September 11, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (CMS-1784-P)

Dear Administrator Brooks-LaSure:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing 6,500 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 society that represents over 4,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective ASC environments. The programs and services of OOSS are designed to ensure top-quality and sustainable patient care and safety in surgical environments that support ever-changing technology and regulation.

We appreciate this opportunity to provide comments on the CY 2024 Medicare Physician Fee Schedule (PFS) proposed rule, which includes the Quality Payment Program (QPP).

Below, we provide an overview of the actions we urge CMS to take as part of this PFS rulemaking. Context and rationale for these requests are provided in the sections that follow.

Medicare Physician Fee Schedule Policies

- ***ASCRS and OOSS urge CMS to use its existing authorities to mitigate the -3.34% reduction to the CY 2024 PFS conversion factor, while continuing to work with Congress on a long-term solution to the Medicare physician payment system challenges.***
- ***ASCRS and OOSS urge CMS to eliminate the complexity add-on code (HCPCS code G2211) that is responsible for more than half of the estimated reduction to the CY 2024 PFS conversion factor.***
- ***ASCRS and OOSS continue to urge CMS to apply the increased E/M values as finalized in the CY 2021 PFS to the post-operative E/M visits in 10- and 90-day global surgical procedure codes.***

- ***ASCRS and OOSS urge CMS to maintain access to audio-only services, including the telephone E/M services, and work with Congress to permanently remove geographic restrictions and originating site requirements.***
- ***ASCRS and OOSS urge CMS to use its existing authorities to reduce the burden of reporting discarded drug modifiers for ophthalmic practices by raising the wastage threshold to 100% for ophthalmic drugs with volumes less than 1 mL per vial.***

Quality Payment Program Policies

- ***ASCRS and OOSS strenuously oppose the increase in the performance threshold from 75 to 82 points for the 2024 performance year.***
- ***ASCRS and OOSS continue to oppose any effort to make MIPS Value Pathways (MVPs) mandatory.***
- ***ASCRS and OOSS urge CMS to adopt subspecialty-specific MVPs, like the measures we put forth for a cataract MVP, for voluntary reporting.***
- ***ASCRS and OOSS strongly oppose the proposal to increase the PI performance period from a minimum of 90-consecutive days to 180-consecutive days.***
- ***ASCRS and OOSS strongly recommend CMS conduct extensive testing and training to ensure resource use reports are understandable, user friendly, and actionable.***
- ***ASCRS and OOSS strongly recommend CMS review the form and content of the Cost Measure specifications.***
- ***ASCRS and OOSS urge CMS to remedy the TIN level attribution for the Diabetes cost measure and have it mirror the TIN-NPI level attribution methodology so that specialty groups treating complications of diabetes, like ophthalmology groups, are not inappropriately attributed this measure.***
- ***ASCRS and OOSS strongly urge CMS to reconsider the proposed increases in the data completeness threshold.***
- ***ASCRS and OOSS oppose the removal of so-called "topped-out" ophthalmology measures, including the topped-out measure methodology, and recommend continuing to award credit for maintaining high quality.***
- ***ASCRS and OOSS recommend that physicians using a QCDR that is fully integrated with their EHR system should be awarded full credit in this category.***
- ***ASCRS and OOSS continue to support the development of specialty-specific Advanced APMs and urge CMS to test the ASCRS-developed Bundled Payment for Same-Day Bilateral Cataract Surgery (BPBCS) model and implement it for voluntary participation.***
- ***ASCRS and OOSS oppose CMS' proposal to publicly report cost measures on Care Compare.***
- ***ASCRS and OOSS oppose any modification that would require clinicians to report on different measures or activities once they have demonstrated consistently high performance on their currently reported measures, and we strongly urge CMS to stop increasing administrative burden on clinicians.***
- ***ASCRS and OOSS urge CMS to implement a 5-point floor for measures that have undergone substantive changes and lost their benchmarks for two years (when a historical benchmark would then be able to be calculated if there is sufficient data).***

MEDICARE PHYSICIAN FEE SCHEDULE

I. Update to the CY 2024 Medicare PFS Conversion Factor

ASCRS and OOSS are extremely concerned with CMS' estimate of the CY 2024 PFS conversion factor – set at approximately $32.75 – that lowers Medicare payments to physicians by $1.14 (or -3.34%). The estimated conversion factor stems from a budget neutrality adjustment of -2.17%; the 0.0 % update adjustment factor required under the *Medicare Access and CHIP Reauthorization Act* (MACRA); and a 1.25% payment update provided under the *Consolidation Appropriations Act, 2023* (CAA, 2023). The estimated conversion factor does not account for lower payments physicians currently receive due to the Medicare sequester (-2%), and those they face if the "Pay-As-You-Go" ("PAYGO") sequester is implemented (-4%). ***We urge the Agency to take steps toward mitigating this reduction using its existing authorities, while continuing to work with congressional lawmakers on a long-term solution to the Medicare physician payment system challenges.***

Inflation Update

The cost of running an ophthalmic practice has far outpaced the price Medicare pays for the services we deliver. According to the American Medical Association (AMA), the ***physician practice costs have increased by 47%, on average, while payments have declined by 26%***, accounting for inflation. Analysis by the Frontier Institute shows that, when adjusted for inflation, the conversion factor should near $70.00, yet the proposed CY 2024 conversion factor is less than half of that amount, at approximately $35.75.[1]

Ophthalmic practices – mostly small, solo- and two-to-four-physician offices – are struggling with the high cost of skilled labor, medical supplies and equipment, and rents, just like all other Medicare providers. However, these other Medicare providers receive positive annual payment updates that reflect their increased costs. For example, hospitals, hospices, skilled nursing facilities, ambulatory surgery centers, etc., receive a market basket adjustment that increases their payments relative to a measure of inflation (e.g., Consumer Price Index (CPI)). These updates are considerable – usually near or above 3%. As the Agency is aware, the forecast for the Medicare Economic Index (MEI) – a measure of inflation faced by physicians with respect to their practice costs and general wage levels – is 3.6% in Q1 of CY 2024.

The lack of a meaningful rate increase that accounts for rising practice costs, such as the MEI, has prompted many ophthalmic practices to sell to private equity (PE) groups to help with key practice functions (e.g., prior authorizations, coding and billing, perform insurance verifications, quality reporting and electronic health record maintenance, compliance reviews, contract negotiation, and provider credentialing), that have become increasingly costly and administratively burdensome, and difficult to manage on top of providing high-quality care to Medicare patients, at the current payment levels. ***CMS should work with Congress to ensure the annual physician payment update is appropriately adjusted for inflation.***

Budget Neutrality

Section 1848(c)(2)(B)(ii)(II) of the *Social Security Act* requires CMS to maintain "budget neutrality," such that increases or decreases in relative values do not cause the amount of expenditures for a given year

[1] See https://frontierinstitute.org/viewpoint-the-losses-to-physician-medicare-reimbursement-in-2022-23-are-mind-boggling-update-to-when-will-enough-be-enough/

to differ by more than $20 million from what expenditures would have been in the absence of the changes. To facilitate this requirement, CMS applies budget neutrality adjustments to the annual conversion factor. This typically results in reductions to the conversion factor.

