ASRS American Society of Retina Specialists

September 6, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: [CMS-1770-P] RIN 0938-AU81, Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Brooks-LaSure:

The American Society of Retina Specialists (ASRS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule. ASRS is the largest retina organization in the world, representing more than 3,000 members in every state, the District of Columbia, Puerto Rico, and 63 countries.

For the Physician Fee Schedule (PFS) sections of the proposed rule, ASRS:

- Responds to CMS' request for information related to developing non-facility values for certain retinal surgeries. ASRS is not aware of independent, high-quality, peer-reviewed clinical data supporting the safety or feasibility of retina surgery performed in an office setting, nor are we aware of any widespread demand by retina specialists or patients for this option. Therefore, we do not recommend CMS move forward with developing practice expense RVUs for the retina procedures included in the proposed rule.

- Responds to CMS' request for information related to global surgery codes. We continue to recommend post-operative E/M visits bundled in global codes be increased to correspond with increased standalone values and continue to support the American Medical Association (AMA) Relative Value Update Committee (RUC) process for revaluing misvalued codes.

- Opposes CMS' years-long downward trend of the percentage of RUC-recommended values it accepts, including certain ophthalmic codes for 2023.

- Requests an exclusion for small-dose ophthalmic drugs—such as those with volumes of 1 mL or less—from the proposed requirement that manufacturers rebate Medicare for discarded portions of Part B drugs, including pre-filled injectable syringes.

- Requests CMS postpone its update of the Medicare Economic Index (MEI) until the AMA can complete its ongoing practice expense data collection effort.

For the Quality Payment Program (QPP) sections of the proposed rule, ASRS:

- Opposes CMS' proposal to include optometrists in the ophthalmology measure set.

20 North Wacker Drive
Suite 2030
Chicago, IL 60606

phone 312 578 8760
fax 312 578 8763
www.asrs.org

- Requests guidance from CMS on the implementation of a proposed 'Social Drivers of Health' measure to be included in the ophthalmology measure set.

- Continues to recommend CMS maintain traditional MIPS as a QPP participation option since retina specialists may have difficulty participating in MVPs in the future due to lack of MVPs pertaining to retinal diseases.

- Expresses continued concern related to the limited ability for specialists to participate in value-based programs.

OFFICE-BASED RETINA SURGERY

ASRS sincerely thanks CMS for the opportunity to provide comments on the potential for performing certain retina surgeries in an office setting before initiating a formal proposal. We have serious reservations about providing payment for performing these delicate procedures in an office setting because we believe it will unnecessarily compromise patient safety; furthermore, we are not aware of significant demand for expanded access to care.

We recommend that CMS ***not*** move forward with developing non-facility practice expense (PE) units for the following procedures:

- 67015, release of eye fluid
- 67036, removal of inner eye fluid
- 67039, laser treatment of retina
- 67040, laser treatment of retina
- 67041, vitrectomy for macular pucker
- 67042, vitrectomy for macular hole
- 67043, vitrectomy for membrane dissect
- 67108, repair detached retina
- 67113, repair detached retina, complex

Retina surgery today is overwhelmingly successful with remarkably few complications. Retina specialists routinely produce good outcomes for the surgeries listed above, often restoring patients' sight or preventing irreversible vision loss. However, seemingly routine cases can quickly become more complex intraoperatively, and thereby carry an inherent, substantial risk to the patient. Producing good outcomes, while being prepared for potential complications, is attributable not just to the retina specialist's skill but to the surgical environment that includes the correct personnel and equipment furnished in an accredited hospital outpatient department (HOPD) or ambulatory surgery center (ASC). Decades of independent and peer-reviewed research has contributed to establishing best practices that lead to good outcomes. We are not aware of similar studies demonstrating the safety and appropriateness of performing these procedures in an office setting. Without this comprehensive and unbiased literature, it is impossible for ASRS to support this initiative or provide definitive recommendations on how office-based retinal surgery can be delivered safely and effectively.

