ASRS American Society of Retina Specialists

September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code-CMS-1676-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018 (July 21, 2017)

Dear Administrator Verma:

The American Society of Retina Specialists (ASRS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule [CMS-1676-P], published on July 21, 2017 in the *Federal Register*, regarding the proposed policy revisions to the 2018 Medicare Physician Fee Schedule (PFS). ASRS is the largest retinal organization in the world, representing more than 3,000 members in every state, the District of Columbia, Puerto Rico, and 59 countries.

The ASRS supports many of the CMS proposals including the reduction of penalties under the Value Modifier program, the efforts to align the 2016 PQRS reporting requirement with the Merit-Based Incentive Payment Program (MIPS) quality reporting requirements and CMS' proposal to accept all RUC work RVU recommendations. Easing the requirements of the preceding quality reporting programs will help to ensure that our members can focus on providing quality care to patients. In addition, we commend CMS for recognizing that the input and expertise of physicians is essential to critically evaluating the broad range of examination codes and procedures physicians perform. We appreciate that CMS recognizes and values the physician voice in this process.

There are a number of provisions in the proposed rule that impact retina specialists and the Medicare beneficiaries they treat. ASRS offers comments in the following areas:

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- **Support the RUC values for CPT codes 76519 and 92136**
- **Allow practices to avoid PQRS payment adjustments in 2018 if they submitted any data in 2016**
- **Exempt practices from negative VM payment adjustments**
- **Allow patient reporting codes to be voluntary, or delay implementation until an analysis of proposed codes can be made in the context of cost**
- **Allow subspecialists to use their taxonomy codes in all areas of the Medicare program**
- **Assign a unique HCPCS code to each biosimilar**
- **Seek full input from the medical community before moving ahead with changes to E/M codes**
- **Involve the retina specialist community in advancing telehealth guidance**

Proposed Valuation of Specific Codes Recommendation: Support the RUC values for CPT codes 76519 and 92136.

For CY 2018, CMS is proposing the RUC-recommended work RVUs for CPT code 76516, 76519, and 92136. CMS is seeking comment on whether their alternative values of 0.44 for CPT codes 76519 and 92136 would improve relativity.

For CPT codes 76519 and 92136, the RUC based its recommendation on the median survey time and its review of the clinical aspects of performing this service. ASRS believes that the RUC-recommended post-service time is reasonable and reflects the typical case. During the post-service, the physician dictates, reviews and signs the report, communicates the results to the patient, discusses the lens implant options, and enters an order for the lens implant. The RUC recommended post-service time is appropriate due to the need for the provider to discuss the multiple lens options and refractive outcomes with the patient. Many of these options were not available when the code was last surveyed. In previous rules, CMS acknowledged that the usage of time ratios to reduce work RVUs is not necessarily appropriate, as often a change in physician time coincides with a change in the physician work intensity per minute. We believe that the alternate CMS proposal to remove the recommended post-service time would negatively impact relatively.

Both the CMS and the RUC have a longstanding position that treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect. Inconsistently applying this method to only certain services under

review creates inherent payment disparities in a payment system that is based on relative valuation. When physician times are updated in the Medicare payment schedule, the ratio of intra-service time to total time, the number and level of bundled post-operative visits, the length of pre-service and length of immediate post-service time may all potentially change for the same service. These changing components of physician time result in the physician work intensity per minute often changing when physician time also changes. The ASRS supports the RUC recommendation for CMS to always account for these nuanced variables.

ASRS would also like to highlight that all RUC recommendations now explicitly state when physician time has changed and address whether and to what magnitude these changes in time impact the work involved. For example, RUC rationales explain the original source (or lack therefore) of time data and whether the source can be relied upon as an appropriate baseline. RUC recommendations also provide rationales justifying changes in physician work intensity, when applicable, often with supporting clinical information. CMS should carefully consider this critical information when determining proposed and final work values.

The ASRS requests that CMS not use the ratio of change in the total time solely to reduce the work of RVU services and instead recommends that CMS finalize the RUC-recommend work RVUs of 0.40 for CPT code 76516, 0.54 for CPT code 76519, and 0.54 for CPT code 92136.

Physician Quality Reporting System Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment Recommendation: Finalize proposal to minimize impact of PQRS payment adjustments.