Over the years, and particularly following the implementation of increased values for the office and outpatient evaluation and management (E/M) code set and the planned addition of a "complexity add-on code" in the CY 2021 PFS, ASCRS and other stakeholders highlighted concerns with the way budget neutrality adjustments are applied, particularly when the change falls outside physicians' control (e.g., changes in practice costs, codes established to meet the administration's policy priorities). Recognizing that the Secretary has limited authority to waive budget neutrality requirements, ***CMS should be more thoughtful in putting forward policies that impact the conversion factor, particularly those that would have a significant impact on an already low conversion factor or favor certain specialties over others, when all physicians – especially small, solo- and two-to-four-physician practices that make up the majority of ASCRS members – are struggling to stay viable in the current financial climate.*** Annual reductions to the conversion factor are even more detrimental for small and solo-physician practices, practices in rural and underserved areas, and practices caring for the most vulnerable and disadvantaged populations.

To mitigate some of the challenges with the mandatory budget neutrality adjustments, ***we urge CMS to work with Congress in support of legislative proposals offered by the AMA,[2] and supported by ASCRS, that would:***

- ***Provide a lookback period to reconcile overestimates and underestimates of pricing adjustments for individual services to allow for the Medicare conversion factor to be calculated with more accuracy based on actual utilization data.***
- ***Refine which services are subject to budget neutrality. For example, when federal policy changes are expected to result in more use of certain services, those services should be exempt from budget-neutrality calculations, including newly covered Medicare services and technologies or high-value services that are being incentivized in an attempt to lower overall Medicare spending.***
- ***Increase the budget-neutrality trigger from $20 million to $100 million, to provide flexibility in making necessary pricing adjustments for individual services without triggering automatic, across-the-board Medicare cuts.***

II. Evaluation and Management (E/M) Services

Complexity Add-on Code (HCPCS code G2211)

ASCRS and OOSS urge CMS to eliminate the "complexity add-on code" (HCPCS code G2211) from the PFS. Consistent with our comments above, the addition of this code is unnecessary, and more importantly, inappropriate.

In its CY 2019 PFS rulemaking, CMS initiated a major overhaul of the office and outpatient evaluation and management (E/M) services. This included proposals to 1) significantly revise the E/M documentation guidelines; 2) collapse levels 2–5 of the new and established office and outpatient E/M

[2] See https://www.ama-assn.org/practice-management/payment-delivery-models/how-medicare-s-budget-neutrality-rule-slanted-against#:~:text=Increase%20the%20budget%2Dneutrality%20trigger,%2Dthe%2Dboard%20Medicare%20cuts.

services; 3) make a single payment for levels 2–5 of the office and outpatient E/M services); and 4) establish two "add-on" codes to mitigate redistributive effect of the aforementioned payment proposals while recognizing the additional relative resources and inherent visit complexity typical of higher-level visits.

Based on stakeholder feedback and following a comprehensive revaluation of the existing office and outpatient E/M services, the Agency rescinded the E/M collapse and single payment. In its CY 2021 PFS rulemaking, CMS finalized increased office and outpatient E/M values and the complexity add-on code. Due to the redistributive impact of these policies, which would have reduced the conversion factor by 10.2%, Congress imposed a 3-year moratorium (through CY 2024) on the complexity add-on code to mitigate the planned conversion factor cuts. Now that the moratorium has expired, CMS intends to implement the complexity add-on code, which as we highlight below, is the primary driver of the budget neutrality adjustment.

ASCRS and OOSS strongly oppose the implementation of the complexity add-on code and urge CMS to eliminate it from the PFS. The work described by this add-on code is already accounted for in the existing office and outpatient E/M services and the improved values, as demonstrated by the pre- and post-service work listed in the Summary of Recommendations by the AMA Relative Value Scale Update Committee (RUC), shown below:

> *"Review prior medical records and data. Incorporate pertinent information into the medical record. Query the PMP, HIE, and other registries, as required. Communicate with other members of the health care team regarding the visit."*
>
> *"Answer follow-up questions from the patient and/or family and respond to treatment failures or complications, or adverse reactions to medications that may occur within 7 days after the visit. Review and analyze interval testing results and refine the differential diagnosis, workup, and treatment plan based on these results. Order additional testing based on these results. Communicate results and plan modifications with patient and/or family. Respond to queries from the pharmacy regarding changes in medications due to formulary or other issues."*[3]

It is clear from the above passages that the add-on code is unnecessary. More importantly, if the add-on code remains, the Medicare program and its beneficiaries would pay twice for the same care. This runs counter to the Agency's long-standing effort to avoid duplication in relative values and associated payments. Therefore, it is inappropriate for CMS to implement this add-on code.

We also question CMS' utilization assumptions, which assert that this add-on code would be billed on 38% of all office and outpatient E/M services in CY 2024.[4] For ophthalmology, CMS' public use files (PUF) assume this service will be billed more than 2.6 million times, and for other specialties, such as pathology, the estimates are even more absurd. As highlighted in comments by the AMA RUC, the American College of Physicians (ACP), representing the majority of physicians likely to use this code, suggest that utilization should be less than 10% of all office visit codes.[5]

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[3] See May 2019 summary of recommendations from the AMA RUC

[4] See 88 *Fed. Reg.* 52353 (August 7, 2023).

[5] See https://acpinternist.org/archives/2023/05/the-case-for-g2211-medicares-visit-complexity-code.htm

The utilization assumptions for the complexity add-on code, while improved from CMS' CY 2021 estimates, continue to drive steep budget neutrality adjustments to the CY 2024 conversion factor. Indeed, CMS notes that 2.0% of the estimated 2.17% budget neutrality adjustment stems from this add-on code. ***All physicians, including those the add-on code and associated payment aims to assist, face difficulty in the current fiscal climate. Policies that unnecessarily and inappropriately reduce the conversion factor must be avoided.***

As a reminder, Medicare's conversion factor is the basis by which Medicare Advantage and private plans set their payment rates. Ophthalmologists attempting to negotiate contracts with these payers will be forced to accept even lower rates than they are now, and in some cases are less than Medicare's, which further contribute to reduced patient access and increased consolidation.

Again, ***we urge CMS to eliminate HCPCS code G2211 from the PFS based on the above concerns, and those outlined by the AMA RUC.***

Post-Operative Visits in Global Surgery

CMS has repeatedly ignored ASCRS' request to increase the value of post-operative E/M visits included in 10- and 90-day global surgical packages to correspond with the increased values for standalone E/M office visits as finalized in the CY 2021 PFS, and we urge CMS to correct this error.

Through enactment of the *Omnibus Budget Reconciliation Act (OBRA) of 1989*, Congress established that Medicare payments to physicians must consider the relative work, practice expense, and malpractice insurance costs required to furnish a particular service, and Medicare reimburse physicians equally for the same service, regardless of their specialty.

In prior years, when E/M values were improved, CMS correctly translated those updated values to the post-operative E/M services in the global surgical codes. However, in the CY 2021 PFS, CMS failed to apply its existing policy, violating the statute and threatening the overall relativity of the PFS.

Previously, CMS has raised concerns about the number and value of post-operative E/M services being provided. With respect to cataract surgery, the post-operative values have been verified in multiple analyses and were reaffirmed in the CY 2022 PFS Final Rule. Even CMS' contractor, RAND Corporation, demonstrated through its reports that ophthalmologists are indeed providing the number and level of post-operative visits following cataract surgery that are accounted for in the global period. Even if CMS continues to believe that the number and level of E/M services being delivered during the global period is overstated, that is an entirely separate matter that should be addressed through the AMA RUC process, where CMS is an active participant.

