October 1, 2020

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

Re: [CMS-1734-P] RIN 0938-AU10; Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule

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 2021 Medicare Physician Fee Schedule (MPFS) proposed rule, which includes the Quality Payment Program (QPP) and the Merit-Based Incentive Payment System (MIPS).

Below is an Executive Summary of key recommended actions:

Medicare Physician Fee Schedule

2021 Proposed Conversion Factor

- **ASCRS and OOSS urge CMS to use its authority and work with Congress to reduce the drastic cuts that are scheduled to take effect on January 1, 2021 due to the 10.6% reduction to the conversion factor that will have a huge negative impact on specialties, like ophthalmology, at a time when physician practices are continuing to struggle as a result of the COVID-19 pandemic. Ophthalmology was one of the hardest hit specialties due to reductions in office visits and the cancellation of surgical procedures, such as cataract surgery, during the public health emergency. Ophthalmic practices are facing a minimum of a 6% cut on January 1, 2021 as a result of this proposed rule. Cataract procedures would be cut by 9%. This would have a devastating impact as it follows a 15% cut in cataract surgery reimbursement in 2020. Ophthalmology practices, especially small private practices, that are struggling to recover will be devastated by these substantial reimbursement cuts.**

Policies Related to Evaluation and Management (E/M) Codes

- **ASCRS and OOSS oppose policies related to the Evaluation and Management (E/M) codes, including the creation of the unnecessary add-on code (GPC1X) and the failure to incorporate the revised E/M values in the global codes.**

  10-and 90-Day Global Surgical Services

  - **We reiterate our strong opposition to CMS' policy that will not apply the 2021 increased values of standalone evaluation and management (E/M) services to the post-operative E/M visits in 10- and 90-day surgical global packages for 2021.** CMS is implementing RUC-recommended increases to standalone E/M services for 2021, and now to other select bundled services and codes, but is not following the RUC's recommendation to extend those increases to global surgical post-operative services. **In this proposed rule, CMS continues to ignore our comments that by applying this update to standalone codes, and other additional codes, the policy violates the Medicare statute by creating a specialty payment differential and impacts the relativity of the physician fee schedule.**

  - **CMS continues to use faulty rationale for not increasing the value of post-operative visits based on a misinterpretation of the Medicare Access and CHIP Reauthorization**

Act of 2015 (MACRA) statute that it cannot modify the codes while it is conducting its ongoing study of global codes. In fact, the MACRA statute notes that while it gives CMS the authority to conduct the study, at the same time, CMS must continue updating values to individual codes as necessary. For example, CMS finalized for 2020 updated values for cataract surgery following a RUC revaluation, which includes three post-operative E/M visits valued at the same level as standalone codes. 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. ASCRS and OOSS urge CMS to remedy this 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—when the standalone E/M increases go into effect in 2021.

Add-On Code for E/M Visits (GPC1X)

- **ASCRS and OOSS urge CMS not to implement the proposed add-on code for E/M visits related to complexity of patients with chronic disease (GPC1X) because it is no longer necessary, over compensates physicians providing primary and complex medical care since the level 4 and 5 visit codes now appropriately value those services, and disrupts the relativity of the fee schedule.**

Telehealth

- **ASCRS and OOSS support the expansion of certain telehealth flexibilities and coverage beyond the Public Health Emergency (PHE) to ensure our members can continue to maximize the benefits of telehealth and enhance patient access to care.**

Quality Payment Program

COVID-19 MIPS Exceptions

- ASCRS and OOSS appreciate CMS providing burden relief via previously announced extreme and uncontrollable circumstances policy exceptions for 2019 and 2020 due to the COVID-19 pandemic. We urge CMS to continue to make these hardship exceptions available during the 2021 performance year.

MIPS Performance Threshold and Category Weights

- **ASCRS and OOSS oppose the CMS proposal to increase the performance threshold to 50 points from 45 points; decrease the Quality category weight from 45% to 40%; and increase**

the Cost category weight from 15% to 20%. CMS should limit the number of changes to MIPS at a time when physicians are struggling to keep up with the demands and expense of daily practice due to the pandemic. There have been major disruptions in ophthalmic practices, such as the cancellation of elective procedures (such as cataract surgery), that will continue to impact CMS' ability to make accurate determinations about appropriate levels of both cost and quality.

