September 23, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: [CMS-1715-P]; RIN 0938-AT72; Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Polices; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations.

Dear Administrator Verma:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing nearly 8,000 ophthalmologists in the United States and abroad who share an 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 this opportunity to provide comments on the 2020 Medicare Physician Fee Schedule (MPFS) proposed rule, which includes the Quality Payment Program (QPP) and the Merit-Based Incentive Payment System (MIPS).

In our comments on this proposed rule, we:

- **Strongly oppose CMS' proposal to maintain the current value of post-operative evaluation and management (E/M) visits in 10- and 90-day surgical global packages for 2021 despite the fact that CMS is implementing RUC-recommended increases to standalone E/M services for 2021, but is not following the RUC's recommendation to extend those increases to global surgical post-operative services. Surgeons providing post-operative visits in the global period are performing the same level of work as if the visit were a standalone E/M visit and should be reimbursed at the same level. Furthermore, failing to increase the values of E/M visits in the global periods disrupts the relativity of the physician fee schedule and violates the statutory requirement that physicians be paid the same for performing the same services, regardless of specialty. CMS' rationale that the post-operative visit values cannot be increased while it is conducting its ongoing study of global codes misinterprets the MACRA statute that gives CMS the authority to conduct the study, and at the same time, update values to individual codes as necessary. If CMS believes that specific codes are overvalued, then it should refer those codes as potentially misvalued to the RUC for review, rather**

than applying this policy broadly to all surgical services. Therefore, ASCRS and OOSS urge CMS to remedy this in the final rule and increase the reimbursement for post-operative E/M services to the same level as standalone visits as it has done following the three previous updates to E/M codes since 1992.

- **In addition, we urge CMS to increase the value of intermediate and comprehensive eye exam codes (92002, 92004, 92012, 92014), which are primarily based on E/M codes, to align with the values CMS is proposing for the standalone E/M visits for 2021.**

- **We also urge CMS to accept the RUC-recommended values for codes 66711, 66X01, 66X02.** For 66711, CMS is proposing an inappropriate crosswalk code that fails to account for the intensity and risk of the procedure and should use the crosswalk code identified by the RUC. For 66X01 and 66X02, CMS is recommending contractor pricing for these codes, despite survey data that supports the RUC values for these codes**.**

- **While we recognize that CMS is attempting to respond to the medical community's call for a simpler and more streamlined participation option in MIPS, we oppose CMS' proposed MIPS Value Pathways (MVPs) that create mandatory participation pathways around conditions or procedures that take away the ability of the physician to determine which measures are appropriate for his/her practice and patient population, include problematic population-health measures, and continue the separate scoring methodology for the four MIPS components.**

- **In addition, due to the expected downward pressure on the conversion factor from increases to E/M codes and the continued expense of participating in the Quality Payment Program, we recommend CMS urge Congress to enact positive updates to the conversion factor beginning in 2020.**

ASCRS and OOSS will provide detailed comments on the following proposals included in the proposed rule:

Medicare Physician Fee Schedule:

- **Opposition to CMS' proposal not to increase the values of post-operative E/M services included in 10- and 90-day global surgical packages.** Follow-up care to patients after surgery requires the same work and resources as standalone E/M visits and is valued equally by the RUC. Since this proposal would disproportionally impact surgeons, CMS would be in violation of current law preventing Medicare for reimbursing physicians of different specialties for the same service. In addition, this proposal would disrupt the relativity of the physician fee schedule. If CMS believes that certain codes include post-operative visits that are not typically being furnished, then it should refer those codes to the RUC as potentially misvalued, rather than devalue all codes with a global period by failing to increase the value of bundled post-operative E/M visits.

- **Recommend that CMS increase the value of eye exam codes (92002, 92004, 92012, 92014) to align with the proposed increased office visits E/M codes for 2021.** Ophthalmologists use these codes, the values of which are primarily based on E/M codes, as well as E/M office visit codes. Therefore, the values should be increased to align with the values CMS is proposing for the standalone E/M visits for 2021.

- **Recommend that the proposed primary care add-on code for E/M visits related to complexity of patients with chronic disease be referred to the CPT editorial panel for definition.** We are concerned that this code is not well defined and should be refined before being put into use.

- **Concerns with the data collection and conclusions drawn from ongoing surveys of post-operative care furnished as part of global surgical services. We oppose using these studies to value surgical services and continue to support the RUC process as the appropriate method for valuing physician services.** In addition, we are providing comments in response to CMS' request for information regarding potential strategies for additional bundling under the MPFS and recommending CMS maintain global surgical packages.

- **Opposition to CMS' proposed values for:**

    - **66711** (Ciliary body destruction; cyclophotocoagulation, endoscopic);

    - **66X01** (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation); and

    - **66X02** (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation).

Quality Payment Program

- **Opposition to CMS' proposal to implement for 2021 new mandatory MVPs.** This proposal would eliminate physicians' ability to select and report on the measures that are most meaningful to their practice and patients. Ophthalmologists have an abundance of clinically relevant measures available currently and should continue to have the opportunity to report on those they determine are most appropriate. We continue to recommend CMS simplify and streamline the scoring of the MIPS program, through voluntary means, such as providing multi-category credit for high-value measures or activities.

- **Opposition to the continued inclusion of FDA-approved pass-through drugs in the cataract surgery episode-based cost measure. CMS should take immediate action to remove the current pass-through drug in the measure and set a policy to prevent any other pass-through drugs from being included in the future.** Including drugs on pass-through defeats the purpose of pass-through to provide un-biased utilization data on the drug. If surgeons believe using pass-through drugs will negatively impact their Cost scores, it will limit patient access to new and innovative drugs that have the potential to improve outcomes and save money in the system.

- **Opposition to the increased weight of the Cost category.** This category weight should remain at a lower level due to the inclusion of the pass-through drug in the cataract episode-based cost measure and the continued inclusion of all cost population health measures.

- **Opposition to CMS' proposal to increase the MIPS performance threshold to 45 points in performance year 2020.** While CMS has not released specialty-specific data on previous years' MIPS performance, the 2017 MIPS experience report indicated that the mean and median 2017 final scores for physicians in small practices were below 45 points—significantly lower than the overall performance. Given the high percentage of ophthalmologists in small practices who are still implementing the MIPS program fully, CMS should lower the 2020 performance threshold to 40 points. In addition, CMS should develop an alternative small practice threshold.

- **Opposition to removal of so-called "topped-out" ophthalmology measures.** We urge CMS to retain current quality measures and continue to award credit for maintaining high quality. Continuing to measure even the most successful procedures, such as cataract surgery, ensures that surgeons are continuing to achieve positive outcomes. In particular, CMS is proposing to remove two cataract surgery outcome measures (192 and 388) that track surgical complications. Removing these measures would limit ophthalmologists' ability to track their outcome rates relative to their peers.

- **Support for refined attribution methodology for the total per capita cost measure.** The updated methodology focuses this measure on primary care as intended and avoids potential attribution to specialists, such as ophthalmologists, who do not manage the patient's overall healthcare.

- **Continued opposition to the "all-or-nothing" scoring of the Promoting Interoperability category.** Physicians should be awarded credit for reporting on the most clinically relevant measures. In addition, we continue to recommend that physicians using a qualified clinical data registry that is fully integrated with their EHR system should be awarded full credit in this category.

- **Continued support for the development of specialty-specific Advanced APMs, as current models are primary care-based and may not be appropriate for specialists, such as ophthalmologists, or encourage their participation.**

Full comments on these issues are below.