The AMA, the surgical community, and other stakeholders have demonstrated that CMS' policy runs counter to the law. Bipartisan lawmakers have raised concerns and requested that CMS restore relativity across PFS services by improving the E/M values in global codes. CMS should follow the precedent set in 1997, 2007, and 2011 (in accordance with the statute) when increased E/M values were applied to post-operative visits included in the global packages. ***ASCRS urges CMS to comply with the law and 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.***

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively
CMS stated that it has received input seeking to consider different approaches for valuing E/M services ("other than the AMA RUC's specialty-specific valuation recommendations"), and references "convening expert panels that might review pertinent research and recommend resource recalibrations for purposes of updating relative values under the PFS" as one approach.

As highlighted in comments by the AMA RUC, the CPT Editorial Panel and the RUC have worked diligently to ensure appropriate coding and valuation for E/M and similar services, as evidenced by a long history of creating new and modifying existing services reported by primary care and cognitive specialty physicians. We disagree that a separate "panel" is needed to value E/M and similar services beyond the processes convened by the AMA, where CMS and primary care specialties actively participate, and those that CMS undertakes on its own. ***Any effort to duplicate the AMA RUC process solely for the purpose of valuing E/M services would be a misuse of taxpayer funds that Congress appropriates to CMS each year to administer the Medicare program.*** It is particularly disappointing that CMS would even raise such a concept as part of this PFS rulemaking given its role in the AMA CPT and RUC processes, its awareness that the same organizations suggesting such a "panel" are equally engaged in the AMA CPT and RUC processes, and the number of primary care services it has proposed in this CY 2024 proposed rule. Finally, CMS is ultimately responsible for ensuring relative values are resource-based and adequately compensate physicians for the costs to deliver care to its beneficiaries. CMS is not required to adopt the recommended values put forward by the AMA. ***We strongly oppose the establishment of a duplicative process to the AMA CPT and RUC for valuing E/M and other primary care services.***

III. Telehealth

Telehealth remains an important tool for the delivery of ophthalmic care, despite the ending of the COVID-19 public health emergency (PHE). ASCRS appreciates CMS' proposed policies to maintain access to telehealth services for beneficiaries, including implementation of requirements set forth in the *Consolidated Appropriations Act, 2023.* ***CMS should continue working with Congress to permanently remove originating site requirements and geographic restrictions, so beneficiaries can continue to receive care at the place of their choosing once the extended flexibilities end in CY 2024.***

ASCRS and OOSS appreciate that the telephone E/M services (CPT codes 99441–99443) are deemed "telehealth services" and will remain actively priced through CY 2024. The availability of audio-only services continues to have a profound impact on Medicare beneficiaries who lack the financial resources and local broadband infrastructure to utilize more traditional telehealth modalities. Our patient population, those who require cataract and other vision correcting procedures, find video-enabled technologies to be more complicated and confusing. Audio-only access to healthcare services is not only valuable, but a necessity, for many Medicare beneficiaries. ***For this reason, we urge CMS to permanently cover and reimburse audio-only services, including the telephone E/M services.***

In addition, we support CMS' proposal to streamline the process by which services are added to the Medicare Telehealth Services List, consolidating services into either "permanent" or "provisional" categories (Category 1 and Category 2, respectively). This will result in less confusion as services are nominated to be included on the Medicare Telehealth Services List.

IV. Discarded Drug Modifiers

The *Infrastructure Investment and Jobs Act* requires manufacturers to provide a refund to CMS for discarded amounts from certain single-dose container or single-use package drugs. In facilitating this provision, CMS requires practices to report either a JW or JZ modifier on their Part B claims to indicate whether there are discarded drug amounts, or no discarded drug amounts, following delivery of a physician-administered medication.

ASCRS and OOSS remain concerned with CMS' discarded drug modifier requirement and the administrative burden it causes on ophthalmic practices. While other specialties that administer medications in the office may routinely discard drug waste from single-use vials or packages, that is not the case for intravitreal drug injections administered by ophthalmologists.

As we shared previously, small amounts of drug product injected into the eye are often in vials containing 1mL or less of the drug. While most of the drug is used, it is impossible to extract every microliter from the vial for injection; there must be sufficient volume in order to properly mix in the vial and draw with a syringe. What remains in the vial is not "wastage" for purposes of the statutory requirements. For ophthalmologists and their staff to reconcile tiny amounts of product remaining in these small vials creates substantial burden for no meaningful gain.

CMS has the authority to raise the wastage threshold applicable to the rebate requirement for drugs with volumes less than 1 mL per vial, which would alleviate the burden on our practices. ***We urge CMS to exempt ophthalmic drugs by using its statutory authority to raise the wastage threshold to 100% for drugs with volumes less than 1 mL per vial.***

QUALITY PAYMENT PROGRAM

ASCRS and OOSS thank CMS for minimizing the number of substantial proposed changes to MIPS, particularly as we continue to deal with the repercussions of the COVID-19 public health emergency.

I. Performance Threshold

CMS is proposing to increase the performance threshold to avoid a penalty to 82 points for the 2024 performance year/2026 payment year. This proposed change results from CMS' proposal to modify the way in which they calculate this and future MIPS performance thresholds – rather than using the mean of a prior performance year, CMS proposes to use the average of performance means of three prior years. The intent of this proposal is to shield clinicians from dramatic annual shifts in the score required to avoid a penalty. **Although we applaud this intent, we strongly oppose this change at present.**

We agree that performance years 2020–2021 were irrevocably impacted by the COVID-19 public health emergency and should not be used for any future performance threshold determinations due to the automatic hardship applied to all clinicians and groups that did not wish to report MIPS.

We strongly disagree with CMS' assertion that performance year 2019 escaped significant impact from COVID-19 automatic hardships. Although these were announced in the March following the performance period, we are aware that many groups that were not confident they could avoid a penalty withdrew consent for third party intermediaries to report their performance data to CMS for the purposes of MIPS. Moreover, due to the automatic COVID hardship applied at the individual level,

clinicians who were eligible at the individual level were able to avoid a MIPS penalty, even if they would have received a penalty at the group level, as, at the individual level, they were assigned the threshold to avoid a penalty. The impact of COVID-19 alone would be sufficient to make including any year from 2019–2021 in the determination of MIPS performance thresholds inappropriate, however, **we have serious concerns about the ability to compare the current ecosystem of MIPS to any year prior to the 2022 performance year:**

- The Quality category, worth 30% of the MIPS Final Score, was much easier prior to performance year 2022.
    - Up to 6 bonus points under the end-to-end electronic reporting bonus (1 point per qualifying measure).
    - Up to 6 bonus points under the high priority measure bonus (2 points per additional outcome measure, 1 point per additional high priority measure).
    - Many specialty measures have become topped out or have been removed since 2019.
- The Cost category, worth 30% of the MIPS Final Score, was largely unscored.
    - Scoring for episode-based cost measures began in performance year 2019.
        - Due to COVID-19, Cost was only scored for those who chose to report MIPS at the group level after the automatic hardships were announced.
    - Based on the results we have seen from the 2022 Cost category, scoring this category has greatly reduced average MIPS scores.
    - The performance feedback provided to clinicians is not actionable and was not made available until more than halfway through 2023.