Potential Facility Standards for OBS

The request for information (RFI) and the nominator's submission of these codes raises the question under what standards these procedures could potentially be performed? ASRS is aware that there are established standards and accreditation for office-based surgery (OBS), but they were not developed specifically to accommodate retina surgery and there is no published literature that confirms they are the appropriate standards for the procedures in question.

HOPDs and ASCs are held to higher standards than those for OBS. For instance, it is unclear whether a separate anesthesia provider would be required for OBS. During surgery, a retina specialist is focused solely on the procedure, which includes complex and delicate microsurgical techniques, and is not generally able to monitor and manage the patient's sedation. In an ASC or HOPD, dedicated anesthesia personnel are universally present and engaged, while they may not be available in an office setting.

Furthermore, HOPDs and ASCs are subject to a host of specific regulations ranging from building and airflow specifications, infection control procedures, emergency planning, staffing requirements and others. Even if the current OBS standards that address these issues are determined to be appropriate for retina surgery, it is likely that it would be difficult to retrofit most physician offices that are not purpose built to accommodate surgical suites to meet these more stringent standards. In addition, a significant capital outlay to purchase surgical and lifesaving equipment may be financially infeasible for many practices.

Patient Selection Criteria

Finally, there is no research to indicate what type of patients would be most appropriate to undergo surgery in an office setting. While patients requiring retina surgery generally have a slightly lower average age than other ophthalmic surgical patients, such as those undergoing cataract surgery, Medicare patients requiring retina surgery are subject to the same potential co-morbidities and risks as other older surgical patients. In fact, ASRS members report that they have recently encountered ASCs referring patients with certain co-morbidities, such as cardiac disease and morbid obesity, to HOPDs because they are higher risk for systemic complications. Many patients with retinal diseases have significant medical problems, such as poorly-controlled diabetes, and require more intensive preoperative, intraoperative and postoperative monitoring than is possible in a physician's office. Retinal procedures typically take an hour or more, which is more time than most other ophthalmic surgeries, such as cataract surgery. The longer duration increases the risk of medical complications if the patient becomes anxious or requires airway assistance because of heavy sedation. A physician office is not appropriate for retinal surgery due to the need to more extensive equipment, monitoring and staffing than possible in a minimalist, office-based setting.

Retina surgery is a complex and delicate undertaking that is often performed under emergent conditions. It is performed safely and effectively in HOPDs and ASCs due to greater resources including equipment, disposables and staffing conducive to good outcomes. Successfully implementing an office-based surgical option would require long-term and focused research before contemplating the payment system to support it. ASRS members, who continued to provide non-stop care throughout the COVID-19 pandemic, do not report significant access issues for surgery and neither are we aware of beneficiaries requesting their surgery in an office rather than a HOPD or ASC. **Given the lack of information on how to perform retina OBS safely and lack of demand, ASRS recommends that CMS not move forward with re-valuing these codes for non-facility PE at this time.**

GLOBAL SURGERY CODES

ASRS questions the necessity of CMS' request for information related to global surgery codes. Going back several years, ASRS, and other surgical specialty groups, have provided detailed comments on the composition and value of 10- and 90-day global codes. We encourage CMS to revisit comment letters submitted on proposed MPFS rules by ASRS and others for additional context, however, we will provide an overview of these comments again here.

Composition of Global Codes

Payment policy over the last several decades has generally tended toward bundling the costs of related services into global or comprehensive payment packages. These bundles, including global surgery, include the value of the resources needed to furnish the service for the typical patient. With this bundling comes the understanding that in some cases a patient may need more or fewer resources than prescribed in the bundle, but that over time, the provider's total reimbursement would be sufficient to care for their patient population. This arrangement is the most efficient option for both the payer and provider, and it is our understanding that CMS seeks to increase bundling or capitated payments through programs other than fee-for-service.