MEDICARE PHYSICIAN FEE SCHEDULE

Positive Updates to the Conversion Factor

- **ASCRS and OOSS urge CMS to recommend that Congress enact legislation to extend positive payment updates to the Medicare Physician Fee Schedule conversion factor.** MACRA's payment update to the conversion factor is scheduled to decrease to 0.0% beginning in CY 2020 through 2026. At the same time that CMS is proposing significant increases to the value of standalone E/M office visits, physicians must continue to make investments in their practices to keep up with the requirements of the QPP, and inflation continues to increase the cost of providing care to Medicare beneficiaries. These combined circumstances will have a diminishing effect on Medicare reimbursements without Congressional action to increase the update to the conversion factor. **We ask**

that CMS join with the medical community in communicating to Congress that it must enact positive payment updates to the conversion factor beginning in 2020.

E/M Proposals

ASCRS and OOSS urge CMS in the final rule to increase the value of post-operative E/M visits included in 10- and 90-day global surgery packages to correspond with the increased values CMS is proposing for standalone E/M office visits beginning in 2021—as it has done each of the three times E/M codes have been revalued since 1992. CMS' proposal disrupts the relativity of the physician fee schedule by reimbursing surgeons at a lower rate for post-operative E/M visits included in the global bundles, even though they are providing the same level of service as if the visit were billed with a standalone code. We disagree with CMS' assertion that it cannot increase the value of the post-operative visits because of the ongoing global codes data collection effort. As an example, CMS is proposing to accept the RUC's recommendation for revaluing the cataract surgery code for 2020. The survey conducted as part of the RUC process verified three post-operative visits furnished with similar work as if they were standalone visits. Since CMS is proposing to accept the RUC's recommendation, it should not distort the relativity of the cataract surgery code, or any other surgical service, or violate the Medicare statute and should value the post-operative visits at the same level as standalone codes. Furthermore, if CMS has concerns that certain services are overvalued, they should be referred to the RUC as misvalued codes for review.

CMS should also increase the value of the comprehensive eye exam codes (CPT 92002, 92004, 92012, 92014) to correspond with the proposed values for office visit E/M services in 2021, because these codes are largely based on the existing E/M values and represent similar work, practice expense, and malpractice costs.

- **CMS' proposal not to increase the value of post-operative E/M services is a direct threat to the overall relativity of the physician fee schedule.** As mandated by Congress, physician services are valued through the resource-based relative value system (RBRVS) that takes into account the relative work, practice expense, and malpractice insurance costs required to furnish a particular service. Since the inception of the fee schedule, post-operative E/M visits have been valued equally to standalone E/M office visits—and have been increased when E/M codes were previously revalued. To abandon this long-standing policy of valuing post-operative and standalone E/M visits for 2021 disrupts the relativity of the fee schedule. **To maintain the relativity of the fee schedule and ensure that services with similar work, practice expense, and malpractice costs are valued equally, CMS must increase the value of post-operative E/M visits included in global surgery bundles to be equal to the value of standalone E/M services.**

- **CMS' proposal is in violation of current statute requiring Medicare to reimburse physicians equally for the same service, regardless of specialty.** Since 10- and 90-day global services are overwhelmingly provided by surgical specialties and not primary care physicians, failing to increase the value of post-operative E/M visits creates an illegal specialty differential. The work, practice expense, and malpractice costs of post-operative visits are equal to those components of standalone E/M services, and therefore, they should be valued at the same level. **To ensure CMS does not run afoul of current statute barring specialty differential payments, the agency should increase the value of post-operative E/M visits included in global surgery bundles to be equal to the value of standalone E/M services.**

- **AMA's RUC recommended that post-operative E/M codes in global services be increased to correspond with the increase in the standalone E/M codes.** CMS is proposing to adopt RUC's recommended values for standalone office visit codes following an extensive review and revaluation. In the proposed rule, CMS notes the extensive energy devoted to updating the codes and the robust survey process. ASCRS and other surgical specialties participated in the survey of E/M codes, and the responses of our members detailing the work related to furnishing these services are reflected in the proposed values. To ensure that post-operative visits were valued for the work furnished, the RUC recommended in a near unanimous vote (27-1) that the values of the E/M services bundled into global codes also be increased to the same levels as standalone codes. **Most importantly, CMS should follow the precedent set in 1997, 2007, and 2011, in accordance with the Medicare statute, when E/M codes were previously revalued, and increase the value of the post-operative visits included in the global packages as it did those three previous times.**

- **ASCRS and OOSS disagree with CMS' rationale for failing to increase the value of E/M services in the global periods because of ongoing data collection related to post-operative care.** The MACRA statute instructed CMS to collect data on the number and level of visits furnished during the global period; however, it also specifically notes that the data collection does not preclude CMS from "revaluing misvalued codes for specific surgical services or assigning values to new or revised codes for surgical services." Therefore, CMS cannot argue that the ongoing data collection supersedes the need to increase the E/M values in the global surgery bundles, particularly to preserve the relativity of the fee schedule and reimburse physicians equally for performing the same services. **Since the value of E/M codes, which are components of global surgery packages, have been revised, increasing the value of E/M services in global surgery codes is in line with CMS' requirement to update and revise codes and does not interfere with the global surgery data collection effort. Instead, CMS should refer specific services it believes to be overvalued to the RUC as part of the misvalued code initiative.**

- **Furthermore, the RUC is the most appropriate venue for revaluing surgical global codes.** CMS is proposing to accept the RUC-recommended value for cataract surgery (66984) in this proposed rule. For that code, RUC survey data indicated that three post-operative visits are typically performed and represent the same work, practice expense, and malpractice costs as furnishing a standalone E/M visit. However, by failing to increase the value of post-operative visits included in global codes, CMS is arbitrarily devaluing not just E/M visits after cataract surgery, but all services without applying the same rigorous analysis employed by the RUC that determines the relative value of each individual service in the physician fee schedule. **If CMS believes that certain codes include post-operative visits that are not being performed, it should refer those specific codes to the RUC as potentially misvalued and requiring review, rather than applying a broad policy to devalue all post-operative E/M services.**

- **The values for intermediate and comprehensive eye exam codes should increase to reflect the updated values of E/M office visit codes for 2021.** While ophthalmologists frequently bill the office visit E/M codes that CMS is proposing to increase in value for 2021, they also regularly bill comprehensive eye exam codes (CPT codes 92002, 92004, 92012, 92014), depending on the characteristics of the visit. Because of similar work, practice expense, and malpractice costs of furnishing the exams, the eye codes are largely based on the value of the office visit E/M codes and therefore should be increased along with the office visit codes to preserve the relativity of these

services. **CMS recognized that eye exam services are linked to E/M services in the proposed rule and solicited comment on whether they should also be increased. ASCRS and OOSS urge CMS to increase the value of comprehensive eye codes to correspond to the increase in the E/M visits for 2021**

- **ASCRS and OOSS recommend CMS' proposed add-on code, GPC1X, be referred to the CPT editorial panel before implementation.** This code—aimed at describing additional services furnished related to the care of a patient with a single, serious, or complex chronic disease—was created by CMS and, as such, did not go through the rigorous CPT process to ensure that any physician billing the code would understand the services it describes. The lack of CPT review of this code is particularly troubling since CMS estimates an approximate $1.5 billion in expenditures based on utilization of the code, which could have a profound impact redistributing value across the fee schedule. **Before proceeding with implementing this code, we recommend CMS refer it to the CPT editorial panel.**

Global Surgery Data Collection and Analysis

ASCRS and OOOS are troubled that CMS is basing its proposal to maintain current post-operative E/M visit values in the global packages in 2021 because the agency is still analyzing data related to post-operative care in the global period. We maintain that data collection for the claims-based reporting of post-operative visits is flawed and should not be used to reduce the value of global surgery codes. Furthermore, RAND's proposal to revalue global packages based on a "reverse building block" methodology is out of line with the statutory requirement that all values be resource-based. We continue to support the RUC process as the appropriate method for valuing physician services.