Since 2019, 60% of the MIPS composite score has become significantly more difficult to score well on for clinicians. In addition, Cost (30% of the MIPS composite score) remains unpredictable with performance feedback that provides very little insight and opportunity to improve. For further discussion of the issues with Cost measures and measure feedback, see the Cost section.

It is a mistake to increase the threshold to avoid a penalty based on performance data from years in which both CMS policies and the environment (COVID-19) created a MIPS program in which it was significantly easier to obtain a higher MIPS Final Score. **As CMS states in this proposed rule, the performance threshold increase "is no longer required by section 1848(q)(6)(D)(iv) of the Act."**

CMS' Regulatory Impact Analysis shows that an estimated 46% of MIPS eligible clinicians would be penalized under this increased threshold, and 54.31% based on the sum of the proposed changes in this rule. We do not believe that nearly half of U.S. clinicians provide substandard care, worthy of penalty. The majority of ophthalmologists are in small practices, and CMS estimates that more than 60% of MIPS eligible clinicians in small practices will be penalized under this proposed rule. We are deeply concerned that policies that seek to penalize half of U.S. clinicians will create incentive for further healthcare consolidation. Provider consolidation has been repeatedly identified as a concern for Medicare prices and access to care.[6,7] It has also been repeatedly demonstrated that consolidation increases cost of care while having little-to-no impact on quality of care.[8,9]

[6] MedPAC Report to the Congress: Medicare Payment Policy | March 2023
[7] MedPAC, "March 2020 Report to the Congress: Medicare Payment Policy," March 13, 2020.
[8] Schwartz et al. "What We Know About Provider Consolidation" (San Francisco, CA: Kaiser Family Foundation, 2020), available at https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/.2020).
[9] Beaulieu ND, Chernew ME, McWilliams JM, et al. Organization and Performance of US Health Systems. *JAMA.* 2023;329(4):325–335. doi:10.1001/jama.2022.24032

II. Targeted Reviews and Performance Feedback

CMS is proposing to change the targeted review period to begin on the day MIPS Final Scores become available in the preview period and end 30 days after the publication of MIPS Payment Adjustments. **ASCRS and OOSS agree that this is a reasonable change and offer our conditional support for this proposed change**. *In order for clinicians to have sufficient time to analyze their scores and write targeted reviews, CMS must provide all detailed performance feedback at the time of the score release. This must include improved Cost measure performance feedback. See the Cost section of this comment letter for more information.*

III. MIPS Value Pathways (MVPs)

Subgroup Proposals and Comment

- **Mandatory Subgroup Reporting**

In 2026, subgroup reporting will become mandatory for multi-specialty practices reporting on MVPs. ASCRS and OOSS support this policy in general, but **we are concerned that an eyecare-only practice that employs midlevel providers (optometrists, NPs, PAs) will be labelled as multi-specialty.** While MVPs remain voluntary, this will be a disincentive for participation. **We ask CMS to address this in future rulemaking and have developed two potential options that could resolve this issue**:

1. Allow practices that are identified as multi-specialty to submit an attestation that their practice provides care for a single clinical area (e.g., eyecare, skin care, orthopedic care, etc.). This could be done during MVP registration, or it could be an application process similar to the MIPS Exception application.
2. CMS could field test a process that uses the primary diagnosis code on claims to determine area of practice. In this way, midlevel providers in single specialty practices would not cause a practice to be inaccurately labelled "multi-specialty."
3. *In addition to one of the above*, CMS could define specialty groups that, when seen in a practice, would be considered a single specialty. For example: Ophthalmology and Optometry.

These strategies balance CMS' desire to provide information to practices prior to the MVP registration period, and allowing groups to report only on the care that they provide. If a strategy is not put in place to address this issue, midlevel providers will be required to report on care that they do not provide, and patients will be given a misleading picture of clinical quality.

- **Subgroup Complex Patient Bonus**

CMS is proposing that subgroups would be assigned the affiliated group's complex patient bonus. Given the operational concerns cited by CMS, **ASCRS and OOSS support this proposal.**

- **Subgroup Reweighting Applications**

ASCRS and OOSS urge CMS to reinstate the policy of allowing subgroups to submit reweighting applications before subgroup reporting becomes mandatory. In this rule, CMS proposes to eliminate

the ability of subgroups to submit reweighting applications due to operational and technical constraints. While temporarily removing the ability for subgroups to submit applications for and receive reweighting at the subgroup level will not have a significant negative impact while subgroup reporting is optional, we encourage CMS to reinstate and operationalize subgroup reweighting *before* subgroup reporting becomes mandatory in 2026.

- **Subgroup Targeted Reviews**

ASCRS and OOSS support CMS' proposal to allow subgroups to submit targeted reviews. We believe this is a commonsense step to ensure that each scored entity is given the ability to request a review of inaccuracies in their respective scores, rather than relying on the administrator at the TIN-level to do so on their behalf.

Develop Voluntary Condition-Based/Procedure MVPs

In the past, CMS has expressed concern that the number of MVPs desired is too high. In ophthalmology, we are highly sub-specialized and cannot reliably or meaningfully be scored in a specialty-wide MVP. Therefore, we urge CMS to consider the adoption of more sub-specialty and condition-based MVPs. ASCRS has been working collaboratively on a cataract surgery-specific MVP.

MVPs Must Remain Voluntary

CMS has consistently stated that they plan to make MVPs mandatory in the future. **ASCRS and OOSS strongly urge CMS to make MVPs a voluntary participation option when implemented.**

- **As we noted in our comments on the CY 2021, 2022, and 2023 MPFS rules, our opposition to the current framework outlined by CMS is that MVPs continue to be chiefly based on CMS' intent to eventually make them mandatory and phase-out MIPS.** We appreciate that CMS continues to seek feedback from stakeholders before making formal proposals or implementing the new framework. However, CMS also intends to build a robust inventory of MVPs and expects that eventually all MIPS eligible clinicians would be required to participate in MIPS either through an MVP or an APM Performance Pathway (APP), while no longer offering traditional MIPS. Given that the goal of MIPS 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. For example, the retina subspecialty focuses specifically on diseases at the back of the eye, neuro-ophthalmologists focus on visual problems related to the nervous system (not the eyes), and cataract and refractive surgeons focus on the front of the eye.

  Given that diversity, it would be difficult to identify a limited set of measures and activities that

would be useful to all ophthalmologists. This was quite evident when CMS initially developed a draft MVP for ophthalmology. As was discussed in our meetings with CMS regarding the draft proposal, not all ophthalmic specialties would have been able to participate.

In the update CMS circulated last year, an MVP encompassing of all ophthalmology would severely limit the ability of ophthalmologists to perform well under MIPS. In the draft Comprehensive Ocular Care MVP, 12 of the 18 available quality measures are either not benchmarked or topped-out. In addition, not all ophthalmic subspecialties have measures available in the draft MVP.