Given that reality, we continue to question CMS' efforts to unbundle or undervalue post-operative visits included in global surgery packages. As noted over several years, we object to the data collection and survey design of previous attempts to observe the number of post-operative visits provided. These efforts were based on limited sets of codes, or relied on certain practitioners to report non-payable codes. While they may serve as a validation for certain procedures—such as the study that was concurrent with the RUC revaluation of cataract surgery—they are no substitute for the intensive and statistically-valid valuation process the RUC uses to value codes and should not be used to extrapolate values for all global codes. The best way to accurately determine the correct number and level of post-operative visits for a particular code is to revalue it through the RUC process.

Updated Post-Operative Values

ASRS continues to recommend that CMS apply the increased values of standalone E/M visits to the post-operative visits included in global codes. Failing to do so is a violation of the Medicare statute requiring all physicians be reimbursed equally for the same services and has significantly disrupted the relativity of the physician fee schedule. Following the revaluation of two retinal detachment repair codes for 2022, the relative values have become so skewed that a retina specialist performing these surgeries would be reimbursed more for solely billing the post-operative follow-up visits as standalone E/M visits than if he or she appropriately billed the global code. In essence, this indicates that CMS believes the physician work for an office visit is more valuable than a complex, microsurgery that requires a retina specialist to undergo several years of additional training to perform. This situation negates the entire premise of the relativity of the fee schedule. At the very least, CMS should apply the increased E/M values to global codes that have been revalued since 2021 when the new E/M values were adopted.

As we have noted in each of our comment letters over the past several years, if CMS believes certain services are misvalued—whether they are global surgery or not—then they should be referred to the RUC for revaluation. The RUC has a long-established process for identifying potentially misvalued codes, including several screens related to global surgery codes, and this is the appropriate mechanism to

address any supposed issues with global surgery. **We urge CMS to abandon other untested alternatives for revaluation and send specific codes it believes are misvalued to the RUC expeditiously.**

RUC RECOMMENDATIONS

Over the last several years, the percentage of RUC-recommended values for specific codes accepted by CMS has declined. For 2023, CMS is proposing to accept only 75% of RUC's recommendations. ASRS is extremely concerned by this alarming trend given that the RUC continues to value these procedures using a detailed analysis that has been refined over many years. As noted above, we believe the RUC is the only forum to value physicians services with a consistent and established process. RUC recommendations are often unanimous and reflect the body's ongoing commitment to upholding the principle of relativity that is the foundation of the physician fee schedule.

We oppose CMS' increasing reliance on inconsistent and at times arbitrary rationale for valuing specific codes. CMS increasingly relies on time and reverse-building block methodologies and ignores the statutory requirements to incorporate the intensity of specific procedures. For instance, retina surgery is exceptionally intensive, requiring three years of residency and two additional years of fellowship training to learn, and is performed through a microscope. Surgical retina cases are often complex and may involve unexpected intraoperative complications. Managing these patients requires considerable mental effort and judgement, with the outcome of the procedure more dependent on the surgeon's skill than the time required to accomplish it. Furthermore, ASRS often objects to CMS' alternative selection of potential crosswalk codes based solely on similar times and with no clinical relation between the intensity and training required for the two procedures. The combined effect of CMS' inconsistent and subjective valuation of physician services is an overall de-valuing of retina and surgical services, relative to other, less-intensive services. **ASRS strongly recommends that CMS only finalize code values that are based on rationale consistent with the established methodology RUC uses.**

Dark Adaptation – CPT 92284

ASRS does not agree with CMS' interpretation that CPT 92284, *Dark adaptation examination with interpretation and report*, is a screening test requiring no meaningful physician work value.

In fact, this code is not a screening test, which is why the RUC referred the code to CPT for editorial revision to include the word "diagnostic" to distinguish this service. While dark adaptation is performed to identify macular degeneration, it is also used to test for several retinal degenerations, including retinitis pigmentosa and cone dystrophies. Survey respondents estimated that it would take 15 minutes to evaluate the results of the examination. After an expert panel reviewed the survey, intra-service time was reduced from 15 minutes to 3 minutes. ASRS believes that 3 minutes is the most valid time estimate based on the knowledge of physician experts familiar with the latest technology and potential range of eye diseases. Therefore, we do not agree that a work value of 0.00 or 0.06 is appropriate for diagnosing the retinal diseases detailed above. Further, the CMS-suggested work value of 0.06 RVU is based on a reverse building block methodology typically used when neither a magnitude estimation of work nor a crosswalk can provide a reasonable value that maintains relativity within the RVS.