- **ASCRS and OOSS are concerned that the first RAND study included in the proposed rule, "*Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-day Global Periods,*" draws inaccurate conclusions about the number of post-operative visits furnished after surgical procedures.** The report includes data collected from physician practices of 10 or more in selected states furnishing certain high-volume procedures who are required to report a non-pay CPT code, 99024, for every post-operative visit. The report found that only about 46% of physicians who are required to report on post-operative care are participating, and of that group of reporters, only 17% are doing so regularly at what CMS terms a "robust" reporting rate. While specialty societies, such as ASCRS, have provided education to members on these requirements, it is evident that a significant proportion of physicians are not aware of the requirements or are hampered by other factors, such as institutional billing systems that do not permit billing non-paying codes. In addition, for surgeons who typically practice in small groups, such as ophthalmologists, visits furnished may be underreported. In addition, this data collection is solely focused on the number of visits performed and does not include information on the level of service provided. **Data collected as part of this effort should not be used in the valuation of surgical services. We continue to support the AMA's RUC process that values physician services through a resource-based methodology.**

- **CMS should not implement the "reverse building block" methodology to revalue global codes recommended in RAND's third study, "*Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods.*"** In this study, RAND suggests that the data collected on post-operative visits from claims could be used to reduce the value of surgical global bundles by the difference in the number of visits reported via claims from the current number of visits included in the global code values for each service. Given that the claims data collected only reflects

the number of visits furnished—and not their level—this potential systematic "one-size-fits-all" methodology is a troubling departure from the norm established from the beginning of RBRVS of determining the relative value of every service. This blunt tool, which would not take into account the level of visit furnished, and devalues all surgical services, stands in opposition to the current methodology employed by the RUC of assigning work RUVs based on the time and intensity of every element of the service—including through the global period—relative to all other services in the fee schedule.

ASCRS and OOSS continue to believe that the RUC process is the most accurate method of determining the value of physician services and maintaining the overall relativity of the fee schedule, and urge CMS not to implement any of the recommendations made by RAND.

Request for Information on Additional Opportunities for Bundling

Continuation of 10- and 90-Day Global Codes

- **ASCRS and OOSS continue to support bundling surgical services into 10- and 90-day global codes that include all services furnished in conjunction with surgical procedures, including post-operative visits.** We recognize and appreciate that CMS is attempting to identify additional opportunities to make bundled payments for procedures or chronic care that encourage efficient use of resources and care coordination. However, CMS' other goal of dismantling the global surgery bundles discussed above seems contradictory to this effort. In a surgical specialty, such as ophthalmology, all procedures are paid with 10- or 90-day global codes and facility payments to ambulatory surgery centers (ASCs) or hospital outpatient departments (HOPDs) are also grouped based on ambulatory payment classifications (APCs). Apart from anesthesia, which can vary based on hospital policy or patient demographics and co-morbidities, there are few opportunities to bundle in additional costs to cataract or other ophthalmic procedures. **We encourage CMS to maintain its current policy of reimbursing for surgical procedures through 10- and 90-day global bundles.**

Separate Payment for FDA-Approved Drugs with a Post-Operative Indication

- **While ASCRS and OOSS strongly support maintaining current surgical global codes, we would also like to take this opportunity to reiterate our ongoing support for paying separately in ASCs for certain new FDA-approved drugs administered during cataract, or other surgery, on pass-through status after they come off of pass-through status.** Currently, CMS makes separate payment for up to three years for new drugs administered in ASCs and HOPDs. This pass-through period allows time for the drug to be introduced to the market, for physicians to gain experience using it, and for CMS to collect utilization data on the drug. Once the pass-through period is over, CMS uses the data it collected to adjust the value of the APC group and bundles the drug into the facility payment as a surgical supply. While we continue to advocate that CMS continue to make separate payment in ASCs under Part B for FDA-approved drugs with a post-operative indication administered during cataract surgery since they are not surgical supplies and have the potential to eliminate some or all post-operative drops paid under Part D, **we are aware that eliminating pass-through status completely has been floated as a potential cost-saving opportunity. We believe that potential policy could limit patient access to new drugs and stifle innovation**, **and therefore**, **CMS must maintain pass-through**

status for new, high-cost drugs in addition to paying separately for FDA-approved drugs with a post-operative indication administered at the time of cataract surgery.

Preservation of Pass-Through Status

- **Maintaining the current pass-through system is imperative to ensure patients have access to new and innovative treatments; however, the bundled facility payment that includes the drug after pass-through status has ended, particularly in ASCs, is not sufficient to ensure patient access to FDA-approved drugs with a post-operative indication that are administered at the time of cataract surgery.** Currently, innovation in cataract surgery is centered on developing these treatments for post-operative, pain, inflammation, or other sequela of the surgery and administered during surgery to reduce or eliminate the need for post-operative drops. These treatments have the potential to improve outcomes by eliminating the need for patients—who are often elderly with physical limitations—to self-administer post-operative drops. Recent data have shown that when ophthalmic drugs go off pass-through and are bundled into the APC group, ASCs—which have a tighter profit margin—in particular are not able to afford the drug as part of the APC payment.

If CMS is seeking additional opportunities to bundle services, we want to reiterate that we are opposed to the current policy of bundling FDA-approved drugs with a post-operative indication into the ASC facility payment after they go off pass-through because the APC reimbursement level is not adequate to ensure access to the drugs in the ASC. Further, continued bundling of these drugs after pass-through is over has the potential to inhibit innovation if manufacturers do not believe they have a payment pathway.

Revaluation of Specific Codes Under the Physician Fee Schedule

- **We oppose the CMS-proposed reduction of the work RVU for 66711 (Ciliary body destruction; cyclophotocoagulation, endoscopic), from the RUC-recommended work RVU of 6.36 to the proposed work RVU of 5.62.** CMS is basing its proposed work RVU on an inferior crosswalk code, 28285 (Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy), which ignores both the value of the intensity and complexity of work in CPT code 66711. Correction of hammertoe is a low-risk procedure on a small appendage and not comparable to endoscopic ciliary photoablation (ECP), which is a high-risk procedure with the risk of vision loss. Furthermore, the CMS proposed work value for CPT 66711 would create a negative intensity of work per unit time (IWPUT), a clear indication that the value is too low for the associated times.

  Therefore, **we urge CMS to accept the RUC-recommended work RVU of 6.36 and the crosswalk of CPT 67210 (Destruction of localized lesion of retina (e.g., macular edema, tumors), 1 or more sessions; photocoagulation), as it is the most appropriate crosswalk available in the database.**

- **ASCRS opposes the CMS-proposal to use contractor-pricing for CPT codes 66X01** (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation), **and 66X02** (Extracapsular

cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation). CPT codes 66X01 and 66X02 reflect complex cataract removal, as both procedures include cataract surgery and a glaucoma procedure on an eye that is more diseased than one undergoing cataract surgery. The RUC-recommended values are supported by the survey values, as they are both less than the 25th percentile of the survey work values. The IWPUT of both codes is less than that of CPT code 66984, indicating that the work values are not excessive for the intensity of the procedures. **We urge CMS to accept the RUC-recommended work RVU of 13.15 for CPT code 66X01 and a work RVU of 10.25 for CPT code 66X02.**

QUALITY PAYMENT PROGRAM

MIPS Value Pathways (MVPs)

ASCRS and OOSS strongly oppose CMS' proposed mandatory MVPs because they would eliminate physicians' ability to report on the measures they believe are the most relevant to their practice and patients. Ophthalmology has developed a comprehensive set of meaningful measures, including several outcome measures, that give ophthalmologists options for selecting those that are the most clinically relevant. Ophthalmologists have no concerns that they have too many options to choose from in the MIPS program, and would be burdened by having to report on a proscribed set of measures in an MVP.

