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OUTPATIENT OPHTHALMIC  
SURGERY SOCIETY

September 2, 2014

Marilyn B. Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule; CMS-1612-P**

Dear Administrator Tavenner:

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.

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 comment on the 2015 Medicare Physician Fee Schedule Proposed Rule with particular focus on the proposed transition of the 10 and 90-day to 0-day global codes the changes to Medicare physician quality reporting programs in 2015, the proposed RUC and CPT revised timeline, the changes to the Open Payments program, the Malpractice Relative Value Unit changes, and the expansion of the Physician Compare website.

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## **Transition from 10 and 90-day to 0-day global codes**

ASCRS and OOSS have significant concerns about the transition from 10 and 90-day to 0-day global codes and believe that this proposal should not be finalized. We believe that CMS' proposal raises data accuracy problems; faces major implementation issues; fails to recognize that the RUC valuation process is effective; could have a negative impact on Medicare beneficiaries; and does not account for the efforts surgical specialties have made at the urging of CMS to move toward developing bundled payments such as the 10 and 90-day global codes.

### **Data Accuracy Problems**

CMS actually noted in the proposed rule that they do not have accurate data with which to remove the practice expense and post-operative visit costs from these 10 and 90 day bundles, which would make it very difficult to effectively implement this proposal. This proposal would affect over 4,200 services on the Medicare Physician Fee Schedule with a 10 or 90-day global period, and therefore would be a significant undertaking. In order to provide thoughtful analysis on this proposal, medical specialty societies must have time to analyze their data and provide CMS with meaningful input once all data is available.

Furthermore, simply using a reverse building block method to systematically convert all 10 and 90-day global codes to 0-day global codes by backing out the bundled E/M services would be inappropriate and methodologically unsound. There are a number of post-operative services included in the 10 and 90-day global codes that cannot be reimbursed for using the currently separately billable E/M codes, such as dressing changes or local incision care, increasing the difficulty CMS will have with finding the practice expense data within these global packages.

There is also a difference between post-operative direct practice expense inputs for global E/M codes and separately reported E/M codes. The E/Ms performed in a global surgical period often include additional supplies and equipment such as specialized dressings and bandages or specialized examination tables or surgical lights that are often more expensive. Therefore, if CMS removes the direct practice expense from the 10 and 90-day surgical codes, they will need to account for these additional direct PE inputs. **Until better data is developed, and the other issues referenced in these comments are addressed, this proposal should not be implemented.**

### **Implementation Difficulties and Increased Surgical Society Input**

CMS also failed to provide adequate information in this proposed rule as to how this proposal would be implemented and failed to allow any stakeholder input into the implementation plan. For example, it is unclear which codes surgeons would be able to bill for postoperative visits, and medical specialty societies have not been consulted as to how CMS should calculate the postoperative visit billing. Both CMS and medical societies

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need more time to thoroughly research and evaluate possible implementation options. **We feel strongly that surgical societies should be able to provide feedback once CMS presents a plan for this proposal, and should have a significant role in helping CMS transition these codes if they decide to do so.**

### **RUC Valuation Process is Effective**

In the proposed rule, and as part of the explanation as to why CMS is proposing to make this change, the agency expressed concerns with the difficulty of verifying the number, type and relative costs of postoperative visits included in global payments, causing concerns that postoperative care is overvalued or no longer reflects the postoperative care provided to the typical patient for each services. We respectfully disagree with this characterization. Through the Relative Value Scale Update Committee (RUC) process, the average postoperative care is determined efficiently and effectively. For example, in 2013 the Cataract Removal (66984) and Complex Cataract (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** that were 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. **Therefore, we feel that the RUC process is effective and there is no need to transition from 10 and 90-day to 0-day global codes in order to effectively determine the level of postoperative care that is provided.**

We understand that CMS is also concerned that currently all postoperative visits are assumed to have occurred in the office setting, and the agency believes there has been a shift toward hospital treatment, and therefore many of these postoperative visits should include a lower facility fee. **We would like to take this opportunity to clarify that all ophthalmic surgical procedures are performed on an outpatient basis in an ASC, hospital outpatient, or office setting. Therefore, all the postoperative visits are performed in an office setting and there is no shift toward hospital treatment.**