ASRS appreciates that CMS proposes to minimize PQRS payment adjustments in response to concerns that PQRS requirements are complex and difficult to meet. We also appreciate that CMS proposes to simplify CY 2016 PQRS criteria to be more understandable and aligned with the Quality Payment Program, specifically, the Merit-based Incentive Payment System (MIPS). Although six measures with no domain or cross-cutting measure requirement would ease reporting requirements, we suggest that physicians who submitted any data should be exempt from penalties. Overall, our members continue to invest significant resources in technologies to avoid Medicare payment penalties. In 2016, many of our members tried to successfully report PQRS, but were unable to find nine measures that were applicable and meaningful for retina specialists. Technical problems outside of our members' control persisted as some of the cloud-based EHRs failed to include ICD-10 codes which are key to receiving credit for some of the PQRS measures. Most significantly, challenges around electronic reporting through QCDRs continue to persist as our members learned as recently as July 2017 that their EHR data fields are

inconsistently mapped to QCDR data fields. **Therefore, we strongly support CMS further revising the criteria for the 2016 reporting period to help physicians who reported any data avoid the 2018 payment adjustment.**

Value-Based Payment Modifier (VM) and Physician Feedback Program Recommendation: Exempt practices that did not meet PQRS reporting criteria from negative VM payment adjustments.

CMS proposes lessening the penalties associated with VM polices for the CY 2018 payment adjustment period. In general, ASRS welcomes this proposal as a start, but believes that CMS has not addressed weaknesses in its methods of adjusting differences in physician specialty and patient risk. The typical patient population cared for by retina specialists is comprised of patients with diabetic retinopathy and elderly patients with wet-AMD who are among the most vulnerable among all ophthalmology patients. The VM does not give adequate protections for physicians in practices with a large percentage of patients who are likely to have high health care costs. In addition, many of the quality measures were not risk-adjusted for socioeconomic factors, therefore physicians working with higher percentages of poor or minority patients would appear to have lower quality in comparison. Without refinements to VM attribution methodologies to distinguish between specialists and subspecialists in the same field, many subspecialists, like retina specialists, may be inappropriately labeled as high cost utilizers due to inaccurate attribution methodologies. For example, subspecialists that routinely provide high cost drugs or procedures would not be distinguished from physicians in the same specialty who do not provide similar treatments, leading to inaccurate "comparisons." The ASRS previously joined the AMA and a large group of state and specialty medical societies to urge CMS to take steps to protect physicians from the high penalties under the 2018 VM, and we specifically asked CMS to exempt any physician who met the 2018 PQRS reporting requirements from mandatory quality tiering under the VM. **Consistent with our previous request, ASRS recommends that CMS exempts practices that did not meet the reporting criteria of the 2018 PQRS from the VM payment adjustment.**

MACRA Patient Relationship Categories and Codes Recommendations: Continue to correct attribution issues.

ASRS appreciates that CMS has acknowledged difficulties with attribution under the current methods. ASRS members report that upon reviewing their QRURs reports, some have found errors in attribution, others indicate that they have not had any patients attributed to them. ASRS agrees that use of patient relationship codes should be voluntary and that there should be an education period to test the use of the proposed modifiers.

In our previous communications with CMS, we raise significant concerns regarding how costs will be attributed to the physician. The typical patient population cared for by retina specialists are comprised of patients with diabetic retinopathy and elderly patients with wet-AMD, many of which have multiple serious medical conditions. Any patient attribution proposal should adequately account for patient comorbidities, patient compliance, and patient demographic and socioeconomic factors. ASRS participates in the technical expert panel to develop episode cost based measures for ophthalmic services and we believe that this would be the appropriate forum to further analyze how applying these modifiers can be used to appropriately measure costs that are within the control of the physician.

As the proposal does not provide a detailed description of how these modifiers will be incorporated into the cost measure methodology with risk adjustment, we ask that CMS provide more information and clarification before physicians are held accountable for their patients' cost of care. We recommend that CMS work with the technical expert panels to further analyze how these patient attribution categories impact cost.

Request for Information on CMS Flexibilities and Efficiencies Recommendation: Allow subspecialists use their available taxonomy codes.

ASRS would like to thank CMS for the opportunity to provide its comments on ideas for regulatory, subregulatory, policy, practice and procedural changes to improve the health care system by reducing unnecessary burdens for clinicians, other providers, patients and their families.

ASRS has repeatedly pointed out that Medicare's specialty designation codes do not distinguish between many subspecialists. As a result, Medicare as well as other insurers who use the Medicare Specialty designation, are relying on data that may make specialists, particularly retina specialists, appear more costly and less efficient. The reason for this difference is that retina patients have a different mix of ophthalmologic diseases and are more advanced in age, have multiple chronic health conditions and typically have a more advanced disease than patients of general ophthalmologists. Thus, caring for these patients is inherently more complex and resource intensive. As a result, it is inappropriate to benchmark retina specialists with general ophthalmologists.