The RUC-recommended crosswalk to CPT 76514 *Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)* is reasonable and is based on time estimates

from those familiar with the newer technology. It is supported by the high degree of similarity between the survey respondents' time and intensity of work estimations for CPT 92284 and CPT 76514. The recommended work value of 0.14 RVU therefore maintains relativity with other procedures. The service will be placed on the New Technology list and reviewed in 3 years to address any further change in physician work. **We therefore strongly recommend that CMS accept the RUC-recommended work value of 0.14 RVU for CPT 92284.**

ASRS does not agree that the direct PE input for the lens set (EQ165) and motorized table (EF030) should be reduced from 24 minutes to 15 minutes. The equipment is unavailable for use during the following activities, all of which occur in the testing room, and which take 9 minutes:

- CA011, provide education/obtain consent: 2 minutes
- CA013, preparation of the room, equipment, and supplies: 2 minutes
- CA014, confirm order, protocol exam: 1 minute
- CA016, initial positioning and monitoring of patient: 1 minute
- CA024, clean room/equipment by clinical staff: 3 minutes

The standard default equipment formula used RUC inputs that reflect the clinical staff time for CA011, CA013, CA014, and C024. The input time for CA016 was reduced from the benchmark of 2 minutes to 1 minute because no intravenous access is required for this test. However, 1 minute was retained because that time is required for initial positioning and monitoring of the patient prior to beginning the test protocol. Because the equipment is unavailable during this time, it is standard practice to include this time when calculating direct PE inputs. Not including these inputs for this one code while including them for all other codes using the standard default equipment formula would alter the relativity of services within the RVS. Therefore, the times for CA011, CA013, CA014, CA016, and CA024 should be included when calculating the time for the lens set (EQ165) and motorized table (EF030). The 9 minutes detailed above, when added to the 15 minutes of CA021, results in the 24 minutes recommended by the RUC. **ASRS strongly believes that the RUC correctly calculated the direct inputs and the time should remain 24 minutes.**

DISCARDED AMOUNTS OF DRUGS IN SINGLE-USE CONTAINERS

ASRS recognizes that CMS is proposing to implement a statute passed by Congress mandating refunds on discarded amounts of Part B drugs furnished in single-use or single-dose containers. However, we are concerned that CMS has not fully contemplated the impact of its proposals which will have the unintended consequences of leading to inadequate amounts of drug in pre-filled syringes for the treatment of retinal conditions. It is typical for drugs used for retinal diseases to have a small amount of extra drug in the syringe. The extra drug is not left in the syringe, but is present in the needle hub after injecting the proper dose into the eye. The prefilled syringes with attached needle are discarded into a sharps container. We recommend CMS provide a wider range of potential exemptions to this policy to prevent negative impacts. **Specifically, we recommend CMS exempt ophthalmic drugs or those with total volumes of 1mL or less from this policy.**

Potential Impact on Retina Specialists

Unlike treatments for systemic conditions, dosing for Part B drugs for retina disease is not based on the patient's weight or body surface area. Instead, frequently used drugs, such as anti-vascular endothelial

growth factor (VEGF) drugs to treat the most common causes of blindness including age-related macular degeneration (AMD) and diabetic retinopathy, are administered in standard doses, and for the drugs currently used the most, packaged in pre-filled injectable syringes. A pre-filled syringe ensures that the retina specialist is able to inject the full dose into the patient's eye.