### **Effect on Medicare Beneficiaries**

Finally, we want to bring to your attention the effect the transition of 10 and 90-day to 0-day global codes might have on Medicare patients. Currently, Medicare patients pay one co-payment amount for all services and visits included in the cataract surgery 90-day bundle, for example. With this new proposal, patients would be required to pay a separate co-payment for the surgical procedure, and at each post-operative appointment. Some patients with complicated cases actually receive many more than the number of post-operative visits that is accounted for in the 90 day global code, which is determined based on a "typical case". After they receive the initial surgical procedure, patients may be dissuaded from attending their postoperative appointments due to the need to pay multiple co-payments.

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## **CMS Efforts to Move Toward More Bundled Payments**

At the urging of CMS, medical specialty societies have moved toward developing bundled payments for many of their procedures over the past decade to make care more cost effective and efficient. The 10 and 90 day global package payment is the very type of bundle that CMS has been promoting over the past decade. Shifting away from bundled payments is counterintuitive and would undermine many of these efforts.

ASCRS and OOSS have significant concerns about the transition from 10 and 90-day to 0-day global codes and believe that is not adequate data information, implementation plans or input from surgical groups for this proposal to be implemented.

## **Quality Reporting Programs**

As the regulatory burden on our doctors through quality reporting requirements continues to increase, helping our doctors successfully avoid the penalties for PQRS, the Value Based Payment Modifier (VBPM) and Meaningful Use programs becomes more difficult. The proposed rule would increase the **total** possible penalties to **nine percent**. Due to the increased requirements and the changes to these programs, such as the elimination of ophthalmology-related PQRS measures and the ability to report through claims, many of our members will be unable to successfully comply with these quality programs. Our members need stability in these programs in order to participate, and we would urge CMS not to continuously change the requirements providers are required to meet before a majority of physicians are successfully participating.

## **2015 Physician Quality Reporting System (PQRS)**

**We oppose the proposed significant increase from three to nine measures to avoid the PQRS penalty, the elimination of several ophthalmic measures, and the dramatic reduction of ophthalmology measures available for our members to report through claims-based reporting.** Since the implementation of the PQRS program, ophthalmology has been one of top performing specialties in successfully reporting. However, the majority of our members are in small practices or solo practitioners, many of whom do not have an EHR system, therefore they cannot report through a registry and have to report via claims. Due to the unavailability of ophthalmology-relevant measures and the elimination of the option to report many of the ophthalmology measures through claims-based reporting, the majority of our members will have a difficult time avoiding the penalty, which now requires successful reporting of nine measures.

## **Measure Removal**

Specifically, CMS is proposing to remove **Measure 14: Age-Related Macular Degeneration: Dilated Macular Examination**, and **Measure 140: Age-Related Macular Degeneration: Counseling on Antioxidant Supplement** completely from PQRS reporting. In addition, CMS is proposing to remove the claims based reporting option for **Measure 12: Primary Open-Angle Glaucoma Optic Nerve Evaluation**, **Measure 19: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care**, **Measure 117: Diabetes: Eye Exam** and

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**Measure 14: Primary Open-Angle Glaucoma: Reduction of Intraocular Pressure by 15 Percent or Documentation of a Plan of Care.** Finally, CMS is proposing to remove from all reporting options other than Electronic Health Record (EHR) PQRS reporting, **Measure 18: Diabetic Retinopathy: Documentation of Present or Absence of Macular Edema and Level of Severity of Retinopathy.**

CMS' rationale for removing Measures 14 and 140 is that eligible professionals are consistently meeting performance on these measures with performance rates close to 100 percent, suggesting there is no gap in quality of care. We understand CMS' intention to remove measures that do not illustrate variation in quality improvement, however, as we have previously explained to CMS, for example, cataract surgery in particular is already a low-cost, highly successful procedure which leaves little room for variations in quality and efficiencies among surgeons. If CMS continues to remove any measures that do not show necessary variation in quality, they will essentially remove all the measures included in the cataract measures group that are meaningful for cataract surgeons, as well. Cataract surgeons will be left reporting on a few general measures that are not related to their scope of practice or quality of care they provide.

