compare website. As stated previously, the VBPM measures are not adequately tested, and many questions remain as to whether the cost and quality measures are an accurate reflection of a practices' cost and quality. **Therefore, this data should not be publicly reported until a later date when enough time has passed to ensure the validity and reliability of these measures.**

**Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)**

CMS asks for input on the provisions in MACRA, specifically the Merit Based Incentive Payment System (MIPS). Overall, ASCRS would caution CMS to phase-in the MIPS requirements gradually, and not increase the requirements of any program, until providers are comfortable with the new MIPS quality reporting system.

**First, ASCRS would urge CMS to delay Stage 3 meaningful use, and work with specialty societies to reduce the thresholds required in Stage 3 to more reasonable levels.** The proposal for Stage 3 meaningful use, would prohibit our members from not only successfully meeting Stage 3 meaningful use, but also being able to successfully participate in the MIPS program, if it is included.

While the quality, resource use, and meaningful use components of the MIPS program were described somewhat in MACRA, the clinical improvement activities category is not yet defined. Given that the quality, resource use and Meaningful Use categories have many measures to meet and can be complex, ASCRS urges CMS to ensure the Clinical Improvement Activities category is as flexible and simplistic as possible. For example,

there are some clinical improvement activities that will make sense for primary care but not specialists, such as timely communication of test results, or use of telehealth. ASCRS encourages CMS to make sure there are enough activities that also apply to specialists for them to easily satisfy this category. We are happy to work with CMS to help develop specialty-specific clinical improvement activities. ASCRS also feels strongly this category should be evaluated simply on whether providers have these activities in place, and should not include thresholds providers must meet. As we stated previously, the move to the new MIPS will be complicated for providers, and CMS should make any new required activities as simple as possible until providers are successfully reporting for MIPS.

CMS also requested information on how the low-volume threshold should be defined for the purposes of excluding certain eligible professionals from the definition of an eligible provider under the new MIPS program. **ASCRS supports a requirement if a provider's Medicare patients make up less than 30 percent of their patient population, they should be excluded from the MIPS program.** This is a similar threshold to the requirement for the Medicaid EHR Incentive program, which requires the patient population must be 30 percent Medicaid to be considered for the program.

Overall, ASCRS strongly encourages CMS to work with medical specialty societies as the MIPS program is developed over the next few years. ASCRS is always willing to attend public forums, or meetings with CMS on specific MIPS issues. We plan to work with CMS to implement the MIPS program going forward with a particular focus on the ability of our specialty to participate.

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Thank you for providing our organization with the opportunity to present our comments on the proposed rule. Should you have any questions about our comments, please do not hesitate to contact Ashley McGlone, Manager of Regulatory Affairs, at amcglone@ascrs.org or 703-591-2220.

Sincerely,

Robert Cionni, MD
President, ASCRS