In addition, there are several other issues within this proposal that make this unworkable. These factors include the use of problematic population-health measures, as well as the burden associated with collecting data for patient-reported outcome measures. Finally, CMS has not provided complete details for how the MVPs will be assigned and scored; however, it appears that clinicians will still be subjected to different scoring in each category and would not receive credit in multiple categories for high-value measures or activities. While we appreciate that CMS has considered feedback from the medical community to simplify and streamline the MIPS program, we do not believe that the MVP program CMS is envisioning to begin in 2021 hits that mark.

- **In our recommendation that the MIPS program be streamlined, ASCRS, OOSS, and others in the medical community proposed a voluntary and flexible system that would award physicians credit across categories for clinically relevant measures and activities.** In comments on previous year's QPP rules, we recommended that CMS take steps to make the scoring more predictable, such as eliminating different scoring methodologies for each category and aligning the points available with the weight of the category. For example, if the Quality category was weighted at 40%, then participants should work toward earning 40 points, rather than the current 60 that then must be adjusted based on the category weight. We appreciate that CMS took some steps toward this by eliminating the confusing base and performance score of the Promoting Interoperability category. In addition, we encouraged CMS to identify areas where physicians could earn multi-category credit. For example, as we will discuss in more detail later in this letter, we continue to recommend physicians using a QCDR integrated with their EHR to collect Quality data also be awarded full credit in the Promoting Interoperability category, since they are using the CEHRT in a more relevant way than the

measures in that category. **We recommended these modifications to reduce confusion physicians often experience trying to adhere to the disparate requirements in each of the categories.**

Mandatory Nature of MVPs

- **ASCRS and OOSS oppose the MVP proposal because it would be a mandatory requirement for physicians who have an available MVP or multiple MVPs.** Unlike its implementation of the MIPS program to date, CMS' MVP proposal seems like a step backward to the legacy programs, where physicians rarely had a choice in what measures they reported or were evaluated on. One of Congress' key goals of the MACRA statute was to create a more holistic quality reporting program that aligned deadlines, removed all-or-nothing scoring, and eliminated the often overlapping and conflicting requirements of the legacy programs. While we believe that MIPS has not completely lived up to that goal—as evidenced by our above recommendations—it is a significant improvement from the legacy programs. Physicians can choose the level of participation that best fits their practice and are able to report on clinically relevant measures. **Under the MVP proposal, physicians would lose the flexibility to choose the measures that are most appropriate for their practice and patient population.**

- **Physicians should be empowered to select and report on the measures that are most meaningful to their practices and patients.** While CMS may have heard from some physicians who believe there is too much choice in the program, it is highly unlikely ophthalmologists would share that sentiment. The ophthalmic community has been successful in developing a focused set of measures—many of which are outcome measures—that reflect our members' practices and patient population. The common complaints we tend to hear from our members do not involve them having difficulty determining which measures or activities are most relevant to them but are more likely related to problems differentiating between the various categories' scoring methodologies. A mandatory MVP program that solely prescribes what specific measure and activities a participant must complete but does not address the inconsistencies in each category's scoring would not reduce burden for physicians. **CMS should continue to allow physicians to select and report on the most clinically relevant measures and should not finalize its proposal for mandatory MVPs that restrict their measures and activities.**

Population Health Measures

- **In addition, ASCRS and OOSS oppose the inclusion of population-health measures and recommend they not be used in the MIPS program at large.** Population-health measures, such as the all-cause hospital readmission currently used in MIPS for large practices or the proposed unplanned admission measure for patients with multiple chronic conditions, are primary care-based and nearly impossible for specialists, such as ophthalmologists, to influence or even predict what patients will be attributed. Ophthalmologists focus entirely on one organ or system. Ophthalmologists only treat patients' eye disease and do not manage their overall healthcare. By definition, population-health measures are focused on managing the outcomes of a group of patients, usually through preventative care and care coordination, which is not possible for most ocular disease. **Using these measures to determine the quality of ophthalmic care is entirely inappropriate and should not be part of the MIPS program.**

- **Ophthalmologists' experience to date with population health measures has been meaningless, and CMS has acknowledged this by excluding them and other specialists from the total per capita cost measure in the Cost category.** Oftentimes, as we saw under the legacy Value-Based Payment Modifier

program, ophthalmologists were attributed measures related to cardiac, urinary, and pulmonary care simply because they happened to bill E/M codes frequently. Our members had no way to predict what patients they would be attributed and could take no action to improve their scores. As referenced above, CMS has recognized that ophthalmologists and other specialists were being attributed the cost of care they did not provide and excluded them from the total per capita cost measure. Given that ophthalmologists and other specialists are excluded from that measure, it is inappropriate to consider subjecting them to other claims-based population health measures. While we understand that CMS may view claims-based measures as a strategy to reduce administrative burden for physicians, ophthalmologists and other specialists view being scored—and potentially penalized—on these meaningless measures as a far greater burden then reporting on clinically relevant measures, such as cataract surgery outcome measures. **In addition, CMS should remove the existing population-health measure from the Quality category—or at the very minimum exclude ophthalmologists and other specialists—and not contemplate further use of population-health measures in MIPS.**

Patient-Reported Outcome Measures

- **ASCRS and OOSS are also concerned that MVPs would place an undue burden on ophthalmology practices by including patient-reported outcome measures for high-volume procedures.** In the proposed rule, CMS notes that MVPs would ideally include patient-reported outcome measures. While we agree that these measures are valuable following cataract surgery, since they can demonstrate that patients are experiencing improved quality of life, they are currently not feasible to use in MIPS. The current patient-reported outcome measures, #303 and #304, are registry-only, which require a 60% data completeness threshold (which CMS is proposing to increase to 70%) of all patients undergoing this high-volume procedure. The American Academy of Ophthalmology's IRIS Registry does not currently offer these measures because it does not have the resources to collect and score the volume of surveys it would receive in conjunction with these measures. In previous years, we have recommended that CMS modify the data completeness threshold for patient-reported measures to require just a representative sample, or reinstate the measures group options available under PQRS that required these and the other cataract outcome measures only be reported on 20 patients. **Therefore, we caution CMS to consider the potential burden associated with patient-reported outcome measures in general and consider reducing the data completeness threshold for patient-reported outcome measures in MIPS.**

Scoring Methodology and Structure

- **While we oppose the overall concept of mandatory MVPs that CMS has put forward in the proposed rule, we are also concerned that CMS has not even provided complete details about how it would score the MVPs. The details CMS does provide, however, would indicate the MVPs would still require physicians to report and be scored in each category, rather than the more holistic approach suggested by the medical community.** As noted above, feedback from our members indicates that the current scoring methodology of the MIPS program is the most confusing element, thereby prompting our recommendations to streamline it. While CMS does not provide specific scoring details in this proposed rule for MVPs, the continued siloed approach would indicate that the scoring would continue to be unpredictable. In addition, CMS should identify methods of standardizing the scoring and which measures or activities could automatically count for credit in multiple categories. This approach would be much closer to eliminating the piecemeal structure of MIPS and continue to give

physicians the options to choose the measures that are most meaningful to their practice and patient population, rather than be arbitrarily placed in a mandatory and rigid MVP structure.