### **Elimination of Claims Based-Reporting**

**These proposed changes effectively leave ophthalmologists with no PQRS claims-based reporting option. Because CMS eliminated almost all ophthalmology measures for claims based reporting in this proposal, many of our members will be forced to face a six percent cut in 2015 due to their inability to successfully report PQRS and thus the Value-Based Payment Modifier.** Many of our members have just started successfully reporting PQRS via claims. CMS stated that the elimination of claims reporting for these measures is in part to encourage providers to move to registry reporting. However, providers need at least three or more years to transition from one method of reporting to another. These yearly changes are extremely difficult for the majority of our members who are solo practitioners or are in small practices and do not have an EHR system.

### **Oppose Patient-Centered Surgical Risk Assessment Measure**

**We also oppose CMS' addition of the Patient-Centered Surgical Risk Assessment and Communication measure. This measure is not designed for cataract surgery and using a clinical data-based, patient specific risk calculator is not something that cataract surgeons typically do in their surgical practice.** This is a hospital measure that was designed for surgical specialties that have greater morbidities and surgical risks than cataract surgeons.

### **Support Addition of Cataract Measures**

Furthermore, while we think reporting on four measures for a measure group is adequate, we support the addition of the two cataract measure options to the Cataract Measures Group: **Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy): Rupture of the Posterior Capsule During Anterior Segment Surgery Requiring Vitrectomy and Cataract Surgery:**

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***Difference Between Planned and Final Refraction: Percentage of Patients Who Achieve Planned Refraction Within +/-1.0D.*** We would urge CMS to add these measures to the claims-based PQRS reporting option, as well so that cataract surgeons have meaningful measures to use for PQRS claims-based reporting. Without the addition of more measures to claims-based reporting, many ophthalmologists without EHR systems will be unable to successfully report for PQRS.

### **Support Flexible PQRS Reporting Options**

CMS noted that they are seeking comment on whether to allow more frequent submission of PQRS reporting data in future rulemaking, such as quarterly or year-round submissions. **We support this proposal with the caveat that this should be added as an option to make PQRS reporting more flexible for providers and more frequent reporting should not be required of any eligible professionals.**

### **Increased Measure Applicability Validation Transparency**

Finally, since CMS is proposing to remove all the relevant cataract measures from claims-based PQRS reporting, **we would urge CMS to make the Measure Applicability Validation (MAV) process more transparent.** With only a few general measures left to report via claims-based reporting, our members need more information on the clusters of measures that CMS considers reportable for each medical specialty.

### **Value Based Payment Modifier (VBPM)**

**ASCRS and OOSS remain opposed to the implementation of the budget-neutral value-based purchasing modifier and urges CMS to delay the application of the VBPM program to all providers.** The expansion of the VPBM to all solo practitioners and groups of two or more eligible professionals for 2017 based on 2015 reporting should be delayed until a greater number of eligible professionals are successfully reporting for PQRS.

In addition, the increase in the VBPM penalty from two percent to four percent is too severe of a penalty too soon after the implementation of the VBPM. Many providers do not understand how the VBPM is calculated, and it is extremely difficult to determine how the quality data will affect each providers VBPM score. Until there is a better understanding among CMS, medical societies and providers of the data and how it affects the VBPM, CMS should keep the penalties low.

**ASCRS and OOSS also oppose the proposal that beginning in 2017 all physicians and non-physician eligible professionals that bill under the Physician Fee Schedule in a groups' Tax Identification Number (TIN) will be counted as a part of that group.** By including non-physician eligible professionals, many groups that did not fall under the ten or more eligible professionals category last year will be included this year, and thus will face the possibility of negative quality tiering penalty during the first year they are in the program.