MIPS Value Pathways (MVPs)

- **ASCRS and OOSS support CMS' proposal to delay the implementation of MVPs until 2022 but continue to oppose any effort to make MIPS Value Pathways (MVPs) mandatory. We believe a physician, and not CMS, is best positioned to determine which measures are appropriate for his/her practice and patient population. Furthermore, forcing specialty physicians, like ophthalmologists, to report on mandatory MVPs would subject them to problematic population-health measures. We are also concerned with CMS' intent to simultaneously propose an initial set of MVPs, along with the implementation policies during the CY 2022 rulemaking cycle.**

APM Performance Pathway

- **ASCRS and OOSS urge CMS to ensure that, under this new pathway, any MIPS APM participant continues to benefit from 0% weighting of the Cost performance category and full credit under the Improvement Activities (IA) performance category consistent with the score assigned at the APM Entity level, regardless of which quality measures they report and whether they report under MIPS at the APM Entity, TIN, or individual level.**

Cataract Surgery Episode-Based Cost Measure

- **We continue to oppose the inclusion of FDA-approved pass-through drugs in the cataract surgery episode-based cost measure. CMS did not respond to our comments on this subject in the 2020 final rule, and therefore, we continue to recommend CMS take immediate action to remove the current pass-through drug in the measure. In addition, CMS should 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 for up to three years. 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.

Measures and Scoring

- **We continue to oppose the removal of so-called "topped-out" ophthalmology measures.** In general, we continue to oppose CMS' topped-out measure methodology and recommend continuing to award credit for maintaining high quality.

- **We continue to oppose 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.

Advanced Alternative Payment Models (APMs)

- **ASCRS and OOSS continue to support 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. We encourage CMS to prioritize models for testing or implementation that have been recommended by the Physician-Focused Payment Model Technical Advisory Committee (P-TAC).**

Full comments on these issues are below:

MEDICARE PHYSICIAN FEE SCHEDULE

Evaluation and Management (E/M) Policies

ASCRS and OOSS oppose certain policies related to the E/M codes proposed and previously finalized that is resulting in a reduction of the conversion factor from $36.0896 to $32.2605 (10.6%) due to budget neutrality requirements. ASCRS, along with the medical community, supported restructuring and revaluing the office-based E/M codes, which increase payments for primary care and other office-based services. However, CMS is moving forward with additional policies that contribute to this unprecedented decrease in the conversion factor including:

- A new, unnecessary "add-on" code for complex patient care (GPC1X)
- Increased E/M values to other services that are comparable to or include E/M visits.

The additional spending to support these increases along with increases to stand-alone E/M visits totals $10.2 billion.

In addition, CMS' continued failure to apply the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) recommended work and time incremental increases for the revised E/M codes in the global codes is unacceptable, particularly in light of the adjustments proposed in this rule for other bundled services, such as maternity codes.

Applying Increased E/M Values to Post-Operative Services in 10- and 90-day Globals

ASCRS and OOSS continue our strong opposition to CMS' continued failure 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 finalized for standalone E/M office visits beginning in 2021. This policy is broadly opposed, not just by ASCRS and OOSS, but across all surgical specialties, the AMA, and from Congress. As we have noted in joint letters from the surgical community, and from bipartisan letters from Congress, CMS must increase the value of the post-operative E/M services in global codes to correspond to increases in the standalone E/M codes for 2021.

CMS is ignoring that it is required by the Medicare statute to reimburse all physicians the same amount for the same work regardless of specialty. In addition, by increasing the value of just the standalone E/M codes, and not applying the increase to the global codes, CMS is disrupting the relativity of the fee schedule. Further, each time E/M codes have been revalued since their inception in 1992, the post-operative E/M services in the global surgical codes have been increased as well. CMS should be consistent with its prior policy and follow the recommendation of the RUC to increase the values.

CMS continues to base its decision not to increase post-operative values in global codes on a flawed assertion that it cannot do so while it conducts its global codes data collection effort. **This ignores an explicit requirement in the MACRA statute that it study the global codes, while at the same time continue to update codes as necessary.** As an example, CMS implemented new values for cataract surgery codes for 2020 following the RUC's revaluation. Not only does this invalidate CMS' claim that it cannot update global codes, the survey conducted as part of the RUC process verified three post-operative visits furnished with similar work as if they were standalone visits. These post-operative visits—and all others included in global codes—should be paid at the same rate as standalone E/M codes. **Furthermore, if CMS is concerned that certain services are overvalued, they should be referred to the RUC as misvalued codes for review.**

