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OUTPATIENT OPHTHALMIC SURGERY SOCIETY

September 6, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Payment Policies under the Physician Fee Schedule Proposed Rule for CY 2014; 78 Fed. Reg. 43,281 (July 19, 2013); CMS-1600; RIN 0938-AR56

Dear Administrator Tavenner:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing more than 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of more than 1,100 ophthalmologists, nurses, and administrators who specialize in providing high quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

We appreciate the opportunity to provide our comments regarding the Centers for Medicare and Medicaid Services' (CMS) Medicare Physician Fee Schedule proposed rule for CY 2014. Please find below specific comments regarding the payment and quality provisions of the proposed rule that have a significant impact on ophthalmology.

Practice Expense Methodology – OPPS/ASC Capped Payment

ASCRS and OOSS oppose the proposal to cap non-facility Practice Expense (PE) RVUs for over 200 physician services at either the Hospital Outpatient Prospective Payment System (OPPS) or ambulatory surgical center (ASC) facility payment rate and urge CMS to withdraw this proposal.

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This proposal, which would cap payments to services performed in the non-facility setting when those payments are greater than what is paid when the same service is performed in either the hospital outpatient or ambulatory surgical center facility setting, is based on the faulty premise that there are greater indirect resource costs when a service is performed in a facility as compared to a non-facility and that cost data is more reliable in the OPPS and in the payment structure for ASCs as compared to resource-based relative value scale (RBRVS) data.

ASCRS and OOSS disagree with the premise that higher payment rates for services in a physician's office must be based on inaccurate data. We believe this is based on inaccurate assumptions as there are major differences in Medicare payment methodologies between the Medicare physician payment system – which is based on RBRVS - and the ambulatory payment classifications (APCs) used for OPPS and ASC payment rates. The RBRVS captures the actual relative resource costs of each individual service as opposed to APCs, which are a bundled payment method that averages low and high-margin hospital services within a single APC. Therefore, these differences make service-by-service comparisons incorrect. It is also important to note that unlike hospitals that have the ability to make up for losses on any given service with profits on another, physicians have no opportunity.

Further, this proposal also applies the cap to 2014 Physician Fee Schedule rates based on a comparison to 2013 OPPS and ASC rates. The new policy, therefore, would not reflect the anticipated payment update of 1.8 percent for the OPPS and 0.9 percent for the ASC payment rates, as well as any proposed APC weight changes. This will result in significant differences between the OPPS/ASC cap and the actual rate being paid in these settings in 2014.

If payments do not cover the direct costs of care provided, physicians may be forced to send patients to more costly settings and in some instances impact the timeliness of the treatment rendered. In addition, for the 78 services where OPPS payments exceed physician fee schedule payments, both the Medicare beneficiary and the program may pay more, not less, for their care.

Medicare Economic Index (MEI) – Revising the MEI Based on MEI Technical Advisory Panel (TAP) Recommendations

While ASCRS and OOSS are supportive of the reconsideration of the MEI – and maintaining updated accurate practice expense data, we are disappointed that CMS does not provide a clear explanation and supporting data on its methodology to assign the proposed change in the weights assigned to work, practice expense, and malpractice that result in revised RVUs. Therefore, we request a delay in the application of these changes until additional information is provided to the stakeholders and public.

In 2012, at the recommendation of the medical community, CMS convened a TAP to conduct a comprehensive review of the MEI. As a result, the panel made thirteen recommendations to improve the accuracy of the MEI, ten of which are included in the proposal. CMS is proposing to revise certain cost categories and price proxies that are distinct from rebasing the MEI, which are affecting the weight assigned to physician compensation. This results in the revised RVUs based on the new weights for the three components, work, practice expense, and malpractice. To reiterate, ASCRS and OOSS are supportive of maintaining updated practice expense data and in

revising the MEI, however we are disappointed that more specific data and information regarding the methodology is not included in the proposal.

Further, ASCRS and OOSS strongly encourage CMS to continue work on the remaining issues identified by the MEI-TAP that are not reflected in this rule. Most important, is the identification and collection of accurate practice cost data to keep the MEI cost shares up to date.

Requirements for Billing "Incident to" Services – Compliance with State Law.