Finally, we think the attribution process for the VBPM is problematic. The process is similar to the Accountable Care Organization Medicare Shared Savings attribution process, where CMS will first assign beneficiaries who

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have had a plurality of primary care services rendered by primary care physician and secondly for beneficiaries who remain unassigned, will assign beneficiaries who have received a plurality of primary care services rendered by non-primary care physicians in the TIN. This means that many specialists will end up with a non-representative pool of beneficiaries on which to judge their VBPM score. **We urge CMS to develop a more fair process for determining the quality and cost scores of the VBPM for specialty surgeons.**

### **RUC/CPT Timeline**

We agree that the transparency and fairness of the process and timeline for publishing and implementing modifications in the Relative Value Units (RVUs) for existing services, particularly those that are facing reductions in RVUs and Medicare payments, should be improved.

Currently, CMS publishes RVU changes in an interim final rule that is usually issued in early November and effective on January 1, meaning that changes to any code values are in place for a year before any modifications are possible. Affected specialties do not have the opportunity to comment on the proposed changes before they become final and the affected physicians only have two months to prepare for what can be significant pay cuts. For example, in 2013 the cataract and complex cataract codes were cut by 13% and 23% percent, and we felt our members should have had the opportunity to review the recommended changes and comment on those cuts before they were finalized.

**However, we do not support the three proposals from CMS.** The first proposal would establish G-codes to preserve the status quo for a year for those codes for which CMS would not receive RUC recommendations in time to consider. We think this would create a large administrative burden for billing offices that will already be transitioning to ICD-10. The second proposal would only provide notice and opportunity to comment for those codes where the RUC recommendations are received in time to include a proposal in the proposed rule. The third option proposed by CMS would merely provide more information about the specific issues being considered without changing the existing process, which we think is insufficient for providers.

**Finally, we support the American Medical Association's proposal, which would use the February CPT meetings to consider proposals unrelated to the Physician Payment Schedule, consider editorial revisions to existing codes and consider coding proposals for newer technology not expected to generate a high volume of claims. This would allow the high volume misvalued codes to be considered at the two previous RUC meetings and be included in the Medicare Physician Fee Schedule proposed rule.**

### **Open Payments / Sunshine Act**

CMS is proposing to remove the existing Sunshine Act reporting exclusion for Continuing Medical Education (CME) activities, citing that they have heard from many groups that felt excluded from the list of exempt

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organizations covered by the exclusion. CMS claims that the section they are removing, 403.904(g) is redundant with the exclusion in 403.904(i)(1).

We feel, however, that 403(i)(1) does not meet our needs. This provision only exempts CME payments or transfers when the applicable manufacturer is unaware of the recipient during the reporting year or by the end of the second quarter of the following reporting year. It is likely that some manufacturers could learn the identities of a covered speaker or participants and will therefore be required to report this CME transfer.

We understand CMS' concerns with excluding some accrediting organizations. Therefore, we urge CMS to retain the rule in 403.904(g) that clearly excludes CME, and to alter the definition of CME to not list specific organizations, but instead simply state that CME providers that are nationally recognized and certified by an accrediting body will be excluded from reporting. While we recognize that this definition is broad, we also believe it is important to make clear that CMS understands and acknowledges the difference between independent and certified accredited CME and promotional education activities and that differentiation should be codified and included in the regulation.

We are also very concerned with the current difficulty that many of our members are having with the Open Payments registration process. We have heard from many providers that the registration is cumbersome and confusing. **We would urge CMS to simplify the registration process, and provide additional time for providers to register and review their data.**

### **Malpractice Relative Value Units Proposed Reductions**

#### **Ophthalmology Malpractice Relative Value Units Error**

While changes in the Malpractice RVUs are typically attributed to the statutorily required review every five years, CMS notes that due to an error they made in calculating the Malpractice RVUs for ophthalmology codes in the previous five year review during CY 2010, ophthalmology and optometry will be reduced by -2 and -1 percent overall. While we understand that CMS made an error in previous calculations, this reduction, combined with other code value reductions will have a significant impact on our members. Since an immediate implementation of these revisions result in significant reductions and would have a dramatic effect on our members, **we would urge CMS to phase in this correction to ophthalmology malpractice RVUs through 2016.**