- **CMS' operationalization of MVPs is also unclear.** In the proposed rule, CMS notes that it would potentially assign physicians to MVPs through the PECOS system, but does not provide what information in the system it would use to do that. In addition, CMS notes it foresees that a single clinician could have multiple MVPs available, but does not address how it would prioritize those or how the clinician would know which he/she was responsible for completing. Finally, CMS notes it envisions the MVPs as a means of facilitating sub-TIN level group reporting, but does not specify how it would accomplish that. ASCRS and OOSS would be concerned that sub-TIN level group reporting could become overly burdensome for clinicians providing eye care, since they already tend to practice in small groups. In a typical three- to five-practitioner comprehensive eye care practice that includes both ophthalmologists providing surgical care and optometrists providing non-surgical care, the limited practice staff would be responsible for reporting a potential cataract surgery MVP just for the ophthalmologists and reporting MIPS or another MVP for the optometrists. The current group reporting option for MIPS allows for small ophthalmic practices to report on both surgical and non-surgical care in a less burdensome manner.

The MVP proposal remains unacceptable because it would be mandatory and prevent physicians from choosing the most clinically relevant measures and activities for their practice and patients. The additional factors of including population health measures, patient-reported outcome measures, scoring methodology and the lack of detail CMS has provided for how it would be implemented further demonstrate that it should not be finalized.

Performance Score

- **ASCRS and OOSS oppose CMS' proposed 2020 performance threshold of 45 points and recommend it be lowered to 40 points.** Ophthalmologists have a high percentage of participation in the program; however, implementing the MIPS program requires time and investment, which can be difficult for ophthalmology practices that are predominantly small groups or solo practices. Ophthalmologists are still adjusting to the new elements and programmatic changes of the MIPS program, such as the recently developed cataract episode-based cost measure, and significant overhaul of the Promoting Interoperability category for 2019. While CMS has not released 2017 MIPS performance data by specialty, it has released performance data that demonstrates small practices were less able to achieve higher scores in the first year of the program. The 2017 small practice mean score of 43.46 and median of 37.67 are both below the 2020 proposed 45-point threshold. We believe CMS should continue its measured approach to increasing the MIPS performance threshold and refrain from setting future years' performance thresholds until additional data are available that indicate physicians in practices of all sizes are likely to be able to achieve the threshold. **We urge CMS to set the 2020 performance threshold at 40 points and release specialty-specific MIPS performance data, which will assist in predicting how likely physicians are to reach MIPS performance thresholds.**

- **In addition, CMS should create an alternative small practice threshold.** We have supported CMS' efforts to make accommodations for small practices, such as special scoring and hardship opportunities, and CMS' own data above bear out that small practices have a more difficult time

participating in MIPS. Small practices may not have the available financial or human resources needed to implement the MIPS program fully at one time, and will need several years to integrate it fully into their practices. **A lower, alternative small practice performance threshold would allow small practices that must invest at a slower pace than large groups, but still want to participate in the program, to implement the program with limited threat of negative payment adjustments.**

Quality Category

Opposition to Removing "Topped-Out Measures"

- **ASCRS and OOSS continue to oppose CMS' topped-out measure methodology and recommend that CMS continue to award credit to physicians who maintain high quality, particularly on outcome measures.** Under the topped-out measure methodology, CMS determines what measures are available by an arbitrary quantitative level that does not take into account the clinical relevance of the measure or the volume of Medicare services it impacts. For example, while cataract surgery is a highly successful surgery, it requires intense training and physical skill to perform. While rare, complications could include total vision loss. Coupled with the high volume of cataract surgery performed on Medicare beneficiaries, CMS risks wide gaps in the number of Medicare services that are subject to quality measurement if it removes measures related to cataract surgery. In addition, it is critical to continue to measure the outcome of highly successful surgeries like cataract surgery to ensure surgeons are continuing to achieve good outcomes. Therefore, CMS should not remove cataract surgery outcome measures and continue to award full credit to surgeons who maintain high quality. The ophthalmic community has worked to develop a robust set of outcome measures related to cataract surgery and surgeons continue to provide high-quality care to their patients, as evidenced in their superior performance on these measures. **We continue to urge CMS to maintain clinically relevant measures related to cataract surgery in the MIPS program, and to award full credit to physicians who maintain high quality.**

- **Specifically, ASCRS and OOSS oppose removing two outcome measures related to cataract surgery for 2020:**
    - **192, Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures, and**
    - **Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy)**

- For these two outcome measures proposed for removal for 2020, CMS' rationale for removal indicates there are limited opportunities for improvement. However, CMS fails to consider that these outcome measures identify if a surgeon is out of step with his or her peers in terms of complication rates. Cataract surgery is a highly successful procedure, so complication rates are extremely low, and therefore, even slight increases in an individual surgeon's rate of complication are concerning. These measures look at patients who are the least likely to have complications because they **do not** have co-morbidities and should otherwise have a good outcome. Given the low incidence of complications, it could be difficult for a surgeon to recognize if his or her results were outside the norm without some sort of tracking mechanism. These measures, reported either through the EHR or registry, allow cataract surgeons real-time awareness of complication rates and provide real opportunities for quality

improvement if it is necessary. **We urge CMS to maintain these highly clinically relevant measures in the MIPS program so surgeons will continue to track these outcomes and seek continuous quality improvement.**

Population Health Measures

- **ASCRS and OOSS oppose the continued inclusion of the all-cause hospital readmission measure in the Quality category and the proposed unplanned hospital admission for patients with multiple chronic conditions measure for 2021.** As noted above in our comments related to the MVP proposal, we strongly oppose the use of these measures in MIPS, especially for specialists like ophthalmologists. These measures are primary care-based, and the attribution methodology potentially holds physicians responsible for care they did not provide. Ophthalmologists have no way to predict what patients will be attributed and have no means to influence their scores. CMS has already acknowledged that ophthalmologists and other specialists have limited opportunities to impact their scores on total per capita cost measure and proposes to exclude them from attribution from that measure. **While we believe that CMS should remove these measures from the program completely, at a minimum, CMS should exclude specialists, such as ophthalmologists, from attribution.**

Cost Category

Opposition to Inclusion of All Pass-Through Drugs in the Cataract Episode-Based Cost Measure

- **ASCRS and OOSS urge CMS to remove from the cataract episode-based cost measure the current FDA-approved drug administered during cataract surgery on pass-through, and signal that any drug that has since come onto the market and is paid on pass-through, or will come onto the market, will not be included in the measure.**

- **As noted above in our comments on the request for information related to bundled services, pass-through status is a vital tool in ensuring that new and innovative drugs are introduced to the market and is used by CMS in the formula to calculate the increase in the ambulatory payment classification (APC) group to account for the drug.** Pass-through status helps introduce a new drug into the marketplace that is used during or immediately after surgical procedures with an average estimated cost that exceeds a certain percentage of the procedure's ambulatory payment classification (APC) payment amount. It is initially put on pass-through status and paid separately for up to three years under Medicare Part B. This encourages the use of new drugs in the facility by allowing physicians time to become familiar with their use without their adding to facility cost. Separate payment for pass-through drugs is also essential to ASCs, in particular, because their lower facility reimbursements would make it difficult to afford new, high-cost drugs.