CMS proposes to revise its "incident to" regulations to require that the individual performing "incident to" services meet any applicable requirements to provide the services, including licensure, enforced by the state in which the services are being provided. **While ASCRS and OOSS agree that any healthcare provider should be in full compliance with all state laws, we have several concerns, including the additional administrative burden, which are outlined below.**

CMS proposes to revise Medicare requirements to specifically make compliance with state law a condition of payment for "incident to" services and supplies, which was recommended by the HHS Office of Inspector General in 2009. Section 1861(s) (2)(A) of the Social Security Act and section 410.26 of Medicare regulations set forth the requirements that must be met to bill Medicare for services and supplies furnished "incident to" the professional services of the physician. Specifically, CMS is proposing to add a new subsection 410.26 (a) (1) with the following language:

> *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

ASCRS and OOSS are concerned how broadly these provisions could be applied as "auxiliary personnel" refers to "an individual who is personally performing the service or some aspect of it." In ophthalmology, we have seen non-physician healthcare providers performing services outside their designated state license and scope of practice, without any type of action being taken by CMS and individual Medicare Carriers. Therefore, we are uncertain whether this new expansion will be enforced so that unqualified providers are prevented from performing services outside of their legal scope and are concerned that in order to ensure compliance, this will add to an already significant Medicare administrative burden for physicians.

2014 Physician Quality Reporting System (PQRS)

This proposed rule includes several key changes to the PQRS, including 2014 PQRS incentive requirements and 2016 PQRS payment adjustments. While ASCRS and OOSS are pleased that CMS has expanded the recognition of registry reporting across its performance programs, we oppose several key proposed changes to the PQRS that are outlined below and urge CMS to reconsider.

By law, 2014 is the final year an EP can quality for an incentive payment (0.5 percent). The 2016 PQRS penalty adjustment (two percent) for those who do not satisfactorily report - is based on the 2014 performance year.

Despite concerns raised by the physician community, CMS will maintain a two-year look-back for applying the PQRS penalties. **In addition, CMS proposes to increase the total number of measures that must be reported from three to nine, increase the total number of measures in a measure group from four to six, and eliminate the option of allowing providers to avoid the 2016 PQRS and VBM penalties by reporting one measure or one group.** The proposal also includes a new PQRS reporting option – satisfactory participation in a "qualified clinical data registry."

While ASCRS and OOSS welcome CMS' efforts to further align quality measure reporting across the various performance programs and increase the number of measures available for reporting, we are concerned with the ever growing difficulty for physicians and their practices in monitoring the yearly changes, as well as the associated administrative burdens. **It is, therefore, important that physicians continue to have options for receiving credit for all quality measurement and improvement activities.**

- **ASCRS and OOSS oppose the CMS proposal to increase the current PQRS reporting requirements from three to nine measures – covering at least three NQF domains in one program year in order to achieve a bonus.** We believe this is too aggressive given that less than one-third of physicians currently participate. Therefore, CMS should maintain the current PQRS reporting requirements or consider a more incremental increase in the number of measures required to be reported.

- **We also encourage CMS to maintain the current option of allowing providers to avoid the 2016 PQRS and VBM penalties by reporting one measure or one group.**

- **We also question the need to increase the minimum number of measures in a measure group from four to six and respectfully request that it be withdrawn.** Ophthalmology has experience in developing appropriate outcomes measures to be included in a measure group (cataract) and maintains that measures should only be added when they are appropriate to the clinical topic and not to reach an arbitrary number that is not based on science.

Specifically, the newly proposed measure Patient-Centered Surgical Risk Assessment and Communication: *The Percent of Patients Who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with The Surgeon* is not applicable for any ophthalmic procedures, and therefore, should not be added to the cataract measures group. A risk calculator does not exist for ophthalmology.

While ASCRS and OOSS are in full support of the transition to clinical data registry and EHR reporting**, we oppose the elimination of the claims-based reporting option until it is clear that all physicians have the capability and knowledge to collect and report on quality measures using registries or EHRs.**

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Qualified Clinical Data Registries

ASCRS and OOSS support the expanded recognition of registry reporting across its quality improvement programs. We are pleased to see this option implemented in the proposed rule, and we agree with the CMS definition of qualified clinical data registries as quality improvement entities that have the capacity to benchmark physicians and provide regular timely feedback. However, ASCRS and OOSS are concerned with the timeline and requirements for the qualified clinical data registries (QCDRs).

Ophthalmology is in the beginning stages of the implementation of a clinical data registry, and therefore, would encourage CMS to incorporate the proposed requirements more gradually, in addition to making the option available to group practices and allowing registries to report on measure groups, as well as single measures.

- ASCRS and OOSS strongly recommend that CMS not hold the QCDRs to the same requirements as conventional PQRS reporting mechanisms – which is not in line with congressional intent for the QCDR program. **Therefore, we recommend that CMS allow QCDRs to define the number of measures that they will report and the sampling strategy for the measures, provided at least one measure is an outcome measure.**

- **In addition, rather than requiring all QCDR-reported measures meet the 50 percent sampling threshold, CMS should require entities that seek to be QCDRs to submit an evidence-based sampling strategy for their measures.** As an alternative, CMS could create two sampling options – a 50 percent threshold for more conventional measures and a 20 percent sample for survey-based or patient experience measures.