Furthermore, ASRS is concerned that patients and consumers may misinterpret the information that is available through the public reporting of measure performance on Physician Compare. While it is laudable to provide as much actionable and pertinent information as possible on this

website, ASRS notes that some information provided on the site may lack a proper context, particularly related to how Part B drugs are included in the total reimbursement that retina specialists receive when using expensive injectable medications. Using the existing taxonomy code would allow CMS to easily differentiate retina specialists, demonstrate those differences to the public and potentially alleviate those misinterpretations.

In addition, if programs such as Physician Compare do not include a separate category for retina specialists, it will be difficult for CMS to meet its stated goal of helping patients "find and choose physicians" that can manage their care in a cost-effective fashion. Finally, as Medicare Advantage plans use "value" metrics to create tiered networks, retina specialists who treat more complex cases than comprehensive ophthalmologists should only be compared with their retina subspecialist peers.

Since CMS cannot easily identify retina specialists through any other means, ASRS recommends that CMS use subspecialty taxonomy codes to allow physicians to pro-actively signal care within their direct control.

Payment for Biosimilar Biologic Products under Section 1847A of the Act
Recommendation: Assign a unique HCPCS code to each biosimilar.

The current policy requires that all biosimilars related to a single reference product are assigned a shared HCPCS code. For Medicare Part B, reimbursement is then calculated based on the average sales price (ASP) of all of the biosimilars with that HCPCS code plus the prevailing percentage adjustment. The current policy of a blended ASP for the biosimilar assumes that these products are identical and interchangeable.

According to the Food and Drug Administration, a "biosimilar product is a biological product that is approved based on a showing that it is **highly similar** to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products." Since biosimilars are not the same molecule and differences in inactive components are allowed, we agree with the AMA that switching between products should be minimized to reduce the possibility of unanticipated adverse events. Moreover, in order to be deemed an ***interchangeable*** **biological product to an FDA-approved reference product, the biosimilar must meet additional standards for interchangeability**. Given that not all biosimiliars elect to be deemed interchangeable, we do not believe the payment policy should presume such standards are met. Given that biosimilars are only "highly similar"

and not all will be deemed interchangeable by the FDA, we believe having a unique HCPCS code for each biosimilar will allow appropriate pharmacovigilance.

In addition, we are concerned that one of the unintended consequences of a blended ASP for biosimilars is that the payment will be variable and may not always cover the physician's acquisition, inventory, carrying cost, administration and related services whereas the reference biological ASP is not. As a result, the blended ASP payment approach puts physicians at financial risk, which can only be reduced by selecting the least expensive biosimilar or the reference drug. Since the drugs are not the exact same, we believe it is more appropriate to assign unique HCPCS and allow physicians and patients to select the best drug based on relative cost and clinical benefit for that patient.

In sum, ASRS believes that CMS should assign a unique HCPSC code to each biosimilar of a particular reference product, so that physicians can not only track and monitor their effectiveness, but also ensure the access to a broad range of treatments.

Request for Comments on Possible Updates to E/M Code Documentation Guidelines. Recommendation: Seek full input from the medical community before moving ahead with changes to E/M codes.

We agree with CMS that the current Evaluation and Management (E/M) documentation guidelines may be administratively burdensome and potentially outdated. Given that the guidelines have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, we agree that there is an opportunity to reduce the complexity and ambiguities in the current documentation requirements. For example, in evaluating the level of risk which helps to determine whether a level 4 or 5 examination code is used in a patient who presents with new onset choroidal neovascularization, the use of moderate or high risk is subjective and could easily be interpreted differently by retina specialists. For moderate risk, the patient must have one or more chronic illnesses with mild exacerbation, progression or side effects of treatment, two or more stable chronic illnesses, undiagnosed new problems with uncertain prognosis, acute illness with systemic symptoms or acute complicated injury. For high risk the patient must have one or more chronic illnesses with severe exacerbation progression or treatment, acute or chronic illnesses with severe exacerbation, progression or side effects of treatment, acute of chronic illnesses or injuries that post a threat to life or bodily function or an abrupt change in neurologic status.