- During the pass-through period, CMS measures the utilization of the drug and, when the drug goes off pass-through status, adjusts the reimbursement level for the bundled facility fee based on the utilization data gathered and the formula. To set the price of the APC group, CMS uses charges on claims and data from cost reports to calculate the average cost of providing a specific service, which includes all packaged items and services, including drug costs, and then groups the service in with other services that have a similar cost or are clinically comparable. CMS then calculates an average

cost for all grouped services to set the price for the APC group. When a drug comes off pass-through, its price is included in the cost data for the service. Therefore, when CMS calculates the average price for the service, the utilization of the drug will impact the average cost of the service: the higher the utilization, the higher the average price, and vice versa. **Pass-through status allows CMS to gather data not influenced by other factors. If drugs on pass-through status are included in the measure, physicians mindful of their score on the cataract surgery measure may modify their use of the drug for reasons other than clinical appropriateness, and thus impact the gathering of utilization data, thereby defeating the purpose of pass-through.**

- **Currently, there are several ophthalmic drugs that have either recently been approved or will be approved in the near future for use during cataract surgery. One such drug—injection, phenylephrine and ketorolac, 4 ml vial—is included in the episode measure.** Specifically, these new FDA-approved drugs administered during cataract surgery that are on now on pass-through, or soon will be, have a post-operative indication, such as post-operative pain and inflammation and/or other sequela of the surgery, and eliminate the need for some or all post-operative eye drops. Reducing or eliminating the need for post-operative eye drops, which are currently furnished under Medicare Part D, represents a substantial cost-saving both to the Medicare program and the patient. In addition, eliminating the need for post-operative eye drops improves patient compliance and leads to better clinical outcomes. However, since Part D costs are not a factor in the cataract episode measure, using these Medicare Part B pass-through medications during cataract surgery and including them in the episode calculation would increase the total episode cost and would inaccurately designate the surgeon as high-cost. **Beyond the primary goal of preserving pass-through status to ensure accurate utilization calculations, we believe including these drugs with a post-operative indication on pass-through would go against the goal of the episode-based cost measures of encouraging physicians to make more efficient use of resources.**

- **The inclusion of pass-through drugs in the cost measure is already having an influence on physician behavior, and drug manufacturers are reporting a decline in the use of these products.** While there is currently only one pass-through drug in the measure, since the creation of the episode measure, two additional drugs administered during cataract surgery have received FDA approval and are being paid on pass-through. The manufacturers of the drug included in the measure are reporting that several practices that have previously used the drug are discontinuing its use because of the potential impact on the Cost category score of MIPS. Also troubling is that ophthalmic practice consultants are recommending surgeons refrain from using any pass-through drugs, including the new ones on the market that are not included in the measure, over fear that they will eventually be included in the measure. **The inclusion of just one pass-through drug is already having impacts on other similar drugs. CMS must act immediately to remove the included pass-through drug and signal that it will not include any pass-through drug in the measure going forward to preserve patient access to these drugs and ensure unbiased utilization data can be collected during the pass-through period to be used as part of the calculation to set the facility payment level.**

  Included in the appendix to these comments:

  - ***Emails received by Omeros, manufacturer of the included pass-through drug, from ophthalmologists discontinuing their use of the drug due to its inclusion in the cataract surgery episode-based cost measure.***

- ***Ophthalmic trade publication articles recommending against use of pass-through drugs because of the episode-based measure.***

- **Including any pass-through drugs in the cataract episode-based cost measure will have a stifling effect on innovation.** Innovation in cataract surgery is currently focused on the development of treatments that are administered at the time of surgery and have a post-operative indication. Developing a new drug for FDA approval is an expensive, time-consuming, and risky proposition for manufacturers. A key factor in their decisions to develop drugs is a reasonable assurance there will be a market for the drug once it is approved. Without certainty that using these drugs will not negatively impact physicians' MIPS scores, and thus discourage physicians to use them, manufacturers will be unwilling to continue innovating in this area. **We urge CMS to exclude all pass-through drugs from the cataract episode-based measure, which will encourage manufacturers to continue developing innovative treatments that improve outcomes and reduce patient burden.**

- **ASCRS and OOSS believe that episode-based cost measures are a more effective method of measuring clinician resource use than population-based measures because they only include the costs of care that are within the physician's control.** However, physicians have no control over the cost of drugs as they enter the market, and therefore, including the cost of these drugs in the measure is contrary to the goals of episodic-based measurement. To ensure that clinicians are not penalized for using drugs on pass-through and that pass-through status is preserved to collect accurate, market-based utilization data, **we recommend that any FDA-approved Medicare Part B drug administered during, or at the end of, cataract surgery that is on pass-through status be excluded from the cataract surgery episode-based cost measure, now and in the future.**

- **While we urge CMS to take immediate action to remove the pass-through drug from the cataract episode measure and implement a policy to not include any pass-through drugs in the cataract episode measure, ASCRS and OOSS recommend CMS update and modify episode-based cost measures through its annual rulemaking.** In previous conversations related to the inclusion of the pass-through drug in the cataract episode-based cost measure, CMS indicated that the issue would be addressed in this proposed rule; however, it was not and there is no discussion of how future changes to this or other measures will be made. In addition, we understand that CMS plans a three-year measure maintenance cycle for the episode measures, similar to the process used for quality measures. However, since CMS makes changes to Medicare payment policy annually, it is unlikely that the issue we have identified with the pass-through drug in the cataract measure will be the only issue to arise, as payment policies may impact other measures differently. **CMS must establish a transparent process of updating the episode-based cost measures in the annual Medicare Physician Fee Schedule rulemaking to ensure that stakeholders have the opportunity to provide input on the measures.**

Total per Capita Cost Measure

- **While ASCRS and OOSS continue to oppose the concept of population-health measures, we support the modified attribution methodology CMS is proposing for the total per capita cost (TPCC) measure and thank CMS for excluding clinicians who provide eye care from attribution under this measure.** As noted previously in our comments, ASCRS and OOSS have strong reservations about claims-based all-

cost population-health measures. The previous attribution methodology for this primary care-based measure was based on billing E/M services, and since ophthalmologists and optometrists frequently bill E/M services, they were often attributed these measures and held accountable for the cost of care they did not provide. **While we continue to oppose the use of population-health measures in general, we appreciate that CMS listened to our feedback and took action to appropriately attribute the TPCC measure to physicians providing primary care.**

Cost Category Weight

- **CMS should maintain the 2019 weight of 15% of the final MIPS score for the Cost category in 2020.** Given that the cataract episode-based cost measure retains the pass-through drug, physicians who use the drug—and have no control over its price—may have their Cost category scores negatively impacted. In addition, despite ophthalmology's proposed exclusion from the TPCC measure, we continue to oppose the use of population-health measures in the MIPS program as a whole. Regardless of whether ophthalmologists are included in the measure, it is difficult for all types of physician—primary care or specialist—to impact their performance on any population-health measure because they will continue to be responsible for the cost or quality of care provided by other physicians. While we recognize that CMS is attempting to ease the transition to program year 2022, when by statute the Cost category must account for 30% of the MIPS final score, we believe that until the current pass-through drug is removed from the measure and the population-health measures are removed from the category, then this category should remain at the current 15% weight. **We continue to urge CMS to remove the pass-through drug from the measure and prevent future drugs on pass-through from being included.**

<u>Promoting Interoperability Category</u>

We recognize that following the overhaul of this category in the 2019 performance year that CMS is not making significant proposals to allow for program stability. **We appreciate that CMS streamlined and simplified the scoring for 2019 but continue to recommend that the "all-or-nothing" methodology be removed. In addition, we continue to recommend that physicians who use QCDRs that integrate with their EHR be awarded full credit in the category**