To reiterate our reasons why CMS must increase the value of post-operative E/M services in global codes:

- **Failing 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, for 2021 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' policy violates the Medicare 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 along with standalone E/M services in 2021.**

- **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 adopted RUC's recommended values for standalone office visit codes following an extensive review and revaluation. CMS has made note of 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 final 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' continued 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 implemented the RUC-recommended value for cataract surgery (66984) in 2020. 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.**

Opposition to E/M add-on code (GPC1X)

ASCRS and OOSS continue to oppose the implementation of the E/M add-on code, GPC1X and urge CMS to withdraw the proposal. This code—aimed at describing additional services furnished related to the care of a patient with a single, serious, or complex chronic disease—was originally created by CMS when their proposal collapsed the E/M codes with a single payment rate for levels 2 through 5 visits. At that time, CMS' justification for the then two proposed add-on codes in the CY 2019 PFS was that the blended payment rate would have resulted in decreased payment for certain specialties that typically bill level 4 and 5 visits, and also decreased payment for primary care by not accounting for the type and intensity of primary care visits.

In addition, the AMA and most all of the medical and surgical specialties agreed that GPC1X was not necessary given the ability to up code based on MDM or time. The AMA RUC, the CPT Editorial Panel, and the large majority of the medical community has continued opposition to the GPC1X add-on code. CMS continues to ignore the comments and opposition and appears to attempt to shift even more money to specific specialties.

This add-on code, the descriptor, and the resources are not justified and instead duplicate the services described by the 30-day global care management codes.

To reiterate:

- Given the changes to the E/M codes, the add-on code is no longer necessary, since the level 4 and 5 visit codes and the code for additional time appropriately value these services.
- The code will disrupt relativity across the Medicare Physician Fee Schedule (PFS) and will inappropriately discriminate among physician specialties, contrary to Congress' mandates in the Omnibus Budget Reconciliation Act (OBRA) of 1989 (P.L. 101-239).

Therefore, we urge CMS not to implement this flawed and unnecessary code.

Telemedicine

ASCRS and OOSS greatly appreciate the flexibilities provided for Medicare telehealth and virtual care services through CMS' COVID-19 blanket waivers and interim final rules. These policies have enabled ophthalmic practices to provide ongoing essential medical care and treatment throughout the pandemic. Using its authorities under the public health emergency (PHE) and those granted by congressional action, CMS was able to assure that Medicare beneficiaries could receive care and treatment from their homes using a variety of technology, including audio-only telephones. Some of our most impactful telehealth visits (impactful to patients *and* to the entire health system) are for new patients. Our members have seen countless examples of urgent triage visits, 2nd opinion consults, and doctor/doctor consults, which enabled timely care for serious conditions. Conversely, these visits minimize unnecessary ED visits and travel for subspecialty care. The following are tele-ophthalmology new-patient examples:

Urgent Virtual Care

An urgent care virtual clinic was created by Bascom Palmer Eye Institute (BPEI) to treat patients with low-acuity conditions remotely, while expediting treatment of high-acuity patients. This minimizes crowding of the dedicated ophthalmic emergency department (ED), minimizes unnecessary ED visits, and keeps patients in the at-risk categories for contracting the severe form of COVID-19 at home. While common conditions like chalazia and conjunctivitis are managed virtually, patients suspicious for more serious issues such as stroke, retinal detachment, vision loss, and eye trauma are expedited for timely in-person evaluation. Many of these patients would have sustained irreparable damage were it not for this virtual care.

Doctor/Doctor Consults

Consults between physicians prove critical, primarily by expediting treatment and minimizing the number of physical encounters with multiple subspecialists. Real-time video slit lamp examinations are also utilized at times. For example, a patient with an atypical corneal infection presented to the BPEI ED. A slit lamp adapter was fastened to the slit lamp and a smartphone was inserted. A Zoom call was initiated from the device and the screen was shared, allowing a corneal subspecialist to view the exam remotely and to direct the referring ophthalmologist and patient through a vision-saving treatment plan.

2nd Opinion Consults

Given travel restrictions, BPEI performs both domestic and international second opinion consults. Patients are scheduled for telehealth appointments with the appropriate specialists and

medical records are uploaded to the EHR. The physicians review the records and perform video consultations. This service is available to help referring physicians as well, which allows them to keep and care for their own patients locally. These visits are essential as they are less costly for patients, avoid unnecessary travel, and allow patients in underserved areas to receive tertiary level care.