We have encouraged the development of MVPs around conditions and procedures. 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 allow specialty societies, if they so desire, to work with CMS on a particular clinical condition or procedure, but these efforts should be clinician led. However, we continue to urge **CMS to allow physicians to select and report on the most clinically relevant measures and designate MVPs as voluntary participation options.**

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. **In fact, ASCRS has been working collaboratively on a cataract surgery-specific MVP.**

Eliminate Flawed Population-Health Measures

- **CMS should rethink its continued plan to include flawed population-health administrative claims measures as a foundation in MVPs, and in the MIPS program at large.** As we have 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. **Using these measures to determine the quality of ophthalmic care is entirely inappropriate. Ophthalmologists should be excluded from these measures and population-health measures should not be included in any ophthalmic MVPs.**

- **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.

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 proposed to be 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, QPP303 and QPP304, are registry-only and will continue to require a 70% data completeness threshold in 2023 (75% in 2024–2026) 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 forcing 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. We appreciate that CMS took some steps toward this in 2021 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.

Finally, although MVPs are meant to be a cohesive, integrated reporting pathway, 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. **As we have in previous comments, 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.**

IV. MIPS Quality Category

Data Completeness Threshold

ASCRS and OOSS strongly **urge CMS to reconsider the proposed increases in the data completeness threshold**. We have previously voiced our concerns surrounding increased burden and barriers to MIPS reporting, particularly for small and rural practices. This continues to be the case and we are deeply concerned with CMS' stated intent to continue to "incrementally increase the data completeness criteria" and to incorporate "high data completeness thresholds in future years."

CMS states that the following factors play into their decision to increase the data completeness threshold and the timeline on which to increase the threshold:

- Experience with MIPS over the past seven years has prepared clinicians for increased data completeness thresholds.
- Increasing data completeness threshold would not pose a substantial burden to MIPS ECs unless they are manually extracting and reporting quality data.
- Higher data completeness thresholds in future years would ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures.

While we understand these reasons, we have seen things play out differently in practice, for example, when a practice switches EHRs during the performance year.

When a practice switches EHRs, the vast majority of the time the new EHR will not include data from encounters that occurred prior to the transition in the measure calculation. The logical next step would be to ask a registry to aggregate the data for submission. This is often logistically difficult for registries to do with limited resources. Alternatively, a practice could report data directly from each EHR to CMS for CMS to aggregate, but CMS has previously finalized that data must be aggregated prior to submission. That leaves practices to aggregate the data themselves. **This creates substantial burden that no amount of experience with MIPS has been able to ameliorate, particularly since practices cannot always decide when to switch EHRs** (e.g., their EHR is decertified, the practice is acquired, their planned transition to a new EHR is delayed, etc.).

CMS has stated that increasing the data completeness threshold would not pose a substantial burden to MIPS ECs unless they are manually extracting and reporting quality data**. If a practice in the situation we described plans to submit eCQMs, they often cannot aggregate this data as a single submission to CMS, leaving the practice to manually extract the data which can be prohibitively burdensome.** Situations like this are common, and practices rely on the current data completeness threshold to allow them to meet reporting requirements.

A typical ophthalmologist sees about 100 patients per week. If we extrapolate that to a 52-week year, we can estimate approximately 5200 patients. To determine statistical significance, most researchers use a 95% confidence level. This means that, 19 times out of 20, a sample of the specified size would yield a similar result. If we choose a tight margin of error (only 1%) and a 95% confidence interval, the size of the patient sample for this ophthalmologist would be 3374 patients (65% of the patients seen by the ophthalmologist during the course of the year). For a general measure like Documentation of Current Medications in the Medical Record, a 65% sample would be representative.

Although the sample size percentage increases as the population size decreases, this is meant for a random sample. What we are seeing from practices in situations such as the one outlined above is not a sample, but rather a census of available patient data. This means that the practice is reporting all measure data available in their current EHR**. A census of available patient data meets CMS' goal** of ensuring that data submitted on quality measures are complete enough to accurately assess quality performance*. If, on the other hand, a practice becomes required to manually extract and aggregate large amounts of quality measure data themselves, it is reasonable to expect unintentional errors.* **It is clear from this common example that higher data completeness thresholds do not always yield more accurate depictions of quality performance.**

We agree that it is important that quality data represent a clinician's true performance, rather than a cherry-picked sample. Circumstances, like EHR switches during the performance year, can make high data completeness thresholds not only hard to meet, but also difficult to meet *accurately.* For the reasons outlined above, we strongly urge CMS to maintain the current data completeness threshold of 70%. **If CMS continues to increase the data completeness threshold, we recommend the following options to ensure that practices are able to continue to report quality data in good faith:**

- CMS-facilitated quality data aggregation: Allow practices to report quality data from multiple EHRs with an indication that they should be aggregated to determine the measure's final score.

- Shortened performance periods for special circumstances: If a practice switches EHRs during the performance period or encounters an unforeseen data completeness-related issue, allow the practice to report on the longest period of consecutive data available. For example:
    - If a practice switches EHRs in March and is unable to submit yearlong aggregate data, the practice would have 9 consecutive months of data available in the new EHR, on which they could report 100% data completeness.
    - If a practice switches EHRs in October, the first EHR would have 9 consecutive months of data available.
    - For practices unable to switch during the first or last quarter of the year (would have less than 9 consecutive months of data), allow the practice to apply for a Quality Category EUC.

- Extreme and Uncontrollable Circumstance Quality Category Exceptions: for practices that switch EHRs during the performance period or encounters an unforeseen data completeness-related issue.

Patient Reported Outcome Measures

As outlined above, there are instances in which increasing data completeness requirements *directly* intensifies administrative burden for physicians and does not align with the Patients Over Paperwork

Initiative. This is particularly true for patient reported outcome (PRO) measures as it is difficult to obtain sufficient patient responses under current thresholds. **In acknowledgment of the widespread difficulty in obtaining PRO responses from patients, we recommend CMS consider setting lower data completeness thresholds for patient-reported outcome measures.**

Support for Maintaining 3-Point Floor for Small Practices

ASCRS and OOSS support CMS' decision to maintain the 3-point floor for quality scoring for small physician practices.

Support for Maintaining 6-Point Bonus for Small Practices

ASCRS and OOSS support CMS' decision to maintain the 6-point quality for small physician practices in all future years.

Scoring for Measures with ICD-10 Changes During the Performance Year

Proposal to Replace the 10% Threshold with an Overall ICD-10 Change Impact Assessment for the Measure

ASCRS and OOSS support this proposal. It is a commonsense approach to fairly evaluate measures with ICD-10 changes during the performance year.

Proposal to Update Claims and MIPS CQM Collection Types in October of the Performance Year

ASCRS and OOSS oppose this proposal and ask CMS to maintain current policy to truncate measures that can no longer be accurately scored due to ICD-10 changes. We disagree with CMS' assertion that this would not result in any misleading results for the measure for Medicare Part B Claims and MIPS CQM Collection Types.

For practices reporting MIPS CQMs, reporting on these measures after the update would rely on individual practices and EHRs to update ICD-10 codes in a timely fashion. This will lead to inconsistency, depending on how the EHR stores the ICD-10 codes. For example, some EHRs are highly structured, and the codes are managed on the backend by the EHR company; therefore, you can be certain that appropriate codes will get updated in time. However, some EHRs have high customization and allow practices to control the codes in their system; therefore, these data sources are unreliable and cannot guarantee that codes will get updated in a timely manner. As a result, this could lead to inaccurate data due to the uncertainty and the required quick turnaround time.