- **We are also concerned with the requirement to have 100 participants as of January 1, 2013, as this will limit the ability of new registries to participate in the first year of the program.** We believe there are entities that meet the CMS definition that may not have had 100 participants a year ago – but are still capable of benchmarking physicians and submitting statistically valid data in 2014.

- ASCRS and OOSS **strongly oppose requiring QCDRs to publically report registry data in the early years of the program.** We do support the alternative requirement that QCDRs benchmark within the registry for purposes of determining relative quality performance.

Electronic Health Record (EHR) Incentive Program

ASCRS and OOSS appreciate CMS' efforts to further recognize registry reporting and implement its authority under the ATRA to allow QCDRs to report for meaningful use and the PQRS. **We also urge CMS to utilize the flexibility offered in the statute and the Stage 2 Final EHR Rule to afford physicians the opportunity to submit measures according to the requirements finalized for the QCDR reporting option in order to satisfy both PQRS and EHR Incentive Program CQM reporting.**

We also believe CMS should extend its authority to recognize physicians who are participating in meaningful QCDR reporting activities as having met all of the requirements of meaningful use, not just the clinical quality measures. Further, physicians who use their certified EHR systems to participate in the QCDR should be deemed as having met the meaningful use requirements.

Physician Compare Web Site

ASCRS and OOSS urge CMS to address the current database accuracy problems prior to posting quality measure performance information.

While several positive changes have been made to the site, including the use of claims data to verify physicians' information and revisions to the search function related to the listing of physicians and specialties, additional improvements are still necessary to ensure the accuracy of the search function, as well as the fundamental demographics of the data. CMS proposes to post on Physician Compare, no earlier than 2015, information regarding physicians' performance in the Group Practice Reporting Option (GPRO) registry, and specific EHR measures reported via the GPRO web interface in 2014. Quality measures would expand to include performance on all measures collected through the GPRO web interface, for all groups, regardless of size, participating in 2014 under the Physician Quality Reporting System (PQRS) GPRO, and for accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). In addition, the proposal includes an expansion of the public reporting for both group practices and individual eligible professionals (EPs) starting in 2015, based on 2014 data.

We still remain concerned about the accuracy and clarity of Physician Compare data. We are very concerned that any quality information published on Physician Compare could be incorrect, not up to date, or misattributed. **Therefore, ASCRS and OOSS urge CMS to address the current accuracy problems with the database prior to posting any group practice quality measure performance. We also believe CMS should refrain from using a system of star ratings to show quality data on the website.** CMS should avoid a system that suggests PQRS measures can be used to rate a physician or is a proxy of quality. ASCRS and OOSS are concerned this type of system could be viewed by consumers as a physician rating.

Once these problems are alleviated – ASCRS and OOSS do support the proposal to provide a 30-day preview period prior to publication of the quality data on the website. ASCRS and OOSS previously recommended that CMS establish a timely and effective process for physicians to review and for the CMS to correct any errors identified in their information on Physician Compare.

Clinician & Group Consumer Assessment of Healthcare Providers & Systems (CG-CAHPS)

CMS is requesting comment on the posting of performance on patient experience survey-based measures for individual EPs beginning with data collected for 2015. In addition, the proposal includes the continuation of the publicly reporting of CG-CAHPS data in 2014, for PQRS GPRO group practices of 100 or more EPs, which participate in the GPRO via the web interface, and for the MSSP ACOs, which report through the GPRO web interface or other CMS- approved tools or interfaces. CMS encourages groups of 25 or more EPs to report CG-CAHPs by making these measures available for reporting through the PQRS and the Value-Based Payment Modifier (VBM).

CMS identifies the CG-CAHPS survey as the most suitable instrument to measure patient experience under the PRS and the VPM programs. While we support the use of this survey, there are other survey instruments, such as the Surgical CAHPS, available which would achieve the same intended goal and more closely assesses the patient experience during an episode of surgical care compared to CG-CAHPS. **Therefore, we request that CMS give physicians the flexibility to select the survey instruments and patient satisfaction measures most appropriate for their practices.**

Value Based Payment Modifier (VBM) and Physician Feedback Program

ASCRS and OOSS remain opposed to the implementation of the budget-neutral value-based purchasing modifier and continue to urge CMS to delay the implementation of the VBM program. Additional time and resources are required to test valid measures of cost and quality, as well as mechanisms that accurately adjust for riskier, more complex clinical scenarios, before moving forward with a policy that modifies physician payment based on "value."