To ensure our members can continue to maximize the benefits of telehealth and enhance patient access to care, ASCRS and OOSS support the extension of certain telehealth flexibilities beyond the end of the current PHE for COVID-19, including for new and established patients. We also encourage CMS to work with Congress to remove Medicare originating site requirements and eliminate the list of originating sites and geographic eligibility requirements. This would ensure Medicare patients can receive care via telehealth from their home or other location deemed appropriate by the secretary. Many patients, especially the elderly, cannot or do not want to use video encounters.

- We believe that site-of-service payment differentials for telehealth visits should be eliminated, and Medicare coverage for "telephone" E/M services (CPT 99441-99443) should be maintained.

Given the positive impact this has had on our members and their patients, many are making investments in virtual platforms, indicating their intent to incorporate more telehealth and virtual care services into their practice mix. These practices have indicated their patients are receiving medically necessary care virtually, where clinically appropriate and indicated.

ASCRS and OOSS support permanently increasing access to telehealth and virtual care services but we recognize the challenges as to how and to what extent, including the potential for increased utilization and spending and possible program integrity vulnerabilities.

QUALITY PAYMENT PROGRAM

ASCRS and OOSS are concerned regarding any attempt to make substantial changes to MIPS at a time when our healthcare system and our physicians are under significant strain due to the pandemic. **Therefore, we oppose CMS' proposal to increase the overall MIPS performance threshold in 2021 from 45 points to 50 points, reduce the Quality category weight from 45% to 40%, and increase the Cost category weight from 15% to 20%. We urge CMS to maintain the status quo.**

MIPS Value Pathways (MVPs)

In the CY 2020 PFS final rule, CMS stated its intent to apply the new MVP framework in the 2021 performance year. However, due to the public health emergency (PHE), CMS is proposing to delay the implementation of MVPs beginning with 2022 MIPS Performance/2024 MIPS payment year, as

well as limiting the MVP proposals to guidance necessary for the collaborative development of MVPs, including updates to the guiding principles, development criteria and a proposed process. ASCRS and OOSS support CMS' proposal to delay the implementation and continue our strong opposition to mandatory MVPs. We strongly urge CMS to make MVPs a voluntary participation option when implemented.

It is crucial that MVPs be voluntary to preserve 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.

Furthermore, there are several elements of CMS' vision for MVPs that would make them unacceptable to ophthalmologists if mandatory, such as the use of problematic population-health measures, as well as the burden associated with collecting data for patient-reported outcome measures.

Finally, CMS has yet to provide complete details for how the MVPs will be scored; however, 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. **We urge CMS to work with the medical community to streamline the program by simplifying scoring and allowing for cross-category credit as a means of truly reducing burden.**

To ensure clinicians may report on the measures and activities most meaningful to their practices, in the least-burdensome manner, CMS should consider the following issues when developing MVPs.

MVPs Must Be Voluntary

- **As we noted in our comments on the CY2020 PFS proposed and final rules, our opposition to the MVPs was chiefly based on CMS' original proposal to make them mandatory.** We appreciate that CMS continues to seek feedback from stakeholders before making formal proposals or implementing the new framework. We also appreciate that CMS took our comments, and those of other medical specialties, into consideration by noting it has not yet determined whether the MVPs will be mandatory. In this proposed rule, CMS indicates that MVPs will be optional for clinicians and that "traditional" MIPS participation options will remain. However, it also intends to build a robust inventory of MVPs and expects that eventually it may propose that all MIPS eligible clinicians would be required to participate in MIPS either through an MVP or an APM Performance Pathway (APP). Given that the goal of the MIPS program is to provide a more flexible approach to quality reporting, clinicians participating in the program must continue to have options in how they participate in the program. It is critical that MVPs remain voluntary and that physicians maintain the ability to participate in either an MVP or remain in the traditional MIPS pathway so they have

continued **flexibility to choose the measures that are most appropriate for their practice and patient population.**

- **Physicians are best suited to select the measures that are most meaningful to their practices and patients.** While ophthalmology is solely focused on the diseases of the eye, there are several different subspecialties, and not all ophthalmologists of a particular specialty focus on the same population of patients. Given that diversity, it would be difficult to identify a limited set of measures and activities that would be useful to all ophthalmologists. In fact, the ophthalmic community recognized this fact several years ago, and has been successful in developing a focused set of measures—many of which are outcome measures—that reflect our members' practices and patient population. **CMS should continue to allow physicians to select and report on the most clinically relevant measures and designate MVPs as voluntary participation options.**