Similarly, it can be extremely burdensome to require practices to update their claim codes for all applicable Quality measures instantly. This would likely result in CMS not receiving accurate patient volume for claims reporting. Once again, some practices may fix claim codes in a timely manner, while others may not have the resources or bandwidth to do so. This would likely result in an inaccurate reflection of quality measure data.

V. MIPS Cost Category

Cost Measure Feedback Reports

We remain concerned that the Cost category has not yielded predictable results based on practice patterns and best practices. The feedback reports our members have received from CMS have offered very little insight. We have seen the Cataract Cost Measure score distributions and benchmark range cut-offs change dramatically, but we do not have the sufficient information to determine anything further.

In the 2018 proposed rule, CMS requested advice on how to provide cost feedback to clinicians and how to improve upon QRUR and sQRUR reports. At the time, we requested the ability to identify how and when services were attributed to clinicians and where the services occurred (ASC vs HOPD).

While we appreciate the increased ease in which clinicians can access their cost reports (linked on their MIPS Score Report) and the patient-level drill down appendix, the data we now have under MIPS is extremely difficult for even seasoned MIPS professionals to interpret and to gain actionable insights from. **ASCRS and OOSS strongly recommend CMS conduct extensive testing and training to ensure resource use reports are understandable, user friendly, and actionable.**

Cost Measure Specifications

ASCRS and OOSS strongly recommend CMS review the form and content of the Cost Measure specifications. We have seen many ambiguities and several components that are implemented in a way that conflicts with the measure specification.

For example, in the Cataract Cost Measure specification, CMS states the following: "The Routine Cataract Removal with IOL Implantation episode-based cost measure evaluates a clinician's risk-adjusted cost to Medicare for patients who undergo a procedure for routine cataract removal with IOL implantation during the performance period." However, we have recently discovered that the measure does not evaluate procedures performed during the performance period, but rather procedures with a cost episode window that ends during the performance period.

It is imperative that the cost measure specifications be both accurate and understandable.

Cost Improvement Score

We support CMS' proposal to change the cost improvement score to being calculated based on category-level improvement rather than measure-specific improvement. This not only aligns with the quality improvement score, but also allows more stable evaluation of year-over-year improvement.

Diabetes Episode-Based Cost Measure

ASCRS and OOSS are deeply concerned about the way the Diabetes cost measure has been implemented, specifically the TIN-level attribution methodology. Contrary to discussions during and after field testing, the measure specification stated that the requirement for an attributed provider to have prescribed at least two diabetes-related medications to different patients would only be applied at the TIN-NPI level, not at the TIN level.

Earlier this year, before 2022 MIPS scores were released, we worked with the American Medical Association to bring these concerns to CMS. The AMA received assurances that the group attribution described in the measure specification was in error and would be fixed. This has not occurred.

We are seeing ophthalmic practices that group report MIPS attributed the entire cost of diabetic care for patients for whom they treat, for example, diabetic cataract. Cataract surgeons are being held accountable for the costs of surgeries to create A-V fistulas for dialysis access, limb amputations, and cardiovascular disease.

These are well-known complications of diabetes. Across all of the diabetes-related complications described above, the 3 most significant risk factors are hyperglycemia, high blood pressure, and hypercholesterolemia. It would be grossly inappropriate for an ophthalmologist to manage a patient's hyperglycemia, high blood pressure, or hypercholesterolemia. If clinicians do not treat these risk factors, then they have no control over the progression of a patient's diabetes and, thus, have no control over the total cost of diabetes care.
We appreciate that CMS and Acumen acknowledged that clinicians who do not manage diabetes should not be attributed the costs of a patient's diabetes care and modified the TIN-NPI level attribution by adding the prescription requirement. Similarly, a group (TIN) that sees a patient for a complication of diabetes may not manage diabetes. This is particularly true in specialties, like ophthalmology, in which practices are often single-specialty. We ask that the same logical step be taken for TINs that do not manage diabetes.

This is clearly seen in the average scores we have seen for ophthalmologists attributed this measure. We have partnered with a MIPS consulting firm to evaluate this measure. They reviewed the reports of their clients that attributed this measure in 2022. Despite many of these practices being high performers on other cost measures, the average score for the more than 50 ophthalmic groups they saw attributed the diabetes cost measure was only 3.71 points. As a specialty, ophthalmology often only sees diabetic patients who have already developed complications. Because of this, even the most efficient ophthalmic practices cannot control diabetes costs, as managing diabetes is well beyond their scope of practice.

ASCRS maintains that physicians should not be held accountable for costs over which they have no control. To ensure meaningful Cost measurement, CMS *must* remedy the TIN level attribution for the Diabetes cost measure and have it mirror the TIN-NPI level attribution methodology so that specialty groups treating complications of diabetes, like ophthalmology groups, are not inappropriately attributed this measure.

Emergency Medicine Episode-Based Cost Measure

We appreciate many of the post-field test changes made to the Emergency Medicine cost measure, but we are disappointed that this measure is being proposed for inclusion in MIPS before a method is developed to ensure that visits that are more appropriate for chronic, outpatient care are not included in this measure as it will skew costs for providers who receive a mix of patients who are frequently lost to follow-up. This is particularly important for specialties, like ophthalmology, that provide a relatively low volume of care in the emergency department.

As emergency medicine providers are the intended population for this measure, and as they are the clinicians who coordinate emergency care, other clinician types – such as ophthalmologists – should be explicitly excluded from EM Cost Measure attribution.

Cataract Surgery Episode-Based Cost Measure

ASCRS and OOSS remain concerned with the requests for comment in the Wave 1 Cataract Cost Measure Reevaluation. We would like to take this opportunity to reaffirm our positions for CMS review, and we urge CMS to review our comments on the reevaluation.

High-Level Summary of our Comments from the Wave 1 Cataract Cost Measure Reevaluation:

- **Trigger Code:** 66984 should remain the only trigger for the cataract episode-based cost measure as it is the only routine cataract code and comprises the vast majority of billed cataract surgeries.
    - Other cataract codes are for complex cataracts that are likely to be more expensive due to factors outside of clinician control. Complex cataract may require additional supplies and increases the likelihood of potential complications.
- **Pass-through drugs:** No pass-through drugs should be included in cost measure calculations. The extra cost will disincentivize surgeons from using the drugs and negatively impact the utilization data CMS collects on pass-through drugs during the pass-through period that is used to determine the increase in the APC group once the drug is bundled into the facility payment.
- **Part B Drug, Dextenza:** Given that Dextenza has the ability to reduce or eliminate the need for Medicare Part D postoperative topical corticosteroids, a class of mediation used routinely after cataract surgery, ASCRS recommends this medication continue to be excluded from the cost measure.
- **Part D Drugs:** Part D drug costs should not be included in cost measures.
    - We question the ability of Acumen/CMS to standardize all Part D drug costs that accurately accounts for the varying costs beneficiaries pay for drugs based on their plan or even the pharmacy where they fill the prescription. Other factors unrelated to the clinical merits of the drug – such as formulary design, pharmacy benefit managers (PBMs), and patient incentives including manufacturer's coupons – make it impossible for the surgeon to predict what drug is the most cost effective and what the patient will pay. Since there are so many factors outside of the physician's control that impact the price or availability of specific drugs, Part D drugs should not be included.
    - Patient factors must be taken into consideration. Cataract surgeons must prescribe patients some combination of drugs to treat post-operative pain, inflammation, and/or infection. There are instances where an ophthalmologist would prescribe self-administered post-operative drops rather than administer a drug with a post-operative indication at the time of the surgery. For example, a patient may be allergic to an active ingredient in a drug that would be administered at the time of surgery. Since the patient is allergic to an ingredient in the medication, the ophthalmologist would not use it during surgery and instead, prescribe self-administered post-operative eye drops. It is essential that CMS recognize that the most appropriate methodology for determining cost should be flexible to allow for choice of a treatment option that is best for the patient and will lead to better outcomes.