#### **Ophthalmology Malpractice Relative Value Units Proposed Reductions**

For 2015, CMS has proposed to include any non-physicians who pay malpractice premiums in its calculation for the update of malpractice RVUs. While we agree generally with the idea that providers who pay for malpractice insurance should have their premiums considered, we do not believe it is appropriate to compare optometrists and ophthalmologists when doing the utilization weighing of risk factors for ophthalmic surgical procedures.

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When CMS looks at the dominant specialty for a given service, it must make sure that the claims reported by non-physician providers, such as optometrists are included for the correct portion of the procedure for which the malpractice expense is being considered. For example, for cataract surgery, the only time that optometrists would bill for this code is when they are co-managing (providing pre-operative or post-operative care) with an ophthalmologist and therefore billing 66984 with a pre or post-operative modifier (54,55,56). Therefore, the inclusion of optometrists in the calculation, making the assumption that optometrists are performing the surgical portion of the procedure, deflates ophthalmic malpractice values for ophthalmic surgical procedures such as cataract surgery significantly, and should be removed. Optometrists are not allowed by state law to perform cataract surgery or any other major ophthalmic surgical procedure. If CMS does not agree to remove optometry from the calculation of malpractice values for ophthalmic surgery, CMS should use a much lower percentage of utilization to accurately reflect the true risk that optometrists encounter during the pre- and post-operative portion of the service. This could be done by ensuring that any claims that were filed with pre and post-operative management modifiers were not counted in the final weighting for any ophthalmic surgical procedures.

### **Potentially Misvalued Codes**

There are six ophthalmology codes on CMS' list of potentially misvalued codes: 65855 Laser surgery of eye; 66821 After cataract laser surgery; 67228 Treatment of retinal lesion; 68761 Close tear duct opening; 92136 ophthalmic biometry; and 92250 Eye exam with photos. Of note, CPT 65855 Laser surgery of the eye was identified through another RUC screen and is scheduled to be reviewed at the April 2015 meeting. The remaining codes will be reviewed, if appropriate, at the next AMA RUC meeting in September 2014.

### **Physician Compare**

ASCRS and OOSS continue to be very concerned regarding the accuracy of information on physician performance, which CMS has begun making public on the Physician Compare website. **We oppose CMS' proposal to make all 2015 PQRS GPRO web interface, registry, and EHR measures for group practices of two or more and ACOs available for public reporting on Physician Compare in 2016. We also oppose CMS' plan to make PQRS individual measures, if technically feasible, available for public reporting in 2016.**

While we support CMS' efforts towards transparency, we are still very concerned about the accuracy of Physician Compare data. We feel that this quality information might be published out of context and could be easily misinterpreted by Medicare patients. In addition, many of the PQRS measures that our members must report in order to meet the PQRS incentives, such as Measure #226 Preventative Care and Screening of Tobacco Use, are not related to their scope of practice. All quality measures that are required to be reported by ophthalmologists on Physician Compare should be applicable to ophthalmic practices and should reflect the quality of care provided by that specialist. We believe CMS should only publish quality data that is relevant to each eligible professional's scope of practice and would actually assist Medicare beneficiaries in making informed decisions when choosing a specific specialist.

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**We also continue to believe that the 30-day preview period for eligible professionals to review their data in advance of publication is too short. Physicians need adequate time to review this data and request that changes be made prior to its publication.**

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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 Ashley McGlone, Manager of Regulatory Affairs, at [amcglone@ascrs.org](mailto:amcglone@ascrs.org) or 703-591-2220, or Michael Romansky, Washington Counsel, OOSS, at [mromansky@ooss.org](mailto:mromansky@ooss.org) or at 301-332-6474.

Sincerely,

Richard Lewis, MD  
President, ASCRS

Y. Ralph Chu, MD  
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