Eliminate Flawed Population-Health Measures

- **CMS should rethink its plan to include flawed population-health measures in MVPs, and in the MIPS program at large.** As we noted in our comments on previous rules and other requests for information, population-health measures, such as the all-cause hospital readmission currently used in MIPS for large practices, 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. 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 ocular disease. We appreciate that CMS has decided not to go forward with implementing a new MIPS measure in 2021 for hospital admissions for patients with multiple chronic diseases. **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. 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 MVPs or MIPS.**

Reduce Reporting Burden of Patient-Reported Outcome Measures

- **ASCRS and OOSS continue to recommend CMS eliminate the burden associated with collecting data for patient-reported outcome measures included in MVPs, and the MIPS program in general.** We have long supported the use of appropriate patient-reported outcome measures and participated in the development of several related to cataract surgery. These measures are valuable following cataract surgery, since they can demonstrate that patients are experiencing improved quality of life, however, they are currently not feasible to use in MIPS because the data completeness threshold is so high, and it is impossible to administer the surveys to patients undergoing this high-volume procedure. The current patient-reported outcome measures, #303 and #304, are registry-only and will require a 70% data completeness threshold in 2021 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. **We urge CMS to reduce the burden associated with patient-reported outcome measures if included in MVPs and MIPS in general.**

Streamline Scoring Methodology

- **Rather than force physicians to report on mandatory MVPs that may not reflect their clinical practice and maintain the complicated separate scoring methodologies for each category, we continue to recommend CMS work to streamline the existing MIPS program. Along with others in the medical community, ASCRS and OOSS have proposed a voluntary and flexible system that would award physicians credit across categories for clinically relevant measures and activities.** In comments on previous years' 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 continue to believe that these modifications would reduce confusion physicians often experience trying to adhere to the disparate requirements in each of the categories and make the program more meaningful for all physicians.**

Again, we maintain our opposition to mandatory MVPs and urge CMS to preserve physician choice.

APM Performance Pathway (APP)

Beginning in 2021, CMS proposes to end the APM Scoring Standard, which is the current MIPS scoring methodology for our members participating in a MIPS APM. It was originally designed to reduce reporting burden by eliminating the need for these physicians to submit data for both MIPS and their APMs. CMS is now proposing to create a new APP that would be available only to MIPS APM participants. The Cost category would be weighted at 0% and the Improvement Activities (IA) would automatically be assigned to the MIPS APM based on the requirements of the MIPS APM. The Quality category would be composed of six population-health measures and would automatically be used for purposes of the Medicare Shared Savings Program quality scoring, therefore, satisfying both programs' reporting requirements.

ASCRS and OOSS are concerned that this approach fails to reduce the MIPS burden for our members – and actually increases the burden relative to the existing rules. CMS already finalized that specialists could report separately under the APM Scoring Standard using measures that are relevant to their practices, which would be used to calculate the APM Entity's quality score, unless the APM reports quality at the APM Entity level. Therefore, specialists would continue to benefit from the Cost and IA Performance category scoring rules.

However, CMS is now proposing that specialists, can only benefit from these rules if they report measures that are not clinically relevant or meaningful to the care they provide and for which they have little if no control over the clinical outcome.

This could create incentives for our members to terminate their participation in MIPS APMs.

- ASCRS and OOSS, therefore, request that CMS ensure that any MIPS participant continues to benefit from the 0% weighting of the Cost performance category and full credit under the IA performance category consistent with the score assigned at the APM entity level, regardless of which quality measures they report and whether they report under MIPS at the APM Entity, TIN, or Individual level.