VI. MIPS Promoting Interoperability (PI) Category

Performance Period

ASCRS and OOSS strongly oppose the proposal to increase the PI performance period from a minimum of 90-consecutive days to 180-consecutive days. Complying with a half-year reporting period for PI is very difficult for the majority of clinicians. There are a number of factors outside of a clinician's control that make half-year compliance very difficult to achieve. Some examples include: switching EHRs, system glitches, updates and downtime, and office relocations. As such, we strongly urge CMS to keep this category representative of factors within physician control by maintaining a 90-consecutive-day performance period.

Change to the Definition of CEHRT

ASCRS and OOSS understand the need to conform with the way in which the Office of the National Coordinator (ONC) plans to define Certified Electronic Health Record Technology (CEHRT) by moving it to be "edition-less".

As we have seen in the transition from the 2015 edition to the 2015 Cures Update, many smaller, specialty-specific EHR vendors have struggled to achieve the update by the 2015 sunset date. Moreover, EHR market consolidation has led to increasing prices. Regulatory burden has been shown to create significant incentive for physicians to consolidate into larger organizations.[10]

ASCRS and OOSS applaud CMS' decision to maintain the small practice and decertification exceptions to MIPS PI. These exceptions will continue to not only avoid disadvantaging small and rural practices faced with these hurdles when certification requirements change but will also avoid providing additional incentive for smaller practices to consolidate.

Maintenance of Automatic Small Practice PI Hardship

ASCRS and OOSS support CMS' decision to maintain the automatic small practice PI hardship exception. This automatic hardship exception and reweighting has helped to alleviate some of the burden experienced by small practices reporting MIPS.

PDMP Measure: Low-Volume Exclusion

ASCRS and OOSS strongly support CMS' proposal to modify the PDMP measure by clarifying that physicians who do not prescribe scheduled medications can claim the low-volume exclusion for this measure and will not be inadvertently disadvantaged.

Ophthalmologists rarely, if ever, prescribe opioid medications. Many have even relinquished their DEA certification. Providing a low-volume exclusion specific to the medications covered under the PDMP measure will allow clinicians who are already doing their part to mitigate the opioid epidemic to avoid being penalized on these measures.

SAFER Guides Measure: Proposal to Require a "Yes" Attestation

ASCRS and OOSS strongly support CMS' proposal to make a "yes" attestation to complete the High Priority SAFER Guide annually. Since 2018, cyberattacks on the U.S. healthcare system have more than doubled.[11] Over the last few years specifically, hacking incidents targeted at outpatient facilities and

[10] (Gaynor et al. 2017)

[11] https://www.fiercehealthcare.com/tech/relentless-cyber-attacks-are-putting-pressure-hospital-finances-fitch-rating

specialty clinics increased dramatically (by 41% in 2021 compared to 2020). In short, cybercriminals are focused on the healthcare sector and have been shifting their focus away from major hospitals and towards outpatient offices.

Cyberattacks cost the U.S. healthcare system over $20 billion a year and have compromised the data of over 45 million people. Unfortunately, this growing trend of cyberattacks on healthcare does not seem to be ending anytime soon.

The possibility of loss of data, extended downtime due to lack of access, and violation of privacy for patients make the resiliency of EHR systems vitally important to healthcare providers. The SAFER guide attestation helps organizations to actively prepare for cybersecurity breaches and attacks.

VII. MIPS Improvement Activities Category

Category Weight, Reporting, and Scoring

ASCRS and OOSS appreciate the consistency in category weight and reporting period for the Improvement Activities Category for performance year 2024. We also strongly support CMS' decision to continue to award small practices double points for each improvement activity (IA).

VIII. Advanced Alternative Payment Models (A-APMs)

Lack of Specialty-Specific A-APMs

ASCRS and OOSS continue to recommend that CMS prioritize implementing voluntary specialty-specific payment models that have already been developed by physician specialties, like the ASCRS Episode-based Cataract Surgery Proposal, rather than attempting to develop new payment models. Currently, most A-APM models are primary care-focused. While some ophthalmologists participate in models, such as ACOs, they are generally not involved in the management of the ACO and are not always able to contribute much quality data. 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 and the continuation of MIPS, 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 has developed the Bundled Payment for Same-Day Bilateral Cataract Surgery (BPBCS) so that cataract surgeons can deliver same-day bilateral cataract surgery to appropriate patients at a lower cost for both patients and Medicare. Instead of each member of the Cataract Surgery Team (the surgeon, facility, and anesthesiologist) receiving separate payments for each individual service, the Team would receive a single bundled payment for all services the patient needs as part of the surgery, and the patient would have a single cost-sharing amount for those services. The bundled payment would give the Team the flexibility to redesign the way surgery is delivered to achieve the best outcomes at the lowest possible cost. The BPBCS would cover the costs of both the surgery and the complications that most commonly occur following surgery – neither Medicare nor the patient would pay more if those complications occurred. We urge CMS to test the BPBCS model and implement it for voluntary participation.

QP Determination Calculations at the Individual Eligible Clinician Level

ASCRS and OOSS are concerned with CMS' proposal to change the QP determination to be solely at the individual clinician level as this will disproportionately negatively impact specialists like ophthalmologists. One of CMS' stated rationales for this proposal is that, by making APM-level QP determinations, they are unintentionally encouraging APMs to eliminate or limit specialist physician participation. This is because specialists furnish proportionally fewer services that lead to attribution of patients or payments to the APM Entity and, thus, are likely to lower the APM's threshold score. Primary care physicians, on the other hand, furnish proportionally more office visits, which are frequently the basis for attribution or patients and payments. We agree with CMS' assertion that it is important for specialists to not be removed from APM Entities because specialists are an important part of the patient care continuum, **however, we disagree that individual-level QP determinations are the best way to solve this problem as it will not encourage specialists to participate in APMs. Rather than placing additional burden on specialists who participate in A-APMs by also requiring them to report MIPS, in addition to meeting the A-APM's participation requirements, we strongly recommend CMS address this problem by addressing beneficiary assignment and the lack of available voluntary specialty models.**

Change in Definition of "Attribution-eligible beneficiary"

CMS states that the methodology used in beneficiary assignment for the Shared Savings Program is "deliberately constructed such that assignment is largely based on primary care, rather than specialty care." **ASCRS and OOSS suggest that assignment methodology should be redesigned to create a complete patient-centered care experience, including specialty care**. Essentially eliminating specialists from the benefits of QP status because of a flawed attribution methodology is inappropriate and downplays the importance of specialty care in complete patient health.