- **CMS should remove the "all-or-nothing" scoring of this category.** As noted above, Congress intended for MIPS to award clinicians for attempting to participate in quality reporting programs, rather than penalize them for not achieving 100% success. In the other categories of MIPS, clinicians can earn some credit—and potentially minimize negative payment adjustments—by reporting what they are able to. Therefore, it seems inconsistent that to score **<u>any</u>** points in the Promoting Interoperability category, clinicians must report on all required measures, regardless of whether they are relevant to their practice. We appreciate that CMS is continuing to offer its small practice hardship exemption, which is valuable to many small ophthalmic practices that may struggle to afford or implement CEHRT in their practices. However, there is no incentive for practices to try and implement CEHRT into their practices if they are unsure they can be completely successful in the category. Awarding partial credit or allowing clinicians to attest to having certain functionality would reduce the burden associated with this category and may encourage more clinicians to participate. **We recommend CMS further modify this category and remove the "all-or-nothing" scoring.**

- **We continue to recommend that CMS award full credit in the Promoting Interoperability category to any physician or group who participates in end-to-end electronic reporting through a QCDR.** Ophthalmologists have access to the IRIS Registry, a QCDR that integrates seamlessly with most EHR systems and provides them with full reporting capabilities for MIPS. The use of the QCDR is a clinically relevant tool to provide a full picture of the physician's performance. PI measures are process related and generally primary care-based. They do not provide useful information to specialists, such as ophthalmologists. **Physicians using a QCDR are participating at a higher, and more meaningful, level in MIPS and should be given full credit in the PI category, so they can concentrate on clinically relevant measures.**

- **We believe this recommendation aligns with our call to continue to streamline and simplify the MIPS program and provide multi-category credit.** A significant percentage of cataract surgeons and multi-specialty ophthalmology practices have already integrated their EHR systems with the IRIS registry. This allows them to make full use of their EHRs to keep track of surgical outcomes and ensure that patients with chronic disease are receiving regular care. We believe this tool meets the ideals of the MIPS programs as envisioned by Congress to take a holistic approach to quality reporting, rather than the rigid framework that CMS is proposing for the MVPs. **We encourage CMS to award full credit in the Promoting Interoperability category for clinicians who have an EHR integrated with a QCDR and to identify additional opportunities for cross-category credit.**

MIPS APM Scoring Standard

- **ASCRS and OOSS oppose CMS' proposal related to scoring physicians who are participants in a MIPS APM that fails to report MIPS data and recommend that should a Medicare Shared Savings Program (MSSP) or Next Generation ACO MIPS APM fail to report data, CMS should award individual or group TIN participants of the entity MIPS scores if they submitted enough data to be scored as MIPS-eligible clinicians.** CMS is proposing that should an MSSP or Next Generation ACO MIPS APM entity fail to submit MIPS data, the agency will aggregate any MIPS data submitted by individual or group level TINs participating in the ACO and award all participants in the MIPS APM entity the same final MIPS score. **This proposal would negatively impact the scores of ophthalmologists participating in the APM entity.**

- **Most ophthalmology practices participating in ACOs that are MIPS APMs continue to collect and submit their own MIPS data, separate from the MIPS APM entity.** Since ACOs do not report any ophthalmic quality data, most participating ophthalmologists continue to track their performance on MIPS ophthalmology measures through the IRIS Registry. In the rare case where the MIPS APM entity failed to report MIPS data, CMS would likely have enough data submitted from participating ophthalmologists or group ophthalmology practices to determine a MIPS score. However, there is no guarantee that other individuals or groups in the entity are collecting and reporting such robust individual quality data, since they are part of the ACO that is supposed to be collecting and reporting data. Therefore, if CMS were to calculate an average performance rate of data submitted across the ACO, ophthalmologists would likely earn a much lower MIPS final score than if they had reported MIPS on their own, since other participants in the entity may have reported only limited or no individual or

group-level data. **In the instance of a MIPS APM entity failing to report MIPS data, we urge CMS to score individual or group TINs separately on the data each submits.**

Advanced Alternative Payment Models (A-APMs)

- **ASCRS and OOSS continue to recommend that CMS prioritize developing and implementing specialty-specific A-APMs.** Currently, most A-APM models are primary care-focused and do not measure any ophthalmic care. While some ophthalmologists participate in models, such as ACOs, they are generally not involved in the management of the ACO and do not contribute quality data to the ACO. A more frequent situation is that ophthalmologists do not have any A-APMs nearby to join, or local A-APMs do not include specialists. While we continue to believe that CMS should preserve a viable fee-for-service option in Medicare because that is the best option for most ophthalmologists who provide surgical care on an episodic basis, there should be some A-APM options available to any ophthalmologist who wants to participate. CMS' work to date in fostering new models has centered on primary care. We are aware that several specialties have submitted A-APM proposals to the Physician-Focused Payment Model Technical Advisory Committee (P-TAC), and that P-TAC has recommended several of these models for implementation, but CMS has not followed through on those recommendations. We believe P-TAC has the requisite knowledge and experience to recognize which models have the potential to improve quality and reduce cost, and we recommend CMS expedite implementing the models it approves. **We recommend CMS widen its approach and begin implementing models for specialists, particularly those approved by P-TAC.**

CONCLUSION

Thank you again for the opportunity to provide comments on this proposed rule. **We urge CMS to modify its 2021 E/M proposals to increase the value of post-operative E/M visits in global surgery codes and urge CMS to increase the value of eye exam codes, which are primarily based on E/M office visits, to correspond with the proposed increase in the E/M visit codes for 2021. We oppose CMS' proposal for the MVPs because it would be mandatory and eliminate physicians' ability to choose the measures that are most meaningful to their practices and patients. In addition, CMS' proposal to include in the MVPs population-health and patient-reported outcome measures, along with its continued siloed scoring approach and lack of details on how they will be implemented further, are all problematic. Finally, we reiterate that CMS must eliminate the inclusion of any pass-through drug from the cataract episode-based cost measure.** If you need additional information, please contact Allison Madson, ASCRS manager of regulatory affairs at amadson@ascrs.org or 703-591-2220.

Sincerely,

Nick Mamalis, MD
President, ASCRS

Maria C. Scott, MD
President, OOSS

Appendix

Sample of correspondence provided by Omeros Corporation (Seattle, WA) from customers indicating they would discontinue use of Omidria due to its inclusion in the cataract episode-based cost measure.

(Individually identifying information removed)

From:
Date: 4/23/19 8:05 PM (GMT-06:00)
To:
Subject: Omidria

Michael,
While our doctors have had a positive experience clinically with Omidria, the issue with MACRA/MIPS and their per case cost and rankings is a big concern. At this time, our facility uses Omidria only on a very small percentage of our cataract surgeries. If the issues were to be resolved there would be possible consideration of resuming usage.

Thank you. And thank you as well for keeping us updated.

Sincerely,

From
Date: May 9, 2019 at 1:44:27 PM EDT
To: Subject: Omidria

Julia,

It has come to my attention through the ASCRS website I will be penalized for using Omidria during Cataract Surgery.

Therefore, I will no longer be using Omidria until it has been removed from the calculation.

I believe in the product and have seen wonderful results. It is not the quality of the medication.

Subject: Impact of Omidria to MIPS score
Importance: High
All,
After a call today with the Omeros team, it appears that their previous legal counsel was incorrect, and that Omidria will be counted in your total cost for cataracts in the MIPS cost calculation. The attached memo outlines their consultant's take on the issue, which you can review for yourself, but basically says that there will be impact to your MIPS cost calculation, which may be offset by other cost and quality impacts. After reviewing the memo, I personally cannot imagine that those cost and quality impacts will offset the additional cost added by using Omidria on every patient, but you may have an experience that aligns with the consultant's arguments. The consultant also stated that Omeros and other entities are arguing this decision with CMS, so there may be a different decision in the future.