When these drugs first came to market after FDA approval, they were packaged in single-use vials and retina specialists had difficulty ensuring the correct dose was drawn into the syringe because of the small (0.05mL) volume needed and viscous nature of the drugs. Air pockets and dead space in the syringe also made obtaining the correct dose a complicated task, and therefore manufacturers must consistently and intentionally provide additional overfill to prevent underdosing. These issues have largely been solved by the pre-filled syringes, but for new products coming to the market, it may be several years after the initial launch before a pre-filled syringe is available for that particular medication. There are currently several new drugs and biosimilars on the market that are anticipated to be packaged in single-use vials for several years before transitioning to pre-filled syringes. We are aware of several other products in the pipeline that will be similarly affected. These drugs' packaging and volume, at a volume greater than the actual dose needed to treat the patient, are set strictly according to FDA-approval and based on scientific evidence to ensure proper dosing.

The proposed rule is unclear as to how, or whether, a physician would report discarding overfill. Given the very small volumes of ophthalmic drugs, it is likely that the overfill would exceed the 10% threshold CMS proposes for reporting with the JW modifier, however, it is not clear whether that would include the intentional overfill or not. In addition, it would be very difficult for a physician or practice to be able to measure exactly how much was discarded when dealing with volumes in the tenths to twentieths of milliliters. Similarly, it is unclear from the proposed rule whether pre-filled syringes, which by definition are designed to deliver the entire quantity of the drug, would be subject to the proposed JZ modifier. In the past, retina specialists have been subject to program integrity actions for not using the JW modifier and ASRS is concerned that this lack of clarity could put our members at risk of further audits. **We strongly encourage CMS to clarify these circumstances in the final rule and provide in-depth resources to assist practices comply with this policy.**

Potential Unintended Consequences on Beneficiaries

Due to the possibility that a manufacturer would have to rebate Medicare for any wastage of a drug and may have to wait several years to offer their product in pre-filled syringes, there is the potential that they will respond by only providing exactly as much as is included in the drug's labeling. ASRS is concerned that given the issues discussed above, patients will not be able to receive a sufficient dose to treat their blinding retinal disease. Furthermore, this could lead to additional drug expenditures as patients who might be stable, for example, on an 8-week dosing schedule, but who become subject to underdosing will require more frequent injections, such as every 4 or 6 weeks, thereby incurring more patient-level risk and increasing costs to the Medicare program.

For manufacturers who are not able to adjust the volume of the drug in single-use containers, such as due to FDA packaging requirements, there is also the possibility that they would simply raise the price of their drug to cover the costs of the potential rebate to Medicare. This would shield the manufacturer from adverse impacts, but potentially increase costs to Medicare, the beneficiary, and third-party payers. This policy should not be implemented in a way that causes an exacerbation of the problem it is trying to solve.

Expanded Exemption Criteria

ASRS recommends that CMS provide additional opportunities for exemption from this policy to prevent the potential negative impacts discussed above. **We recommend an exemption for all ophthalmic drugs or limited to those with volumes of 1mL or less, including pre-filled injectable syringes.** We believe this accommodation will ensure retina specialists can appropriately dose patients with retinal disease and prevent manufacturers from taking action to circumvent the policy. We support CMS' proposal to exempt drugs new to the market for 18 months and encourage CMS to use that time to work with manufactures to understand the unique characteristics of their products that may require them to provide additional quantities of drug that is not intended as wastage.

MEI UPDATE

ASRS appreciates CMS' effort to update elements of the physician fee schedule with more timely and relevant data sources—particularly during a time of increased inflation that has impacted physician practices significantly—however, **we recommend CMS postpone its update of the MEI proposed in this rule until the AMA has completed its practice cost data collection effort.** We understand that CMS is well-aware of AMA's ongoing effort and question why the agency would propose to move ahead without this important data that has historically factored in significantly to the MEI. We are concerned that CMS's proposal leans too heavily on other data sources that would reduce the proportion of physician work factored into the MEI. CMS should pause its current effort to ensure it can incorporate AMA's data.