In addition, the current guidelines fail to recognize the team-based approach to care, which for retina specialists includes certified ophthalmic technicians who traditionally perform some

elements of the history taking and examination. Current portions of documentation guidelines note that registered nurses can perform some tasks, but the other types of professionals, such as ophthalmic technicians, are not mentioned and this ambiguity leads to extraneous work that detracts from the specialists working at the appropriate level of their training and abilities.

While there may be an opportunity to update or clarify some of the documentation requirements for E/M codes related to EHRs, we do not believe that the underlying code set requires reevaluation. Specifically, we would oppose any proposal that reduces the requirements for history and physical exam and bases the code level only on medical decision-making and/or time. Retina specialists manage patients with complex retinal diseases that require both intense medical decision-making and time spent with the patient. For a typical patient with new onset choroidal neovascularization, the retina specialist must recommend an anti-VEGF medication and initiation of an oral nutritional supplement (e.g., Age-Related Eye Disease Study 2 vitamin) after appropriate tests including fluorescein angiography and optical coherence tomography are performed and reviewed with the patient. The discussion of the three available anti-VEGF medications is lengthy since one (bevacizumab) is not FDA-approved for use in the eye. The other two options (ranibizumab and aflibercept) are FDA-approved, but very expensive and may require higher copays or pre-authorization to use depending on the patient's secondary insurance. Once the anti-VEGF drugs is chosen, patients must be educated about two possible treatment regimens that initially includes monthly injections and a treat-and-extend schedule or PRN treatment requiring monthly office visits indefinitely. The discussion related to the nutritional supplement also can be lengthy as it involves a thorough vetting of current medications and vitamins as well as a discussion of the risks and benefits of high-dose vitamin supplementation. Since prompt treatment improves visual outcomes, all of this typically occurs in the patient's first visit to their retina specialists. This discussion of treatment options is similar to the discussion that a patient with cancer must have with their oncologist when they choose among one of several possible treatment regimens such as surgery, chemotherapy or radiation. The history, physical exam, medical decision-making, and time are integral to determining the level of E/M service and should be maintained. Such code modifications have the potential to make it more difficult for patients to access specialist care if the intensity of these services are consistently undervalued. Since the codes are well established, changing documentation requirements could be more of a burden if physicians and practices have to learn a new system. **Regardless, no changes in the E/M codes should be made without significant clinical input and involvement from the specialists, the CPT Editorial Panel, the RUC and allied health professionals and EHR vendors.**

Medicare Telehealth Services Recommendation: Involve the retina specialist community in advancing telehealth guidance

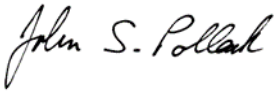
ASRS supports CMS' intent to expand coverage of telehealth and remote patient monitoring services in the Medicare program. As ASRS members are on the cutting edge of developing imaging technologies suited for these services, we urge CMS to include the input of retina specialists as it updates and broadens its guidance in this important and evolving area of medicine. ASRS members are increasingly seeing patients with advanced eye disease that could be prevented or treated earlier with the convenience of remote patient monitoring. One such population this is particularly relevant to is the growing diabetic population and its related comorbidity of diabetic retinopathy, a potentially blinding eye condition. Currently, however, only screening for patients with established retinal disease is reimbursed, which unfortunately is a more costly approach to patient care, instead of identifying disease early when it is more amenable to treatment and reduces the ultimate cost to our health care system. **Thus, we strongly encourage CMS to consider expanding coverage for remote patient monitoring services which would allow the identification of earlier disease manifestations in a less costly care setting.**

Conclusion

ASRS appreciates the opportunity to provide comments on the 2018 Medicare Physician Fee Schedule Proposed Rule. We support CMS's initiatives to reduce the regulatory burden on physicians. We reiterate our support for the RUC process in valuing and revaluing codes in 2018. We continue to urge CMS to provide additional information on how patient modifiers will factor into assigning cost scores. ASRS strongly advocates for a unique HCPCS code for each biosimilar. We ask for clarity in Evaluation and Management documentation guidelines, but do not support a comprehensive re-evaluation of E/M codes. We look forward to partnering with CMS to advance telehealth guidance. If we may provide any additional information, please contact Jill Blim, ASRS Executive Vice President at jill.blim@asrs.org.

Sincerely,

Mark S. Humayun, MD, PhD
President



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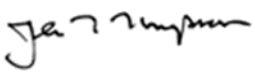

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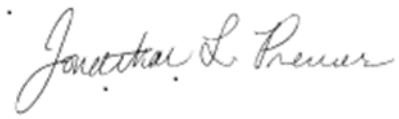

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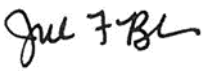

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