Bottom line, please evaluate this in terms of your Omidria usage and MIPS strategy. We will carry it and have it available for anyone wishing to continue to use it. However, if you and your practice decide to stop using it or to change your approach to using it, please let me know, so that we can be prepared to support you.

Thank you,
Melanie

From:
Date: May 9, 2019 at 5:46:19 PM CDT
To: Subject: Re: OMIDRIA - MACRA/MIPS
Hi Ryan,
Thanks for reaching out. I read much of Rachel's analysis which is very thorough and impressive. You both clearly understand my (and others) concerns. In the end, it seems that the "financial penalty" for using Omidria will be minimal and may even possibly be offset by other potential advantages for some efficient practices who operate at efficient surgical facilities. The penalty will grow, however, as cost increases to 30% of MIPS so some of these arguments which apply today may not be so applicable next year or the year after. Bottom line is that this offering pass through status on one hand for Omidria and then penalizing physicians who use it on the other by applying a negative multiplier to their glaucoma and diabetic office exams is bad for patients, physicians who want to help our patients by offering the best results and really, really bad for Omeros. It's just really bad policy. As a solo practice physician without the resources to hire professionals to master MIPS, I am understandably hesitant to do anything which will potentially lower my score.

Thanks and Have a great weekend, Ryan.

From:
Date: June 4, 2019 at 11:23:05 AM CDT
To: Subject: Reimbursement in future
Kelly,
My concern is the high reimbursement cost of your drug will be figured in our cost per case in the future by CMS. We are very conservative in our efforts to use Omidria only when we need it. Having said this, I am concerned that the high cost of the drug could negatively impact our cost per case when reviewed by CMS.

Thanks for forwarding my concerns.

From:
Sent: Tuesday, March 12, 2019 3:40 PM
To:
Subject: RE: Omidria

Hi Jeff – I will be in the office all day on 3/21 so just let me know what time works for you after 10am. That being said, we do not plan on ordering any more Omidria unless passthrough drugs are removed from the cataract cost measure in MIPS reporting.

From:
Sent: Wednesday, July 17, 2019 12:56:04 PM
To: Subject: RE: Omidria/MIPS

Actually, the MIPS White Paper did a very good job attempting to show how things could be offset based on other quality measures. The only problem is we are in the upper echelon of MIPS on those other quality measures and because of that, we would gain no advantage by "improving" quality on those other measures. It might be a good offset for practices who are not scoring well on those other measures. Thanks Mike. Up until this came up, the program was most definitely a win win. Darn Government. Makes no sense what they decided to do on this.

-----Original Message-----
From:
Sent: Tuesday, July 30, 2019 4:13 PM
To:
Subject: Omidria

Hello Michael,

I revisited Omidria usage today with our surgeons. They will not reconsider using Omidria until it has been confirmed that it no longer counts against them in the cost category of MIPS.

##

Ophthalmology Management Article. Accessible here:

https://www.ophthalmologymanagement.com/issues/2019/june-2019/coding-amp;-reimbursement

Coding & Reimbursement

Protect your MIPS Cost score

By Suzanne L. Corcoran
June 1, 2019

A great deal has been written about CMS' Quality Payment Program and MIPS, and we are not going to rehash all of that here. However, in 2019, we are faced with a brand new episode-based cost measure for ophthalmology — Routine Cataract Removal with IOL Implantation — that will impact many practices' MIPS Cost score. Read on for the details.

Q. What is an episode-based cost measure?

A. Episode-based cost measures represent the cost to Medicare for the items and services provided to a patient during an episode of care. In all supplemental documentation, "cost" generally means the standardized Medicare-allowed amount, which includes both Medicare and trust fund payments, as well as any applicable beneficiary deductible and coinsurance amounts.

Q. How does this apply to cataract?

A. The Routine Cataract Removal with IOL Implantation episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for beneficiaries who undergo routine cataract removal with IOL during the performance period (CY 2019). The sole episode-based cost measure applied to ophthalmologists is the cataract surgery episode measure. This is because it is the only one related to any ocular procedures or conditions.

The cost measure score is the clinician's risk-adjusted cost for the episode group averaged across all episodes attributed to the clinician. This procedural measure includes costs of services that are clinically related to the attributed clinician's role during each episode. An episode starts 60 days prior to the clinical event that opens, or "triggers," the episode through 90 days after the trigger.

The episode-based measures seek to quantify the cost of care related to a specific procedure or condition, and include the total costs of preoperative testing, the surgery itself, facility costs, anesthesia costs and postoperative care not included in the global surgical bundle.

Q. What costs are included?

A. For procedural episodes, CMS will attribute episodes to a MIPS-eligible clinician who renders a trigger service (in this case, 66984). Pertinent costs fall within a time window of 60 days prior to the trigger service and 90 days afterward. Only covered items and services are counted. The cost of noncovered items and services, on the other hand, are ignored.

For example, an eye exam to determine the need for cataract surgery and the associated biometry to select an IOL power are counted. Anesthesia is counted. The ASC or HOPD facility fee is counted. Any injected medications during surgery, such as pass-through drugs that receive separate payment, are counted. Importantly, the treatment of complications paid for by Part B Medicare within the 90-day postop period, whether by the surgeon or other eye-care physician, is counted.

Example: Clinician A performs cataract surgery with IOL (66984) for Patient K on Jan. 2, 2019. This service triggers a Routine Cataract Removal with IOL Implantation episode, which is attributed to Clinician A. Clinician B performs a lens repositioning procedure, which is considered a clinically related service, during the episode window on Jan. 11, 2019. Because lens repositioning is considered to be clinically related to the triggering procedure, the cost of the repositioning procedure will be assigned to Clinician A's episode.

Q. What costs are excluded?

A. A number of things, and not all cataract cases count. First, and most important, this is a Medicare Part B program only; any other patients are excluded from the calculation. Second, this is only regular cataract surgery (66984); complex cataract surgery (66982) is excluded. Patients with significant co-morbidities, as described in CMS quality measure #191, do not count; CMS has said it will use a 120-day look back period to identify these co-morbidities (eg, iridocyclitis, corneal ulcer, glaucoma, posterior segment disease).

In addition, non-covered items and services are excluded. Patient-pay refractive services, like astigmatism correction and toric or presbyopia-correcting IOLs, are not included.

Q. Surgery performed at a HOPD has considerably higher costs than an ASC. Do HOPD-based surgeons always take a hit?

A. No. CMS has considered this factor and uses different risk-adjusted cost calculations for HOPD and ASC. CMS recognizes that HOPD-allowed amounts are greater. However, since the episode-based cost is a new element of MIPS, we cannot be sure how this will be applied.

Q. What can we do to minimize our costs?

A. Consider the following options to minimize your costs:

- Review pertinent co-morbid diagnoses on eye exams; be sure these are reported on claims
- Expand ICD-10 coding for cataract surgery
- Attend to differences between routine and complex; be sure your operative reports are clear and complete
- Minimize complications; eg, YAG capsulotomy within 90 days, CME after cataract surgery
- Reduce unusual costs (eg, pass-through drugs)
- Choose ASC over HOPD when medically appropriate
- Explore alternatives:
    - Bilateral cataract surgery
    - In-office cataract surgery **OM**

REFERENCE

1. CMS Measure Specification Sheet, Quality Measure #191. [Author's note: The CMS web site is set up such that no direct link to the Measure file is available.]

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