Despite serious unresolved methodological issues, the CMS proposal would more than double the number of physicians who are subject to the VBM and would also increase penalties from a maximum of 1 percent to 2 percent. While the law requires the VBM to be phased in over a three-year period where it will eventually apply to all physicians, CMS is basing adjustments in any given year on a performance year two years earlier. Therefore, any requirements included in the 2016 payment adjustment essentially take effect in 2014.

Further, despite the fact that last year, CMS changed their original proposal to apply the VBM to 25 or more to 100 or more – the agency is now proposing to apply the VBM to physicians in groups of ten or larger in 2016, which extends the payment adjustment to an estimated 58 percent of physicians. Specifically, payments for those physicians affected would be cut by 2 percent in 2016, unless they successfully participated in one of the PQRS group options or unless 70 percent of the physicians and other eligible professionals in the group participated in the PQRS as individuals. In addition, successful PQRS participants would then be subject to a second "quality tiering" phase where groups are compared nationally on quality and cost and have the potential to earn an unspecified bonus or penalty of up to 2 percent.

Again, we continue to believe the VBM is a flawed concept that cannot be equitably applied across the board to all physicians.

Therefore, ASCRS and OOSS are opposed to CMS's proposal to increase the VBM penalty from one percent to two percent; mandating participation in the tiering option as opposed to the current voluntary option; and making Medicare Spending per Beneficiary (MSPB) an additional cost measure. We also are opposed to the expansion to groups of 10 or more EPS from the current 100 or more EPS, as this is too aggressive for the second year of this program.

- **As indicated above, we believe CMS should maintain the maximum downward adjustment at 1 percent of physician fee schedule payments to allow smaller physician groups the same level of phase-in that larger groups have had.**

- **In lieu of the move to expand the modifier to groups of 10 or more EPS, ASCRS recommends that CMS consider increasing that number to 50 or more EPs**. CMS should delay expanding the value-based modifier beyond this group until it has issued QRURs to all physicians in the summer of 2013.

- **ASCRS and OOSS are opposed to the CMS proposal to make quality tiering mandatory for all groups of ten or more practitioners.** No one yet knows how the voluntary quality tiering option affected the groups included in the first phase of the VBM. While we can agree that starting with a voluntary version of the tiering mechanism is reasonable, there are numerous questions that should be evaluated before it becomes mandatory.

- **ASCRS and OOSS oppose CMS' dependence on measures (cost and outcome) that were never developed for and tested in physician practices, particularly in the absence of any CMS analysis of how these measures affect different types and sizes of practices and in the context of the proposed mandatory tiering process.**

- **In addition, ASCRS and OOSS have concerns regarding the validity of the MSPB measure. The risk adjustment methodology does not adequately account for the socioeconomic status – which impacts the various levels of patient complexity, including patient compliance, that are not within the physicians' control. Unintended consequences may be that higher risk and disadvantaged patients lose access to the care they need because of the threat of penalties.**

- **We are also adamantly opposed to extending the modifier to solo practitioners and groups of fewer ten physicians in 2017.**

Physician Feedback Program

In CY 2012, CMS distributed feedback reports to individual physicians and groups based on CY 2011 performance. CMS plans to provide feedback reports in September 2013 - at the TIN level to all groups of physicians with 25 or more EPs based on CY 2012 data, as well as distributing feedback reports based on CY 2013 data the summer of 2014. These reports will include performance on quality and cost measures used to score the composites of the value-based payment modifier.

While ASCRS and OOSS appreciate the availability of these reports to all physicians in 2014, it is not clear that this information will be provided in time to inform physicians about their 2013 utilization, which is the basis for the 2015 payment period. Groups are required to make the decision whether to participate in the quality tiering in December 2013 for the purpose of the 2015 payment adjustment, but will not receive performance data until late summer of 2014.

To reiterate, while we appreciate the fact that CMS is under congressional pressure to meet the requirements for applying the modifier to all physicians by 2017, we do not agree that is reason enough to move forward on this untested methodology with no assessment between phases to analyze results and adjust accordingly. We remain strongly opposed to any policy that is budget neutral with no floors and ceilings that arbitrarily takes from one physician to give to another. The value-based payment modifier, as currently authorized, will only interfere with the physician-patient relationship and impede the delivery of high quality specialty care. With the

multitude of unresolved challenges related to the measurement of physician resource use, attribution, and the adjustment of physician payments based on value, **ASCRS and OOSS continue to urge CMS to delay the implementation of the VBM system.**

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Thank you for providing our organizations 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 Nancey McCann, ASCRS Director of Government Relations or 703-591-2220, or Michael Romansky, Washington Counsel, OOSS, at mromansky@ooss.org or at 301-332-6474.

Sincerely,

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