QUALITY PAYMENT PROGRAM

Opposition to Including Optometry in the Ophthalmology Measure Set

ASRS strongly opposes grouping optometrists with retina specialists and other ophthalmologists in the same MIPS measure set. Currently, the ophthalmology measure set includes measures for delicate ocular surgical procedures such as retinal detachment repair and cataract surgery. Ophthalmologists must complete four years of medical school, a hospital residency and three years of residency training—and most retina specialists complete an additional two-year fellowship. Optometrists, by comparison, have no such training and are barred by state law from performing the intraocular surgeries included in this measure set.

ASRS recommends CMS not finalize this proposed change.

Request for Further Guidance on Social Drivers of Health Measure

ASRS strongly supports efforts to improve health equity and reduce barriers that prevent beneficiaries from receiving the care they need. Retina specialists are acutely aware of the burden the treatments they provide can place on patients. Patients with retinal disease, such as AMD, are elderly and may have limited vision. To receive an intravitreal injection of anti-VEGF drugs, patients must have a family member or caregiver accompany them, and often do so on a roughly monthly basis. Unreliable access to transportation or inflexible working schedules often prevents patients from attending appointments at the most ideal intervals. Addressing these root causes would help improve visual outcomes.

Given these realities, ASRS believes a measure aimed at addressing social drivers of health could be useful, however, we are unsure how this measure would accomplish that. It appears to be formatted as a process measure that would solely determine whether the physician screened for these potential barriers, rather than took a specific action. In the proposed rule, CMS notes that this could prompt physicians and other providers to make referrals as necessary, but does not provide details of what is expected or what methods or tools physicians should use to collect this information. In addition, it is not apparent whether CMS is intending to propose exclusions for this measure for patients who cannot or refuse to provide the information, similar to the measure for the hospital inpatient program. Finally, it is ASRS's understanding that this measure has not been fully tested and validated for the MIPS program

ASRS recommends that CMS not finalize this measure until it is fully specified and tested.

Continued Availability of Traditional MIPS

In previous years' comments, ASRS has expressed skepticism that CMS' framework for the MVP program would improve on the existing, and admittedly imperfect MIPS program. We have long-requested CMS streamline traditional MIPS to include a more intuitive scoring methodology, consistent reporting requirements across the categories and a focus solely on measures and activities that are clinically-relevant. In fact, we believe that the MVP concept exacerbates these issues rather than addresses them, by adding in a confusing sub-group reporting scheme and including problematic population health measures that retina specialists have no ability to influence their performance on.

Currently, we do not believe that there are sufficient measures or activities available to create an MVP for retina specialists. CMS contemplated an "eye care" MVP in previous years that not only would have inappropriately grouped optometrists in with retina specialists and other ophthalmologists, but centered on measures for cataract surgeons and offered no meaningful difference from traditional MIPS for retina specialists who typically don't do any routine cataract surgeries. Given this situation, we continue to recommend that CMS maintain the traditional MIPS option so retina specialists and other sub-specialists will have a modicum of choice to select measures and activities that are clinically relevant.

Availability of APMs for Specialists

In this proposed rule, CMS is concerned that the statutory framework will leave APM participants without a payment update or provide less of an incentive to move from MIPS. ASRS believes that concern is irrelevant because there are no APM options for retina specialists to begin with. As we have noted since the beginning of the QPP, existing models, such as accountable care organizations (ACOs) are primary-care focused and often do not want to include higher-cost specialists. For several years, ASRS and our partners in the Alliance of Specialty Medicine have requested CMS focus on developing, testing, and implementing models for specialists, yet, CMS seems to be redoubling its efforts to expand existing models that do not include specialists or seeking new ones modeled on primary care. CMS has yet to take any action on models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and most specialty societies have abandoned efforts to submit their proposals through that channel. Without a concerted effort by CMS to engage with the specialty community on innovative value-based payment models, there will not be further transition to APMs—regardless of any potential financial incentives.

CONCLUSION

Thank you again for the opportunity to provide comments on this proposed rule. If you have additional questions, please contact Allison Madson, vice president of health policy, at allison.madson@asrs.org.

Sincerely,

Philip J. Ferrone, MD, FASRS
President