Quality Category

CMS Should Consider Evaluating Performance Based on Historical Benchmarks, As Well As Performance Year Benchmarks – Using Whichever Results in a More Favorable Score for Each Measure

- **In this rule, CMS proposed to use performance period, not historical, benchmarks to score quality measures for the 2021 performance year due to the concern that it may not have a representative sample of historic data for CY 2019 due to the PHE, which has impacted data submission for MIPS in 2020 and could skew benchmarking results.**
- **While performance year benchmarks are not ideal (because they do not provide physicians with a target to aim for going into the performance year), we agree with CMS' concern regarding relying on potentially incomplete and unrepresentative data from 2019. Therefore, as a compromise, we recommend that CMS consider evaluating performance based on historical (i.e., 2019) benchmarks, as well as performance year (i.e., 2021), and using whichever results in a more favorable score for each measure.**
- **This will give physicians a baseline of information to guide measure selection decisions going into the 2021 performance year.**
- **In addition, given the PHE potential impact on performance data from 2019-2021, we urge CMS to adopt a universal scoring floor of 5 points, which would help mitigate the disruptive PHE effects on benchmarks and incentivize participation among clinicians who might have otherwise opted to apply for the hardship exemption.**

Opposition to Removing "Topped-Out Measures" and Request to Suspend Topped-Out Measure Scoring Caps for 2021

- **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 replace cataract surgery outcome measures in the program, refrain from removing any further 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.**

- Due to the pandemic, we also request that CMS suspend the topped-out measure scoring caps for 2021. As we have already indicated, we oppose the elimination of topped-out measures, as well as capped scoring. Current determinations of topped-out performance may not be accurate due to the ever-changing program requirements from year to year. All these concerns are amplified in light of the COVID-19 pandemic.

Cost Category

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

- **ASCRS and OOSS continue to 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. We are disappointed that CMS continues to ignore our comments and requests and urge the agency to remove the current pass-through drug from the measure for 2021.**

- **Pass-through status, which can be granted for up to 3 years, is a vital tool in ensuring that new, innovative, and expensive drugs are introduced to the market, and the utilization during this time is used by CMS in the formula to calculate the increase in the ambulatory payment classification (APC) group to account for the drug once the drug comes off pass-through.** Pass-through status helps introduce a new and expensive 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 continue to be included in the measure, physicians mindful of their score on the cataract surgery cost measure will continue to 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 are approved for use during cataract surgery. One such drug—injection, phenylephrine and ketorolac, 4 ml vial—is currently included in the episode measure.** Specifically, these FDA-approved drugs administered during cataract surgery that are on now on pass-through 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 substantial cost savings 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.**

- **As we have previously indicated, the inclusion of pass-through drugs in the cost measure continues to have 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 many practices that have previously used the drug are discontinuing its use because of the potential impact on the Cost category score of MIPS, and we have shared this information with CMS. Also troubling is that ophthalmic practice consultants continue to recommend 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 an impact on other similar drugs. We urge CMS 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.

- **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 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 previous proposed rules, however, there has never been a discussion of how future changes to this or other measures will be made. Furthermore, CMS has not responded to our comments on the previous proposed and final rules. 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 MPFS rulemaking to ensure that stakeholders have the opportunity to provide input on the measures.**

Promoting Interoperability Category

As CMS looks toward developing policies reducing the burden of the MIPS program, **we continue to recommend that the "all-or-nothing" methodology be removed. We also urge CMS to consider a more diverse set of measures that offer more relevant options for specialists. In addition, we continue to recommend that physicians who use QCDRs that integrate with their EHR be awarded full credit in this category.**

- **CMS should remove the "all-or-nothing" scoring of this category.** 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 **any** 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 continue to recommend CMS modify this category and remove the "all-or-nothing" scoring.**

- **We also 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 continue to 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.**

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 always 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.**

- **ASCRS and OOSS continue to believe that the Physician-Focused Payment Model Technical Advisory Committee (P-TAC) is the appropriate body to review and recommend models for CMS to implement.** As we have previously indicated, several specialties have submitted A-APM proposals to the P-TAC, and P-TAC has recommended several of these models for implementation, but CMS and its Innovation Center have not followed through on those recommendations. Instead, CMS has pursued multiple new models centered on primary care that were not vetted by P-TAC, or do not incorporate the feedback the panel has suggested. P-TAC has been open to the proposals put forward by different specialties that would increase the opportunities for a wider group of specialties beyond primary care to participate in new models. 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 continue to 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 final rule. **We urge CMS to identify a solution with the assistance of Congress that will eliminate the negative financial impact of its 2021 E/M related policies on our members, including increasing the value of post-operative E/M visits in global surgery codes and withdrawing the proposed add-on code (GPC1X). We continue to oppose mandatory MVPs and urge they remain voluntary to maintain physicians' ability to choose the measures that are most meaningful to their practices and patients. 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 Nancey McCann, ASCRS Director of Government Relations at nmccann@ascrs.org.

Sincerely,

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