CMS' proposal to change the **definition of "attribution-eligible beneficiary" to include any beneficiary who has received a covered professional service furnished by a clinician for whom CMS is making the QP determination would be a step along the path to correcting this issue, but, rather than basing this new methodology on changing QP determination to be at the individual clinician level, we strongly recommend CMS apply this change to QP determinations made at the APM Entity level.**

Requiring 100% of A-APM Participants to use CEHRT

ASCRS and OOSS agree that health IT use can drive innovation, however, we do not believe that this proposal will achieve the desired results. We are particularly concerned about the impact this proposal, if finalized, will have in conjunction with the proposed change to the definition of CEHRT to be "edition-less" (even if limited only to the base EHR requirements). As we have seen in the transition from the 2015 edition to the 2015 Cures Update, many smaller, specialty-specific EHR vendors have struggled to achieve the update by the 2015 sunset date. By continuing to allow A-APMs the flexibility to provide clinicians time to either select a new vendor or to wait for their vendor to achieve the update, CMS will prevent adding additional barriers to entry into the EHR marketplace and into the A-APM. Over the past couple of years, we have seen increasing EHR vendor consolidation as a result of the EHR certification changes. We are deeply concerned that, rather than providing the flexibility for innovation, this combination of proposals will drive further consolidation and stifle innovation.

Moreover, market consolidation leads to increasing prices. Although there is a small practice and a decertification exception under MIPS, these are not available under A-APMs. By removing the flexibility currently available by requiring 75% of participants (rather than 100%) to use CEHRT, CMS will be disadvantaging these smaller practices and will see decreased A-APM participation among small practice-based specialties (such as ophthalmology). This additional burden creates additional incentive for physicians to consolidate into larger organizations.[12] Moreover, as EHR prices increase, we are likely to see additional consolidation in the healthcare provider space. Provider consolidation has been repeatedly identified as a concern for Medicare prices and access to care.[13,14] It has also been repeatedly demonstrated that consolidation increases cost of care while having little to no impact on quality of care.[15,16]

IX. Public Reporting

ASCRS and OOSS oppose CMS' proposal to publicly report cost measures on Care Compare. As discussed in the Cost section, even clinicians and MIPS policy experts have found it difficult to interpret Cost scores from the feedback received. Some practices have had no change in practice patterns and have received a substantially different Cost score in 2022 compared to 2019, despite providing generally efficient and high-quality care both years. If experts in clinical care cannot fully understand and contextualize these scores, the average patient will not be able to either. Indeed, we are concerned the scores will be misleading. Patients care about the cost to themselves, not to Medicare. Given the way average costs are calculated for MIPS Cost measures, patients may well be misled, causing them to pay more out-of-pocket, even if CMS pays less.

X. RFI: Promoting Continuous Improvement in MIPS

In this rule, CMS has proposed policies that would penalize nearly half of MIPS eligible clinicians, make it more difficult to sufficiently report on Quality measures, increase the burden of reporting on measures that experience ICD-10 code changes, and increase the requirements for EHR use. At the same time, 2022 Cost measures are beginning to have a significant impact on MIPS scores and performance feedback is not actionable. In this context, CMS has included a RFI asking how to force providers have "continuous improvement" and "transform the way that care is delivered."

In this context, ASCRS and OOSS would like to emphasize that clinicians would like to focus on providing quality care to their patients, not on learning how to document new measures so that they map appropriately to reflect their performance. **ASCRS and OOSS oppose any modification that would require clinicians to report on different measures or activities once they have demonstrated consistently high performance on their currently reported measures.** This literally punishes clinicians who deliver high quality care by giving them more work to do as they will need to find new measures and work with their EHR and registry to document and map those measures so that their performance is captured correctly. Meanwhile, CMS increases the threshold to avoid a penalty, removes available Quality measures, and creates substantive changes to measures that cause the measure to lose its benchmark.

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[12] (Gaynor et al. 2017)
[13] MedPAC Report to the Congress: Medicare Payment Policy | March 2023
[14] MedPAC, "March 2020 Report to the Congress: Medicare Payment Policy," March 13, 2020.
[15] Schwartz et al. "What We Know About Provider Consolidation" (San Francisco, CA: Kaiser Family Foundation, 2020), available at https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/.2020).
[16] Beaulieu ND, Chernew ME, McWilliams JM, et al. Organization and Performance of US Health Systems. *JAMA.* 2023;329(4):325–335. doi:10.1001/jama.2022.24032

The burden of complying with MIPS has specifically been cited by MedPAC as a factor driving healthcare consolidation. Though well-intentioned, **we strongly urge CMS to stop increasing administrative burden on clinicians.** MIPS and the frequent programmatic changes have forced clinicians to continuously focus on these administrative burdens, instead of the patient sitting in front of them. Because of this, MIPS has been tied to burnout and workforce attrition.[17,18,19]

Scoring Measures with Substantive Changes

There are some ways to reduce this burden while incentivizing performance of different Quality measures. When CMS makes substantive changes to an existing Quality measure, that measure loses its benchmark. Similar to what CMS does for measures new to MIPS, we suggest that CMS implement 5-point floors for measures that have undergone substantive changes and lost their benchmarks for two years (when a historical benchmark would then be able to be calculated if there is sufficient data). This will decrease the stress and burden caused by the dwindling supply of germane, benchmarked, not-topped-out Quality measure while also incentivizing clinicians to explore a Quality measure that may be new to them.

Topped-Out Measures

The dwindling number of available specialty-specific or germane Quality measures is an issue that is exacerbated by the topped-out measure lifecycle. **As we have stated previously in these comments, 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 consider 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 maintain 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.**

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[17] Khullar D, Bond AM, Qian Y, O'Donnell E, Gans DN, Casalino LP. Physician Practice Leaders' Perceptions of Medicare's Merit-Based Incentive Payment System (MIPS). J Gen Intern Med. 2021 Dec;36(12):3752-3758. doi: 10.1007/s11606-021-06758-w. Epub 2021 Apr 9. PMID: 33835310; PMCID: PMC8034038.

[18] Nguyen, OT, Turner, K, Parekh, A, et al. Merit-based incentive payment system participation and after-hours documentation among US office-based physicians: Findings from the 2021 National Electronic Health Records Survey. *J Eval Clin Pract*. 2023; 29: 397-402. doi:10.1111/jep.13796

[19] **Frequency and Causes of Burnout in US Community Oncologists in the Era of Electronic Health Records**. Ajeet Gajra, Bela Bapat, Yolaine Jeune-Smith, Chadi Nabhan, Andrew J. Klink, Djibril Liassou, Sonam Mehta, and Bruce Feinberg. JCO Oncology Practice 2020 16:4, e357-e365

CONCLUSION

In closing, we continue to be deeply concerned about the focus in this rule on increasing the burden and penalties on clinicians. This can particularly be seen in the "Promoting Continuous Improvement in MIPS" RFI and the Regulatory Impact Assessment estimating that more than 60% of small practices would be penalized based on the 2024 performance year proposals in this proposed rule. We ask CMS to focus on building and maintaining a program that ensures value, not penalties.

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Thank you again for the opportunity to provide comments on this proposed rule. If you need additional information, please contact Mark Cribben, ASCRS Director of Government Relations, at mcribben@ascrs.org and Michael Romansky, JD, OOSS Counsel, at mromansky@verizon.net.

Sincerely,

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